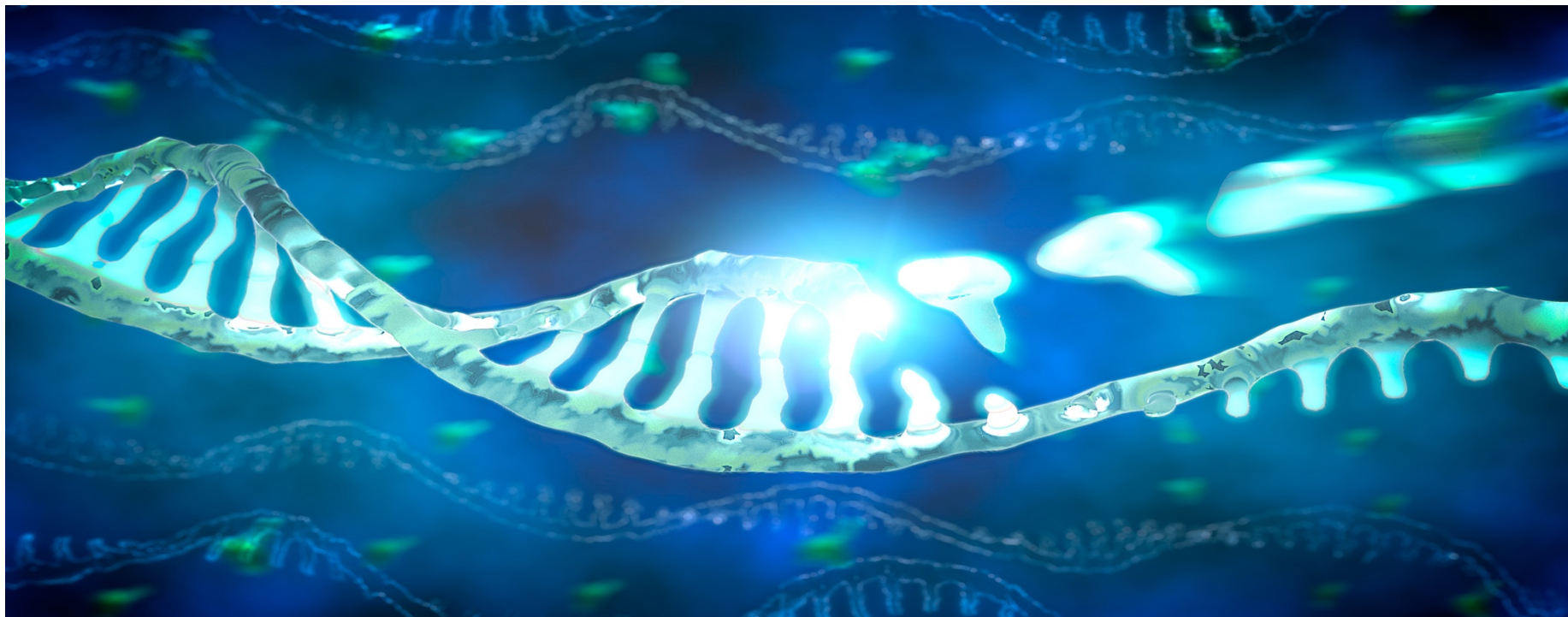


Clinical trials appendix

Q1 2019 results update



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from clinicaltrials.gov to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 31 March 2019, unless otherwise specified.

It includes estimated timelines with regards to trial completion and first external presentations of primary data. These estimates are subject to change, as programmes recruit faster or slower than anticipated and many times are event driven.

