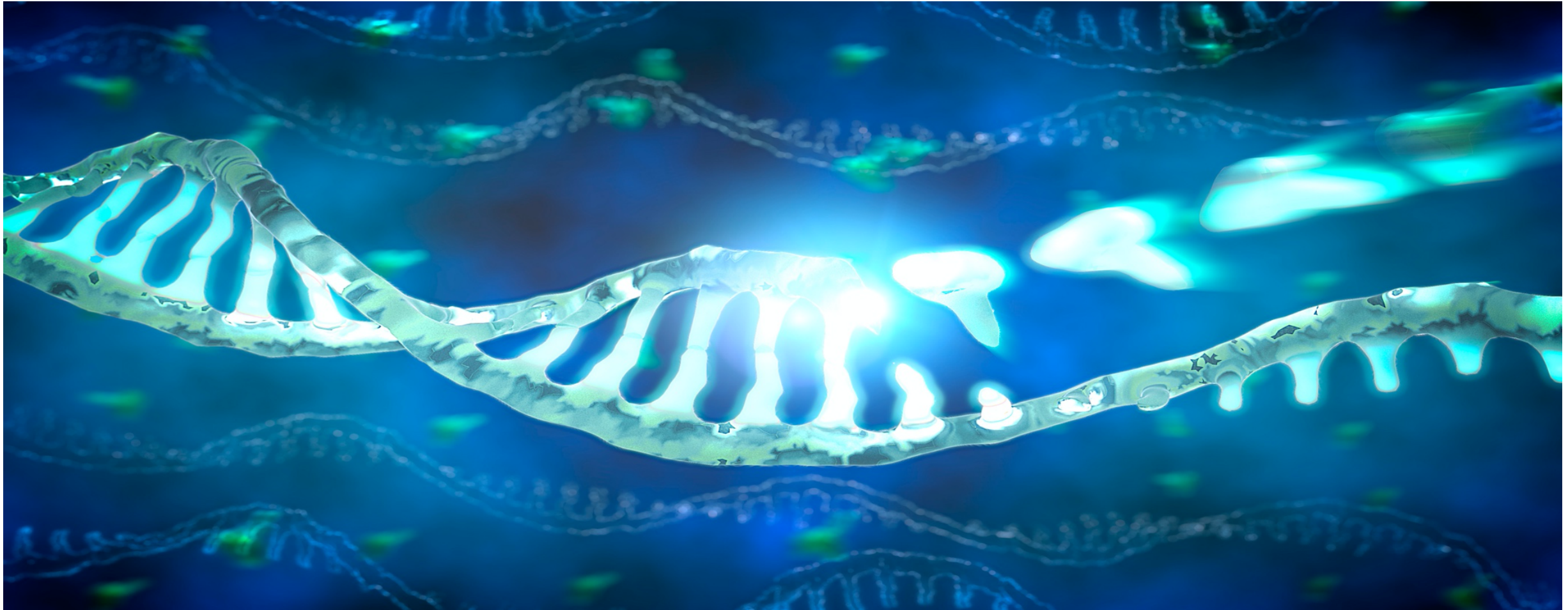


Clinical trials appendix

Year-to-date and Q3 2020 results update



Movement since Q2 2020 update

New to Phase I	New to Phase II	New to Pivotal trial	New to registration
<p><u>NME</u> AZD7442 COVID-19 mAb combination prevention and treatment of COVID-19</p> <p>AZD8701 FOXP3 solid tumours</p> <p>MEDI8367 $\alpha\beta$8 chronic kidney disease</p>	<p><u>Additional indication</u> cotadutide GLP-1/glucagon dual agonist diabetic kidney disease</p> <p>verinurad URAT1 inhibitor HF with a preserved ejection fraction</p> <p><u>Lifecycle management</u> Enhertu[#] DESTINY-PanTumour02 HER2 targeting antibody drug conjugate HER2-expressing solid tumors</p>	<p><u>Additional indication</u> capivasertib[#] + abiraterone CAPItello-281 AKT inhibitor + abiraterone PTEN deficient metastatic hormone sensitive prostate cancer</p> <p><u>Lifecycle management</u> Calquence + R-CHOP ESCALADE BTK inhibitor + R-CHOP 1st-line Diffuse Large B Cell Lymphoma</p> <p>Enhertu[#] DESTINY-Breast06 HER2 targeting antibody drug conjugate post-ET HER2low/HR+ breast cancer 2L</p> <p>Fasenra MESSINA IL-5R eosinophilic esophagitis</p> <p>Imfinzi + CTx MERMAID-1 PD-L1 mAb + CTx stage II-III adjuvant NSCLC</p> <p>Lynparza[#] LYNK-003 PARP inhibitor platinum sensitive 1st-line colorectal cancer</p>	<p><u>NME</u> anifrolumab TULIP 1 & TULIP 2 [US & EU] ¹ Type I IFN receptor mAb systemic lupus erythematosus</p> <p><u>Lifecycle management</u> Symbicort SYGMA [CN] ¹ as needed in mild asthma</p> <p>Tagrisso ADAURA [US & CN] ¹ EGFR inhibitor adjuvant EGFRm non-small cell lung cancer</p>
Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from registration
<p><u>NME</u> MEDI5117 China IL-6 mAb YTE rheumatoid arthritis</p>			<p><u>Lifecycle management</u> Enhertu[#] DESTINY-Gastric01 [JP] ² HER2 targeting antibody drug conjugate HER2-overexpressing advanced gastric or gastroesophageal junction adenocarcinoma patients who have progressed on two prior treatment regimens</p>

Phase progressions based on first patient dose achievement.

† Registrational Phase II/III trial # Partnered and/or in collaboration ¹ Submission accepted ² Approved



Q3 2020 new molecular entity (NME)¹ pipeline


Phase I 20 New Molecular Entities		Phase II 25 New Molecular Entities		Phase III 10 New Molecular Entities	
AZD0466 BCL2/xL haematological and solid tumours	<i>Imfinzi</i> #+adavosertib# PD-L1+Wee1 solid tumours	adavosertib# Wee1 ovarian cancer, solid tumours	<i>Imfinzi</i> #+AZD4635 PD-L1+A2aR prostate cancer	<i>Imfinzi</i> + <i>Lynparza</i> # BAYOU PD-L1+PARP bladder	capivasertib#+abiraterone CAPItello-281 AKT+abiraterone PTEN deficient mHSPC
AZD1390 glioblastoma	<i>Imfinzi</i> #+RT (platform) CLOVER PD-L1+RT HNSCC NSCLC SCLC	AZD2811 nanoparticle Aurora solid tumours, haematological malignancies	<i>Imfinzi</i> #+ <i>Lynparza</i> # ORION PD-L1+PARP 1L mNSCLC	<i>Lynparza</i> #+AZD6738 VIOLETTE PARP+ATR breast	capivasertib#+fulvestrant CAPItello-291 AKT+fulvestrant locally-advanced (inoperable) or metastatic breast
AZD4573 CDK9 haematological malignancies	<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 solid tumours	AZD4635 A2aR inhibitor prostate cancer	<i>Imfinzi</i> #+MEDI0457# PD-L1+DNA HPV vaccine HNSCC	MEDI5752 PD-1/CTLA-4 solid tumours	capivasertib#+chemotherapy CAPItello-290 AKT+chemotherapy mTNBC 1L
AZD5153 BRD4 haematological and solid tumours	<i>Imfinzi</i> #+tremelimumab+chemo PD-L1+CTLA-4 1L PDAC oesophageal SCLC	AZD9833 SERD ER+ breast	<i>Imfinzi</i> #+monalizumab# PD-L1+NKG2a solid tumours	oleclumab+AZD4635 CD73+A2aR prostate cancer	<i>Imfinzi</i> #+/-tremelimumab+chemo POSEIDON PD-L1+/-CTLA-4+SoC 1L NSCLC
AZD5991 MCL1 haematological malignancies	<i>Imfinzi</i> #+selumetinib# PD-L1+MEK solid tumours	capivasertib# AKT prostate	<i>Imfinzi</i> #+oleclumab PD-L1+CD73 solid tumours	oleclumab+chemo or <i>Imfinzi</i> # + oleclumab + chemo CD73+chemo or PD- L1+CD73+chemo pancreatic	<i>Imfinzi</i> #+/-tremelimumab+CRT ADRIATIC PD-L1+/-CTLA-4+CRT LS-SCLC
AZD7648# DNAPK solid and haematological tumours	IPH5201# CD39 solid tumours	<i>Imfinzi</i> (platform) HUDSON PD-L1+multiple novel ONC therapies post IO NSCLC	<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 biliary tract oesophageal	Post-1L <i>Tagrisso</i> (platform) ORCHARD EGFR+multiple novel ONC therapies EGFRm NSCLC	<i>Imfinzi</i> #+tremelimumab HIMALAYA PD-L1+CTLA-4 1L HCC
AZD8701 FOXP3 solid tumours	MEDI1191 IL12 mRNA solid tumours	<i>Imfinzi</i> # (platform) BALTIC PD-L1+CTLA-4, WEE1+Carboplatin, ATR+PARP ES-SCLC R/R	<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 gastric cancer	<i>Tagrisso</i> combo# TATTON EGFR+PD-L1/MEK/MET NSCLC	<i>Imfinzi</i> #+tremelimumab KESTREL PD-L1+CTLA-4 1L HNSCC
AZD9496 SERD ER+ breast	MEDI2228 BCMA ADC multiple myeloma	<i>Imfinzi</i> # (platform) COAST PD-L1+multiple novel ONC therapies NSCLC	<i>Imfinzi</i> +FOLFOX+bevacizumab (platform) COLUMBIA1 PD-L1+chemo+VEGF+ multiple novel ONC therapies 1L MSS-CRC	<i>Tagrisso</i> +savolitinib# SAVANNAH EGFR+MET advanced EGFRm NSCLC	<i>Imfinzi</i> #+tremelimumab+SoC NILE PD-L1+CTLA-4+SoC 1L urothelial cancer
<i>Calquence</i> (platform) PRISM BTK + multiple novel onc therapies r/r aggressive NHL	MEDI5395 rNDV GMCSF solid tumours	<i>Imfinzi</i> # (platform) NeoCOAST PD-L1+multiple novel ONC therapies NSCLC			<i>Lynparza</i> #+ <i>Imfinzi</i> # DUO-E PARP+PD-L1 1L endometrial cancer
<i>Calquence</i> +ceralasertib BTK+ATR haematological tumours	oleclumab+ <i>Tagrisso</i> CD73+EGFR EGFRm NSCLC				<i>Lynparza</i> #+ <i>Imfinzi</i> #+bevacizumab DUO-O PARP+PD-L1+VEGF 1L ovarian


Under Review

0 New Molecular Entities

¹ Includes novel combinations and additional indications for assets where the lead is not yet launched

Partnered and/or in collaboration; † Registrational Phase II/III trial

 Oncology

 Precision medicine approach being explored



Q3 2020 new molecular entity (NME)¹ pipeline

Phase I 17 New Molecular Entities	Phase II 21 New Molecular Entities	Phase III 5 New Molecular Entities	Under Review 1 New Molecular Entity		
<p>AZD0284 RORg psoriasis / respiratory</p>	<p>AZD8154 Inhaled PI3Kgd asthma</p>	<p>abediterol# LABA asthma / COPD</p>	<p>MEDI3506 IL-33 AD / COPD / asthma / COVID-19</p>	<p>AZD1222# SARS-CoV-2 COVID vaccine</p>	<p>anifrolumab# TULIP 1 & TULIP 2 Type I IFN receptor SLE</p>
<p>AZD0449 Inhaled JAK inhibitor asthma</p>	<p>AZD8233 hypercholesterolemia cardiovascular</p>	<p>anifrolumab# Type I IFN receptor lupus nephritis</p>	<p>MEDI5884# cholesterol modulation cardiovascular</p>	<p>brazikumab# IL23 crohns disease</p>	
<p>AZD1402# inhaled IL-4Ra asthma</p>	<p>AZD9977 MCR cardiovascular</p>	<p>anifrolumab# Type I IFN receptor SLE SC</p>	<p>MEDI6012 LCAT cardiovascular</p>	<p>nirsevimab# RSV mAb-YTE passive RSV immunisation</p>	
<p>AZD2373 Podocyte health nephropathy</p>	<p>MEDI0618# PAR2 antagonist osteoarthritis pain</p>	<p>AZD4831 MPO HFpEF</p>	<p>MEDI7352 NGF/TNF OA pain / PDN</p>	<p>PT027 ICS/SABA asthma</p>	
<p>AZD2693 nonalcoholic steatohepatitis</p>	<p>MEDI1341# alpha synuclein parkinson's disease</p>	<p>AZD5718 FLAP coronary artery disease</p>	<p>navafenterol # MABA COPD</p>	<p>tezepelumab# NAVIGATOR SOURCE TSLP severe uncontrolled asthma</p>	
<p>AZD4041# orexin 1 receptor antagonist opioid use disorder</p>	<p>MEDI1814# amyloidβ alzheimer's disease</p>	<p>AZD7986# DPP1 COPD</p>	<p>suvratoxumab α-Toxin Staphylococcus pneumonia</p>		
<p>AZD5634 inhaled ENaC cystic fibrosis</p>	<p>MEDI6570 LOX-1 CV disease</p>	<p>AZD8601# VEGF-A cardiovascular</p>	<p>tezepelumab# TSLP atopical dermatitis</p>		
<p>AZD6615 hypercholesterolemia CV disease</p>	<p>MEDI8367 avb8 chronic kidney disease</p>	<p>AZD9567 SGRM chronic inflammatory diseases</p>	<p>tezepelumab# TSLP COPD</p>		
<p>AZD7442 long-acting antibody combination COVID-19</p>		<p>brazikumab IL23 ulcerative colitis</p>	<p>velsecorat (AZD7594) Inhaled SGRM asthma / COPD</p>		
		<p>cotadutide GLP-1/glucagon T2D / obesity / NASH / DKD</p>	<p>verinurad URAT-1 CKD / HFpEF</p>		
		<p>MEDI3506 IL-33 diabetic kidney disease</p>			



Q3 2020 lifecycle management (LCM)¹ pipeline

Phase I 1 Project	Phase II 8 Projects	Phase III 26 Projects	Under Review 1 Project
<i>Imfinzi</i> #+azacitidine# PD-L1+azacitidine MDS	<i>Calquence</i> CALAVI-US & CALAVI-RoW BTK inhibitor COVID-19	<i>Calquence</i> # BTK inhibitor 1st line MCL	<i>Imfinzi</i> #+VEGF EMERALD-2 PD-L1+VEGF adjuvant HCC
	<i>Enhertu</i> # DESTINY-CRC-01 ADC colorectal cancer	<i>Calquence</i> # BTK inhibitor r/r CLL, high risk	<i>Imfinzi</i> # post-SBRT PACIFIC-4 PD-L1 post-SBRT stage I/II NSCLC
	<i>Enhertu</i> # DESTINY-Gastric02 ADC gastric	<i>Calquence</i> #+venetoclax+obinutuzumab BTK+BCL-2+anti-CD20 1st line CLL	<i>Imfinzi</i> # POTOMAC PD-L1 non muscle invasive bladder cancer
	<i>Enhertu</i> # DESTINY-Lung01 ADC NSCLC	<i>Calquence</i> +R-CHOP ESCALADE BTK+R-CHOP 1L DLBCL	<i>Imfinzi</i> #+CRT PACIFIC-2 PD-L1+CRT NSCLC
	<i>Enhertu</i> # DESTINY-PanTumor02 HER2 targeting ADC HER2-expressing solid tumours	<i>Enhertu</i> # DESTINY-Breast02 ADC breast	<i>Imfinzi</i> #+CRT PACIFIC-5 (China) PD-L1+CRT locally-advanced stage III NSCLC
	<i>Imfinzi</i> # (platform) BEGONIA PD-L1 1L mTNBC	<i>Enhertu</i> # DESTINY-Breast03 ADC breast	<i>Imfinzi</i> #+CtX MERMAID-1 PD-L1 stage II-III adjuvant NSCLC
	<i>Imfinzi</i> # (platform) MAGELLAN PD-L1 1L mNSCLC	<i>Enhertu</i> # DESTINY-Breast04 ADC breast	<i>Imfinzi</i> #+CTx neoadjuvant AEGEAN PD-L1+CTx locally-advanced stage II-III NSCLC
	<i>Lynparza</i> # (basket) MK-7339-002 / LYNK002 PARP HRRm cancer	<i>Enhertu</i> # DESTINY-Breast06 ADC breast	<i>Imfinzi</i> #+CTx NIAGARA PD-L1+CTx muscle invasive bladder cancer
		<i>Imfinzi</i> # CALLA PD-L1 adj. locally-advanced cervical cancer	<i>Imfinzi</i> #+CTx TOPAZ-1 PD-L1+CTx 1L biliary tract cancer
			<i>Tagrisso</i> ADAURA EGFR adj. EGFRm NSCLC
			<i>Imfinzi</i> #+VEGF+TACE EMERALD-1 PD-L1+VEGF+TACE locoregional HCC
			<i>Lynparza</i> # LYNK-003 PARP platinum sensitive 1L colorectal cancer
			<i>Lynparza</i> # OlympiA PARP gBRCA adjuvant breast
			<i>Lynparza</i> # SOLO-3 PARP BRCAm PSR ovarian
			<i>Lynparza</i> +abiraterone# PROpel PARP+NHA prostate cancer
			<i>Tagrisso</i> LAURA EGFRm locally-advanced unresectable NSCLC
			<i>Tagrisso</i> +chemo FLAURA2 EGFR+chemo 1L adv EGFRm NSCLC



Q3 2020 lifecycle management (LCM)¹ pipeline

Phase I 0 Projects	Phase II 2 Projects	Phase III 10 Projects	Under Review 2 Projects
	<i>Breztri</i> LABA/LAMA/ICS asthma	<i>Farxiga/Forxiga</i> Dapa-CKD SGLT2 CKD	<i>Brilinta/Brilique</i> THALES P2Y12 stroke
	roxadustat# HIF-PH inhibitor chemo induced anaemia	<i>Farxiga/Forxiga</i> DELIVER SGLT2 HFpEF	<i>Symbicort</i> SYGMA as needed in mild asthma
		<i>Farxiga/Forxiga</i> DETERMINE- Preserved SGLT2 HFpEF	
		<i>Farxiga/Forxiga</i> DETERMINE-Reduced SGLT2 HFpEF	
		<i>Fasenra</i> MANDARA IL-5R EGPA	
		<i>Fasenra</i> MESSINA IL-5R eosinophilic esophagitis	
		<i>Fasenra</i> NATRON IL-5R hypereosinophilic syndrome	
		<i>Fasenra</i> # OSTRO, ORCHID IL-5R nasal polyps	
		<i>Fasenra</i> # RESOLUTE IL-5R COPD	
		roxadustat# HIFPH anaemia MDS	



Estimated key regulatory submission acceptances

					brazikumab crohns disease
				capivasertib + fulvestrant locally advanced or mBC CAPItello-291	<i>Fasenra</i> severe asthma (China)
				capivasertib + CTx 1L mTNBC CAPItello-290	nirsevimab passive RSV immunisation
				capivasertib + abiraterone PTEN deficient mHSPC CAPItello-281	PT027 asthma
NME	anifrolumab SLE (Japan) TULIP	AZD7442 SARS-CoV-2	<i>Imfinzi</i> + tremelimumab HCC HIMALAYA	<i>Imfinzi</i> + tremelimumab + SoC urothelial NILE	<i>Lynparza</i> + <i>Imfinzi</i> + bevacizumab ovarian DUO-O
	AZD1222 SARS-CoV-2	tezepelumab asthma NAVIGATOR	<i>Imfinzi</i> +/- tremelimumab NSCLC POSEIDON	<i>Imfinzi</i> + tremelimumab + CRT LDS-SCLC ADRIATIC	<i>Lynparza</i> + <i>Imfinzi</i> endometrial cancer DUO-E
	H2 2020	H1 2021	H2 2021	2021+	
LCM	<i>Tagrisso</i> adjuvant NSCLC (EU) ADAURA	<i>Calquence</i> r/r CLL, high risk ELEVATE-RR	<i>Enhertu</i> DESTINY-Breast03	<i>Calquence</i> + venetoclax + obinutuzumab 1L CLL AMPLIFY	<i>Imfinzi</i> cervical CALLA
	<i>Farxiga</i> CKD DAPA-CKD	<i>Lynparza</i> prostate PROFOUND (China)	<i>Imfinzi</i> NSCLC PEARL	<i>Calquence</i> 1L MCL ECHO	<i>Imfinzi</i> non muscle invasive bladder POTOMAC
		<i>Imfinzi</i> + CRT NSCLC PACIFIC-2	<i>Imfinzi</i> + VEGF + TACE locoregional HCC EMERALD-1	<i>Calquence</i> + R-CHOP 1L DLBCL ESCALADE	<i>Lynparza</i> platinum sensitive 1L colorectal LYNK-003
		<i>Fasenra</i> nasal polyps OSTRO	<i>Lynparza</i> breast OLYMPIA	<i>Enhertu</i> DESTINY-Breast02	<i>Tagrisso</i> locally adv. unresectable NSCLC LAURA
			<i>Lynparza</i> ovarian SOLO-3	<i>Enhertu</i> DESTINY-Breast04	<i>Tagrisso</i> + CTx EGFRm NSCLC FLAURA2
			<i>Lynparza</i> + abiraterone prostate PROPEL	<i>Enhertu</i> DESTINY-Breast06	<i>Bydureon Bcise</i> type-2 diabetes (China)
			<i>Farxiga</i> HF (HFpEF) DELIVER	<i>Imfinzi</i> adjuvant NSCLC BR.31	<i>Duaklir</i> Genuair COPD (China)
			<i>Imfinzi</i> neoadjuvant NSCLC AEGEAN	<i>Fasenra</i> COPD RESOLUTE	
			<i>Imfinzi</i> + chemo muscle invasive bladder NIAGARA	<i>Fasenra</i> EGPA MANDARA	
			<i>Imfinzi</i> + CTx biliary tract TOPAZ-1	<i>Fasenra</i> eosinophilic esophagitis MESSINA	
			<i>Imfinzi</i> + CTx stage II-III adjuvant NSCLC MERMAID-1	<i>Fasenra</i> HES NATRON	
			<i>Imfinzi</i> + VEGF adjuvant HCC EMERALD-2	<i>Fasenra</i> nasal polyps ORCHID (China / Japan)	
			<i>Imfinzi</i> + CRT NSCLC PACIFIC-5 (China)	roxadustat anemia in MDS	
			<i>Imfinzi</i> post-SBRT NSCLC PACIFIC-4	<i>Xigduo XR/Xigduo</i> type-2 diabetes (China)	

Note. NME section includes novel combinations and additional indications for assets where the lead is not yet launched

■ Oncology ■ BioPharmaceuticals



Designations

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Accelerated approvals

<i>Lynparza</i> ovarian cancer SOLO-2 (US)
<i>Tagrisso</i> EGFRm T790M NSCLC (US)
<i>Imfinzi</i> bladder cancer (US)
<i>Calquence</i> MCL (US)
<i>Enhertu</i> unresectable or HER2+ MBC 3L (DESTINY-Breast01) (US)

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Breakthrough / PRIME¹ / Sakigake²

<i>Tagrisso</i> EGFRm T790M NSCLC (US)
<i>Lynparza</i> prostate cancer PROFOUND (US)
<i>Imfinzi</i> bladder cancer 1L (US)
<i>Calquence</i> MCL (US)
<i>Imfinzi</i> stage III NSCLC 1L PACIFIC (US)
<i>Tagrisso</i> NSCLC 1L FLAURA (US)
tezepelumab asthma (US)
nirsevimab RSV mAB (US)
nirsevimab RSV mAB (EU) ¹
selumetinib NFI type 1 SPRINT (US)
<i>Enhertu</i> DESINTY-BREAST01 (US)
<i>Calquence</i> CLL (US)
<i>Enhertu</i> gastric cancer (JP) ²
<i>Enhertu</i> HER2+/HER2low gastric 3L DESTINY-Gastric01 (US)
<i>Enhertu</i> HER2mut NSCLC 2L+ DESTINY-Lung01 (US)
<i>Tagrisso</i> adjuvant NSCLC ADAURA (US)
<i>Forxiga</i> CKD (DAPA-CKD)

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Fast Track

MED13902 Psi-PcrV pneumo Px (US)
savratomumab Staph HAP (US)
<i>Imfinzi</i> NSCLC (US)
nirsevimab (MED18897) RSV mAB (US)
<i>Imfinzi</i> HNSCC HAWK (US)
anifrolumab SLE (US)
<i>Lynparza</i> ovarian cancer SOLO-2 (US)
<i>Tagrisso</i> EGFRm T790M NSCLC (CN)
<i>Farxiga</i> HF rEF (US)
<i>Farxiga</i> chronic kidney disease (US)
cotadutide non-alcoholic steatohepatitis (US)
<i>Farxiga</i> MI RRCT DAPA-MI (US)