Project postings on clinicaltrials.gov are updated on a continuous basis as projects progress. For the most up to date information on our clinical programmes please visit clinicaltrials.gov



List of abbreviations

ADA	Anti-drug antibody	ICS	Inhaled corticosteroid	pMDI	Pressurised metered dose inhaler
ADC	Antibody-drug conjugate	IM	Intra muscular	PoC	Proof of concept
AE	Adverse event	IR	Immediate release	PR	Partial response
AUC	Area under curve	IV	Intravenous	Q2W	Quaque (every) two weeks
BD/BID	Bis in die (two times a day)	LABA	Long acting beta agonist	Q3W	Quaque (every) three weeks
CE	Clinically evaluable	LAMA	Long acting muscarinic agonist	Q4W	Quaque (every) four weeks
CMAX	Maximum concentration absorbed	LCM	Lifecycle management	Q8W	Quaque (every) eight weeks
CNS	Central nervous system	LPCD	Last patient commenced dosing	QD	Quaque die (one time a day)
DCR	Disease control rate	MAD	Multiple ascending dose	QOD	Quaque altera die (every other day)
DDI	Drug-drug interaction	MDI	Metered-dose inhaler	QoL	Quality of life
DFS	Disease free survival	MTD	Maximum tolerated dose	SAD	Single ascending dose
DLT	Dose-limiting toxicity	NME	New molecular entity	SC	Subcutaneous
DoR	Duration of response	OCS	Oral corticosteroid	SoC	Standard of care
DPI	Dry powder inhaler	ORR	Objective response rate	TID	Ter In die (three times a day)
FDC	Fixed-dose combination	OS	Overall survival	VEGF	Vascular endothelial growth factor
FEV	Forced-expiratory volume	PARP	Poly ADP ribose polymerase	XR	Extended release
FPCD	First patient commenced dosing	PD	Pharmacodynamics		
HRRm	Homologous recombination repair mutation	PFS	Progression-free survival		
		PK	Pharmacokinetics		



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Approved medicines and late-stage development

Early-stage development



Movement since Q4 2018 update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
<p>Additional indication MEDI7247 ASCT2 antibody drug conjugate solid tumours</p>	<p>NME trastuzumab deruxtecan[#] DESTINY-Breast01 ADC HER2-positive, unresectable and/or metastatic breast cancer subjects previously treated with trastuzumab emtansine</p> <p>Additional indication capivasertib[#] AKT inhibitor prostate cancer</p> <p>Imfinzi[#] + Lynparza[#] ORION PD-L1 mAb + PARP inhibitor NSCLC</p> <p>(oleclumab + chemotherapy) or (Imfinzi[#] + oleclumab + chemotherapy) (CD73 mAb+chemo) or (PD-L1 mAb+CD73 mAb+chemo) metastatic pancreatic cancer</p> <p>trastuzumab deruxtecan[#] DESTINY-Gastric01 ADC HER2-overexpressing advanced gastric or gastroesophageal junction adenocarcinoma patients who have progressed on two prior treatment regimens</p> <p>trastuzumab deruxtecan[#] ADC HER2-expressing advanced colorectal cancer</p> <p>trastuzumab deruxtecan[#] HER2-over-expressing or -mutated, unresectable and/or metastatic NSCLC</p> <p>Lifecycle Management Imfinzi[#] (platform) BEGONIA PD-L1 mAb breast cancer</p> <p>Imfinzi[#] (platform) MEGELLAN PD-L1 mAb NSCLC</p> <p>Imfinzi[#] + (oleclumab or monalizumab[#]) COAST PD-L1 mAb + (CD73 mAb or NKG2A mAb) NSCLC</p> <p>Imfinzi[#] + (oleclumab or monalizumab[#] or danvatirsen[#]) NeoCOAST PD-L1 mAb + (CD73 mAb or NKG2A mAb or STAT3 inhibitor) NSCLC</p> <p>Lynparza[#] (basket) MK-7339-002 / LYNK002 PARP inhibitor HRRm cancer</p>	<p>NME Lynparza[#] + Imfinzi[#] + bevacizumab DUO-O PARP inhibitor + PD-L1 mAb + VEGF inhibitor 1st-line ovarian cancer</p> <p>Additional indication trastuzumab deruxtecan[#] DESTINY-Breast02 ADC HER2-positive, unresectable and/or metastatic breast cancer pretreated with prior standard of care HER2 therapies, including trastuzumab emtansine</p> <p>trastuzumab deruxtecan[#] DESTINY-Breast03 ADC HER2-positive, unresectable and/or metastatic breast cancer subjects previously treated with trastuzumab and taxane</p> <p>trastuzumab deruxtecan[#] DESTINY-Breast04 ADC HER2-low, unresectable and/or metastatic breast cancer subjects</p> <p>Lifecycle Management Calquence[#] + venetoclax + obinutuzumab BTK inhibitor + BCL-2 inhibitor + anti-CD20 mAb 1st-line chronic lymphocytic leukaemia</p> <p>Imfinzi[#] CALLA PD-L1 mAb adjuvant locally-advanced cervical cancer</p>	<p>Lifecycle Management Farxiga³ DECLARE-TIMI 58 [US & EU]¹ SGLT2 inhibitor CV outcomes trial in patients with type-2 diabetes</p>
Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from Registration
<p>NME Imfinzi[#] + dabrafenib + trametinib PD-L1 mAb + BRAF inhibitor + MEK inhibitor melanoma</p> <p>Imfinzi[#] + Iressa PD-L1 mAb + EGFR inhibitor NSCLC</p> <p>AZD0156 ATM inhibitor solid tumours</p> <p>AZD4785 KRAS inhibitor solid tumours</p>	<p>NME AZD4547 FGFR inhibitor solid tumours</p> <p>AZD8186 PI3k inhibitor solid tumours</p> <p>Imfinzi[#] + MEDI0680 PD-L1 mAb + PD-1 mAb solid tumours</p> <p>prezalumab[#] B7RP1 mAb primary Sjögren's syndrome</p>		<p>Lifecycle Management Farxiga³ DEPICT [US & JP]² SGLT2 inhibitor type-1 diabetes</p>