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Priority Review / RTOR³

<i>Tagrisso</i> EGFRm T790M NSCLC (JP)
<i>Tagrisso</i> EGFRm T790M NSCLC (US)
<i>Imfinzi</i> bladder cancer 2L (US)
<i>Tagrisso</i> NSCLC AURA3 (US)
<i>Calquence</i> MCL (US)
<i>Lynparza</i> breast cancer OLYMPIAD (US)
roxadustat CKD (CN)
<i>Tagrisso</i> NSCLC FLAURA (US)
<i>Imfinzi</i> stage III NSCLC PACIFIC (EU)
<i>Imfinzi</i> stage III NSCLC PACIFIC (JP)
<i>Lynparza</i> tablet (US)
<i>Lynparza</i> tablet (CN)
<i>Lynparza</i> breast cancer OLYMPIAD (JP)
<i>Tagrisso</i> NSCLC 1L FLAURA (JP)
<i>Lumoxiti</i> HCL PLAIT (US)
<i>Lynparza</i> ovarian SOLO-1 (US)
<i>Lynparza</i> ovarian SOLO-1 (CN)
<i>Breztri Aerosphere</i> (PT010) COPD (CN)
<i>Tagrisso</i> NSCLC 1L FLAURA (CN)
<i>Breztri Aerosphere</i> (PT010) (CN)
<i>Lokelma</i> hyperkalaemia (CN)
<i>Lynparza</i> pancreatic 1L (US)
<i>Enhertu</i> DESINTY-BREAST01 (US)
<i>Farxiga</i> HF DAPA-HF (US)
<i>Imfinzi</i> +/-treme+SOC SCLC 1L CASPIAN (US)
<i>Lynparza</i> prostate PROFOUND (US)
<i>Lynparza</i> +Avastin ovarian 1L PAOLA-1 (US)
<i>Koselugo</i> /selumetinib NFI type 1 SPRINT (US)
<i>Calquence</i> CLL ELEVATE-TN, ASCEND ³ (US)
<i>Brilinta</i> stroke THALES (US)
<i>Imfinzi</i> Q4W regimen NSCLC, bladder (US)
<i>Tagrisso</i> adjuvant NSCLC ADAURA (US)
<i>Enhertu</i> HER2+/HER2low gastric 3L DESTINY-Gastric01 (US)

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Orphan

<i>Lynparza</i> ovarian cancer SOLO-2 (US)
<i>Lumoxiti</i> HCL PLAIT (US)
<i>Lumoxiti</i> HCL PLAIT (EU)
<i>Crestor</i> paediatric (US)
cediranib VEGFR tki (US)
<i>Iressa</i> EGFRm NSCLC (US)
<i>Tagrisso</i> EGFRm T790M NSCLC (US)
AZD3241 MPO (EU)
<i>Calquence</i> CLL 1L (US)
<i>Calquence</i> MCL (US)
<i>Calquence</i> WM (US)
<i>Calquence</i> CLL 1L (EU)
selumetinib thyroid cancer ASTRA (US)
<i>Lynparza</i> breast cancer OLYMPIAD (JP)
<i>Lynparza</i> ovarian cancer SOLO-2 (JP)
<i>Koselugo</i> /selumetinib NFI type 1 SPRINT (US)
<i>Koselugo</i> /selumetinib NFI type 1 SPRINT (EU)
<i>Lynparza</i> pancreatic cancer POLO (US)
<i>Fasenra</i> EGPA (US)
<i>Fasenra</i> HES (US)
saracatinib IPF (US)
<i>Imfinzi</i> +/-treme+SOC SCLC 1L CASPIAN (US)
<i>Fasenra</i> EoE (US)
<i>Imfinzi</i> +treme HCC 1L HIMALAYA (US)
<i>Lynparza</i> pancreatic cancer POLO (JP)
<i>Enhertu</i> HER2+/HER2low gastric 3L DESTINY-Gastric01 (US)
<i>Koselugo</i> /selumetinib NFI type 1 SPRINT (JP)

ACCELERATED APPROVAL, these regulations allowed medicines for serious conditions that addressed an unmet medical need to be approved based on a surrogate endpoint.

BREAKTHROUGH DESIGNATION is a process designed to expedite the development and review of medicines which may demonstrate substantial improvement over available therapy. ¹PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need. ²SAKIGAKE is aimed at early introduction of innovative medicines, medical devices, etc. that are initially developed in Japan.

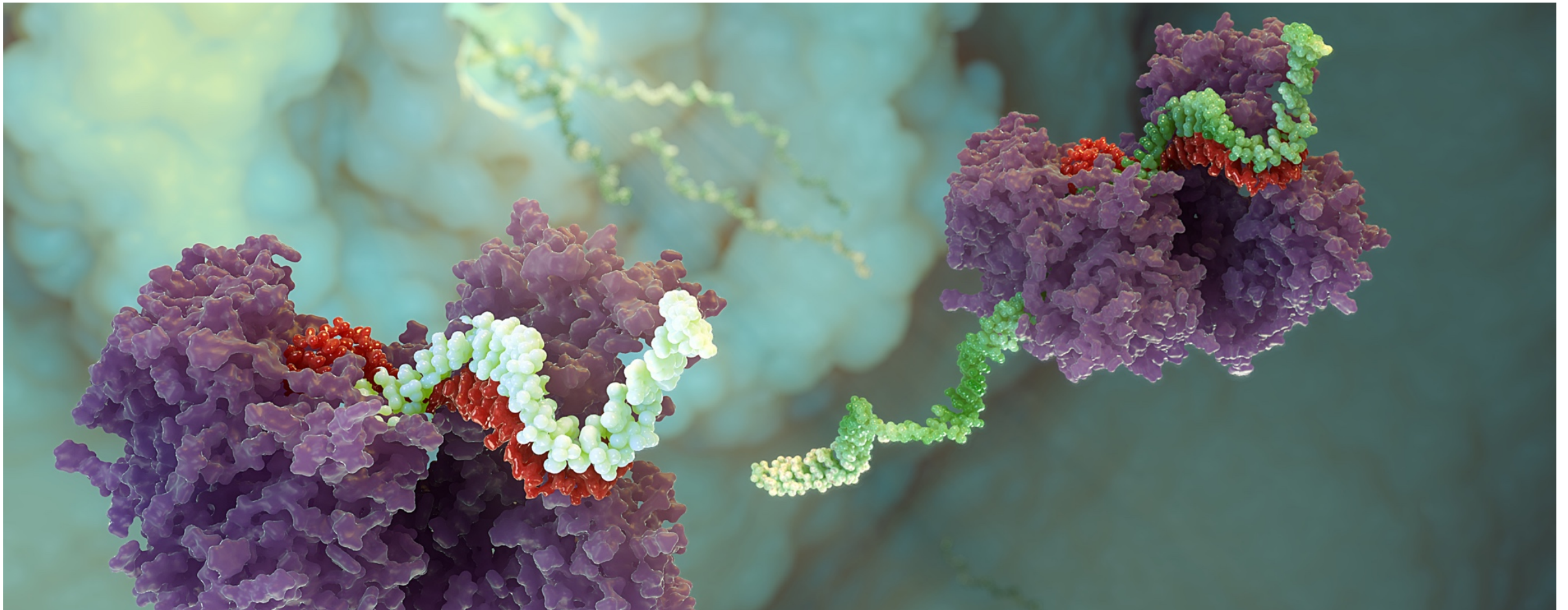
FAST TRACK is a process designed to facilitate the development, and expedite the review of medicines to treat serious conditions and fill an unmet medical need. ³REAL-TIME ONCOLOGY REVIEW (RTOR) and Project Orbis is an initiative of the FDA Oncology Centre of Excellence (OCE) providing a framework for concurrent submission and review of oncology products among international partners.

PRIORITY REVIEW DESIGNATION is the US FDA's goal to take action on an application within 6 months.

ORPHAN DRUG DESIGNATION, intended for treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 patients in the US, or that affect more than 200,000 patients but are not expected to recover the costs of developing and marketing a treatment drug.



Oncology - approved medicines and late-stage pipeline



Tagrisso (highly-selective, irreversible EGFRi)

NSCLC

Trial	Population	Patients	Design	Endpoints	Status
Phase III ADAURA NCT02511106	Adjuvant EGFRm NSCLC	682	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> QD following complete tumour resection, with or without chemo Arm 2: placebo Global trial - 25 countries	<ul style="list-style-type: none"> Primary endpoint: DFS Secondary endpoints: DFS Rate, OS, OS Rate, QoL 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q1 2019 Data readout: Q2 2020 Trial unblinded due to efficacy DFS primary endpoint met
Phase III LAURA NCT03521154	Maintenance therapy in patients with locally advanced, unresectable EGFRm Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy	200	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> Arm 2: placebo Global trial - 17 countries	<ul style="list-style-type: none"> Primary endpoint: PFS (BICR) Secondary endpoints: CNS PFS, OS, DoR, ORR, DCR 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2021+
Phase III ASTRIS NCT02474355	Real world setting in adult patients with advanced or metastatic, EGFRm T790M+ NSCLC	3,020	Single-arm trial - <i>Tagrisso</i> Global trial - 16 countries	<ul style="list-style-type: none"> Primary endpoints: OS and safety Secondary endpoint: PFS 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q4 2017
Phase II ELIOS NCT03239340	EGFR TKI treatment-naïve patients with locally-advanced or metastatic EGFRm NSCLC	150	Single arm trial - <i>Tagrisso</i> Global trial - five countries	<ul style="list-style-type: none"> Primary Endpoint: proportion of patients with a given tumour genetic and proteomic marker at the point of disease progression as defined by the investigator Secondary endpoint: PFS, ORR, DoR 	<ul style="list-style-type: none"> FPCD: Q2 2018
Phase I ODIN-BM NCT03463525	Patients with EGFRm NSCLC with brain metastases	8	Single-arm trial - <i>Tagrisso</i>	<ul style="list-style-type: none"> Primary Endpoints: assessments of brain standard uptake value (SUV) and pharmacokinetics (PK) Secondary endpoints: PK 	<ul style="list-style-type: none"> FPCD: Q4 2018 LPCD: Q1 2020 Data anticipated: H1 2021



Tagrisso (highly-selective, irreversible EGFRi)

NSCLC, combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III NeoADAURA NCT04351555	Neoadjuvant EGFRm NSCLC	351	Arm 1: placebo plus plus pemetrexed/carboplatin or pemetrexed/cisplatin Arm 2: <i>Tagrisso</i> plus pemetrexed/carboplatin or pemetrexed/cisplatin Arm 3: <i>Tagrisso</i> Global trial – 23 countries	<ul style="list-style-type: none"> Primary endpoint: mPR Secondary endpoints cPR, EFS, DFS, OS 	<ul style="list-style-type: none"> FPCD Q4 2020 Data anticipated: 2021+
Phase III FLAURA2 NCT04035486	1st-line EGFRm NSCLC	586	Arm 1: <i>Tagrisso</i> plus pemetrexed/carboplatin or pemetrexed/cisplatin Arm 2: <i>Tagrisso</i> Global trial – 22 countries	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: OS, LOS, ORR, DoR, Depth of response, PFS2, QoL, PK 	<ul style="list-style-type: none"> FPCD: Q4 2019 Data anticipated: 2021+
Phase II ORCHARD NCT03944772	Advanced EGFRm NSCLC patients who have progressed on first line <i>Tagrisso</i> treatment	182	Modular design platform trial: <ul style="list-style-type: none"> Module 1: <i>Tagrisso</i> + savolitinib Module 2: <i>Tagrisso</i> + gefitinib Module 3: <i>Tagrisso</i> + necitumumab Module 4: carboplatin + pemetrexed + <i>Imfinzi</i> Module 5: <i>Tagrisso</i> + alectinib Module 6: <i>Tagrisso</i> + selpercatinib No intervention: observational cohort Global trial - 8 countries	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: PFS, DoR, OS, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q3 2019 Data anticipated: 2021+
Phase II SAVANNAH NCT03778229	EGFRm / MET+, locally advanced or metastatic NSCLC who have progressed following treatment with <i>Tagrisso</i>	172	<ul style="list-style-type: none"> Single arm trial: <i>Tagrisso</i> + savolitinib Global trial	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints include PFS, DoR and OS 	<ul style="list-style-type: none"> FPCD Q1 2019 Data anticipated: 2021+
Phase Ib TATTON NCT02143466	Advanced EGFRm NSCLC TKI failure	344	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> + <i>Imfinzi</i> Arm 2: <i>Tagrisso</i> + savolitinib Arm 3: <i>Tagrisso</i> + selumetinib Enrolment to <i>Tagrisso</i> + <i>Imfinzi</i> arm will not restart Global trial	<ul style="list-style-type: none"> Safety, tolerability, pharmacokinetics and preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data anticipated: H2 2020



Imfinzi (PD-L1 mAb)

NSCLC, early disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III MERMAID-1 NCT04385368	Completely resected Stage II and III NSCLC	332	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + SoC chemo Arm 2: placebo + SoC chemo 	Primary endpoint: <ul style="list-style-type: none"> DFS Secondary endpoint: <ul style="list-style-type: none"> DFS, OS, 	<ul style="list-style-type: none"> Initiating Data anticipated: 2021+
Phase III AEGEAN NCT03800134	Neoadjuvant NSCLC patients Stage II and III resected NSCLC (incl. EGFR/ALK positive)	800	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + platinum-based chemo Arm 2: placebo + platinum-based chemo 	Primary endpoint: <ul style="list-style-type: none"> mPR, EFS Secondary endpoint: <ul style="list-style-type: none"> pCR 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase III ADJUVANT BR.31 NCT02273375 Partnered	Adjuvant NSCLC patients Ib (≥4cm) – stage IIIa resected NSCLC (incl. EGFR/ALK positive)	1,360	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> mg/kg i.v. Q4W x 12m Arm 2: placebo Global trial	Primary endpoint: <ul style="list-style-type: none"> DFS Secondary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD Q1 2020 Data anticipated: 2021+
Phase III PACIFIC-2 NCT03519971	Unresected, locally-advanced NSCLC	300	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> i.v. Q4W + chemo/RT Arm 2: placebo + chemo/RT ex US global trial	Primary endpoint: <ul style="list-style-type: none"> PFS ORR Secondary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q3 2019 Data anticipated: H1 2021
Phase III PACIFIC-4 NCT03833154	<i>Imfinzi</i> with SBRT in unresected, Stage I/II NSCLC	630	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> i.v. Q4W with definitive SBRT Arm 2: placebo with definitive SBRT 	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q2 2019 Data anticipated: 2021+
Phase III PACIFIC-5 NCT03706690	Unresected, locally-advanced NSCLC	360	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> i.v. Q4W following chemo/RT Arm 2: placebo following chemo/RT ex US global trial, China focus	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase II/III Lung Master Protocol NCT02154490 Partnered	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	140	<ul style="list-style-type: none"> Subtrial A: <i>Imfinzi</i> (non-match for other biomarker driven subtrials) i.v. Q2W single arm <i>Imfinzi</i> Phase II only Subtrial B: PI3K inhibitor vs. docetaxel Subtrial C: CDK4/6 inhibitor vs. docetaxel Subtrial D: AZD4547 (FGFR inhibitor) vs. docetaxel Subtrial E: C-MET/HGFR Inhibitor + erlotinib vs. erlotinib 	Primary endpoints: <ul style="list-style-type: none"> ORR PFS OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 Data anticipated: 2021+



Imfinzi (PD-L1 mAb) +/- tremel (CTLA-4 mAb)

Lung cancer, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III PEARL NCT03003962	NSCLC 1L	650	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Q4W Arm 2: chemotherapy <p>Asia trial</p>	Primary endpoint: • OS	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2019 Data anticipated: H1 2021
Phase III POSEIDON NCT03164616	NSCLC 1L	1,000	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + chemo Arm 2: <i>Imfinzi</i> + tremelimumab + chemo Arm 3: SoC 	Primary endpoint: • OS • PFS	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q4 2018 Data readout: Q4 2019 PFS primary endpoint met OS data anticipated: H2 2021
Phase II MAGELLAN NCT03819465	NSCLC 1L	200	<ul style="list-style-type: none"> Arm A1: <i>Imfinzi</i> Arm A2: <i>Imfinzi</i> + danvatirsen Arm A3: <i>Imfinzi</i> + oleclumab Arm A3: MEDI5752 Arm B1: <i>Imfinzi</i> + Investigator's choice of chemo Arm B2: <i>Imfinzi</i> + danvatirsen + Investigator's choice of chemo Arm B3: <i>Imfinzi</i> + oleclumab + Investigator's choice of chemo Arm B4: MEDI5752 	Primary endpoint: • Safety & tolerability Secondary endpoint: • ORR, DoR, PFS, OS, PK, ADA	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase III ADRIATIC NCT03703297	Limited stage SCLC 1L following platinum-based concurrent chemoradiation therapy	600	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab (4 doses) Arm 2: <i>Imfinzi</i> Arm 3: placebo 	Primary endpoints: • PFS • OS	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2021+
Phase III CASPIAN NCT03043872	Extensive stage SCLC 1L	805	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab + EP (carboplatin or cisplatin + etoposide) Arm 2: <i>Imfinzi</i> + EP (carboplatin or cisplatin + etoposide) Arm 3: EP (carboplatin or cisplatin + etoposide) 	Primary endpoint: • OS	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q2 2018 Data readout: Q2 2019 OS Primary endpoint met for <i>Imfinzi</i> monotherapy OS primary endpoint not met for <i>Imfinzi</i> + tremelimumab
Phase II BALTIC NCT02937818	SCLC	72	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab Q4W Arm B: adavosertib and carboplatin BID Arm C: ceralasertib and <i>Lynparza</i> 	• Primary endpoint: ORR	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: H1 2021



Imfinzi (PD-L1 mAb)

Other cancers, early disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III POTOMAC NCT03528694	Non-muscle invasive bladder cancer	975	<ul style="list-style-type: none"> Arm 1: BCG (Induction + maintenance) Arm 2: <i>Imfinzi</i> + BCG (Induction only) Arm 3: <i>Imfinzi</i> + BCG (Induction + maintenance) 	Primary endpoints: <ul style="list-style-type: none"> DFS 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q4 2020 Data anticipated: 2021+
Phase III NIAGARA NCT03732677	Muscle-invasive bladder cancer	960	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> in combination with gemcitabine + cisplatin, <i>Imfinzi</i> maintenance Arm 2: gemcitabine + cisplatin 	Copriamary endpoints: <ul style="list-style-type: none"> pCR EFS 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H2 2021
Phase III EMERALD-1 NCT03778957	Locoregional HCC	600	<ul style="list-style-type: none"> Arm A: TACE in combination with <i>Imfinzi</i> Arm B: TACE in combination with <i>Imfinzi</i> + bevacizumab Arm C: TACE in combination with placebo 	Primary endpoint PFS for Arm A vs Arm C Secondary endpoint PFS for Arm B vs Arm C , OS	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: H2 2021
Phase III EMERALD-2 NCT03847428	Adjuvant therapy in HCC	888	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + bevacizumab Arm 2: <i>Imfinzi</i> + placebo Arm 3: placebo + placebo 	Primary endpoint: <ul style="list-style-type: none"> RFS for Arm 2 vs Arm 3 Secondary endpoint: <ul style="list-style-type: none"> RFS Arm 1 vs Arm 3, OS, RFS at 24m 	<ul style="list-style-type: none"> FPCD: Q2 2019 Data anticipated: 2021+
Phase III KUNLUN NCT04550260	Locally advanced, unresectable ESCC	600	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + definitive CRT Arm 2: placebo + definitive CRT 	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Pending Data anticipated: 2021+
Phase III MATTERHORN NCT04592913	Resectable GC/GEJC	900	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + FLOT Arm 2: placebo + FLOT 	Primary endpoint: <ul style="list-style-type: none"> EFS Secondary endpoint: <ul style="list-style-type: none"> OS Arm 1 vs Arm 2 pCR Arm 1 vs Arm 2 	<ul style="list-style-type: none"> Not yet recruiting Data anticipated: 2021+



Imfinzi (PD-L1 mAb) +/- treme (CTLA-4 mAb)

Other cancers, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III NILE NCT03682068	Bladder cancer 1L	885	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab + SoC Arm 2: <i>Imfinzi</i> + SoC Arm 3: SoC 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2021+
Phase III KESTREL NCT02551159	HNSCC 1L	823	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Arm 2: <i>Imfinzi</i> + tremelimumab Arm 3: SoC 	Primary endpoints: <ul style="list-style-type: none"> OS Secondary endpoint: <ul style="list-style-type: none"> PFS, ORR, DoR, safety, biomarkers 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD Q1 2017 Data anticipated: H1 2021
Phase III HIMALAYA NCT03298451	HCC 1L	1,324	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: <i>Imfinzi</i> Arm 3: sorafenib 	Primary endpoint: <ul style="list-style-type: none"> OS Secondary endpoint: <ul style="list-style-type: none"> PFS, TTP, ORR 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q4 2019 Data anticipated: H2 2021
Phase II NCT02527434	Urothelial bladder cancer triple-negative breast cancer pancreatic ductal-adenocarcinoma	76	<ul style="list-style-type: none"> Arm 1 tremelimumab (urothelial bladder cancer) Arm 2 tremelimumab (triple-negative breast cancer) Arm 3 tremelimumab (pancreatic ductal-adenocarcinoma) 	Primary endpoint: <ul style="list-style-type: none"> ORR Secondary endpoints: <ul style="list-style-type: none"> Safety, DoR 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2016 Data readout: Q4 2018
Phase III TOPAZ-1 NCT03875235	BTC 1L	757	<ul style="list-style-type: none"> Treatment Arm 1 <i>Imfinzi</i> + gemcitabine + cisplatin Treatment Arm 2 placebo + gemcitabine + cisplatin Global trial	Primary endpoint: <ul style="list-style-type: none"> OS Secondary endpoint: <ul style="list-style-type: none"> PFS, ORR, DoR 	<ul style="list-style-type: none"> FPCD Q2 2019 Data anticipated: H2 2021
Phase III CALLA NCT03830866	Locally advanced cervical cancer	714	<ul style="list-style-type: none"> Arm 1 <i>Imfinzi</i> + EBRT + brachytherapy with platinum Arm 2 placebo + EBRT + brachytherapy with platinum Global trial	Primary <ul style="list-style-type: none"> PFS Secondary <ul style="list-style-type: none"> OS, CR rate, DoR, ORR, safety/tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+



Imfinzi (PD-L1 mAb) +/- treme (CTLA-4 mAb)

Other cancers, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III STRONG NCT03084471	Advanced solid malignancies	1,200	<ul style="list-style-type: none"> • Arm 1: <i>Imfinzi</i> • Arm 2: <i>Imfinzi</i> + tremelimumab 	<ul style="list-style-type: none"> • Primary endpoint: safety 	<ul style="list-style-type: none"> • FPCD: Q2 2017 • Data anticipated: 2021+
Phase I Combination in Advanced Solid Tumours NCT02658214	Solid tumours	80	<ul style="list-style-type: none"> • Arm 2 SCLC: <i>Imfinzi</i> + tremelimumab + carboplatin + etoposide • Arm 3 TNBC: <i>Imfinzi</i> + tremelimumab + chemo • Arm 4 TNBC: <i>Imfinzi</i> + tremelimumab + chemo • Arm 5 GEJ: <i>Imfinzi</i> + tremelimumab + oxaliplatin + 5-FU + leucovorin • Arm 6 PDAC: <i>Imfinzi</i> + tremelimumab + chemo • Arm 7 ESSC: <i>Imfinzi</i> + tremelimumab + chemo 	<ul style="list-style-type: none"> • Safety 	<ul style="list-style-type: none"> • FPCD: Q1 2016 • LPCD: Q1 2019 • Data anticipated: 2021+
Phase I Immunotherapy in Combination With Chemoradiation in Patients With Advanced Solid Tumours CLOVER NCT03509012	HNSCC, NSCLC, SCLC	102	<ul style="list-style-type: none"> • HNSCC Arm 1 • NSCLC Arm 1 • NSCLC Arm 2 • NSCLC Arm 3 • SCLC Arm 2 • SCLC Arm 3 • SCLC Arm 4 	<ul style="list-style-type: none"> • Safety 	<ul style="list-style-type: none"> • FPCD: Q2 2018 • Data anticipated: H1 2021
Phase II BEGONIA NCT03742102	mTNBC 1L	110	<ul style="list-style-type: none"> • Arm 1 <i>Imfinzi</i> + paclitaxel • Arm 2 <i>Imfinzi</i> + paclitaxel + capivasertib • Arm 4 <i>Imfinzi</i> + paclitaxel + danvatirsen • Arm 5 <i>Imfinzi</i> + paclitaxel + oleclumab <p>Global trial</p>	<p>Primary endpoint:</p> <ul style="list-style-type: none"> • Safety and tolerability <p>Secondary endpoint:</p> <ul style="list-style-type: none"> • ORR, PFS, DoR, OS, PK, ADA 	<ul style="list-style-type: none"> • FPCD: Q1 2019 • Data anticipated: 2021+



Lynparza (PARP inhibitor)

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III OlympiA NCT02032823 Partnered	BRCAM adjuvant breast cancer	1,836	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> BiD 12 month duration Arm 2: placebo 12-month duration Global trial partnership with BIG and NCI/NRG	<ul style="list-style-type: none"> Primary endpoint: invasive disease-free survival (IDFS) Secondary endpoint: distant disease-free survival and OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q2 2019 Data anticipated: H1 2021
Phase III POLO NCT02184195	gBRCAM pancreatic cancer	154	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg twice daily as maintenance therapy until progression Arm 2: placebo tablets BID Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q1 2019 Data readout: Q1 2019 Primary endpoint met
Phase III PROfound NCT02987543	Metastatic castration-resistant prostate cancer HRRm, 2L+	387	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> BID Arm 2: physician's choice: enzalutamide 160mg once daily or abiraterone acetate 1,000mg once daily Global trial	<ul style="list-style-type: none"> Primary endpoint: radiologic PFS Secondary endpoints: ORR, Time to Pain Progression, OS 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q4 2018 Data readout : Q3 2019 Primary endpoint met



Lynparza (PARP inhibitor)

Imfinzi combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III DuO-O NCT03737643	Advanced ovarian cancer 1L	1,256	Non tBRCAm (tumour BRCA) patients <ul style="list-style-type: none"> Arm 1: bevacizumab Arm 2: bevacizumab + <i>Imfinzi</i> Arm 3: bevacizumab + <i>Imfinzi</i> + <i>Lynparza</i> tBRCAm patients <ul style="list-style-type: none"> bevacizumab (optional) + <i>Imfinzi</i> + <i>Lynparza</i> Global trial	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, PFS2 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase III DUO-E NCT04269200	Advanced and recurrent endometrial cancer 1L	699	<ul style="list-style-type: none"> Arm 1: chemo + <i>Imfinzi</i> placebo followed by <i>Imfinzi</i> placebo and <i>Lynparza</i> placebo Arm 2: chemo + <i>Imfinzi</i> followed by <i>Imfinzi</i> + <i>Lynparza</i> placebo Arm 3: chemo + <i>Imfinzi</i> followed by <i>Imfinzi</i> + <i>Lynparza</i> Global Trial	Primary endpoint <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, PFS2, ORR, DoR 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: 2021+
Phase II ORION NCT03775486	Stage IV NSCLC whose disease has not progressed following SoC chemo + <i>Imfinzi</i> Maintenance therapy 1L	250	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + <i>Lynparza</i> Arm 2: <i>Imfinzi</i> + placebo Global trial	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, ORR, DoR, PFS in HRRm, PK, ADA 	<ul style="list-style-type: none"> FPCD Q1 2019 Data anticipated: H1 2021
Phase II BAYOU NCT03459846	Platinum-Ineligible unresectable Stage IV urothelial cancer	154	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + <i>Lynparza</i> Arm 2: <i>Imfinzi</i> + placebo Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: OS, DoR, ORR, PFS in HRRm, PFS6, PK, ADA, PRO 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q3 2019 Data anticipated : H2 2020
Phase I / II MEDIOLA NCT02734004	gBRCAm ovarian cancer 2L+ gBRCAm HER2-negative breast cancer 1-3L SCLC 2L+ Gastric cancer 2L+	148	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> + <i>Imfinzi</i> Dose until progression Global trial	Primary endpoints: <ul style="list-style-type: none"> DCR at 12 weeks Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q2 2017
Phase I / II MEDIOLA (Ovarian expansion) NCT02734004	gBRCAm ovarian cancer 2L+ Non-gBRCAm ovarian cancer 2L+ Non-gBRCAm ovarian cancer 2L+	115	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> + <i>Imfinzi</i> Arm 2: <i>Lynparza</i> + <i>Imfinzi</i> Arm 3: <i>Lynparza</i> + <i>Imfinzi</i> + bevacizumab Dose until progression Global trial	Primary endpoints: <ul style="list-style-type: none"> DCR at 12 weeks ORR Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q2 2020



Lynparza (PARP inhibitor)

Other combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III PAOLA-1 NCT02477644 Externally sponsored	Advanced ovarian cancer 1L maintenance	806	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> maintenance therapy for two years or until disease progression Arm 2: placebo for two years or until disease progression Global trial	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, PFS2 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q2 2018 Data readout: Q3 2019 Primary endpoint met
Phase III PROpel NCT03732820	Metastatic castration-resistant prostate cancer 1L	720	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> + abiraterone Arm 2: placebo + abiraterone Global trial	Primary Endpoint: <ul style="list-style-type: none"> rPFS Secondary endpoints: <ul style="list-style-type: none"> TFST, TTPP, OS 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H2 2021
Phase II VIOLETTE NCT03330847	TNBC	350	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> + ceralasertib Arm 2: <i>Lynparza</i> Trial conducted in 15 countries: North America, Europe and Asia	<ul style="list-style-type: none"> PFS ORR / OS Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2018 Data anticipated: H2 2021
Phase II/III GY005 NCT02502266 Externally sponsored	Recurrent platinum resistant/refractory ovarian cancer	680	<ul style="list-style-type: none"> Arm 1: chemo Arm 2: cediranib + <i>Lynparza</i> Arm 3: cediranib Arm 4: <i>Lynparza</i> US/Canada sites	Primary endpoints: <ul style="list-style-type: none"> PFS, OS Secondary endpoints: <ul style="list-style-type: none"> ORR, QoL, safety 	<ul style="list-style-type: none"> FPCD: Q2 2016 Data anticipated: 2021+
Phase II LYNK-002 NCT03742895 Partnered	HRRm or HRD-positive advanced cancer	370	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> Global trial	Primary endpoints: <ul style="list-style-type: none"> ORR Secondary endpoints: <ul style="list-style-type: none"> DOR, OS, PFS, AE, Prog by CA-125 	<ul style="list-style-type: none"> FPCD: Q1 2019
Phase III LYNK-003 NCT04456699 Partnered	Advanced colorectal cancer 1L maintenance	525	<ul style="list-style-type: none"> Arm 1: bevacizumab + 5-FU maintenance Arm 2: bevacizumab + <i>Lynparza</i> maintenance Arm 3: <i>Lynparza</i> maintenance Global trial	Primary endpoints: <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, ORR, DoR, AEs 	<ul style="list-style-type: none"> FPCD: Q3 2020 Data anticipated: 2021+
Phase II DUETTE NCT04239014	Ovarian post-PARPi maintenance PSR	192	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> + ceralasertib Arm 2: <i>Lynparza</i> Arm 3: placebo Global trial	Primary endpoint <ul style="list-style-type: none"> PFS Secondary endpoints <ul style="list-style-type: none"> TTSP, ORR, OS Safety and tolerability 	<ul style="list-style-type: none"> Initiating Data anticipated: 2021+



Enhertu (trastuzumab deruxtecan, HER2 ADC)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase II DESTINY-Breast01 NCT03248492 Partnered	HER2-positive, unresectable and/or metastatic breast cancer patients previously treated with trastuzumab emtansine	230	Randomised, open label, sequential assignment • <i>Enhertu</i>	Primary endpoint ORR Secondary end points DoR, CBR, CBR, PFS, OS	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q4 2018 Data readout: Q2 2019 Primary objective met
Phase III DESTINY-Breast02 NCT03523585 Partnered	HER2-positive, unresectable and/or metastatic breast cancer pretreated with prior standard of care HER2 therapies, including trastuzumab emtansine	600	Randomised open label parallel assignment • <i>Enhertu</i> Physicians choice of • Lapatinib + capecitabine • Trastuzumab + capecitabine	Primacy endpoint PFS Secondary endpoints OS, ORR, DoR, CBR	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated H2 2021
Phase III DESTINY-Breast03 NCT03529110 Partnered	HER2-positive, unresectable and/or metastatic breast cancer patients previously treated with trastuzumab and taxane	500	Randomised open label parallel assignment • <i>Enhertu</i> • Ado-trastuzumab emtansine	Primary endpoint PFS Secondary endpoints OS, ORR, DoR, CBR	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated H2 2021
Phase III DESTINY-Breast04 NCT03734029 Partnered	HER2-low, unresectable and/or metastatic breast cancer patients	540	Randomised open label parallel assignment • <i>Enhertu</i> • Physicians choice of SoC chemo (choice of capecitabine, eribulin, gemcitabine, paclitaxel or nab-paclitaxel)	Primary end point PFS Secondary end points OS, DoR, ORR	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated H2 2021
Phase III DESTINY-Breast06 NCT04494425	HER2-Low, Hormone Receptor Positive Breast Cancer Patients Whose Disease Has Progressed on Endocrine Therapy in the Metastatic Setting	850	Randomised open label parallel assignment • <i>Enhertu</i> • Investigator's choice standard of care chemotherapy (capecitabine, paclitaxel, nab-paclitaxel)	Primary end point PFS Secondary end points OS, DoR, ORR	<ul style="list-style-type: none"> FPCD Q2 2020
Phase Ib/II DESTINY-Breast07 NCT04538742	HER2-positive Metastatic Breast Cancer	350	Randomised open label sequential assignment • <i>Enhertu</i> • <i>Enhertu</i> + <i>Imfinzi</i> • <i>Enhertu</i> + pertuzumab • <i>Enhertu</i> + paclitaxel • <i>Enhertu</i> + <i>Imfinzi</i> + paclitaxel	Primary end point AE, SAE Secondary end points ORR, PFS, DoR, OS	<ul style="list-style-type: none"> Initiating
Phase Ib DESTINY-Breast08 NCT04556773	HER2-low Metastatic Breast Cancer	185	Non-Randomised open label parallel assignment • <i>Enhertu</i> + capecitabine • <i>Enhertu</i> + <i>Imfinzi</i> + paclitaxel • <i>Enhertu</i> + capivasertib • <i>Enhertu</i> + anastrozole • <i>Enhertu</i> + <i>Faslodex</i>	Primary end point AE, SAE Secondary end points ORR, PFS, DoR, OS	<ul style="list-style-type: none"> Initiating



Enhertu (trastuzumab deruxtecan, HER2 ADC)

Gastric cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase II DESTINY-Gastric01 NCT03329690 Partnered	HER2-overexpressing advanced gastric or gastroesophageal junction adenocarcinoma patients who have progressed on two prior treatment regimens	220	Randomised open label parallel assignment <ul style="list-style-type: none"> • <i>Enhertu</i> • SoC chemo Asian trial 2 countries	Primary end point ORR Secondary end points PFS, OS, DoR, DCR, TTF, range of PK endpoints	<ul style="list-style-type: none"> • FPCD: Q4 2017 • LPCD: Q2 2019 • Data readout Q1 2020 • Primary endpoint met
Phase II DESTINY-Gastric02 NCT04014075 Partnered	HER2-positive gastric cancer that cannot be surgically removed or has spread	72	Open label single group assignment <ul style="list-style-type: none"> • <i>Enhertu</i> Global trial 5 countries	Primary endpoint ORR Secondary endpoints PFS, ORR, OS, DoR	<ul style="list-style-type: none"> • FPCD: Q4 2019
Phase Ib/II DESTINY-Gastric03 NCT04379596	HER2-overexpressing gastric or gastroesophageal junction cancer patients	210	<ul style="list-style-type: none"> • Open label parallel assignment • Part 1: To determine recommended Phase 2 dose • 5 Arms combine <i>Enhertu</i> with standard of care chemotherapies (5-FU, capecitabine, oxaliplatin) and / or durvalumab • Part 2: To assess efficacy of the selected combinations • Arm 2A Standard chemotherapy (control) • Arm 2B <i>Enhertu</i> monotherapy • Arm 2C <i>Enhertu</i> with chemotherapy • Arm 2D <i>Enhertu</i> with chemotherapy and durvalumab Global trial 8 countries	Part 1 Primary endpoint safety Part 2 Primary endpoint ORR Secondary end points DoR, DCR, PFS, OS, range of PK endpoints, ADAs	<ul style="list-style-type: none"> • FPCD Q2 2020



Enhertu (trastuzumab deruxtecan, HER2 ADC)

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II DPT02 NCT04482309	HER2 expressing tumours	280	Non randomised single group assignment • <i>Enhertu</i>	Primary endpoint: ORR Secondary endpoints: DoR, DCR, PFS, OS	• FPCD Q4 2020
Phase II DESTINY-CRC01 NCT03384940 Partnered	HER2-expressing advanced colorectal cancer	90	Non randomised single group assignment • <i>Enhertu</i>	Primary endpoint ORR Secondary endpoints PFS, OS, DoR, range of PK endpoints	• FPCD Q1 2018 • LPCD Q2 2019 • Data readout: Q2 2020 • Primary endpoint met
Phase II DESTINY-Lung01 NCT03505710 Partnered	HER2-over-expressing or mutated, unresectable and/or metastatic NSCLC	170	Non randomised parallel group assignment • <i>Enhertu</i>	Primary endpoint ORR Secondary endpoints DoR, PFS, OS	• FPCD Q2 2018 • Data anticipated H2 2021
Phase I J101 NCT02564900 Partnered	Advanced solid malignant tumours	278	Non randomised single group assignment • <i>Enhertu</i>	Primary endpoints ORR, number of subjects with AEs, tumour response Secondary endpoints PK	• FPCD Q3 2015 • Data read out Q3 2018
Phase I NCT04042701 Partnered	HER2-expressing locally advanced/metastatic breast or NSCLC	115	• Non randomised parallel group assignment • <i>Enhertu</i> + pembrolizumab Global trial 2 countries	Primary endpoints DLT, ORR Secondary endpoints DoR, DCR, PFS, TTR, OS	• FPCD Q1 2020
Phase I NCT03523572 Partnered	HER2-expressing breast and urothelial cancer	99	• Non randomised sequential assignment • <i>Enhertu</i> + nivolumab Global trial 7 countries	Primary endpoints DLT, ORR, TEAEs Secondary endpoints DoR, DCR, PFS, TTR, OS, ORR (investigator)	• FPCD Q2 2018



Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III ACE-CL-007 (ELEVATE-TN) NCT02475681	Previously untreated CLL	535	<ul style="list-style-type: none"> Arm A: chlorambucil + obinutuzumab Arm B: <i>Calquence</i> + obinutuzumab Arm C: <i>Calquence</i> 	<ul style="list-style-type: none"> Primary endpoint: PFS (Arm A vs. Arm B) Secondary endpoints: IRC (independent review committee) assessed ORR, OS (Arm A vs. Arm B vs. Arm C) 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q2 2019 Primary endpoint met
Phase III ACE-CL-311 NCT03836261	Previously untreated CLL fit	780	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> + venetoclax Arm B: <i>Calquence</i> + venetoclax + obinutuzumab Arm C: FCR or BR 	<ul style="list-style-type: none"> Primary – IRC PFS (A vs C) Secondary - IRC PFS (B vs C); INV PFS (A vs C; B vs C) 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase III ACE-CL-309 (ASCEND) NCT02970318	Relapsed/refractory CLL	306	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: rituximab + idelalisib or bendamustine (investigator's choice) 	<ul style="list-style-type: none"> Primary endpoint: IRC assessed PFS (arm A vs. Arm B) Secondary endpoints: INV-assessed ORR, OS, DoR, PROs 	<ul style="list-style-type: none"> FPCD Q3 2016 Data readout: Q2 2019 Primary endpoint met
Phase III ACE-CL-006 (ELEVATE-RR) NCT02477696	Relapsed/refractory high risk CLL	533	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: ibrutinib 	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: comparison of incidence of infections, RTs (Richter's Transformation) and atrial fibrillation, OS 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data anticipated: H1 2021
Phase III ACE-LY-308 NCT02972840	Previously untreated MCL	546	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> + bendamustine + rituximab Arm B: bendamustine + rituximab 	<ul style="list-style-type: none"> Primary endpoint: PFS by Lugano Classification for NHL Secondary endpoints: IA, PFS, ORR, DoR, time to response, OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2021+
Phase III ESCALADE NCT04529772	DLBCL	600	<i>Calquence</i> + rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone	<ul style="list-style-type: none"> Safety, ORR 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: 2021+
Phase II ACE-CL-208 NCT02717611	Relapsed/ refractory CLL, intolerant to ibrutinib	60	<i>Calquence</i> monotherapy	<ul style="list-style-type: none"> ORR at 36 cycles 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: H1 2020
Phase II 15-H-0016 NCT02337829	Relapsed/refractory and treatment naïve/del17p CLL/SLL	48	<ul style="list-style-type: none"> <i>Calquence</i> monotherapy Arm A: lymph node biopsy Arm B: bone marrow biopsy 	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2021+
Phase I/II ACE-CL-001 NCT02029443	CLL/SLL/Richter's transformation	306	<i>Calquence</i> monotherapy Dose escalation and expansion	<ul style="list-style-type: none"> Safety, PK, PD 	<ul style="list-style-type: none"> FPCD: Q1 2014 Data anticipated: 2021

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I/II ACE-LY-001 NCT02328014	B-cell malignancies	40	Dose escalation and expansion trial of the combination of <i>Calquence</i> and ACP-319 (Pi3K inhibitor)	<ul style="list-style-type: none"> Safety ORR 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: H1 2020
Phase I/II ACE-LY-005 NCT02362035	Haematological malignancies	161	<i>Calquence</i> + pembrolizumab	<ul style="list-style-type: none"> Safety Secondary endpoints: ORR, DoR, PFS, OS, TTNT (time to next therapy) 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2021
Phase I/II ACE-WM-001 NCT02180724	Waldenstrom microglobulinaemia	106	<i>Calquence</i> monotherapy	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data readout: Q4 2019
Phase Ib ACE-LY-002 NCT02112526	Relapsed/refractory de novo activated B-cell DLBCL	21	<i>Calquence</i> monotherapy	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data anticipated: H2 2019
Phase Ib ACE-LY-106 NCT02717624	MCL	70	<i>Calquence</i> in combination with bendamustine and rituxumab <ul style="list-style-type: none"> Arm A: treatment naïve Arm B: relapsed/refractory Arm C: treatment naïve: <i>Calquence</i> + venetoclax + rituxumab 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2021+
Phase Ib ACE-MY-001 NCT02211014	Relapsed/refractory MM	28	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: <i>Calquence</i> + dexamethasone 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data readout: Q2 2019
Phase I ACE-LY-003 NCT02180711	Relapsed/refractory follicular lymphoma	80	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: <i>Calquence</i> + rituximab Arm C: <i>Calquence</i> + rituximab + lenolidomide 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2021+
Phase I ACE-CL-002 NCT02157324	Relapsed/refractory CLL/ SLL	12	<i>Calquence</i> in combination with ACP-319 dose escalation	<ul style="list-style-type: none"> Safety, PK, PD 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data anticipated: H2 2020
Phase I ACE-CL-003 NCT02296918	CLL/SLL/PLL	69	<i>Calquence</i> + obinutuzumab <ul style="list-style-type: none"> Arm A: relapsed/refractory Arm B: treatment naïve Arm C: relapsed/refractory <i>Calquence</i> + venetoclax + rituxumab Arm D: treatment naïve 	<ul style="list-style-type: none"> Safety, ORR Secondary endpoints: PD, PFS, TTNT, OS 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2021+

Calquence (BTK inhibitor)

Blood and other cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I NCT03198650	Japanese adults with advanced B-cell malignancies	34	<ul style="list-style-type: none"> • <i>Calquence</i> monotherapy • Dose confirmation and expansion • <i>Calquence</i> + obinutuzumab 	<ul style="list-style-type: none"> • Safety • PK 	<ul style="list-style-type: none"> • FPCD: Q2 2017 • Data anticipated: 2021+
Phase I/II CL-110 NCT03328273	CLL r/r	62	<ul style="list-style-type: none"> • Arm A: ceralasertib (AZD6738) monotherapy • Arm B: <i>Calquence</i> + ceralasertib (AZD6738) 	<ul style="list-style-type: none"> • Identify dose of ceralasertib and safety of co-administration of <i>Calquence</i> + ceralasertib 	FPCD: Q1 2018 Data anticipated: H1 2021
Phase I/II LY-110 NCT03205046	B-cell malignancies r/r	25	<ul style="list-style-type: none"> • Part 1: <i>Calquence</i> daily + vistusertib daily • Part 2: <i>Calquence</i> daily + vistusertib 5 days on/2 days off 	<ul style="list-style-type: none"> • MTD and optimal dosing schedule • Safety 	FPCD: Q3 2017 Data anticipated: H2 2020
Phase III CL-312 NCT04008706	CLL TN and r/r	600	<ul style="list-style-type: none"> • Arm A: treatment naïve • Arm B: relapsed/refractory • Arm C: prior BTKi therapy • Arm D: concomitant vitamin K antagonists 	<ul style="list-style-type: none"> • Safety 	Data anticipated: 2021+
Phase Ib/II PRISM NCT03527147	Relapsed/refractory aggressive NHL	88	<ul style="list-style-type: none"> • Arm 1: <i>Calquence</i> + danvatirsen • Arm 2: <i>Calquence</i> + ceralasertib • Arm 3: <i>Calquence</i> + Hu5F9G4 + Rituxan • Arm 4: <i>Calquence</i> + AZD5153 <p>An open-label platform trial with trial centres in US and UK</p>	<ul style="list-style-type: none"> • Primary outcome; safety & tolerability • Secondary outcomes; ORR, DOR, PFS, OS 	FPCD: Q2 2018 Data anticipated: 2021
Phase Ib/II ACE-ST-209 NCT02586857	≥ 2L glioblastoma multiforme	52	<ul style="list-style-type: none"> • Arm A: <i>Calquence</i> 200mg BID • Arm B: <i>Calquence</i> 400mg QD 	<ul style="list-style-type: none"> • Safety, ORR 	<ul style="list-style-type: none"> • FPCD: Q1 2016 • Data anticipated: H2 2019
Phase I/II D8220C0007 NCT03932331	Chinese adults r/r MCL and r/r CLL	105	<ul style="list-style-type: none"> • Part 1: R/r B-cell MalignanciesPhase II • Part 2: Cohort A: r/r MCL • Part 2: Cohort B: r/r CLL 	<ul style="list-style-type: none"> • Safety, ORR 	<ul style="list-style-type: none"> • FPCD: Q2 2020
Phase I D8220C00018 NCT04488016	Healthy volunteers	28	<p>Part 1: Rel bioavailabilty for capsule vs tablet Part 2: Rel bioavailabilty for oral solution of tablet</p>	<ul style="list-style-type: none"> • Safety 	<ul style="list-style-type: none"> • FPCD: Q2 2019 • Data anticipated: 2021+



Koselugo (selumetinib, MEK inhibitor)

Paediatric neurofibromatosis type 1, solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase II SPRINT NCT01362803 Partnered	Paediatric NF1	50 (stratum 1) 25 (Stratum 2)	<ul style="list-style-type: none"> Single arm: <i>Koselugo</i> 25mg/m² BID with 2 strata: <ul style="list-style-type: none"> Stratum 1: PN related morbidity present at enrolment Stratum 2: no PN related morbidity present at enrolment 	<ul style="list-style-type: none"> Complete partial and complete response rate measured by volumetric MRI; Duration of response and functional outcomes/QoL 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q4 2016 Data readout: Q1 2019 Primary endpoint met
Phase Ib <i>Koselugo</i> + MK-8353 (ERK inhibitor) NCT03745989 Partnered (Merck Lead trial)	Advanced solid tumours	80 (dose escalation trial)	Phase Ib open-label trial of MK-8353 in combination with <i>Koselugo</i> in participants with advanced solid tumours	<ul style="list-style-type: none"> DLTs AEs Trial drug discontinuations due to an AE 	<ul style="list-style-type: none"> FPCD: Q1 2019
Phase I Japan PK / Safety study Partnered	Paediatric Inoperable NF1-PN patients	9-12	Open-label Phase I clinical study to assess safety and PK of <i>Koselugo</i> in Japanese paediatric NF1-PN patients	<ul style="list-style-type: none"> Primary endpoints safety Secondary endpoints of PK/anti-tumour effect 	<ul style="list-style-type: none"> FPCD: Q3 2020



Lumoxiti (moxetumomab pasudotox, CD22 mAb)

Blood cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
<p>Phase III PLAIT</p> <p>NCT01829711</p> <p>Partnered</p>	Adults with relapsed or refractory HCL	80	<ul style="list-style-type: none"> Multicentre, single-arm, open-label Phase III trial <i>Lumoxiti</i> i.v. at the recommended dose 	<ul style="list-style-type: none"> Primary endpoint: rate of durable CR (complete response): CR maintained for > 180 days Secondary endpoints <ul style="list-style-type: none"> Efficacy: CR rate, ORR, Duration of CR and ORR, TTR, PFS Safety and tolerability PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data readout: Q3 2017 Primary endpoint met