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Q1 2019 New Molecular Entity (NME)¹ pipeline

Phase I 21 New Molecular Entities	Phase II 25 New Molecular Entities	Phase III 14 New Molecular Entities	Under Review 0 New Molecular Entities	
AZD1390 glioblastoma	<i>Imfinzi</i> #+tremelimumab+chemo PD-L1+CTLA-4 1L PDAC oesophageal SCLC	adavosertib#+chemotherapy Wee1+chemo ovarian cancer	<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 gastric cancer	trastuzumab deruxtecan# DESTINY-Breast02 ADC breast
AZD4573 CDK9 haematological malignancies	<i>Imfinzi</i> +selumetinib# PL-L1+MEK solid tumours	AZD2811# Aurora solid tumours	<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 biliary tract oesophageal	trastuzumab deruxtecan# DESTINY-Breast03 ADC breast
AZD5153 BRD4 solid tumours	MEDI2228 BCMA ADC multiple myeloma	AZD4635 A2aR inhibitor solid tumours	<i>Imfinzi</i> +Lynparza# BAYOU PD-L1+PARP bladder	trastuzumab deruxtecan# DESTINY-Breast04 ADC breast
AZD5991 MCL1 haematological malignancies	MEDI3726# PSMA ADC prostate	AZD6738 ATR solid tumours	Lynparza#+adavosertib# PARP+Wee1 solid tumours	<i>Imfinzi</i> #+tremelimumab DANUBE PD-L1+CTLA-4 1L bladder
AZD9496 SERD ER+ breast	MEDI5083 CD40 ligand fusion protein solid tumours	capivasertib# AKT breast prostate	Lynparza#+AZD6738 PARP+ATR gastric	<i>Imfinzi</i> #+tremelimumab HIMALAYA PD-L1+CTLA-4 1L HCC
AZD9833 SERD ER+ breast	MEDI5752 PD-1/CTLA-4 solid tumours	<i>Imfinzi</i> #+(oleclumab or monalizumab# or danvatirsen#) NeoCOAST PD-L1+(CD73 or NKG2A or STAT3) NSCLC	Lynparza#+AZD6738 or +adavosertib# VIOLETTE PARP+ATR or PARP+Wee1 breast	<i>Imfinzi</i> #+tremelimumab KESTREL PD-L1+CTLA-4 1L HNSCC
Calquence+AZD6738 BTK+ATR haematological tumours	MEDI7247 ASCT2 ADC haematological malignancies solid tumours	<i>Imfinzi</i> #+(oleclumab or monalizumab#) COAST PD-L1+(CD73 or NKG2A) NSCLC	Lynparza#+ <i>Imfinzi</i> MEDIOLA PARP+PD-L1 ovarian breast gastric SCLC	<i>Imfinzi</i> #+tremelimumab NEPTUNE PD-L1+CTLA-4 1L NSCLC
Calquence+danvatirsen BTK+STAT3 haematological malignancies	oleclumab CD73 solid tumours	<i>Imfinzi</i> #+AZD5069 or <i>Imfinzi</i> #+danvatirsen# PD-L1+(CXCR2 or STAT3) HNSCC bladder NSCLC	oleclumab+chemo or <i>Imfinzi</i> #+oleclumab+chemo CD73+chemo or PD-L1+CD73+chemo pancreatic NSCLC	<i>Imfinzi</i> #+tremelimumab+CRT ADRIATIC PD-L1+CTLA-4+CRT LD-SCLC
<i>Imfinzi</i> #+adavosertib# PD-L1+Wee1 solid tumours	oleclumab+AZD4635 CD73+A2aR EGFRm NSCLC	<i>Imfinzi</i> #+Lynparza# ORION PD-L1+PARP NSCLC	Tagrisso combo# TATTON EGFR+PD-L1/MEK/MET NSCLC	<i>Imfinzi</i> #+tremelimumab+SoC CASPIAN PD-L1+CTLA-4+SoC 1L SCLC
<i>Imfinzi</i> #+RT (platform) CLOVER PD-L1+RT HNSCC NSCLC SCLC	oleclumab+Tagrisso CD73+EGFR EGFRm NSCLC	<i>Imfinzi</i> #+MEDI0457# PD-L1+DNA HPV vaccine HNSCC	trastuzumab deruxtecan# [†] DESTINY-Breast01 ADC breast	<i>Imfinzi</i> #+tremelimumab+SoC NILE PD-L1+CTLA-4+SoC 1L urothelial cancer
<i>Imfinzi</i> #+tremelimumab PD-L1+CTLA-4 solid tumours		<i>Imfinzi</i> #+monalizumab# PD-L1+NKG2a solid tumours	trastuzumab deruxtecan# [†] DESTINY-Gastric01 ADC gastric	<i>Imfinzi</i> #+tremelimumab+SoC POSEIDON PD-L1+CTLA-4+SoC 1L NSCLC
		<i>Imfinzi</i> #+oleclumab PD-L1+CD73 solid tumours	trastuzumab deruxtecan# ADC colorectal cancer	Lynparza#+ <i>Imfinzi</i> #+bevacizumab DUO-O PARP+PD-L1+VEGF 1L ovarian
			trastuzumab deruxtecan# ADC NSCLC	savolitinib# SAVOIR MET pRCC
				selumetinib# [†] SPRINT MEK paediatric neurofibromatosis type-1