Savolitinib (MET inhibitor)

NSCLC and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT01985555 Partnered	Advanced NSCLC (all comers)	85	<ul style="list-style-type: none"> Dose escalation trial Conducted in China	<ul style="list-style-type: none"> Primary endpoint: safety and tolerability Secondary endpoint: PK profile 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: H2 2020
Phase II NCT02897479 Partnered	Lung PSC and other NSCLC	65	<ul style="list-style-type: none"> Single arm trial: savolitinib QD Conducted in China	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoint: PFS, safety parameters 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: H1 2020



Capivasertib (AKT inhibitor)

Breast cancer, prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III CAPItello-290 NCT03997123	Locally advanced or metastatic TNBC	800	Double-blind randomised comparative trial • Arm 1: capivasertib + paclitaxel • Arm 2: placebo + paclitaxel	• PFS • OS	• FPCD Q3 2019 • Data anticipated: 2021+
Phase III CAPItello-291 NCT04305496	Locally advanced (Inoperable) or metastatic HR+/HER2- breast cancer	834	Double-blind randomised comparative trial • Arm 1: capivasertib + <i>Faslodex</i> • Arm 2: placebo + <i>Faslodex</i>	• PFS	• FPCD Q2 2020 • Data anticipated: 2021+
Phase III CAPItello-281 NCT04493853	De novo PTEN deficient metastatic hormone sensitive prostate cancer	1,000	Double-blind randomised comparative trial • Arm 1: capivasertib + abiraterone • Arm 2: placebo + abiraterone	• rPFS	• FPCD Q3 2020 • Data anticipated 2021+



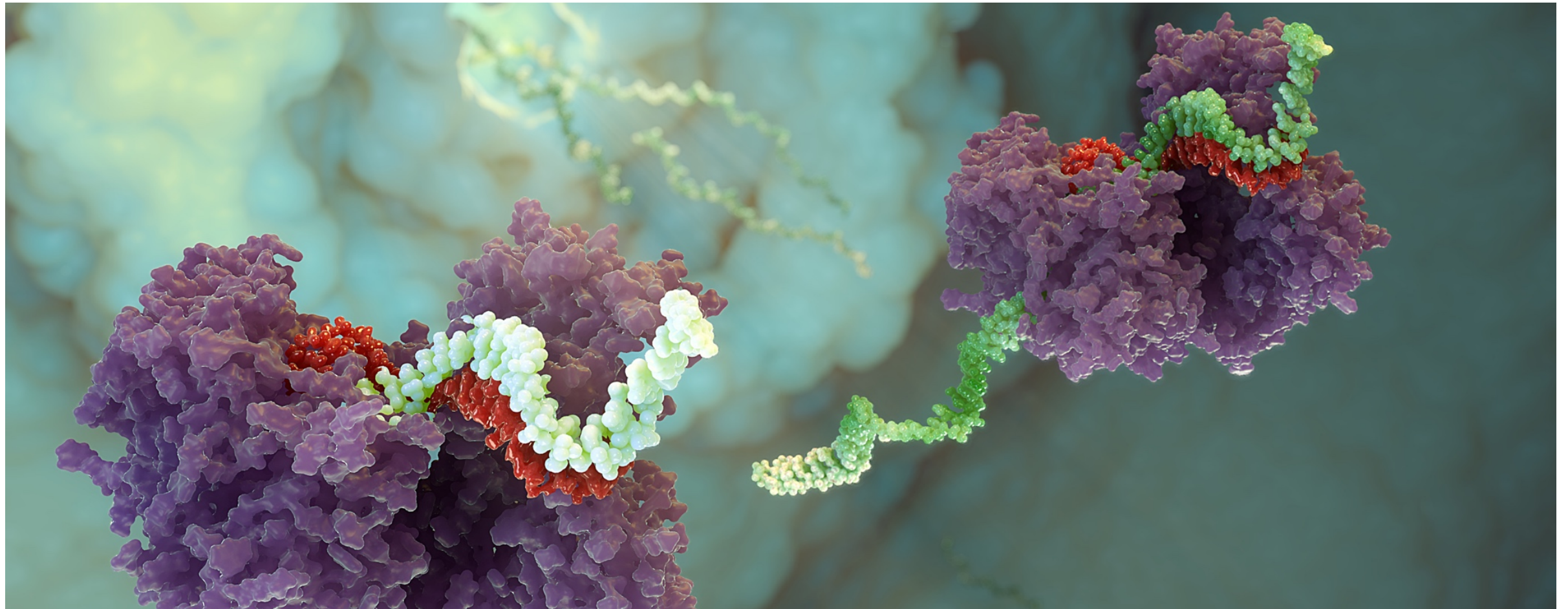
Monalizumab (NKG2a mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II NCT02671435	Advanced solid tumours	381	Escalation phase • monalizumab + <i>Imfinzi</i> i.v. Expansion phase • monalizumab + <i>Imfinzi</i> i.v. recommended dose Exploration phase • monalizumab + <i>Imfinzi</i> i.v. recommended dose + SoC systemic therapy with or without biologic agent and monalizumab in combination with a biologic agent in adult subjects with CRC Global trial	Primary endpoints: • Safety • Exploration Phase: Objective Response per RECIST • Secondary endpoints include tumour response (OR, DC, DoR, PFS and OS), immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2021+
Phase III INTERLINK-1 NCT04590963	Recurrent or Metastatic SCCHN, 2L	600	• Arm A: monalizumab + cetuximab i.v. • Arm B: placebo + cetuximab i.v. Global trial	• Primary: OS • Secondary: PFS, ORR, DoR	• FPCD: Q4 2020 • Data anticipated: 2021+



Oncology - early-stage development



Imfinzi (PD-L1 mAb)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase I/II STUDY 1108 NCT01693562	<i>Imfinzi</i>	Solid tumours	1,022	<ul style="list-style-type: none"> Dose escalation: 5 cohorts at Q2W and 1 cohort at Q3W Dose expansion: 16 tumour type cohorts at the Q2W MTD defined during dose escalation Dose exploration: cohort at 20mg Q4W <p>Global trial - nine countries</p>	<ul style="list-style-type: none"> Safety Optimal biologic dose Secondary endpoints include PK, immunogenicity and antitumour activity 	<ul style="list-style-type: none"> FPCD: Q3 2012 LPCD: Q4 2016 Data readout: Q4 2020
Phase I NCT02117219	<i>Imfinzi</i> , azacitidine	Myelodysplastic syndrome	79	<p>Dose escalation and dose expansion trial</p> <ul style="list-style-type: none"> Part 1: <i>Imfinzi</i> Part 2 Arm 1: <i>Imfinzi</i> and tremelimumab Part 2 Arm 2: <i>Imfinzi</i>, tremelimumab and azacitidine <p>Global trial - four countries</p>	<ul style="list-style-type: none"> Safety and tolerability of monotherapy and combination Secondary endpoints include duration of response, PFS and OS, PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2014 Data anticipated: Q2 2020
Phase I NCT02900157	MEDI9090	Solid tumours	42	<p>Multi-centre, open-label, single-arm trial for adult subjects</p> <p>US and Japan trial centers</p>	<ul style="list-style-type: none"> Safety, PK, number of subjects reporting infusion related reaction 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q1 2017 Data readout: Q3 2020
Phase II HUDSON NCT03334617	<i>Imfinzi</i> <i>Lynparza</i> vistusertib ceralasertib (AZD6738) danvatirsen oleclumab <i>Enhertu</i> cediranib	NSCLC	340	<p>5 modules encompassing 16 cohorts</p> <ul style="list-style-type: none"> Module 1; <i>Imfinzi</i> and <i>Lynparza</i> Module 2; <i>Imfinzi</i> and danvatirsen Module 3; <i>Imfinzi</i> and ceralasertib (AZD6738) Module 4; <i>Imfinzi</i> and vistusertib Module 5; <i>Imfinzi</i> and oleclumab Module 6; <i>Imfinzi</i> and <i>Enhertu</i> Module 7; <i>Imfinzi</i> and cediranib Module 8; Ceralasertib <p>Open-label, biomarker-directed, multi-centre Phase II umbrella trial in patients with NSCLC, who progressed on an anti-PD-1/PD-L1 containing therapy</p>	<ul style="list-style-type: none"> Primary outcome; ORR Secondary outcomes; efficacy including OS, PFS, DCR, and safety and tolerability, DoR 	<ul style="list-style-type: none"> FPCD: Q1 2018 Data anticipated: 2021+
Phase II COAST NCT03822351	<i>Imfinzi</i>	Stage III NSCLC unresectable	189	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> Arm B: <i>Imfinzi</i> + oleclumab Arm C: <i>Imfinzi</i> + monalizumab 	<p>Primary</p> <ul style="list-style-type: none"> OR per RECIST v1.1 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: Q4 2020
Phase II NeoCOAST NCT03794544	<i>Imfinzi</i>	Resectable, early stage NSCLC	84	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> Arm B: <i>Imfinzi</i> + oleclumab Arm C: <i>Imfinzi</i> + monalizumab Arm D: <i>Imfinzi</i> + danvatirsen 	<p>Primary</p> <ul style="list-style-type: none"> Major pathological response rate 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: Q1 2020



Imfinzi (PD-L1 mAb)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase Ib/II COLUMBIA 1 NCT04068610	Imfinzi	1L metastatic MSS-CRC	112	<ul style="list-style-type: none">Part 1 S1 FOLFOX + bevacizumab + Imfinzi + oleclumabPart 2 Control 1 FOLFOX + bevacizumabPart 2 E1 FOLFOX + bevacizumab + Imfinzi + oleclumab	Primary <ul style="list-style-type: none">Part 1: SafetyPart 2: Efficacy - OR Secondary <ul style="list-style-type: none">Part 1: Efficacy – OR, BOR, DoR, PFSPart 2: Safety and Efficacy (BOR, DoR, DC, PFS, OS)	<ul style="list-style-type: none">FPCD: Q3 2019Data anticipated: H2 2020



Imfinzi (PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II STUDY 22 NCT02519348	Hepatocellular carcinoma	545	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab Arm B: <i>Imfinzi</i> 2L Arm C: tremelimumab 2L Arm D: <i>Imfinzi</i> + tremelimumab Arm E: <i>Imfinzi</i> in combination with bevacizumab 	<ul style="list-style-type: none"> Primary endpoints: Safety & tolerability, DLTs Secondary endpoints: ORR, DoR, OS 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: H2 2020
Phase Ib STUDY 006 NCT02000947	NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	459	<ul style="list-style-type: none"> Dose escalation: minimum 5 cohorts exploring various treme Q4W and <i>Imfinzi</i> i.v. Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment Dose expansion: MTD for the combination in escalation to be explored in expansion <p>North American, EU and ROW trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Optimal biologic dose for the combination OR <p>Secondary endpoints include antitumour activity, PK and immunogenicity</p>	<ul style="list-style-type: none"> FPCD: Q4 2013 LPCD: Q4 2016 Data readout: Q3 2020
Phase I STUDY 10 NCT02261220	Solid tumours (basket trial)	380	<ul style="list-style-type: none"> Dose expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 7 tumour types Dose exploration: 2 cohorts exploring various Q4W treme and <i>Imfinzi</i> dose combinations and 2 cohorts exploring various Q2W treme and <i>Imfinzi</i> dose combinations <p>North American, EU and ROW trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Optimal biologic dose for the combination <p>Secondary endpoints include anti-tumour activity, PK/PD and immunogenicity</p>	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2017 Data readout: Q4 2020



Imfinzi (PD-L1 mAb) + MEDI0457 (DNA HPV Vaccine)

Head and neck squamous cell carcinoma (HNSCC)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/IIa NCT03162224	HPV associated recurrent/metastatic head and neck cancer	50	Multi-centre, open label trial to evaluate the safety and efficacy of combination treatment with MEDI0457 and <i>Imfinzi</i>	Primary endpoints: Safety & Tolerability, ORR Secondary endpoints: PK, ADA, DCR, OS, PFS	<ul style="list-style-type: none"> FPCD: Q3 2017 Data anticipated: H2 2020



Datopotamab deruxtecan, DS-1062 (TROP2 ADC)

NSCLC

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03401385 Partnered	NSCLC TNBC	350	Open label, two-part (dose escalation, dose expansion) • Datopotamab deruxtecan Japan, US	<ul style="list-style-type: none"> • Primary endpoint: safety • Secondary endpoint: PK, antitumor activity, anti-drug antibodies 	<ul style="list-style-type: none"> • FPCD: Q1 2018
Phase I TROPION-Lung02 NCT04526691 Partnered	NSCLC (without actionable mutation)	86	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) • Datopotamab deruxtecan + pembrolizumab Japan, US	<ul style="list-style-type: none"> • Primary endpoint: safety • Secondary endpoint: ORR, DOR, PFS, OS, PK, anti-drug antibodies 	<ul style="list-style-type: none"> • FPCD: Q4 2020
Phase I TROPION-Lung04 NCT04612751 Partnered	NSCLC (without actionable mutation)	74	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) • Datopotamab deruxtecan + <i>Imfinzi</i> US	<ul style="list-style-type: none"> • Primary endpoint: safety • Secondary endpoint: : ORR, DOR, PFS, OS, PK, 	<ul style="list-style-type: none"> • Initiating
Phase II TROPION-Lung05 NCT04484142 Partnered	NSCLC (with actionable mutation)	150	Randomised, open label • Datopotamab deruxtecan Global trial	<ul style="list-style-type: none"> • Primary endpoint: ORR • Secondary endpoint: DOR, PFS, OS, safety 	<ul style="list-style-type: none"> • Initiating



AZD0466 (Bcl2/xL inhibitor)

Approved medicines

Late-stage development

Early development

Oncology

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04214093	Advanced hematologic malignancies or solid tumours	102	Monotherapy dose escalation, consisting of two arms: <ul style="list-style-type: none">• Arm A: Patients with low risk for tumour lysis syndrome (solid tumours, lymphomas, myelomas)• Arm B: Patients with high risk for tumour lysis syndrome (relapsed/refractory haem malignancies)	<ul style="list-style-type: none">• Primary: safety• Secondary: PK, anti-tumour activity	<ul style="list-style-type: none">• FPCD: Q4 2019• Data anticipated: 2021+

CVRM

R&I

Other



MEDI1191 (IL12 modRNA)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03946800	Advanced solid tumours	87	First-time-in-human Phase I, open-label, dose-escalation and expansion trial of MEDI1191 administered intratumourally as monotherapy and in combination with <i>Imfinzi</i>	<ul style="list-style-type: none">• Primary endpoint: safety and tolerability• Secondary endpoints: PK, immunogenicity and efficacy	<ul style="list-style-type: none">• FPCD: Q2 2019• Data anticipated: 2021+



AZD1390 (ATM inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

Trial	Population	Subjects	Design	Endpoints	Status
Phase I NCT03423628	Recurrent glioblastoma eligible for re-irradiation, brain metastases and leptomeningeal disease, newly-diagnosed glioblastoma patients	132	<ul style="list-style-type: none">Designed to evaluate the safety, tolerability and PK of AZD1390 in combination with radiation therapy in patients with GBM and brain metastases from solid tumoursDose and schedule of AZD1390 administration will be adjusted during assessment of safety and tolerability during this Phase I trial Conducted across seven sites in USA and UK	<ul style="list-style-type: none">Primary: investigate the safety, tolerability, and MTD of AZD1390 administered in combination with radiation therapy in brain malignancies	<ul style="list-style-type: none">FPCD Q2 2018Data anticipated: 2021+

CVRM

R&I

Other



Adavosertib (AZD1775, WEE-1 inhibitor)

Ovarian cancer, uterine serous cancer, solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase II D6010C00004 NCT02272790	Platinum-resistant (PR) ovarian cancer	95	<ul style="list-style-type: none"> Arm B: paclitaxel + adavosertib Arm C: carboplatin + adavosertib Global trial	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: DoR, PFS, OS, DCR, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q2 2018 Data readout: Q3 2019
Phase I D6015C00002 NCT02617277	Advanced solid tumours	56	<ul style="list-style-type: none"> Dose escalation trial to determine MTD (adavosertib + <i>Imfinzi</i>) Conducted in US	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2018 Data readout Q4 2019
Phase II D601HC00002 NCT04590248	Uterine serous carcinoma	120	<ul style="list-style-type: none"> Adavosertib monotherapy Phase IIb, open-label, single-arm, multi-center study Global trial 	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: DoR, depth of response, PFS 	<ul style="list-style-type: none"> Initiating



MEDI2228 (BCMA antibody drug conjugate)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03489525	Relapsed/refractory multiple myeloma	142	First-time-in-human Phase I, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	Primary endpoints: <ul style="list-style-type: none">• Safety• Determination of MTD Secondary endpoints: pPK, immunogenicity, ORR, DCR, DoR, PFS, OS	<ul style="list-style-type: none">• FPCD: Q2 2018• Data anticipated: 2021+



AZD2811NP (AURN)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02579226	Solid tumours	72	<ul style="list-style-type: none">• Arm 1: AZD2811NP dose escalation• Arm 2: AZD2811NP dose expansion SCLC	<ul style="list-style-type: none">• Safety and tolerability• PK and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: H2 2020
Phase I NCT03217838	AML/high-risk MDS	124	<ul style="list-style-type: none">• Part A: AZD2811NP monotherapy / azacitidine combination / venetoclax combination dose escalation cohorts• Part B: AZD2811NP monotherapy / azacitidine combination / venetoclax combination dose expansions to further explore the tolerability, PK and clinical activity	<ul style="list-style-type: none">• Safety and tolerability• PK and efficacy	<ul style="list-style-type: none">• FPCD: Q3 2017• Data anticipated: 2021+



AZD4573 (CDK9 inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03263637	Relapsed/refractory haematologic malignancies	45	Arm 1: dose escalation in haematological malignancies excluding AML/ALL/high-risk MDS/CMML/CLL. Arm 2: dose escalation in relapsed or refractory AML, ALL, high-risk MDS, CMML, CLL and Richter's syndrome. i.v. route of administration Trial conducted in NL, UK, GE	Primary: • safety/PK; Secondary: • efficacy	<ul style="list-style-type: none">• FPCD: Q4 2017• Data anticipated: H2 2020



AZD4635 (A_{2A}R inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02740985	Phase Ia: patients with advanced solid tumours Phase Ib: Post-immunotherapy NSCLC Other post-immunotherapy solid tumours Immune checkpoint-naïve mCRPC Immune checkpoint-naïve CRC Other immune checkpoint-naïve solid tumours	313	Phase Ia – solid tumours or mCRPC: • AZD4635 monotherapy • AZD4635 + <i>Imfinzi</i> • AZD4635 + abiraterone • AZD4635 + enzalutamide • AZD4635 + <i>Imfinzi</i> + oleclumab • AZD4635 + docetaxel. Phase Ib: AZD4635 monotherapy or AZD4635 + <i>Imfinzi</i> dose expansions in NSCLC, mCRPC, CRC and other post-immunotherapy and immune checkpoint-naïve solid tumours Conducted at sites in the US	Primary outcome measure: • Safety and tolerability Secondary outcome measures: • Preliminary assessment of anti-tumour activity	• FPCD: Q2 2016
Phase I NCT03710434	Healthy male volunteers	21	• Part A 2-period randomised crossover trial of single doses of AZD4635, nanosuspension or solid oral formulation in fasted state • Part B, 4-period, open-label, randomised, crossover trial of single doses of AZD4635 in the same subjects from Part A to assess food effect, pH effect and formulation variants Both parts conducted at a site in the UK	Primary outcome measures: • C _{max} and exposure (AUC) of AZD4635 solid oral formulation and nano-suspension	• FPCD: Q4 2018 • LPCD: Q2 2019
Phase II NCT04089553	Prostate cancer	60	ARM 1: AZD4635 + <i>Imfinzi</i> ARM 2: AZD4635 + oleclumab Conducted at sites in the US	• Primary outcome measure: Efficacy; (ORR and PSA response) • Secondary outcome measure: Efficacy, PK, safety and tolerability	• FPCD: Q3 2019
Phase I NCT03980821	Japanese patients with advanced solid malignancies	12	AZD4635 dose escalation Conducted at sites in Japan	Primary outcome measure: • Safety and tolerability Secondary outcome measure: • PK and preliminary anti-tumour activity	• FPCD: Q3 2019
Phase II NCT04495179	Prostate cancer	160	ARM A: AZD4635 + <i>Imfinzi</i> ARM B: AZD4635+ <i>Imfinzi</i> + cabazitaxel Conducted at sites in US, Europe, UK and Korea	• Primary outcome measure: Efficacy (rPFS) • Secondary outcome measure: Efficacy (OS, PSA response, ORR, DoR)	• FPCD: Q3 2020



AZD5153 (BRD4 inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib NCT03205176	Relapsed/refractory solid tumours, lymphomas	60	Monotherapy dose escalation in advanced solid tumours and lymphomas Dose escalation of AZD5153 in combination with <i>Lynparza</i> in platinum resistant/refractory HGS patients.	<ul style="list-style-type: none">• Primary: safety• Secondary: efficacy, PK	<ul style="list-style-type: none">• FPCD: Q2 2017• Data anticipated: H1 2021



MEDI5395 (rNDV GMCSF)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03889275	Select advanced solid tumours	164	First-time-in-human Phase I, open-label, dose-escalation and expansion arm of MEDI5395 in combination with <i>Imfinzi</i>	<ul style="list-style-type: none">• Primary endpoint: safety and tolerability• Secondary endpoints: PK, PD, immunogenicity and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2019• Data anticipated: 2021+



MEDI5752 (PD-1/CTLA-4 bispecific mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/IIa NCT03530397	Advanced solid tumours	188	Open-label, dose-escalation and dose-expansion: <ul style="list-style-type: none"> Dose-escalation: MEDI5752 i.v. Dose-expansion: MEDI5752 i.v. as monotherapy and in combination with chemotherapy Arm A: MEDI5752 i.v. Arm B: MEDI5752 i.v., pemetrexed and carboplatin Arm C: Pembrolizumab, pemetrexed and carboplatin 	Primary endpoints: <ul style="list-style-type: none"> dose-escalation: safety & determination of MTD dose-expansion: assessment of antitumour activity based on OR Secondary endpoints: <ul style="list-style-type: none"> PK, ADA, tumoural baseline PD-L1, assessment of antitumour activity based on OR, DoR, DCR, PFS, OS 	<ul style="list-style-type: none"> FPCD: Q2 2018
Phase Ib NCT04522323	Advanced renal cell carcinoma	52	Open-label, dose-escalation and dose-expansion to explore the safety, tolerability and anti-tumour activity of MEDI5752 in combination with axitinib:	Primary endpoint: <ul style="list-style-type: none"> dose-escalation: safety & tolerability Secondary endpoints: <ul style="list-style-type: none"> PK, ADA and antitumour activity of MEDI5752 + axitinib based on PFS, OR, DoR, DCR, TTR, OS 	<ul style="list-style-type: none"> FPCD: Q3 2020



AZD5991 (MCL1 inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib/IIa NCT03218683	Relapsed/refractory haematologic malignancies	177	<ul style="list-style-type: none">• Arm1: monotherapy dose escalation & expansions in relapsed/refractory haematological malignancies• Arm2: combination dose escalation (AZD5991+venetoclax) in relapsed/refractory AML/MDS;• i.v. route of administration• US only	<ul style="list-style-type: none">• Primary: safety• Secondary: PK, efficacy	<ul style="list-style-type: none">• FPCD: Q3 2017• Data anticipated: H2 2021



Ceralasertib (AZD6738, ATR inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02264678	Solid tumours	250	<ul style="list-style-type: none"> • Arm 1: ceralasertib + carboplatin • Arm 2: ceralasertib dose escalation, ceralasertib + <i>Lynparza</i> • Arm 3: ceralasertib + <i>Imfinzi</i> <p>Trial conducted in North America, Europe and South Korea</p>	<ul style="list-style-type: none"> • Safety and tolerability • PK and efficacy 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • Data anticipated: 2021+
Phase I NCT03022409	HNSCC	44	<p>Window of opportunity</p> <ul style="list-style-type: none"> • Arm 1: ceralasertib • Arm 2: <i>Lynparza</i> <p>Trial conducted in US, France, Taiwan and the UK</p>	<ul style="list-style-type: none"> • Biomarker change 	<ul style="list-style-type: none"> • FPCD: Q4 2017 • Data anticipated: H2 2020
Phase II PLANETTE NCT04564027	Solid tumours mCRPC	52	<ul style="list-style-type: none"> • Cohort A: ceralasertib; ATM-altered AST • Cohort B: ceralasertib; ATM-altered mCRPC 	<p>Cohort A: ORR Cohort B: Composite RR</p>	<ul style="list-style-type: none"> • Initiating



AZD7648 (selective DNA-PK inhibitor)

Advanced solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03907969	Advanced malignancies	234	<ul style="list-style-type: none"> First in human modular dose escalation and dose expansion trial Arm 1 - AZD7648 monotherapy Arm 2 - AZD7648 + Pegylated Liposomal Doxorubicin Arm 3 - AZD7648 + <i>Lynparza</i> Countries: US, UK 	<ul style="list-style-type: none"> Primary outcome measures: safety and tolerability Secondary outcome measures: PK, Cytochromes P450, preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2019 Data anticipated: 2021+



AZD8701 (FOXP3 antisense oligonucleotide)

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I/IIb NCT04504669	Advanced solid tumours	123	Dose escalation and dose expansion trial Arm 1: AZD8701 monotherapy Arm 2: AZD8701 & <i>Imfinzi</i> combination therapy Global trial - four countries - US, CA, FR, ES i.v. route of administration	Primary endpoints: safety & tolerability Secondary endpoints: PK, PD, preliminary anti-tumour activity	<ul style="list-style-type: none">• FPCD: Q3 2020• Data Anticipated: 2021+



Oleclumab (MEDI9447, CD73 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02503774	Advanced malignancies	348	<p>Dose escalation phase</p> <ul style="list-style-type: none"> oleclumab i.v. oleclumab i.v. + <i>Imfinzi</i> i.v. <p>Dose expansion phase</p> <ul style="list-style-type: none"> oleclumab i.v. recommended dose + <i>Imfinzi</i> i.v. <p>US, South Korean and Australian trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Determination of MTD <p>Secondary endpoints include preliminary anti-tumour activity, PK, PD, immunogenicity and biomarker activity</p>	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: 2021+
Phase Ib/II NCT03611556	Pancreatic 1L and 2L with prior gemcitabine-based chemotherapy	339	<ul style="list-style-type: none"> Arm A1: gemcitabine and nab paclitaxel i.v. Arm A2: gemcitabine and nab paclitaxel i.v. + oleclumab i.v. Arm A3: gemcitabine and nab paclitaxel i.v. + oleclumab i.v. + <i>Imfinzi</i> i.v. Arm B1: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. Arm B2: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. + oleclumab i.v. Arm B3: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. + oleclumab i.v. + <i>Imfinzi</i> i.v. <p>US, Norway, Spain and Australian trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety and anti-tumour activity <p>Secondary endpoints include PFS, PK, immunogenicity, safety and anti-tumour activity</p>	<ul style="list-style-type: none"> FPCD: Q2 2018 Data anticipated: H2 2021
Phase Ib/II NCT03381274	NSCLC	98	<ul style="list-style-type: none"> Arm A: oleclumab i.v. + <i>Tagrisso</i> <p>US, South Korean and Taiwan trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety ORR <p>Secondary endpoints:</p> <ul style="list-style-type: none"> DoR, DCR, PFS, OS, PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2018 Data anticipated: 2021+



AZD9496 (SERD, oral)

Breast cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03236974	ER+ breast cancer	c. 50	<ul style="list-style-type: none">This is an open label randomised multicentre pre-surgical pharmacodynamics trial to compare and assess the biological effects of AZD9496 and <i>Faslodex</i> in postmenopausal women with ER+, HER2- primary breast cancer. Patients will receive AZD9496 or <i>Faslodex</i> and will have a pre-dose and an on-treatment core biopsy after 5-14 days of commencing treatment.	<ul style="list-style-type: none">Primary outcome measures: PD changes to ER expression following treatment with AZD9496 or <i>Faslodex</i>Secondary outcome measures: pharmacodynamics changes to Ki67 and PgR expression following treatment with AZD9496 or <i>Faslodex</i>Safety, tolerability + pharmacokinetics	<ul style="list-style-type: none">FPCD: Q4 2017Data readout: Q1 2020



AZD9833 (SERD, oral)

Breast cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03616587	ER+ breast cancer	240	<ul style="list-style-type: none"> Open label multicentre trial of AZD9833 administered orally in patients with advanced ER+ HER2 negative breast cancer. The trial design allows an escalation of dose with intensive safety monitoring to ensure the safety of patients. The trial will determine the maximum tolerated dose of AZD9833 as monotherapy and in combination with palbociclib. In addition, randomised expansion cohort(s) at potential therapeutic dose(s) in patients will be enrolled to further determine the safety, tolerability, pharmacokinetics and biological activity of AZD9833 alone and in combination with palbociclib 	<ul style="list-style-type: none"> Primary outcome measures: safety and tolerability Secondary outcome measures: multiple dose PK of AZD9833 alone and in combination with palbociclib antitumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2018
Phase II NCT04214288	ER+ breast cancer	288	<ul style="list-style-type: none"> Randomised, open-label, parallel-group, multicentre trial aimed to compare the efficacy and safety of oral AZD9833 versus intramuscular (IM) <i>Faslodex</i> in women with advanced breast cancer. 	<ul style="list-style-type: none"> Primary outcome measure: mPFS 	<ul style="list-style-type: none"> FPCD: Q2 2020
Phase II NCT04588298	ER+ breast cancer	84	<ul style="list-style-type: none"> Randomised, open-label, parallel-group, multicentre trial to investigate the biological effects of AZD9833 in women with ER positive, HER2 negative primary breast cancer 	<ul style="list-style-type: none"> Primary outcome measure: change in ER expression between pre- and on-treatment tumour biopsies 	<ul style="list-style-type: none"> Initiating
Phase I NCT04541433	ER+ breast cancer	18	<ul style="list-style-type: none"> Open-label study designed to evaluate the safety, tolerability, pharmacokinetics, and anti-tumour activity of AZD9833 in Japanese women with endocrine resistant ER+ HER2- breast cancer that is not amenable to treatment with curative intent. 	<ul style="list-style-type: none"> Primary outcome measures: safety and tolerability Secondary outcome measures: multiple dose PK of AZD9833 	<ul style="list-style-type: none"> Initiating
Phase I NCT04546347	Healthy volunteers	36	<ul style="list-style-type: none"> Randomised, open-label study to determine the relative bioavailability of different oral AZD9833 tablet formulations and an AZD9833 oral solution, the effect of food on the pharmacokinetics of an oral AZD9833 tablet formulation, and the absolute bioavailability of AZD9833 study in healthy post-menopausal female volunteers. 	<ul style="list-style-type: none"> Primary outcome measure: relative bioavailability of AZD9833 delivered as different tablet formulations and the effect of food 	<ul style="list-style-type: none"> FPCD: Q3 2020



IPH5201 (CD39 mAb)

Solid tumours

Approved medicines

Late-stage development

Early development

Oncology

CVRM

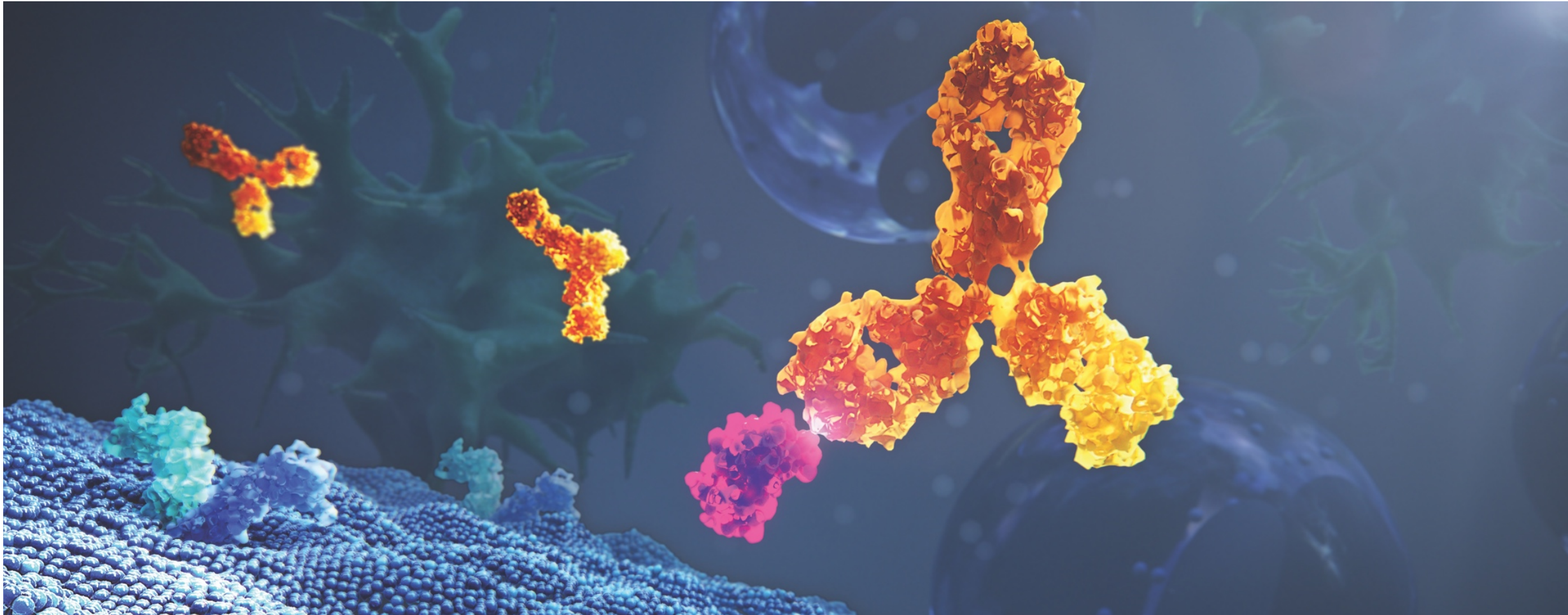
R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04261075 Partnered	Advanced Solid tumours	204	<ul style="list-style-type: none">• First time in human Phase I, open-label, dose-escalation trial to determine MTD of IPH5201 as monotherapy, or in combination with <i>Imfinzi</i> +/- oleclumab.• Part 1: IPH5201 monotherapy dose escalation to MTD• Part 2: IPH5201 + <i>Imfinzi</i> dose escalation to MTD• Part 3: IPH5201 + <i>Imfinzi</i> + Oleclumab dose escalation to MTD• Route of Administration: IV• Geographical Regions: 4 countries - US and 3 in EU.	Primary endpoints: AE, SAE, DLT Secondary endpoints: OR, DC, PK, ADA	<ul style="list-style-type: none">• FPCD: Q1 2020• Data anticipated: 2021+



BioPharmaceuticals - approved medicines and late-stage pipeline



Farxiga (SGLT2 inhibitor)

Heart failure and chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III Dapa-HF NCT03036124	CHF patients with HFrEF	4,744	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg or 5 mg QD + SoC therapy Arm 2: placebo + SoC therapy Global trial - 20 countries 	<ul style="list-style-type: none"> Primary endpoint: time to the first occurrence of any of the components of the composite: CV death or hospitalisation for HF or an urgent HF visit 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD Q4 2018 Data readout: Q3 2019 Primary endpoint met
Phase III Dapa-CKD NCT03036150	Patients With CKD	4,304	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg or 5 mg QD Arm 2: placebo Global trial - 21 countries 	<ul style="list-style-type: none"> Primary endpoint: time to the first occurrence of any of the components of the composite: $\geq 50\%$ sustained decline in eGFR or reaching ESRD or CV death or renal death 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q2 2020 Data readout: Q2 2020 Primary endpoint met
Phase III DELIVER NCT03619213	CHF patients with HFpEF	6,100	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD Arm 2: placebo Global trial - 21 countries 	<ul style="list-style-type: none"> Primary endpoint: time to the first occurrence of any of the components of the composite: CV death or hospitalisation for HF or an urgent HF visit 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H2 2021
Phase III DETERMINE-preserved NCT03877224	CHF patients with HFpEF	500	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD Arm 2: placebo Global trial - 12 countries 	Family of primary endpoints: <ul style="list-style-type: none"> Change from baseline in the KCCQ-TSS at Week 16. Change from baseline in the KCCQ-PLS at Week 16. Change from baseline in 6 min walking distance at Week 16 	<ul style="list-style-type: none"> FPCD: Q2 2019 LPCD: Q3 2020 Data readout: Q3 2020 Primary endpoints not met
Phase III DETERMINE-reduced NCT03877237	CHF patients with HFrEF	300	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD Arm 2: placebo Global trial - 9 countries 	Family of primary endpoints: <ul style="list-style-type: none"> Change from baseline in the KCCQ-TSS at Week 16. Change from baseline in the KCCQ-PLS at Week 16. Change from baseline in 6 min walking distance at Week 16 	<ul style="list-style-type: none"> FPCD: Q2 2019 LPCD Q1 2020 Data readout: Q3 2020 One primary endpoint met



Brilinta (P2Y12 receptor antagonist)

Cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints (primary)	Status
Phase III THEMIS NCT01991795	Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	19,000	<ul style="list-style-type: none"> • Arm 1: <i>Brilinta</i> 60mg BiD • Arm 2: placebo BiD on a background of acetylsalicylic acid if not contra-indicated or not tolerated Global trial – 42 countries	<ul style="list-style-type: none"> • Primary endpoint: composite of CV death, non-fatal MI and non-fatal stroke Secondary endpoints: <ul style="list-style-type: none"> • Prevention of CV death • Prevention of MI • Prevention of ischaemic stroke • Prevention of all-cause death 	<ul style="list-style-type: none"> • FPCD: Q1 2014 • LPCD: Q2 2016 • Data readout: Q1 2019 • Primary endpoint met
Phase III THALES NCT03354429	Patients with acute ischaemic stroke or transient ischaemic attack	11,000	<ul style="list-style-type: none"> • Arm 1: <i>Brilinta</i> 90mg BiD • Arm 2: placebo BiD on a background of acetylsalicylic acid if not contra-indicated or not tolerated Global trial – 28 countries	Primary endpoint: <ul style="list-style-type: none"> • Prevention of the composite of subsequent stroke and death at 30 days Secondary endpoints include: <ul style="list-style-type: none"> • Prevention of subsequent ischaemic stroke at 30 days • Reduction of overall disability at 30 days 	<ul style="list-style-type: none"> • FPCD: Q1 2018 • LPCD: Q4 2019 • Data readout: Q1 2020 • Primary endpoint met



Lokelma (sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase II PRIORITIZE HF NCT03532009	Patients with chronic heart failure and hyperkalaemia or at high risk of developing hyperkalaemia	182	<ul style="list-style-type: none"> Arm 1: <i>Lokelma</i> 5g QD for 12 weeks. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD Arm 2: placebo QD for 12 weeks Global trial – nine countries	<ul style="list-style-type: none"> Primary endpoint: difference between <i>Lokelma</i> and placebo in RAAS (renin–angiotensin–aldosterone system) blockade treatment. 	<ul style="list-style-type: none"> FPCD: Q3 2018 LPCD: Q2 2020 Data readout: H2 2020



Roxadustat (HIF-PH inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III ANDES NCT01750190 Partnered	Anaemia in CKD in patients not receiving dialysis	922	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: placebo Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q4 2012 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III ALPS NCT01887600 Partnered		597	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: placebo Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q2 2013 • LPCD: Q4 2017 • Data readout: Q3 2018 • Primary endpoint met Sponsored by Astellas
Phase III DOLOMITES NCT02021318 Partnered		616	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: darbepoetin alfa Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q1 2014 • LPCD: Q4 2019 • Data readout: Q1 2020 • Primary endpoint met Sponsored by Astellas
Phase III OLYMPUS NCT02174627		2,781	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: placebo Global trial	<ul style="list-style-type: none"> • Primary efficacy endpoint: Haemoglobin response • Primary safety objective: Contribute CV safety data to pooled safety • analyses across the Phase III program 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q4 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by AstraZeneca
Phase III ROCKIES NCT02174731	Anaemia in CKD in patients receiving dialysis	2,133	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	<ul style="list-style-type: none"> • Primary efficacy endpoint: Haemoglobin response • Primary safety objective: Contribute CV safety data to pooled safety • analyses across the Phase III program 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by AstraZeneca
Phase III SIERRAS NCT02273726 Partnered	Anaemia in CKD in patients receiving dialysis	741	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III PYRENEES NCT02278341 Partnered		838	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: epoetin alfa or darbepoetin alfa Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • LPCD: Q3 2018 • Data readout: Q3 2018 • Primary endpoint met Sponsored by Astellas



Roxadustat (HIF-PH inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III HIMALAYAS NCT02052310 Partnered	Anaemia in newly initiated dialysis patients	1,043	<ul style="list-style-type: none"> • Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q4 2013 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III NCT03263091 Partnered	Anaemia in lower risk MDS patients	184	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo US/global trial	<ul style="list-style-type: none"> • Primary endpoint: Proportion of patients achieving transfusion independence 	<ul style="list-style-type: none"> • FPCD: Q3 2017 • Data anticipated: 2021+ Sponsored by FibroGen
Phase II/III NCT03303066 Partnered	Anaemia in lower risk MDS patients	175	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo China	<ul style="list-style-type: none"> • Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> • FPCD: Q2 2018 • Data anticipated: 2021+ Sponsored by FibroGen
Phase II NCT04076943 Partnered	Anemia in patients receiving chemotherapy treatment for non-myeloid malignancies	100	US	<ul style="list-style-type: none"> • Primary endpoint: Maximum change in hemoglobin within 16 weeks from baseline without RBC transfusion 	<ul style="list-style-type: none"> • FPCD: Q3 2019 • LPCD: Q3 2020 • Data anticipated: H1 2021 Sponsored by FibroGen



Eklira/ Tudorza (LAMA, DPI)

COPD

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Number of patients	Design	Endpoints	Status
Phase I NCT03276052	Healthy Chinese volunteers	18	Open-label, 2-period ascending dose incomplete block, cross-over trial <ul style="list-style-type: none">• Arm 1: aclidinium bromide 200 µg DPI• Arm 2: aclidinium bromide 400 µg DPI• Arm 3: aclidinium bromide 800 µg DPI Global trial – one Country	<ul style="list-style-type: none">• To investigate the PK of aclidinium bromide and its metabolites after single and multiple doses (BID) of aclidinium bromide 200 µg, 400 µg and 800 µg• To evaluate the safety, and tolerability of aclidinium bromide 200 µg, 400 µg and 800 µg after single and multiple dose administration (BID)	<ul style="list-style-type: none">• Initiating• Data anticipated: H2 2021



Duaklir Genuair (LAMA/LABA, DPI)

COPD

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase III AVANT NCT03022097	Patients with stable COPD	1,060	<ul style="list-style-type: none">• Arm 1: <i>Duaklir Genuair</i> 400/12 µg DPI• Arm 2: aclidinium bromide 400 µg DPI• Arm 3: formoterol fumarate 12 µg DPI• Arm 4: tiotropium 18 µg DPI <p>Global trial – five countries</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none">• Change from baseline in one hour morning post-dose dose FEV1 <i>Duaklir Genuair</i> 400/12 µg compared to Acclidinium bromide at Week 24• Change from baseline in morning pre-dose (trough) FEV1 of <i>Duaklir Genuair</i> 400/12 µg compared to Formoterol fumarate at Week 24• Change from baseline in trough FEV1 of Acclidinium bromide 400 µg compared to placebo at Week 24	<ul style="list-style-type: none">• FPCD: Q1 2017• Data anticipated: H2 2021

Oncology

CVRM

R&I

Other



Breztri, Trixeo (PT010, LAMA/LABA/ICS, pMDI)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02536508	Moderate to very severe COPD	500	Treatments (52-week treatment period) <ul style="list-style-type: none"> BGF (budesonide, glycopyrronium, and formoterol fumarate) MDI 320/14.4/9.6µg BID pMDI GFF (glycopyrronium and formoterol fumarate) MDI 14.4/9.6µg BID pMDI BFF (budesonide and formoterol fumarate) MDI 320/9.6µg BID pMDI Randomised, double-blind, chronic-dosing, multi-centre Country – US	Primary endpoints: <ul style="list-style-type: none"> Bone mineral density sub-trial endpoint. change from baseline in BMD of the lumbar spine measured using DXA (dual energy X-ray absorptiometry) scans of L1-L4 at week 52 Ocular sub-trial safety endpoint change from baseline in LOCS III at week 52 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q3 2016 Data readout: Q1 2018 Primary endpoints met
Phase III ETHOS NCT02465567	Moderate to very severe COPD	8,588	Treatments (1-year treatment period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg BID pMDI BGF MDI 160/14.4/9.6µg BID pMDI BFF MDI 320/9.6µg BID pMDI GFF MDI 14.4/9.6µg BID pMDI Randomised, double-blind, multi-centre and parallel-group Multi-country	<ul style="list-style-type: none"> Primary endpoint: rate of moderate or severe COPD exacerbations Secondary endpoint: time to first moderate or severe COPD exacerbation 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q3 2018 Data readout: Q3 2019 Primary endpoint met
Phase III KRONOS NCT02497001	Moderate to very severe COPD	1,800	Treatments (24-week treatment period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg BID pMDI GFF MDI 14.4/9.6µg BID pMDI BFF MDI 320/9.6µg BID pMDI <i>Symbicort Turbuhaler</i> 400/12µg BID DPI Randomised, double-blind, parallel-group, and chronic dosing and multi-centre Multi-country	Primary Endpoints: <ul style="list-style-type: none"> FEV₁ area under curve from 0 to 4 hours (AUC₀₋₄) over 24 weeks (BGF MDI vs. BFF MDI and BGF MDI vs. <i>Symbicort Turbuhaler</i>) Change from baseline in morning pre-dose trough FEV₁ over 24 weeks (BGF MDI vs. GFF MDI) TDI focal score over 24 weeks (BGF MDI vs. BFF MDI and BGF MDI vs. GFF MDI) 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q2 2017 Data readout: Q1 2018 8/9 Primary endpoints met
Phase III NCT03262012	Moderate to very severe COPD	324	Treatments (28-week treatment period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg BID pMDI GFF MDI 14.4/9.6µg BID pMDI BFF MDI 320/9.6µg BID pMDI <i>Symbicort Turbuhaler</i> 400/12µg BID DPI Randomised, double-blind, parallel-group, chronic dosing, multicenter Country: Japan	Primary outcome measures: <ul style="list-style-type: none"> Long-term safety and tolerability (52 weeks): adverse events, 12-lead ECG, laboratory tests, vital signs 	<ul style="list-style-type: none"> FPCD Q3 2016 LPCD Q4 2017 Data readout: Q3 2018 Primary safety endpoint met



Daliresp/ Daxas (PDE4 inhibitor, oral)

COPD

Approved medicines
Late-stage development
Early development

Trial	Population	Patients	Design	Endpoints	Status
Post Launch PASS NCT03381573	COPD	124,080	<ul style="list-style-type: none">This is a retrospective cohort trial comparing COPD patients aged 40 years and older with new exposure to roflumilast with up to 5 unexposed (i.e., not roflumilast-exposed) COPD controls matched by propensity score (PS), age, sex, and year of cohort entry. The trial is using electronic healthcare databases in the US (Military Health System database), Germany (German Pharmacoepidemiological Research Database), and Sweden (national databases including healthcare, death, and demographics data).	<ul style="list-style-type: none">Primary endpoint: all-cause mortality (up to five years)	<ul style="list-style-type: none">Data anticipated: 2021+

Oncology
CVRM
R&I
Other



Fasenra (IL5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III MELTEMI NCT02808819	A multi-centre, open-label, safety extension trial with <i>Fasenra</i> for asthmatic adults on ICS plus LABA2 Agonist Age 18-75 years	447	<ul style="list-style-type: none"> • Arm 1: <i>Fasenra</i> 30mg Q4W s.c. • Arm 2: <i>Fasenra</i> 30mg Q8W s.c. Global trial - 15 countries	<ul style="list-style-type: none"> • Primary endpoint: safety and tolerability 	<ul style="list-style-type: none"> • FPCD: Q2 2016 • LPCD: Q3 2019 • Data readout: Q3 2020 • Primary endpoint met
Phase IIIb PONENTE NCT03557307	Severe eosinophilic asthmatics receiving HD ICS + LABA and chronic OCS with or without additional asthma controller(s). Age 18 Years and older	598	Arm 1: <i>Fasenra</i> 30mg Q8W s.c. 38-week trial Global trial – 16 countries	<ul style="list-style-type: none"> • Primary endpoint: reduction of oral corticosteroid dose 	<ul style="list-style-type: none"> • FPCD: Q3 2018 • LPCD: Q3 2019 • Data anticipated: Q4 2020 • Primary endpoint met
D3250C00036 China ICS/LABA Trial (MIRACLE) NCT03186209	Severe, uncontrolled asthma, despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	666	<ul style="list-style-type: none"> • Arm 1: <i>Fasenra</i> 30mg Q8W s.c. • Arm 2: placebo s.c. 56-week trial Global trial – 4 countries	<ul style="list-style-type: none"> • Primary endpoint: annual asthma exacerbation rate • Secondary endpoints: assess pulmonary function, asthma symptoms, other asthma control metrics 	<ul style="list-style-type: none"> • FPCD: Q4 2017 • Data readout: 2021+