Q1 2019 New Molecular Entity (NME)¹ pipeline

Phase I 13 New Molecular Entities	Phase II 22 New Molecular Entities	Phase III 3 New Molecular Entities	Applications Under Review 1 New Molecular Entity
AZD0284 RORγ psoriasis/respiratory	abediterol# LABA asthma/COPD	MEDI5884# cholesterol modulation cardiovascular	anifrolumab# TULIP Type I IFN receptor SLE
AZD0449 Inhaled JAK inhibitor asthma	anifrolumab# Type I IFN receptor SLE SC	MEDI6012 LCAT cardiovascular	PT027 ICS/SABA asthma
AZD1402# inhaled IL-4Ra asthma	anifrolumab# Type I IFN receptor lupus nephritis	MEDI7352 NGF/TNF osteoarthritis pain, painful diabetic neuropathy	tezepelumab# NAVIGATOR SOURCE TSLP severe uncontrolled asthma
AZD5634 inhaled ENaC cystic fibrosis	AZD1419# inhaled TLR9 asthma	MEDI8852 influenza A treatment	
AZD8154 Inhaled PI3Kgd asthma	AZD4831 MPO HFpEF	MEDI8897# passive RSV prophylaxis	
AZD8233 hypercholesterolemia cardiovascular	AZD5718 FLAP coronary artery disease	PT010 LABA/LAMA/ICS asthma	
AZD9977 MCR cardiovascular	AZD7594 Inhaled SGRM asthma/COPD	svratoxumab α-Toxin Staphylococcus pneumonia	
MEDI0700# BAFF/B7RP1 SLE	AZD7986# DPP1 COPD	tezepelumab# TSLP atopic dermatitis	
MEDI1341 alpha synuclein parkinson's disease	AZD8601# VEGF-A cardiovascular	verinurad URAT-1 chronic kidney disease	
MEDI1814# amyloidβ alzheimer's disease	AZD8871# MABA COPD		
MEDI3506 IL-33 COPD	AZD9567 SGRM RA/respiratory		
MEDI6570 LOX-1 CV disease	cotadutide GLP-1/glucagon type-2 diabetes / obesity		
MEDI7219 anti-diabetic type-2 diabetes	MEDI3902 Psl/PcrV Pseudomonas pneumonia		

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



Q1 2019 Lifecycle Management (LCM)¹ pipeline

Phase I 1 Project	Phase II 5 Projects	Phase III 20 Projects	Applications Under Review 0 Projects
<i>Imfinzi</i> #+azacitidine# PD-L1+azacitidine MDS	<i>Imfinzi</i> # PD-L1 solid tumours	<i>Calquence</i> # BTK inhibitor 1st line MCL	<i>Imfinzi</i> #+CTx neoadjuvant AEGEAN PD-L1+CTx locally-advanced stage III NSCLC
	<i>Imfinzi</i> # (platform) BEGONIA PD-L1 breast cancer	<i>Calquence</i> # BTK inhibitor 1st line CLL	<i>Imfinzi</i> #+CTx NIAGARA PD-L1+CTx muscle invasive bladder cancer
	<i>Imfinzi</i> # (platform) MAGELLAN PD-L1 NSCLC	<i>Calquence</i> # BTK inhibitor <i>t/r</i> CLL, high risk	<i>Imfinzi</i> #+VEGF+TACE EMERALD-1 PD-L1+VEGF+TACE locoregional HCC
	<i>Lynparza</i> # (basket) MK-7339-002 / LYNK002 PARP HRRm cancer	<i>Calquence</i> # BTK inhibitor <i>t/r</i> CLL	<i>Lynparza</i> # OlympiA PARP gBRCA adjuvant breast
	<i>Lynparza</i> #+cediranib CONCERTO PARP+VEGF recurrent Pt-R ovarian	<i>Calquence</i> #+venetoclax+obinutuzumab BTK+BCL-2+anti-CD20 1st line CLL	<i>Lynparza</i> # POLO PARP pancreatic cancer
		<i>Imfinzi</i> # CALLA PD-L1 adj. locally advanced cervical cancer	<i>Lynparza</i> # PROfound PARP prostate cancer
		<i>Imfinzi</i> # PEARL (China) PD-L1 1L NSCLC	<i>Lynparza</i> # SOLO-3 PARP BRCAm PSR ovarian
		<i>Imfinzi</i> # POTOMAC PD-L1 non muscle invasive bladder cancer	<i>Lynparza</i> +abiraterone# PROpel PARP+NHA prostate cancer
		<i>Imfinzi</i> #+CRT PACIFIC-2 PD-L1+CRT NSCLC	<i>Tagrisso</i> ADAURA EGFR adj. EGFRm NSCLC
		<i>Imfinzi</i> #+CRT PACIFIC-5 (China) PD-L1+CRT locally-advanced stage III NSCLC	<i>Tagrisso</i> LAURA EGFRm locally advanced unresectable NSCLC

8 ¹ Includes significant LCM projects and parallel indications for assets beyond Phase III
Partnered and/or in collaboration; [†]Registrational Phase II/III trial



Q1 2019 Lifecycle Management (LCM)¹ pipeline

Phase I 0 Projects	Phase II 0 Projects	Phase III 10 Projects	Applications Under Review 4 Projects
		<i>Brilinta/Brilique</i> HESTIA P2Y12 paeds w/ sickle cell	<i>Farxiga/Forxiga</i> DECLARE outcomes
		<i>Brilinta/Brilique</i> THALES P2Y12 stroke	<i>Nexium</i> (CN only) stress ulcer prophylaxis
		<i>Brilinta/Brilique</i> THEMIS P2Y12 diabetes & CAD outcomes	saxagliptin+dapagliflozin metformin DPP4+SGLT2 type-2 diabetes
		<i>Epanova</i> STRENGTH outcomes	<i>Symbicort</i> SYGMA as needed in mild asthma
		<i>Farxiga/Forxiga</i> SGLT2 HF _r EF	
		<i>Farxiga/Forxiga</i> SGLT2 CKD	
		<i>Farxiga/Forxiga</i> DELIVER SGLT2 HF _p EF	
		<i>Fasenra</i> # IL-5R COPD	
		<i>Fasenra</i> # OSTRO IL-5R nasal polyposis	
		roxadustat# HIFPH anaemia MDS	



Estimated key regulatory submission acceptances

NME

roxadustat anaemia in CKD (US)			
selumetinib SPRINT			
Imfinzi + tremelimumab KESTREL			
Imfinzi + tremelimumab NEPTUNE			
Imfinzi + tremelimumab DANUBE			
Imfinzi +/- tremelimumab CASPIAN			
Imfinzi +/- tremelimumab POSEIDON	Lokelma (China)	trastuzumab deruxtecan	
trastuzumab deruxtecan DESTINY-Breast01 (US)	Lumoxiti (EU)	Imfinzi + tremelimumab + CRT ADRIATIC	PT027 asthma
		Imfinzi + tremelimumab HIMALAYA	Fasenra severe asthma (China)
		Imfinzi + tremelimumab + SoC NILE	tezepelumab NAVIGATOR
		Lynparza + Imfinzi + bevacizumab DUO-O	

LCM

H2 2019	2020	2020+	
Calquence CLL	Imfinzi PEARL	Calquence 1L MCL	Brilinta HESTIA
Lynparza POLO	Lynparza PAOLA-1	Calquence +venetoclax+obinutuzumab 1L CLL	Farxiga DAPA-CKD
Lynparza SOLO-3	Lynparza PROFOUND	Imfinzi POTOMAC	Farxiga HFpEF DELIVER
Brilinta THEMIS	Farxiga DAPA-HF	Imfinzi CALLA	roxadustat anemia in MDS
Lokelma (JP)	Brilinta THALES	Imfinzi BR.31 ADJUVANT	Duaklir Genuair (China)
Symbicort SYGMA (China)	Epanova STRENGTH	Imfinzi + CRT PACIFIC-2	
	Fasenra OSTRO	Imfinzi + CRT PACIFIC-5 (China)	
	Xigduo (China)	Imfinzi + chemo AEGEAN	
		Imfinzi + chemo NIAGARA	
		Imfinzi + VEGF + TACE EMERALD-1	
		Lynparza OLYMPIA	
		Lynparza + abiraterone PROPEL	
		Tagrisso LAURA	
		Tagrisso ADAURA	



Designations

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Accelerated approvals

Lynparza ovarian cancer SOLO-2 (US)
Tagrisso EGFRm T790M NSCLC (US)
Imfinzi bladder cancer (US)
Calquence MCL (US)

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Breakthrough Therapy

Tagrisso EGFRm T790M NSCLC (US)
Lynparza prostate cancer PROFOUND (US)
Imfinzi bladder cancer 1L (US)
Calquence MCL (US)
Imfinzi stage III NSCLC 1L PACIFIC (US)
Tagrisso NSCLC 1L FLAURA (US)
tezepelumab asthma (US)
MEDI8897 RSV mAB (US)
selumetinib NFI type 1 SPRINT (US)