Fasenra (IL5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III BORA NCT02258542	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	2,133	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. Arm 2: <i>Fasenra</i> 30mg Q8W s.c.* <ul style="list-style-type: none"> placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial – 24 countries	<ul style="list-style-type: none"> Primary endpoint: safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data readout: Q3 2018 Primary endpoint met
Phase III GREGALE NCT02417961	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 18-75 years	162	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. 28-week (adults) Global trial – two countries	<ul style="list-style-type: none"> Primary endpoint: functionality, reliability, and performance of a pre-filled syringe with <i>Fasenra</i> administered at home 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q2 2016 Primary endpoint met
Phase III ARIA NCT02821416	A double-blind, randomised, parallel group, placebo-controlled multi-centre trial to evaluate the effect of <i>Fasenra</i> on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years	46	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. Arm 2: placebo s.c. 37-week trial	<ul style="list-style-type: none"> Primary endpoint: safety and tolerability Primary endpoint: the effect of <i>Fasenra</i> on allergen induced eosinophil changes in sputum and allergen-induced late asthmatic response 	<ul style="list-style-type: none"> FPCD Q4 2016 LPCD: Q2 2019 Data anticipated: H2 2020
Phase III ALIZE NCT02814643	A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of <i>Fasenra</i> on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years	103	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. with one dose of seasonal influenza virus vaccine IM Arm 2: placebo Q4W s.c. with one dose of seasonal influenza virus vaccine intra muscular 12-week trial	Primary endpoints: <ul style="list-style-type: none"> Post-dose strain-specific HAI) antibody GMFRs Post-dose strain-specific serum HAI antibody GMTs Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer 	<ul style="list-style-type: none"> FPCD: Q3 2016 Data readout: Q3 2017 Primary endpoint met



Fasenra (IL5R mAb)

Severe, uncontrolled asthma, COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III GRECO NCT02918071	Severe asthma on ICS-LABA Age 18-75 years	121	Open label <i>Fasenra</i> 30mg Q4w 28-week trial Global trial - two countries	<ul style="list-style-type: none"> Primary endpoint: percentage of patients/caregivers who successfully self administer at home 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data readout: Q4 2017 Primary endpoint met
Phase IIIb ANDHI NCT03170271	A multi-centre, randomised, double-blind, parallel group, placebo controlled, Phase IIIb trial to evaluate the safety and efficacy of <i>Fasenra</i> 30 mg s.c. in patients with severe asthma uncontrolled on SoC treatment. Age 18-75	659	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q8W s.c. Arm 2: placebo s.c. 24-week trial Global trial – 15 countries	<ul style="list-style-type: none"> Primary endpoint: rate of asthma exacerbations Secondary outcome measures: Saint George Respiratory Questionnaire (SGRQ) 	<ul style="list-style-type: none"> FPCD: Q3 2017 LPCD: Q1 2019 Data readout: Q4 2019 Primary endpoint met
Phase I AMES NCT02968914	Healthy volunteers age 18-55 years	180	Open label trial to compare 30 mg <i>Fasenra</i> PK administered by APFS or AI device 8-week trial Global trial – two countries	<ul style="list-style-type: none"> Primary endpoint: PK comparability 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data readout: Q3 2017
Phase III RESOLUTE NCT04053634	Patients with moderate to very severe COPD with a history of frequent exacerbations on a background triple therapy (ICS/LABA/LAMA) Age 40-85 years	868	<ul style="list-style-type: none"> Double-blind, placebo controlled, single dose (100mg q8w) 56-week treatment Global trial 	<ul style="list-style-type: none"> Primary endpoint: annualized rate of moderate or severe exacerbations over 56 weeks 	<ul style="list-style-type: none"> FPCD Q4 2019 Data anticipated: 2021+



Fasenra (IL5R mAb)

Nasal polyposis and other eosinophilic diseases

Trial	Population	Patients	Design	Endpoints	Status
Phase III OSTRO NCT03401229	Patients with severe bilateral nasal polyposis who are still symptomatic despite standard of care therapy Age 18-75 years	413	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q8W s.c. Arm 2: placebo s.c. 56-week trial Global trial- 8 countries	<ul style="list-style-type: none"> Primary endpoint: effect of <i>Fasenra</i> on nasal polyp burden and on patient reported nasal blockage 	<ul style="list-style-type: none"> FPCD: Q1 2018 LPCD: Q2 2019 Data readout: Q3 2020 Met primary endpoints
Phase III ORCHID NCT04157335	Patients with eosinophilic chronic rhinosinusitis with severe nasal polyposis Age 18-75 years	148	Arm 1: <i>Fasenra</i> 30mg Q8W s.c. Arm 2: placebo Q8W s.c. 56-week trial Asian countries (4 countries)	<ul style="list-style-type: none"> Primary endpoint: Change in endoscopic total nasal polyp score and Change in mean nasal blockage score 	<ul style="list-style-type: none"> FPCD: Q4 2019 Data anticipated: 2021+
Phase III MANDARA NCT04157348	Patients with relapsing or refractory EGPA on corticosteroid therapy with or without stable immunosuppressive therapy Age 18 years and older	140	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. Arm 2: mepolizumab 300mg Q4W s.c. 52-week trial with a minimum 1 year open label extension Global trial- 9 countries	<ul style="list-style-type: none"> Primary endpoint: Proportion of patients achieving remission (BVAS=0 and OCS dose \leq 4mg/day) at both weeks 36 and 48. 	<ul style="list-style-type: none"> FPCD: Q4 2019 Data anticipated: 2021+
Phase III NATRON NCT04191304	Patients with HES (history of persistent eosinophilia >1500 cells/ μ L with evidence of end organ manifestations attributable to eosinophilia) and signs or symptoms of HES worsening/flare at Visit 1 Age 12 years and older	120	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. Arm 2: placebo Q4W s.c. 24-week trial with a minimum 1 year open label extension Global trial- 9-12 countries	<ul style="list-style-type: none"> Primary endpoint: Time to first HES worsening/flare. 	<ul style="list-style-type: none"> FPCD Q3 2020 Data anticipated: 2021+
Phase III MESSINA NCT04543409	Documented diagnosis of EoE Age 12 to 65 years	170	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W s.c. Arm 2: placebo Q4W s.c. 24-week double blind treatment period and open label period(s)	<ul style="list-style-type: none"> Primary endpoints: Histologic response at week 24 Change from baseline in DSQ score at week 24 	<ul style="list-style-type: none"> FPCD Q4 2020 Data anticipated: 2021+



Fasenra (IL5R mAb)

Dermatology

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase III FJORD	Patients with symptomatic (newly diagnosed or relapsing) Bullous Pemphigoid	120	<ul style="list-style-type: none"> • Arm 1: <i>Fasenra</i> regimen • Arm 2: placebo <p>36-week double blind treatment period and open label period</p> <p>Global trial</p>	<ul style="list-style-type: none"> • Primary endpoint: Proportion of patients with sustained (≥ 2 months) remission off OCS at 36 weeks 	<ul style="list-style-type: none"> • Initiating • Data anticipated: 2021+
Phase II ARROYO	Patients with moderate/severe Chronic Spontaneous Urticaria, and resistant to H1 treatment	160	<ul style="list-style-type: none"> • Arm 1: <i>Fasenra</i> regimen 1 • Arm 2: <i>Fasenra</i> regimen 2 • Arm 3: placebo <p>24-week double blind treatment period and open label period</p> <p>Global trial</p>	<ul style="list-style-type: none"> • Primary endpoint: Change from baseline in ISS7 at week 12 	<ul style="list-style-type: none"> • Initiating • Data anticipated: 2021+
Phase II HILLIER NCT04605094	Patients with moderate to severe Atopic Dermatitis despite treatment with topical medications	160-200	<ul style="list-style-type: none"> • Arm 1: <i>Fasenra</i> regimen • Arm 2: placebo <p>16-week double blind treatment period and open label periods</p> <p>Global trial</p>	<ul style="list-style-type: none"> • Primary endpoint: Proportion of patients with an IGA 0/1 and a decrease in IGA of ≥ 2 points at week 16 	<ul style="list-style-type: none"> • Initiating • Data anticipated: 2021+



Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III NAVIGATOR NCT03347279 Partnered	Severe asthma Age 12-80 years	1,061	<ul style="list-style-type: none"> Arm 1: tezepelumab s.c. Arm 2: placebo s.c. 52 week trial Global trial – 18 countries	<ul style="list-style-type: none"> Primary endpoint: Annual asthma exacerbation rate Secondary endpoints: Change from baseline in pre-BD FEV1, asthma related QoL (AQLQ(S)+12), asthma control (ACQ-6) 	<ul style="list-style-type: none"> FPCD: Q1 2018 LPCD: Q3 2019 Data anticipated: H2 2020
Phase III SOURCE NCT03406078 Partnered	Severe asthma Age 18-80 years	150	<ul style="list-style-type: none"> Arm 1: tezepelumab s.c. Arm 2: placebo s.c. 48 week trial Global trial – seven countries	<ul style="list-style-type: none"> Primary endpoint: Reduction from baseline in daily OCS dose while not losing asthma control Secondary endpoint: Annual asthma exacerbation rate 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q4 2019 Data anticipated: H2 2020
Phase III DESTINATION NCT03706079 Partnered	Severe asthma Age 12-80 years	~975	<ul style="list-style-type: none"> Arm 1: tezepelumab s.c. Arm 2: placebo s.c. Extension trial to NAVIGATOR and SOURCE. 52 week trial (subjects from NAVIGATOR); 56 week trial (subjects from SOURCE) Global trial – 18 countries	<ul style="list-style-type: none"> Primary endpoint: Exposure adjusted rates of AEs/SAEs Secondary endpoints: Annual asthma exacerbation rate 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2021+
Phase III PATH-HOME NCT03968978 Partnered	Severe asthma Age 12-80 years	216	<ul style="list-style-type: none"> Arm 1: tezepelumab s.c. via autoinjector (AI) Arm 2: tezepelumab s.c. via accessorized pre-filled syringe (APFS) 24 week trial Global trial – 4 countries	Primary endpoint: Proportion of health care professionals and patients /caregivers who successfully administrated tezepelumab in clinic and at home with an APFS or an AI, respectively	<ul style="list-style-type: none"> FPCD: Q2 2019 LPCD: Q3 2019 Data anticipated: H2 2020



Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma & COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase II CASCADE NCT03688074 Partnered	Severe asthma Age 18-75 years	116	<ul style="list-style-type: none"> • Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 28 week trial Global trial – five countries	<ul style="list-style-type: none"> • Primary endpoint: number of airway submucosal inflammatory cells/mm² of bronchoscopic biopsies 	<ul style="list-style-type: none"> • FPCD: Q4 2018 • LPCD: Q4 2019
Phase III DIRECTION NCT03927157 Partnered	Severe asthma Age 18-80 years	396	<ul style="list-style-type: none"> • Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 52 week trial Regional Asia trial – three countries	<ul style="list-style-type: none"> • Primary endpoint: Annual asthma exacerbation rate • Secondary endpoints: Change from baseline in pre-BD FEV₁, asthma related QoL (AQLQ(S)+12), asthma control (ACQ-6) 	<ul style="list-style-type: none"> • FPCD: Q3 2019
Phase III NOZOMI NCT04048343 Partnered	Severe asthma 12-80 years	65	Arm 1: tezepelumab s.c. 52 week trial Local trial - Japan	<ul style="list-style-type: none"> • Primary endpoint: Number of patients with adverse events 	<ul style="list-style-type: none"> • FPCD: Q2 2019 • LPCD: Q4 2019
Phase IIa COURSE NCT04039113 Partnered	Moderate to very severe COPD Age 40-80	282	<ul style="list-style-type: none"> • Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 52 week trial Global trial – 10 countries	<ul style="list-style-type: none"> • Primary endpoint: Rate of moderate or severe COPD exacerbations 	<ul style="list-style-type: none"> • FPCD Q3 2019 • Data anticipated: 2021+



PT027 (SABA/ICS, pMDI)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III MANDALA NCT03769090 Managed by Avillion	Moderate to severe asthma	3,100	Treatments (minimum 24-week treatment period) <ul style="list-style-type: none"> BDA (budesonide albuterol) MDI 80/180 µg prn BDA MDI 160/180 µg prn AS (albuterol sulphate) MDI 180 µg prn Randomised, double-blind, multi-centre, parallel group Multi-country	Primary endpoint: <ul style="list-style-type: none"> Time to first severe asthma exacerbation Secondary endpoints: <ul style="list-style-type: none"> Severe exacerbation rate (annualised) Total corticosteroid exposure over the treatment period Asthma Control Questionnaire -5 change from baseline and responder analysis at Week 24 Asthma quality of life questionnaire for 12 years and older/paediatric asthma quality of life questionnaire change from baseline and responder analysis at week 24 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H2 2021
Phase III DENALI NCT03847896 Managed by Avillion	Mild to moderate asthma	600	Treatments (12 week treatment period) <ul style="list-style-type: none"> BDA MDI 80/180 µg QID BDA MDI 160/180 µg QID BD MDI 160 µg QID AS MDI 180 µg QID placebo MDI QID Randomised, double-blind, multi-centre and parallel-group Multi-country	Dual primary endpoints: <ul style="list-style-type: none"> Change from baseline in FEV1 AUC0-6 hours over 12 weeks Change from baseline in trough FEV1 at week 12 	<ul style="list-style-type: none"> FPCD: Q2 2019 Data anticipated: H2 2021
Phase III TYREE NCT04234464 Managed by Avillion	Asthma with exercise induced bronchoconstriction	60	Treatments (single dose) <ul style="list-style-type: none"> BDA MDI 160/180 µg placebo MDI QID Randomised, double-blind, multi-centre crossover Country: US	Primary endpoint: <ul style="list-style-type: none"> The maximum percentage fall from post-dose, pre-exercise baseline in forced expiratory volume in 1 second (FEV1) observed up to 60 minutes post-exercise challenge 	<ul style="list-style-type: none"> FPCD Q1 2019 FPCD: Q1 2020 Data anticipated: H2 2020



Anifrolumab (type I interferon receptor mAb)

Lupus (SLE / LN)

Trial	Population	Patients	Design	Endpoints	Status
Phase III TULIP SLE 1 NCT02446912	Moderate to severe SLE	450	<ul style="list-style-type: none"> Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks Arm 2: 150mg i.v. anifrolumab Q4W for 48 weeks Arm 3: placebo i.v. Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: response in SLE responder index at week 52 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2017 Data readout: Q3 2018 Primary endpoint not met
Phase III TULIP SLE 2 NCT02446899	Moderate to severe SLE	360	<ul style="list-style-type: none"> Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks Arm 2: placebo i.v. Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: response in SLE responder index at week 52 BICLA at week 52 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2017 Data readout: Q3 2019 Primary endpoint met
Phase III TULIP LTE NCT02794285	Moderate to severe SLE	630	<ul style="list-style-type: none"> Arm 1: 300mg i.v. anifrolumab Q4W for 152 weeks Arm 2: placebo i.v. Q4W for 152 weeks 	<ul style="list-style-type: none"> Primary endpoint: extension to evaluate long-term safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q4 2018 Data anticipated: 2021+
Phase II NCT01438489	Moderate to severe SLE patients	307	<ul style="list-style-type: none"> Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks Arm 2: 1000mg i.v. anifrolumab Q4W for 48 weeks Arm 3: placebo i.v. Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: response in SLE responder index at 6 months 	<ul style="list-style-type: none"> FPCD: Q1 2012 LPCD: Q1 2015 Data readout: Q3 2014
Phase II NCT01753193	Moderate to severe SLE patients	218	<ul style="list-style-type: none"> Arm 1: anifrolumab, i.v. Q4W for 104 weeks 	<ul style="list-style-type: none"> Primary endpoint: open-label extension to evaluate long-term safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2013 Data readout: Q4 2018
Phase II NCT02962960	Moderate to severe SLE patients	32	<ul style="list-style-type: none"> Arm 1: 150mg s.c. every other week Arm 2: 300mg s.c. every other week Arm 3: placebo s.c. every other week 	<ul style="list-style-type: none"> PK/PD, safety, tolerability, primary analysis at week 12, secondary analysis at week 52 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q4 2017 Data readout: Q1 2018
Phase II TULIP-LN1 NCT02547922	Active Proliferative LN	150	<ul style="list-style-type: none"> Arm 1: 900 mg i.v. Q4W for 12 weeks then 300mg i.v. anifrolumab Q4W for 36 weeks Arm 2: 300 mg i.v. anifrolumab Q4W for 48 weeks Arm 3: placebo i.v. Q4W for 48 weeks 	<ul style="list-style-type: none"> Response in proteinuria at week 52 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2018 Data anticipated: H1 2021



Brazikumab (IL-23 inhibitor)

Inflammatory Bowel Disease (Crohn's Disease, Ulcerative Colitis)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb / III INTREPID NCT03759288	Crohn's Disease	1,140	<ul style="list-style-type: none"> Arm 1: brazikumab 1440 mg IV induction + 240 mg SC maintenance every 4 weeks Arm 2: brazikumab 720 mg IV induction + 240 mg SC maintenance every 4 weeks Arm 3: adalimumab 160 mg SC on day 1 and 40 mg maintenance every 2 weeks Arm 4: placebo 	Primary <ul style="list-style-type: none"> Endoscopic response and clinical remission at week 12 Secondary <ul style="list-style-type: none"> Endoscope response and clinical remission at both weeks 12 and 52 Endoscopic remission and clinical remission at week 52 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2021+
Phase III NCT03961815	Crohn's Disease	1,000	<ul style="list-style-type: none"> Open label extension 	<ul style="list-style-type: none"> Safety of long-term treatment with brazikumab 	<ul style="list-style-type: none"> FPCD: Q1 2020 Data anticipated: 2021+
Phase II EXPEDITION NCT03616821	Ulcerative Colitis	375	<ul style="list-style-type: none"> Arm 1: brazikumab 2100 mg IV on days 1, 15, 43 + 210 or 105 mg SC maintenance every 4 weeks Arm 2: brazikumab 1400 mg IV on days 1, 15, 43 + 210 or 105 mg SC maintenance every 4 weeks Arm 3: brazikumab 700 mg IV on days 1, 15, 43 + 210 or 105 mg SC maintenance every 4 weeks Arm 4: vedolizumab 300 mg IV on days 1, 15, 43, 99 and every 9 weeks maintenance every 2 weeks Arm 5: placebo 	Primary <ul style="list-style-type: none"> Clinical remission at week 10 Secondary <ul style="list-style-type: none"> Sustained clinical remission at week 54 	<ul style="list-style-type: none"> FPCD: Q3 2018 Data anticipated: 2021+
Phase II NCT04277546	Ulcerative Colitis	300	<ul style="list-style-type: none"> Open label extension 	<ul style="list-style-type: none"> Clinically significant adverse events 	<ul style="list-style-type: none"> FPCD: Q1 2020 Data anticipated: 2021+



Nirsevimab (MEDI8897, Respiratory syncytial virus mAb-YTE)

Infection

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb NCT02878330	29-35 WK GA (Gestational age) infants	1,453	<ul style="list-style-type: none"> Randomised, double-blind, placebo-controlled trial Route of administration: intramuscular 	<ul style="list-style-type: none"> Safety and efficacy 	<ul style="list-style-type: none"> FPCD: Q4 2016 LPCD: Q4 2017 Data readout: Q4 2018 Primary endpoint met
Phase II/III MEDLEY NCT03959488	High risk preterm (born 35 weeks 0 day or less GA), CHD and CLD infants eligible to receive palivizumab	1,500	<ul style="list-style-type: none"> Randomised, Double-blind, palivizumab-controlled Route of administration: intramuscular <p>Global trial – 32 countries</p>	<ul style="list-style-type: none"> Primary: Safety and tolerability Secondary: PK, ADA and descriptive efficacy 	<ul style="list-style-type: none"> FPCD: Q3 2019 Data readout: 2021+
Phase III MELODY NCT03979313	Healthy infants (born 35 weeks 0 days or greater GA)	3,000	<ul style="list-style-type: none"> Randomised, Double-blind, placebo-controlled Route of administration: intramuscular <p>Global trial – 31 countries</p>	<ul style="list-style-type: none"> Primary: Efficacy Secondary: Safety, PK, ADA 	<ul style="list-style-type: none"> FPCD: Q3 2019 Data readout: 2021+
Phase II Japan IC NCT04484935	Immunocompromised Japanese children who are ≤ 24 months of age at the time of dose administration	30	<ul style="list-style-type: none"> Open-label, Uncontrolled, single-dose Study Route of administration: intramuscular <p>Japan only</p>	<ul style="list-style-type: none"> Primary: Safety and tolerability Secondary: PK, ADA, efficacy 	<ul style="list-style-type: none"> FPCD: Q3 2020 Data readout: 2021+



AZD1222 (SARS-CoV-2)

Prevention of COVID-19

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II COV001 (UK) NCT04324606 Partnered	Healthy adults Age 18-55 years	1,077	Single-blinded, randomised, controlled, multi-centre trial <ul style="list-style-type: none"> AZD1222 Control vaccine: MenACWY UK	<ul style="list-style-type: none"> Primary endpoint: efficacy and safety Secondary endpoints: safety, tolerability, reactogenicity, and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2020 LPCD: Q2 2020
Phase I/II COV005 (SA) NCT04444674 Partnered	Healthy adults Age 18-65 years HIV+ subgroup	2,000	Adaptive, double-blinded, randomised placebo-controlled trial <ul style="list-style-type: none"> AZD1222 Placebo South Africa	<ul style="list-style-type: none"> Primary endpoint: efficacy, safety, and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: Q4 2020
Phase II/III COV002 (UK) NCT04400838 Partnered	Main efficacy trial: healthy adults aged ≥18 years Healthy adults 56 - <70 years Healthy adults ≥70 years Healthy children 5 – 12 years	12,390	Single-blinded, randomised, controlled, multi-centre trial with sequential age escalation/de-escalation immunogenicity sub-studies that include prime boost <ul style="list-style-type: none"> AZD1222 Control vaccine: MenACWY UK	<ul style="list-style-type: none"> Primary endpoint: efficacy and safety Secondary endpoints: safety, tolerability, reactogenicity, and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: Q4 2020
Phase III D8110C00001 (US, global) NCT04516746	Healthy adults Age 18-65 years	40,000	Adaptive, double-blinded, randomised placebo-controlled trial <ul style="list-style-type: none"> AZD1222 Placebo US, with intent to expand to other countries	<ul style="list-style-type: none"> Primary endpoints: efficacy, safety, tolerability, and reactogenicity Secondary endpoints: immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2020 Data anticipated: H1 2021
Phase III COV003 (Brazil) NCT04536051 Partnered	Health professionals and adults with high potential for exposure to SARS-CoV-2 Age 18-55 years	10,000	Single-blinded, randomised, controlled multi-centre trial <ul style="list-style-type: none"> AZD1222 Control vaccine: MenACWY Brazil	<ul style="list-style-type: none"> Primary endpoint: efficacy Secondary endpoints: safety, tolerability, reactogenicity, and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: Q4 2020
Phase III D8111C00001 NCT04540393	Healthy adults Age ≥18 years	100	Open-label, non-comparative trial Russia	<ul style="list-style-type: none"> Primary endpoints: safety, tolerability Secondary endpoints: immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2020
Phase I/II D8111C00002 NCT04568031	Healthy adults Age ≥18 years	256	Double-blinded, randomised, placebo-controlled multi-centre trial <ul style="list-style-type: none"> AZD1222 Placebo Japan	<ul style="list-style-type: none"> Primary endpoints: safety, tolerability, reactogenicity, immunogenicity Secondary endpoints: immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2020
Phase I/II COV004 (Kenya)	Healthy adults	400	Double-blinded, randomised, placebo-controlled multi-centre trial <ul style="list-style-type: none"> AZD1222 Control vaccine: rabies Kenya	<ul style="list-style-type: none"> Primary endpoints: safety, tolerability, reactogenicity, immunogenicity Secondary endpoints: immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2020

AZD7442 (LAAB combination of AZD8895 & AZD1061)