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Fast Track

MEDI3902 Psl-PcrV pneumo Px (US)
savratoxumab Staph HAP (US)
Imfinzi NSCLC (US)
MEDI8897 RSV mAB (US)
Imfinzi HNSCC HAWK (US)
anifrolumab SLE (US)
Lynparza ovarian cancer SOLO-2 (US)
Tagrisso EGFRm T790M NSCLC (CN)

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Priority Review / PRIME

Tagrisso EGFRm T790M NSCLC (JP)
Tagrisso EGFRm T790M NSCLC (US)
Imfinzi bladder cancer 2L (US)
Tagrisso NSCLC AURA3 (US)
Calquence MCL (US)
Lynparza breast cancer OLYMPIAD (US)
roxadustat CKD (CN)
Tagrisso NSCLC FLAURA (US)
Imfinzi stage III NSCLC PACIFIC (EU)
Imfinzi stage III NSCLC PACIFIC (JP)
Lynparza tablet (US)
Lynparza tablet (CN)
Lynparza breast cancer OLYMPIAD (JP)
Tagrisso NSCLC 1L FLAURA (JP)
Lumoxiti HCL PLAIT (US)
Lynparza ovarian SOLO-1 (US)
Lynparza ovarian SOLO-1 (CN)
PT010 Triple MDI COPD (CN)
MEDI8897 RSV mAB (EU)
Tagrisso NSCLC 1L FLAURA (CN)

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Orphan Drug

Lynparza ovarian cancer SOLO-2 (US)
Lumoxiti HCL PLAIT (US)
Lumoxiti HCL PLAIT (EU)
Crestor paediatric (US)
cediranib VEGFR tki (US)
Iressa EGFRm NSCLC (US)
Tagrisso EGFRm T790M NSCLC (US)
AZD3241 MPO (EU)
Calquence CLL 1L (US)
Calquence MCL (US)
Calquence WM (US)
Calquence WM (EU)
Calquence CLL 1L (EU)
Calquence MCL (EU)
selumetinib thyroid cancer ASTRA (US)
Lynparza breast cancer OLYMPIAD (JP)
Lynparza ovarian cancer SOLO-2 (JP)
selumetinib NFI type 1 SPRINT (US)
selumetinib NFI type 1 SPRINT (EU)
Lynparza pancreatic cancer POLO (US)
Fasenra EGPA (US)
Fasenra HES (US)
saracatinib IPF (US)

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.

Breakthrough Designation is a process designed to expedite the development and review of medicines which may demonstrate substantial improvement over available therapy.