Prevention and treatment of COVID-19

Trial	Population	Patients/Subjects	Design	Endpoints	Status
Phase I NCT04507256	Healthy adults Age 18-55 years	60	Double-blinded, randomised, placebo controlled, single ascending dose study AZD7442/placebo (10:2) Single center, UK	<ul style="list-style-type: none"> Primary endpoint: safety, tolerability and PK Secondary endpoints: immunogenicity 	<ul style="list-style-type: none"> FPPD: August 2020 LPCD: October 2020
Phase III (PROVENT) D8850C00002 NCT# pending	Adults having increased risk for inadequate response to active immunization or having increased risk for SARS-CoV-2 infection	5,000	Double-blinded, randomized, placebo controlled, multi center study to determine safety and efficacy AZD7443/placebo (2:1) Pre-exposure Countries: USA, UK, Belgium, France, Spain	<ul style="list-style-type: none"> Primary endpoint: positive symptomatic illness post –dose Secondary endpoints: Incidence of nucleocapsid antibodies, incidence of emergency visits, incidence of PCR positive, incidence of ADA to AZD7442 in serum and ZD7442 serum concentrations 	<ul style="list-style-type: none"> Initiating
Phase III (STORMCHASER) D8850C00003 NCT# pending	Adults with potential exposure To an identified individual with confirmed SARS-COV2 infection and at risk of developing COVID-19	1,125	Double-blinded, randomized, placebo controlled, multi center study to determine safety and efficacy AZD7443/placebo (2:1) Post-exposure Countries: USA and UK	<ul style="list-style-type: none"> Primary endpoint: positive symptomatic illness post –dose Secondary endpoints: Incidence of nucleocapsid antibodies, incidence of COVID-19 related death, incidence of all cause mortality, incidence of ADA to AZD7442 in serum and ZD7442 serum concentrations 	<ul style="list-style-type: none"> Initiating



COVID-19 trials

Treatment of COVID-19

Approved medicines

Late-stage development

Early development

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase IIb CALAVI- US NCT04380688	<i>Calquence</i>	COVID-19	61	<ul style="list-style-type: none"> Arm 1: <i>Calquence</i> + best supportive care Arm 2: best supportive care alone 	<ul style="list-style-type: none"> Primary outcomes: safety, subject alive and free of respiratory failure at Day 28 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: H2 2020
Phase IIb CALAVI- RoW NCT04346199	<i>Calquence</i>	COVID-19	140	<ul style="list-style-type: none"> Arm 1: <i>Calquence</i> + best supportive care Arm 2: best supportive care alone 	<ul style="list-style-type: none"> Primary outcome: subject alive and free of respiratory failure at Day 14 	<ul style="list-style-type: none"> FPCD: Q2 2020 Data anticipated: H2 2020
Phase III DARE-19 NCT04350593	<i>Farxiga</i>	COVID-19	900	<ul style="list-style-type: none"> Current SoC or current SoC + <i>Farxiga</i> 	<ul style="list-style-type: none"> Primary outcome measures: time to first occurrence of either death from any cause or new/worsened organ dysfunction through 30 days of follow up 	<ul style="list-style-type: none"> Data anticipated H2 2020
Phase II TACTIC-E NCT04393246	<i>Farxiga</i>	COVID-19	1,407	<ul style="list-style-type: none"> Current SoC or current SoC + <i>Farxiga</i> + ambrisentan 	<ul style="list-style-type: none"> Primary Outcome Measures: time to incidence of the composite endpoint of: death, mechanical ventilation, extracorporeal membrane oxygenation, cardiovascular organ support, or renal failure 	<ul style="list-style-type: none"> Data anticipated H2 2020
Phase IIa TACTIC-COVID NCT04355637	<i>Pulmicort</i>	COVID-19	300	<ul style="list-style-type: none"> Current SoC or SoC + <i>Pulmicort</i> 	<ul style="list-style-type: none"> Primary outcome measures: proportion of patients in both arms fulfilling the criteria for treatment failure 	<ul style="list-style-type: none"> Data anticipated H2 2020
Phase IIIa STOIC NCT04416399	<i>Pulmicort</i>	COVID-19	478	<ul style="list-style-type: none"> Current SoC or SoC + <i>Pulmicort</i> 	<ul style="list-style-type: none"> Primary Outcome Measures: emergency department attendance of hospitalisation related to COVID-19 	<ul style="list-style-type: none"> Data anticipated H2 2020
Phase IIIa INHASCO NCT04331054	<i>Symbicort</i>	COVID-19	436	<ul style="list-style-type: none"> Current SoC or SoC + <i>Symbicort</i> 	<ul style="list-style-type: none"> Primary Outcome Measures: time (in days) to clinical improvement within 30 days after randomisation 	<ul style="list-style-type: none"> Data anticipated H2 2020
Phase II ACCORD	MEDI3506	COVID-19	180	<ul style="list-style-type: none"> Current SoC or current SoC + MEDI3506 	<ul style="list-style-type: none"> Primary endpoints: time to a 2-point improvement on a 9-point category ordinal scale, discharge from hospital, or considered fit for discharge whichever comes first by Day 29 	<ul style="list-style-type: none"> Data anticipated H1 2021

Oncology

CVRM

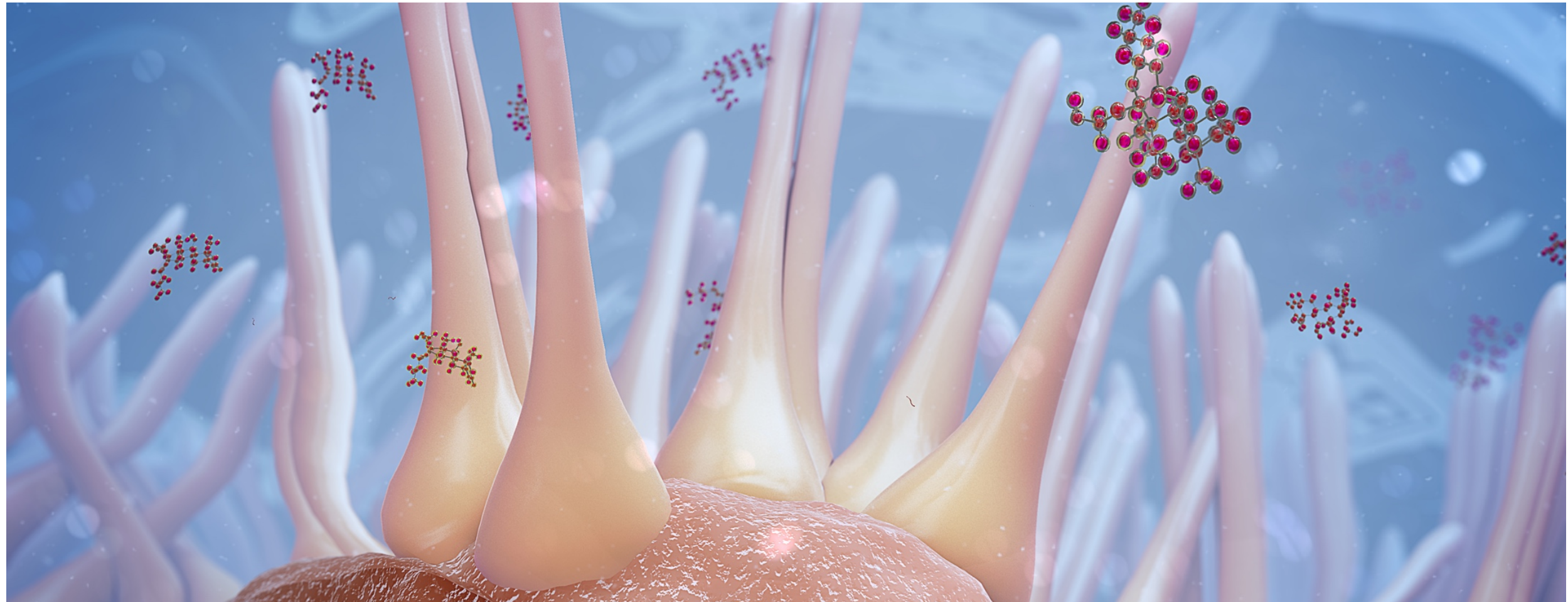
R&I

Other

COVID-19



BioPharmaceuticals - early-stage development



Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/CKD, NASH

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03555994	Adults with type-2 diabetes	44	<ul style="list-style-type: none"> Part A: cotadutide or placebo s.c. Part B: cotadutide s.c. or placebo s.c. or liraglutide s.c. Sweden, Netherlands, UK 	<ul style="list-style-type: none"> Primary: change in hepatic glycogen concentration postprandially, adjusted by liver volume Secondary: safety Secondary: tolerability Secondary: immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2018 Part A LPCD: Q4 2018 Data readout: Q1 2019 Part B FPCD: Q1 2020 LPCD: H1 2021
Phase II NCT03596177	Overweight and obese patients with type-2 diabetes	27	<ul style="list-style-type: none"> Cotadutide or placebo s.c. UK 	<ul style="list-style-type: none"> Primary: efficacy body weight loss Secondary: change in total energy intake Secondary: change in total energy expenditure, active energy expenditure, resting energy expenditure Secondary: safety 	<ul style="list-style-type: none"> FPCD: Q4 2018 LPCD: Q4 2019 Data readout: Q4 2020
Phase II NCT04019561	Obese patients with non-alcoholic fatty liver disease (NAFLD)/non-alcoholic steatohepatitis (NASH)	72	<ul style="list-style-type: none"> Arm1: cotadutide high dose s.c. Arm2: placebo high dose s.c. Arm3: cotadutide low dose s.c. Arm4: placebo low dose s.c. US 	<ul style="list-style-type: none"> Primary: safety and tolerability Secondary: change in hepatic fat fraction, Secondary: change in liver fat volume Secondary: change in visceral adipose tissue 	<ul style="list-style-type: none"> FPCD: Q4 2019 LPCD: H1 2021 Data Readout: H2 2021
Phase II NCT04515849	A Study of Cotadutide in participants who have chronic kidney disease with type 2 diabetes mellitus	225	<ul style="list-style-type: none"> Arm1: cotadutide 100 micrograms Arm2: cotadutide 300 micrograms Arm3: cotadutide 600 micrograms Arm4: semaglutide Arm5: placebo 	<ul style="list-style-type: none"> Primary: efficacy change in UACR Secondary: Change in HbA1c Secondary: Change in glucose measured by CGM Secondary: Effects on body weight Secondary: Safety, tolerability, Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2020 LPCD: H2 2021 Data readout: H2 2021
Phase I NCT04091373	Healthy adult patients	36		<ul style="list-style-type: none"> Primary: to evaluate exposure following a single s.c of cotadutide at each of 3 different sites of injection Secondary: immunogenicity Secondary: safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2019 LPCD: Q1 2020 Data readout: Q4 2020



Verinurad (RDEA3170, URAT1 inhibitor)

CKD, HFpEF

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03990363	Patients with: <ul style="list-style-type: none"> sUA \geq6.0 mg/dL eGFR \geq25 mL/min/1.73 m² Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI formula) Mean UACR between 30 mg/g and 5000 mg/g 	725	<ul style="list-style-type: none"> Arm A; Verinurad 12 mg + allopurinol 300 mg Arm B Verinurad 7.5 mg + allopurinol 300 mg Arm C; Verinurad 3 mg + allopurinol 300 mg Arm D; Verinurad placebo + allopurinol 300 mg Arm E; Verinurad placebo + allopurinol placebo <p>This trial is multi-centre trial conducted in USA, China, Czech Republic, France, Hungary, Israel, Italy, Mexico, Poland, Romania, Slovakia, South Africa, Spain</p>	Ratio of urinary albumin to urinary creatinine Changes in eGFR, Cystatin C, and uric acid	<ul style="list-style-type: none"> FPCD: Q3 2019 Data anticipated: H2 2021
Phase I NCT03118739	Healthy volunteers	24	<ul style="list-style-type: none"> Treatment A: Verinurad 24 mg ER8 formulation + 300 mg allopurinol Treatment B: Verinurad 40 mg IR formulation + 300 mg allopurinol Treatment C: Matched placebos for both verinurad and allopurinol <p>The trial is a single-centre, randomised, placebo-controlled, double-blind, 3-period, cross-over trial conducted in Germany</p>	To assess the effect of a single dose of verinurad given as either a 24 mg extended-release (ER8) formulation (therapeutic exposure) or a 40 mg immediate-release (IR) formulation (supra-therapeutic exposure), both in combination with allopurinol 300 mg, on the QT interval corrected for heart rate using Fridericia's formula (QTcF) compared to placebo	<ul style="list-style-type: none"> FPCD: Q3 2020 Data readout: H2 2020
Phase I NCT04532918	Healthy volunteers	14	<ul style="list-style-type: none"> Treatment A: Verinurad 7.5 mg ER8 formulation + 300 mg Allopurinol under fasted conditions Treatment B: Verinurad 7.5 mg IR formulation + 300 mg allopurinol + cyclosporin 600 mg under fasted conditions Treatment C: Verinurad 7.5 mg IR formulation + 300 mg allopurinol + rifampicin 600 mg under fasted conditions <p>The trial is a single-centre, randomised, open-label, 3-period, fixed sequence, trial conducted in Germany</p>	To quantify the effects of cyclosporine, a broad transporter inhibitor, and rifampicin, an OATP1B1/3 inhibitor, on verinurad pharmacokinetics (PK).	<ul style="list-style-type: none"> FPCD: Q3 2020 LPCD: Q3 2020 Data readout: Q4 2020
Phase II NCT04327024	patients with heart failure with preserved ejection fraction	435	<ul style="list-style-type: none"> Arm A: verinurad 12 mg + allopurinol 300 mg Arm B: verinurad placebo + allopurinol 300 mg Arm C: verinurad placebo + allopurinol placebo <p>The trial is a multi-centre trial conducted in Argentina, Australia, Austria, Bulgaria, Canada, Germany, Mexico, Poland, Russia, Slovakia South Korea, USA</p>	Peak V02 Change from baseline at Week 28 in exercise capacity Change from baseline at Week 28 in Kansas-City Cardiomyopathy Questionnaire-Total Symptom Score (KCCQ-TSS)	<ul style="list-style-type: none"> FPCD: Q3 2020 LPCD: Q2 2022 Data readout: Q3 2022



Verinurad (RDEA3170, URAT1 inhibitor)

HFpEF

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT04327024	Patients with heart failure with preserved ejection fraction	435	<ul style="list-style-type: none">• Arm A: verinurad 12 mg + allopurinol 300 mg• Arm B: verinurad placebo + allopurinol 300 mg• Arm C: verinurad placebo + allopurinol placebo The trial is a multi-centre trial conducted in Argentina, Australia, Austria, Bulgaria, Canada, Germany, Mexico, Poland, Russia, Slovakia South Korea, USA	Peak V02 Change from baseline at Week 28 in exercise capacity Change from baseline at Week 28 in Kansas-City Cardiomyopathy Questionnaire-Total Symptom Score (KCCQ-TSS)	<ul style="list-style-type: none">• FPCD: Q3 2020• Data readout: 2021+



AZD2373

Chronic Kidney Disease

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04269031	Healthy volunteers	48	SAD Dose escalation in 6 cohorts with 6 volunteers receiving AZD2373 and 2 volunteers receiving placebo in each cohort Trial conducted in the US	Primary: • Safety and tolerability Secondary; • PK parameters	• FPCD: Q1 2020



AZD2693 (resolution of NASH)

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

NASH

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04142424	Healthy volunteers	48	SAD 6 cohorts with 6 volunteers receiving AZD2693 and 2 volunteers receiving placebo in each cohort Route of administration: subcutaneous injections Trial conducted in the US.	Primary: • Safety and tolerability Secondary; • PK	<ul style="list-style-type: none">• FPCD: Q4 2019• Data anticipated: H1 2021



AZD3366

Cardiovascular Disease

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04588727	Healthy volunteers	87	SAD Part A Dose escalation in 6 cohorts with 6 volunteers receiving AZD3366 and 2 volunteers receiving placebo in each cohort Part B 12 subjects receiving AZD3366 and ticagrelor and ASA Trial conducted in the US	Primary: • Safety and tolerability Secondary; • PK parameters	• FPCD: Q4 2020



MEDI3506 (IL33 ligand mAb)

Diabetic Kidney Disease (DKD)

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT04170543	Adult patients with diabetic kidney disease	168	Randomised, double-blind, placebo-controlled, multicenter trial to evaluate the efficacy, safety, PK, and immunogenicity of MEDI3506 in adult patients with diabetic kidney disease	<ul style="list-style-type: none">Efficacy and safety	<ul style="list-style-type: none">FPCD: Q4 2019



AZD4831 (MPO inhibitor)

Cardiovascular disease

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02712372	Healthy patients	c. 96	SAD trial (one trial site in Germany) <ul style="list-style-type: none"> Planned to investigate 6 different dose levels vs. placebo but up to 10 cohort may be used 	<ul style="list-style-type: none"> Safety and tolerability PK parameters 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q4 2016 Data readout Q2 2017
Phase I NCT03136991	Healthy patients	c. 40	MAD (one trial site in USA) <ul style="list-style-type: none"> The planned number of cohorts is four but up to five cohorts may be included 	<ul style="list-style-type: none"> Safety and tolerability PK parameters 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q4 2017 Data readout: Q1 2018
Phase IIa NCT03756285	HFpEF	96	Arm 1: AZD4831 Arm 2: placebo Global trial – five countries	<ul style="list-style-type: none"> Primary endpoint: The change from baseline in MPO activity in % after AZD4831 treatment 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data readout: H2 2020
Phase I NCT04232345	Healthy patients	40	SAD trial in Japanese and Chinese patients	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD Q1 2020



AZD5718 (FLAP inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa NCT03317002	CAD	129	<ul style="list-style-type: none"> Arm 1: AZD5718 Dose A Arm 2: AZD5718 Dose B Arm 3: placebo <p>Global trial – three countries in Europe</p>	<ul style="list-style-type: none"> Primary endpoint: PD effect of AZD5718 by assessment of u-LTE4 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q4 2019
Phase I NCT03948451	Healthy patients	6	<p>hADME trial (one trial site in UK)</p> <ul style="list-style-type: none"> Oral administration <p>Open-label trial to characterize the absorption, distribution, metabolism and excretion following a single oral dose of [14C]AZD5718 in healthy male volunteers</p>	<ul style="list-style-type: none"> Mass balance, with routes and rates of elimination of [14C]AZD5718. Metabolite profiling and structural identification PK and total radioactivity 	<ul style="list-style-type: none"> FPCD: Q2 2019 LPCD: Q2 2019
Phase I NCT04087187	Healthy patients	14	<p>BA trial (one trial site in UK)</p> <p>An open-label, randomized, 3-period, 3-treatment, crossover trial to assess the drug absorption into the blood after administration of 3 doses of AZD5718</p>	<ul style="list-style-type: none"> To evaluate the pharmacokinetics and exposure of 3 different doses of AZD5718 Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2019 LPCD: Q4 2019
Phase I NCT04210388	Healthy patients	12	<p>BA trial (one trial site in UK)</p> <p>The trial is a randomized, single-dose, open-label, combined 2x2 dose and 3x3 dose crossover design in fixed sequence.</p>	<p>To evaluate:</p> <ul style="list-style-type: none"> The relative bioavailability of different formulations Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2020 LPCD: Q1 2020



AZD6615 (PCSK9 inhibitor, oral)

Approved medicines

Late-stage development

Early development

Oncology

Dyslipidemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04055168	Healthy volunteers	40	SAD 3 cohorts of non-Asian subjects (Part 1) and 2 cohorts of Japanese subjects (Part 2). 6 subjects receiving AZD6615 and 2 subjects receiving placebo in each cohort. Trial conducted in the US.	Primary: • Safety and tolerability Secondary; • PK and PD parameters	• FPCD: Q3 2019

CVRM

R&I

Other



AZD8233 (PCSK9 inhibitor, sub-cutaneous)

Dyslipidemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03593785	Healthy subjects	72	SAD 7 cohorts with 6 subjects receiving AZD8233 and 2 subjects receiving placebo in each cohort Trial conducted in the US.	Primary: • Safety and tolerability Secondary; • PK and PD parameters	• FPCD: Q3 2018
Phase I NCT04155645	Dyslipidemia	33	MAD Up to 3 cohorts with 8 subjects receiving AZD8233 and 3 subjects receiving placebo in each cohort Trial conducted in the US	Primary: • Safety and tolerability Secondary; • PK and PD parameters	• FPCD Q1 2020



MEDI8367

Chronic Kidney Disease

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04365218	Healthy volunteers Chronic Kidney Disease	70	Single ascending dose 6 cohorts Arm 1: MEDI8367 Arm 2: placebo Subcutaneous administration Trial conducted in the US	Primary: • Safety and tolerability Secondary; • PK parameters • ADA	• FPCD: Q3 2020



AZD8601 (VEGF-A modified RNA)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02935712	Type 2 diabetic patients	c. 60	SAD trial (one trial site in Germany) <ul style="list-style-type: none"> Planned to investigate 3 different dose levels vs. placebo but up to 5 cohort may be used 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q3 2017 Data readout: Q1 2018
Phase IIa NCTT03370887	HF	Up to 33	Phase IIa trial (two trial sites in Finland) <ul style="list-style-type: none"> Arm 1: AZD8601 Dose A Arm 2: AZD 8601 Dose B Arm 3: placebo 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2018



Heart failure

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03435276	Healthy volunteers	27	MAD Dose escalation in 3 cohorts with 6 subjects receiving AZD9977 and 3 volunteers receiving placebo in each cohort Trial conducted in the UK.	Primary: • Safety and tolerability Secondary; • PK parameters	<ul style="list-style-type: none"> • FPCD: Q1 2018 • LPCD: Q2 2018 • Data readout: Q3 2018
Phase I NCT03450759	Healthy volunteers	12	Bioavailability trial Investigation of four different oral formulations of AZD9977 and influence of food. Trial conducted in the UK.	Primary: • relative bioavailability vs. oral suspension (reference) • PK parameters	<ul style="list-style-type: none"> • FPCD: Q2 2018 • LPCD: Q2 2018 • Data readout: Q3 2018
Phase I NCT03682497	HF	60	Proof of differentiation To compare the effect of AZD9977 with spironolactone on serum potassium	Primary: • serum potassium	<ul style="list-style-type: none"> • FPCD Q4 2018 • LPCD Q1 2019
Phase I NCT03843060	Healthy volunteers	14	DDI To assess the effect of itraconazole on the pharmacokinetics of AZD9977 Trial conducted in the US	Primary: • PK parameters Secondary; • Safety and tolerability	<ul style="list-style-type: none"> • FPCD: Q1 2019 • LPCD: Q1 2019 • Data readout: Q3 2019
Phase I NCT03801967	Healthy volunteers	45	JSMAD Single and multiple-ascending dose administration in Japanese healthy volunteers. Trial conducted in the UK	Primary: • Safety and tolerability Secondary; • PK parameters	<ul style="list-style-type: none"> • FPCD: Q1 2019 • LPCD: Q2 2019 • Data readout: Q3 2019
Phase I NCT03804645	Healthy volunteers	12	Bioavailability trial Investigation of four different oral formulations of AZD9977 and influence of food. Trial conducted in the UK	Primary: • relative bioavailability vs. capsule formulation (reference) • PK parameters	<ul style="list-style-type: none"> • FPCD: Q1 2019 • LPCD: Q2 2019 • Data readout: Q3 2019
Phase I NCT04469907	Renal Impairment	32	Renal Impairment Single dose administration of AZD9977 conducted in participants with severe renal impairment and compared with matched participants with normal renal function Trial conducted in the US	Primary: • PK parameters Secondary: • Safety and tolerability	<ul style="list-style-type: none"> • FPCD: Q3 2020 • LPCD: H1 2021 • Data readout: H1 2021



Biologics

Cardiovascular & metabolic diseases

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase IIb EudraCT 2017-004521-32	MEDI6012 rhLCAT	Subjects 30-80 years of age inclusive, presenting with acute STEMI	540	<ul style="list-style-type: none"> Cohort A: 2-dose regimen 300 mg of MEDI6012 or placebo on day 1 (loading dose) prior to pPCI followed by a second inpatient dose of 150 mg or placebo on Day 3 by i.v. push. Cohort B: 6-dose regimen 300 mg of MEDI6012 or placebo on day 1 prior to pPCI followed by a second inpatient dose of 150 mg or placebo on day 3 and outpatient maintenance doses of 100 mg or placebo on days 10, 17, 24, and 31 by i.v. push. 	Primary endpoints: Infarct size as a percentage of left ventricle (LV) mass at 10-12 weeks post-MI (myocardial infarction) compared to placebo Secondary endpoints: <ul style="list-style-type: none"> Ejection Fraction at 10-12 weeks post-MI compared to placebo. Change in NCPV in the coronary arteries from at 10-12 weeks post-MI compared with placebo Myocardial mass and LV volumes at end-systole and end-diastole Incidence of TEAEs and treatment-emergent SAEs. LCAT mass and ADAs 	<ul style="list-style-type: none"> FPCD: Q2 18 Data anticipated: 2021+
Phase IIa NCT03351738	MEDI5884 cholesterol modulation	Adults with stable CHD	133	<ul style="list-style-type: none"> MEDI5884 (5 dose cohorts) vs. placebo in stable CHD patients 	<ul style="list-style-type: none"> Safety profile in terms of AEs, vital signs, ECG, lab variables Changes in HDL-C over time PK, immunogenicity, and Apolipoprotein B 	<ul style="list-style-type: none"> FPCD Q4 2017 Data readout: Q4 2018
Phase I NCT03654313	MEDI6570	Atherosclerotic cardiovascular disease	88	<ul style="list-style-type: none"> SAD followed by multi ascending dose with 3 monthly doses in T2DM subjects 	<ul style="list-style-type: none"> Primary endpoints: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2021



AZD0449 (inhaled JAK-1 inhibitor)

Asthma

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03766399	Healthy subjects and patients with mild asthma	156	SAD/MAD/Bridge trial (UK) Part 1 SAD <ul style="list-style-type: none"> Dose escalation in 6 cohorts with 6 subjects receiving AZD0449 and 2 subjects receiving placebo in each cohort i.v. cohort with 2x6 subjects Part 2 MAD: <ul style="list-style-type: none"> 2 cohorts of (6, 6,) mild asthmatics receiving two different doses of AZD0449 and (3,3) patients receiving placebo in each cohort 1 cohort of 6 patients receiving 1 dose of AZD0449 and 2 patients receiving placebo Part 3 bridge <ul style="list-style-type: none"> 1 cohort of 6 patients receiving 1 dose of AZD0449 (DPI formulation) and 2 patients receiving placebo. Up to 18 mild asthmatic patients will receive AZD0449 (DPI) and 18 patients receiving placebo. Interim analysis planned after 9 +9 patients. Trial conducted in the UK	Primary endpoint: <ul style="list-style-type: none"> Safety and tolerability Secondary endpoint: <ul style="list-style-type: none"> PK parameters FENO 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H1 2021



AZD1402 (IL4 receptor antagonist)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib NCT03574805 Partnered	Patients with mild asthma	84	PoM. A dose-escalating, single blind trial to assess the safety, tolerability, and pharmacokinetics of multiple doses of PRS-060 administered by oral Inhalation In subjects with mild asthma Australia	Primary endpoint: <ul style="list-style-type: none"> Safety and tolerability Secondary endpoint: <ul style="list-style-type: none"> PK parameters Potential immunogenicity Change in FENO 	<ul style="list-style-type: none"> FPCD: Q3 2018



MEDI3506 (IL33 ligand mAb)

COPD, atopic dermatitis

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SAD / MAD) NCT03096795	SAD: healthy subjects with mild atopy J-SD: healthy Japanese subjects MAD: GOLD I-II COPD	SAD: 56 J-SD: 8 MAD: 24	SAD: • 7 sequential placebo-controlled single dose cohorts by either SC or IV route (active N=6 / placebo N = 2 within each cohort) J-SD: • single placebo-controlled single dose cohort by IV route (active N=6 / placebo N = 2 within cohort) MAD: • 3 sequential placebo-controlled multiple dosing cohorts by SC route (active N=6 / placebo N = 2 within each cohort) Conducted in UK	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q2 2019 Data anticipated: H2 2020
Phase II NCT04212169	Adult subjects with atopic dermatitis	152	Randomised, blinded, placebo-controlled trial to determine the efficacy and safety of different strengths of MEDI3506 by SC route Conducted in US, Australia, Germany, Poland & UK	<ul style="list-style-type: none"> Primary: change from baseline at week 16 in Eczema Area and Severity Index (EASI) score Secondary: safety and other efficacy measures 	<ul style="list-style-type: none"> FPCD: Q4 2019
Phase II NCT04570657	Adult participants with uncontrolled moderate to severe asthma	228	Randomised, double-blind, placebo-controlled trial to evaluate the efficacy, safety, pharmacokinetics (PK) and immunogenicity of different doses of MEDI3506 by SC route Conducted in US, Argentina, Germany, Hungary, Poland & South Africa	<ul style="list-style-type: none"> Primary: change from baseline at week 16 in FEV1 Secondary: safety and other efficacy measures 	<ul style="list-style-type: none"> Initiating



AZD7986 (DPP1)

COPD

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02653872	Healthy volunteers	15	<p>This is a phase I, non-randomised, fixed sequence, 3-period, drug-drug interaction trial to assess the PK of AZD7986 in healthy subjects when administered alone and in combination with multiple doses of verapamil and itraconazole or diltiazem</p> <ul style="list-style-type: none"> • Arm 1: AZD7986 (alone) treatment period 1 • Arm 2: verapamil (with AZD7986) treatment period 2 • Arm 3: itraconazole (with AZD7986) treatment Period 3 • Arm 4: diltiazem (with AZD7986) treatment period 3 	<ul style="list-style-type: none"> • Safety and tolerability • PK/PD and DDI 	<ul style="list-style-type: none"> • FPCD: Q1 2016 • Data readout: Q2 2016
Phase I NCT02303574	Healthy volunteers	89	<p>A phase I, randomised, single-blind, placebo-controlled, 2-part trial to assess the safety, tolerability, PK and food effect of single and multiple oral doses of AZD7986 in healthy volunteers.</p> <ul style="list-style-type: none"> • Arm 1: AZD7986, single and multiple oral doses • Arm 2: placebo, single and multiple doses 	<ul style="list-style-type: none"> • Safety and tolerability • PK/PD • Bioavailability 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • Data readout: Q3 2016



AZD8154 (PI3K $\gamma\delta$ inhibitor)

Asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03436316	Healthy subjects	78	SAD/MAD A Phase I trial to assess the safety, tolerability and PK of AZD8154 following single dose administration and multiple dose administration in healthy subjects	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters	<ul style="list-style-type: none">• FPCD: Q3 2018• LPCD: Q3 2019• Data readout: Q4 2019

Oncology

CVRM

R&I

Other



AZD8871 (MABA, inhaled)

Respiratory

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa NCT03645434	Patients with COPD	73	Randomised, double-blind, placebo and active-controlled crossover trial. Eligible patients will be randomised in 1:1:1:1:1:1 ratio to 1 of 6 treatment sequences and will receive 1 of the following 3 treatments sequence in the form of dry powder inhalation: <ul style="list-style-type: none">• AZD8871 600 µg once daily• Anoro® Ellipta® (55 µg umeclidinium [UMEC]/ 22 µg vilanterol [VI]) once daily• Placebo	Primary endpoint: <ul style="list-style-type: none">• Change from baseline in trough FEV₁ on day 15 Secondary endpoints: <ul style="list-style-type: none">• To characterize the pharmacokinetics of AZD8871 following multiple inhaled doses• To assess safety and tolerability of AZD8871	<ul style="list-style-type: none">• FPCD: Q4 2018• LPCD: Q2 2019• Data readout: Q3 2019



AZD9567 (SGRM, oral)

Respiratory

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02760316	Healthy subjects	71	MAD trial with a total of 6 dose levels of AZD9567: 10 mg, 20mg, 40mg, 80mg and 125 mg as well as with 3 dose levels of prednisolone: 5 mg, 20 mg and 40 mg	Primary endpoint: <ul style="list-style-type: none"> To assess the safety and tolerability of AZD9567 following multiple oral ascending doses in subjects with BMI between 28 and 38 kg/m² and with a positive glucose tolerance test (7,8 to 11,0 mmol/L) Secondary endpoints: <ul style="list-style-type: none"> To characterise the pharmacokinetics of AZD9567 following multiple oral administration of ascending doses To characterise the pharmacodynamics of AZD9567 assessed as effect on glucose homeostasis through OGTT (oral glucose tolerance test) in comparison with prednisolone 	<ul style="list-style-type: none"> FPCD: Q2 2016 Data readout: Q2 2018
Phase IIa NCT03368235	Patients with active RA	21	A randomised, double-blind, parallel trial to assess the efficacy, safety and tolerability of AZD9567 compared to prednisolone 20 mg in patients with active rheumatoid arthritis	Primary endpoint: <ul style="list-style-type: none"> To assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active RA in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs (Disease-modifying antirheumatic drugs) Secondary endpoints: <ul style="list-style-type: none"> To further assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active rheumatoid arthritis in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs (e.g. SJC 66/TJC68, ACR response criteria) To evaluate the pharmacokinetic profile of AZD9567 	<ul style="list-style-type: none"> FPCD: Q1 2018 Data readout: Q2 2020



AZD0284 (ROR γ inverse agonist)

Plaque psoriasis vulgaris

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02976831	Healthy subjects	80	Part 1 (SAD) <ul style="list-style-type: none"> Seven different dose levels investigated vs. placebo Oral administration 	<ul style="list-style-type: none"> Safety and tolerability and PK following oral administration with single ascending dose Preliminary assessment of the effect of food on the single dose PK parameters of AZD0284 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q2 2017
			Part 2 (MAD) <ul style="list-style-type: none"> Three different dose levels investigated vs. placebo in healthy subjects Oral administration 	<ul style="list-style-type: none"> Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses PoM confirmed by demonstrating that oral dosing of AZD0284 reduces IL-17 secretion by ex vivo stimulated whole blood T cells 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2017
Phase I NCT03029741	Healthy subjects	6	A single centre, open-label, non-randomised, single dose trial performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The trial will assess the absolute bioavailability of a single oral dose of AZD0284 and the pharmacokinetics (PK) of a single intravenous (IV) microdose of [¹⁴ C] AZD0284 in healthy male and female subjects. Oral AZD0284 and [¹⁴ C] AZD0284 intravenous solution are referred to as the investigational products in this trial	<ul style="list-style-type: none"> Determination of absolute bioavailability of AZD0284 Safety and tolerability of AZD0284 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2017
Phase Ib NCT03310320	Patients with moderate to severe plaque psoriasis	15	This was a randomised, double-blind, placebo-controlled, multi-centre, parallel group Phase Ib study, designed to evaluate the pharmacodynamic (PD) effects, clinical efficacy and safety of AZD0284 compared with placebo as measured by the relative change from baseline in Psoriasis Area and Severity Index (PASI) score and biomarkers associated with the mechanism of disease and AZD0284.	<ul style="list-style-type: none"> Relative change from baseline of IL-17A and CCL20 mRNA expression levels in lesional skin at Week 4. Percent improvement from baseline in individual PASI score at Week 4 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q1 2018



MEDI0618 (PAR2 antagonist mAb)

Approved medicines

Late-stage development

Early development

Oncology

CVRM

R&I

Other

Osteoarthritis pain

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02508155	Painful osteoarthritis of the knee	64 (healthy volunteers)	<ul style="list-style-type: none">• SAD• Up to 8 i.v. cohorts are planned vs. placebo• 1 s.c. cohortis planned vs. placebo Europe only	<ul style="list-style-type: none">• Safety, tolerability and PK	<ul style="list-style-type: none">• FPCD: Q4 2019



MEDI1341 (alpha-synuclein mAb)

Parkinson's Disease

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03272165	Healthy volunteers	48	<ul style="list-style-type: none">• SAD• Up to 6 i.v. cohorts are planned vs. placebo US only	<ul style="list-style-type: none">• Safety, tolerability, PK, PD	<ul style="list-style-type: none">• FPCD: Q4 2017• Data anticipated: H1 2021
Phase I NCT04449484	Parkinson's Disease	36	<ul style="list-style-type: none">• MAD• Up to 3 i.v. cohorts are planned vs placebo• US only	<ul style="list-style-type: none">• Safety, tolerability, PK, PD	<ul style="list-style-type: none">• FPCD: Q3 2020• Data anticipated: 2021+

Oncology

CVRM

R&I

Other



AZD4041 (orexin 1 receptor antagonist)

Opioid use disorder

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT04076540 Partnered with Eolas Therapeutics Inc and NIH.	Healthy volunteers	48 healthy volunteers	<ul style="list-style-type: none"> • Randomised, double blind, single ascending dose • Up to 6 cohorts are planned vs. placebo Single centre in US only	<ul style="list-style-type: none"> • Safety, tolerability, PK, PD 	<ul style="list-style-type: none"> • FPCD: Q4 2019 • Data anticipated: H1 2021



AZD5634 (ENaC, inhaled)

Cystic Fibrosis

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02679729	Healthy volunteers	56	<p>A randomised, single-blind, placebo-controlled trial to assess the safety, tolerability and pharmacokinetics of AZD5634 following single-ascending inhaled doses (Part A) and after single inhaled and intravenous doses (Part B) in healthy subjects</p> <ul style="list-style-type: none"> • Arm 1: AZD5634 following inhaled administration of SAD (Part A) and following administration of single inhaled and i.v. doses (Part B) • Arm 2: placebo 	<ul style="list-style-type: none"> • Safety and tolerability • PK/PD 	<ul style="list-style-type: none"> • FPCD: Q1 2016 • Data readout: Q4 2016
Phase Ib NCT02679729	Patients with cystic fibrosis	9	<p>A randomised blinded placebo-controlled, cross-over trial to assess the effect of AZD5634 on mucociliary clearance as well as safety, tolerability, and PK parameters following single inhaled dose administration to patients with cystic fibrosis</p> <ul style="list-style-type: none"> • Arm 1: subjects were administered single dose of placebo in period 1 and AZD5634 in period 2 • Arm 2: subjects were administered single dose of AZD5634 in period 1 and placebo in period 2 	<ul style="list-style-type: none"> • Safety and tolerability • PK/PD 	<ul style="list-style-type: none"> • FPCD: Q2 2017 • Data readout: Q2 2018



MEDI7352 (NGF TNF bispecific mAb)

Approved medicines

Late-stage development

Early development

Osteoarthritis pain

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02508155	Painful osteoarthritis of the knee	160	<ul style="list-style-type: none">SAD & MADUp to 12 i.v. cohorts are planned vs. placebo1 s.c. cohorts are planned vs. placebo Europe only	<ul style="list-style-type: none">Safety, tolerability, PK, PD	<ul style="list-style-type: none">FPCD: Q1 2016Data anticipated: H1 2021
Phase II NCT03755934	Painful diabetic neuropathy	271	<ul style="list-style-type: none">Multiple dose trialUp to 4 i.v. cohorts are planned vs. placebo Europe only	<ul style="list-style-type: none">Dose response, safety, tolerability, PK, PD	<ul style="list-style-type: none">FPCD Q4 2018Data anticipated: 2021

Oncology

CVRM

R&I

Other



Other biologics

Infections

Approved medicines

Late-stage development

Early development

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II EudraCT 2014-001097-34	Anti-Staph AT (suvratoxumab, MEDI4893)	Intubated ICU	213	<ul style="list-style-type: none">• Placebo-controlled, single-dose, dose-ranging• Route of administration: intravenous	<ul style="list-style-type: none">• Efficacy and safety	<ul style="list-style-type: none">• FPCD: Q4 2014• Data readout: Q4 2018
Phase II NCT02696902	Anti-Pseudomonas A mAb (MEDI3902)	Intubated ICU	195	<ul style="list-style-type: none">• Placebo-controlled, single-dose, dose-ranging• Route of administration: intravenous	<ul style="list-style-type: none">• Efficacy and safety	<ul style="list-style-type: none">• FPCD: Q2 2016• Data anticipated: H2 2020

Oncology

CVRM

R&I

Other



List of abbreviations

14C	Radioactive isotope of carbon, Carbon 14
1L, 2L, 3L	1st, 2nd or 3rd line
5-FU	5-fluorouracil
A2AR	Adenosine A2A receptor
ACQ	Asthma control questionnaire
ACR	American college of rheumatology response scoring system
ADA	Anti-drug antibodies
ADC	Antibody-drug conjugate
ADP	Adenosine diphosphate
AE	Adverse Event
AI	Auto-injector
AKT	Protein kinase B
ALK	Anaplastic large-cell lymphoma kinase
APFS	Accessorised pre-filled syringe
AQLQ	Asthma quality of life questionnaire
AS	Albuterol sulphate
ATM	Ataxia-telangiectasia mutated kinase
ATR	Ataxia telangiectasia and rad3-related protein
AUC	Area under curve
B7RP	B7-related protein-1
BA	Bioavailability
BAFF	B-cell activating factor
BCG	Bacillus Calmette–Guérin
BCMA	B-cell maturation antigen
BDA	Budesonide albuterol
BFF	Budesonide and formoterol fumarate
BGF	Budesonide, glycopyrronium and formoterol fumarate
BICR	Blinded independent central review
BID	Bis in die (twice per day)
BIG	Big ten cancer research consortium
BMD	Bone mineral density
BMI	Body mass index
BRCAwt	Breast cancer wild-type gene
BRD4	Bromodomain-containing protein 4
BTC	Biliary tract carcinoma
BTK	Bruton's tyrosine kinase
CA-125	Cancer antigen 125
CAD	Coronary artery disease
CBR	Clinical benefit rate
CCL20	Chemokine (C-C motif) ligand 20
CD	Cluster of differentiation
CDK	Cyclin-dependent kinase
CE	Clinically evaluable
CHD	Coronary heart disease
Chemo	Chemotherapy

CHF	Chronic heart failure
CKD	Chronic kidney disease
CLL	Chronic lymphocytic leukaemia
CMAx	Maximum observed plasma concentration
C-MET	Tyrosine-protein kinase Met
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
CR	Complete response
CRC	Colorectal cancer
CrCl	Creatinine clearance
CRR	Complete response rate
CTC	Circulating tumour cell
CTLA-4	Cytotoxic T-lymphocyte–associated antigen 4
CV	Cardiovascular
CVOT	Cardiovascular outcomes trial
CVRM	Cardiovascular renal and metabolism
CXCR2	C-X-C Motif chemokine receptor 2
DB	Double blind
DC	Disease control
DCR	Disease control rate
DDI	Drug-drug Interaction
dECG	Differentiated electrocardiogram
DFS	Disease free survival
DLBCL	Diffuse large B-cell lymphoma
DLT	Dose-limiting toxicity
DMARDs	Disease-modifying antirheumatic drugs
DNA	Deoxyribonucleic acid
DoCR	Durability of complete response
DoR	Duration of response
DPI	Dry powder inhaler
DXA	Dual energy X-ray absorptiometry
EBRT	External beam radiation therapy
ECG	Electrocardiogram
EFS	Event-free survival
eGFR	Estimated glomerular filtration rate
EGFR	Epidermal growth factor receptor
ER	Oestrogen receptor
ERK	Extracellular signal-regulated kinase
ESR	Externally sponsored trial
ESR1	Oestrogen receptor 1
ESSC	Esophageal squamous cell carcinoma
FDC	Fixed-dose combination
FeNO	Fractional nitric oxide concentration in exhaled breath
FEV	Forced-expiratory volume
FGFR	Fibroblast growth factor receptor

FLAP	5-lipoxygenase-activating protein
FPDC	First patient commenced dosing
FPG	Fasting plasma glucose
GA	Gestational age
GBM	Glioblastoma
gBRCAm or tBRCAm	Germline or tumour BRCA mutation somatic
GEJ	Gastric/gastro-oesophageal junction
GFF	Glycopyrronium and formoterol fumarate
GLP-1	Glucagon-like peptide-1
GMFRs	Geometric mean fold rises
GMTs	Geometric mean titers
HAI	Haemagglutination-inhibition
HbA1c	Hemoglobin A1c
HCC	Hepatocellular carcinoma
HD	High dose
HDL-C	High-density lipoprotein cholesterol
HER2	Human epidermal growth factor receptor 2
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HFREF	Heart failure with reduced ejection fraction
HGFR	Met/hepatocyte growth factor receptor
HGSC	High grade serous carcinoma
hHF	Hospitalisation for heart failure
HIF-PHI	Hypoxia inducible factor - prolyl hydroxylase inhibitor
HNSCC	Head and neck squamous-cell carcinoma
HPV	Human papillomavirus
HRD	Homologous recombination deficiency
HRRm	Homologous recombination repair mutation
i	inhibitor
IA	Investigator-assessed
ICS	Inhaled corticosteroid
ICU	Intensive care unit
IDFS	Invasive disease-free survival
IL	Interleukin
i.m.	Intramuscular
IRC	Independent review committee
ISS	Investigator-sponsored studies
i.v.	Intravenous
J-SD	Japanese single dose
Ki67	Protein that is encoded by the MKI67 gene in human
LAAB	Long acting antibody



List of abbreviations

LABA	Long acting beta agonist	PASI	Psoriasis area severity index	SAE	Serious adverse event
LAMA	Long acting muscarinic agonist	PBD	Pyrralobenzodiazepine	SBRT	Stereotactic body radiation therapy
LCAT	Lecithin-cholesterol acyltransferase	pCR	Pathological complete response	s.c.	Subcutaneous
LCM	Lifecycle management	PD	Pharmacodynamics	SCLC	Small cell lung cancer
LN	Lupus nephritis	PD-1	Programmed cell death protein 1	SD	Stable disease
LOCS III	Lens opacities classification system III	PDAC	Pancreatic ductal adenocarcinoma	SGLT2	Sodium-glucose transport protein 2
LPCD	Last patient commenced dosing	PDE4	Phosphodiesterase type 4	SGRM	Selective glucocorticoid receptor modulator
LV	Left ventricle	PD-L1	Programmed death-ligand 1	SGRQ	Saint George respiratory questionnaire
m	Mutation	PET	Positron-emission tomography	SJC	Swollen joint count
mAb	Monoclonal antibody	PFS	Progression free survival	SLE	Systemic lupus erythematosus
MABA	Muscarinic antagonist-beta2 agonist	PgR	Progesterone receptor	SLL	Small lymphocytic lymphoma
MACE	Major adverse cardiac events	PI3K	Phosphoinositide 3-kinase	SMAD	Single and multiple ascending dose trial
MAD	Multiple ascending dose	PIK3CA	Phosphatidylinositol 3 kinase catalytic alpha gene	SoC	Standard of care
MCC	Mucociliary clearance	PK	Pharmacokinetics	sPGA	Static physicians global assessment score
MCL	Mantle cell lymphoma	PLL	Prolymphocytic leukaemia	STAT3	Signal transducer and activator of transcription 3
MCL1	Myeloid leukemia cell differentiation protein 1	pMDI	Pressurised metered dose inhaler	sUA	Serum uric acid
mCRPC	Metastatic castrate-resistant prostate carcinoma	PN	Plexiform neurofibromas	T2DM	Type 2 Diabetes Mellitus
MD	Medium dose	POC	Proof of concept	T790M	Threonine 790 substitution with methionine
MDI	Metered-dose inhaler	POM	Proof of mechanism	TACE	Transarterial Chemoembolization
MDS	Myelodysplastic syndrome	pPCI	Primary percutaneous coronary intervention	TEAEs	Treatment-emergent adverse events
MEK	Mitogen-activated protein kinase	PR	Partial response	TID	Ter in die (three times a day)
MET	Tyrosine-protein kinase Met	pre-BD	Pre-bronchodilator	TJC	Tender joint count
MI	Myocardial infarction	PRO	Patient reported outcome	TKI	Tyrosine kinase Inhibitor
MMT	Mixed meal test	PRR	Recurrent platinum resistant	TLR	Toll-like receptor 9
MPO	Myeloperoxidase	PS	Propensity score	TNBC	Triple negative breast cancer
mPR	Major pathological response	PSA	Prostate-specific antigen	TNF	Tumour necrosis factor
MRI	Magnetic resonance imaging	PSC	Pulmonary sarcomatoid carcinoma	TSLP	Thymic stromal lymphopoietin
MTD	Maximum tolerated dose	PSMA	Prostate-specific membrane antigen	TTF	Time to treatment failure
NaC	Sodium channel	PTEN	Phosphatase and tensin homolog gene	TTNT	Time to next therapy
NCI	National cancer institute (US)	Q2,3,4,8W	Quaque (every) two, three... weeks	TTP	Time to tumour progression
NCPV	Noncalcified plaque volume	QD	Quaque in die (once a day)	UACR	Urine albumin creatinine ratio
NF1	Neurofibromatosis type 1	QID	Quarter in die (four times a day)	UMEC	Umeclidinium
NGF	Nerve growth factor	QOD	Quaque altera die (every other day)	URAT1	Uric Acid Transporter 1
NHL	Non-Hodgkin's lymphoma	QoL	Quality of Life	VEGF	Vascular endothelial growth factor
NIH	National Institute of Health (US)	QTcF	Corrected QT interval by Fredericia	YTE	Triple-amino-acid (M252Y/S254T/T256E [YTE]) substitution
NKG2a	Natural killer cell C-type lectin receptor G2A	RA	Rheumatoid Arthritis		
NME	New molecular entity	RAAS	Renin-angiotensin-aldosterone system		
NRG	National clinical trials network in oncology (US)	RECIST	Response evaluation criteria in solid tumours		
NSCLC	Non-small cell lung cancer	RFS	Relapse-free survival		
OCS	Oral corticosteroid	rhLCAT	Recombinant human Lecithin-cholesterol acyltransferase		
OD	Once daily	RORγ	Related orphan receptor gamma		
OGTT	Oral glucose tolerance test	r/r	Relapsed/refractory		
ORR	Objective response rate	RT	Radiation therapy		
OS	Overall survival	SABA	Short-acting beta2-agonist		
PARP	Poly ADP ribose polymerase	SAD	Single ascending dose		



Clinical trials appendix

Year-to-date and Q3 2020 results update