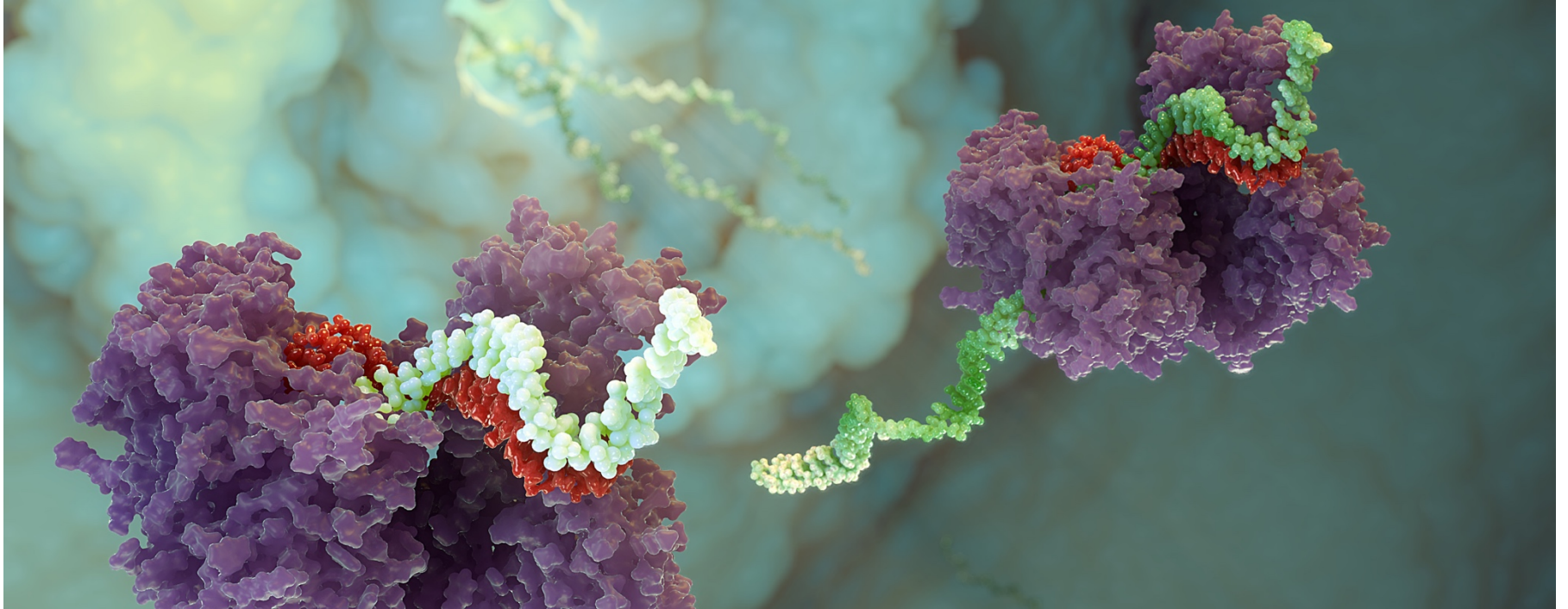
Accelerated Approval, these regulations allowed medicines for serious conditions that addressed an unmet medical need to be approved based on a surrogate endpoint.

Priority Review Designation is the US FDA's goal to take action on an application within 6 months. PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need

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)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III ADAURA NCT025111106	Adjuvant EGFRm	700	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> 80mg QD following complete tumour resection, with or without chemotherapy Arm 2: placebo Global trial - 25 countries	<ul style="list-style-type: none"> Primary endpoint: Disease Free Survival (DFS) Secondary endpoints: DFS Rate, OS, OS Rate, QoL 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q1 2019 Data anticipated: 2020+
Phase III LAURA NCT035211154	Maintenance therapy in patients with locally advanced, unresectable EGFRm+ Stage III whose disease has not progressed following platinum-based chemoradiation therapy	200	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> 80mg Arm 2: placebo Global trial - 11 countries	<ul style="list-style-type: none"> Primary endpoint: PFS (via blinded independent central review (BICR)) Secondary endpoints: CNS PFS, OS, DoR, ORR, DCR 	<ul style="list-style-type: none"> FPCD: Q3 2018 Data anticipated: 2020+
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: 2020+
Phase Ib TATTON NCT02143466	Advanced EGFRm TKI failure	308	<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>Imfinzi</i> combination arms 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: 2020
Phase III ASTRIS NCT02474355	Real world setting in adult patients with advanced or metastatic, EGFR T790M+	3,020	Single-arm trial - <i>Tagrisso</i> 80mg 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+	150	Single arm trial – <i>Tagrisso</i> 80 mg 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



Imfinzi (PD-L1 mAb)

Non-small cell lung cancer (NSCLC), early use

Trial	Population	Patients	Design	Endpoints	Status
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 IV 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 Data anticipated: 2020+
Phase II/III Lung Master Protocol NCT02154490 Partnered	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	140	Umbrella trial with five arms based on biomarker expression: <ul style="list-style-type: none"> Substudy A: <i>Imfinzi</i> (non-match for other biomarker driven substudies) IVQ2W single arm <i>Imfinzi</i> Phase II only Substudy B: PI3K inhibitor vs. docetaxel Substudy C: CDK4/6 inhibitor vs. docetaxel Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel Substudy 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: 2020+
Phase III PACIFIC-2 NCT03519971	Unresected, locally-advanced NSCLC	300	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> IV Q4W + chemo/RT (radiation therapy) 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 Data anticipated: 2020+
Phase III PACIFIC-4 NCT03833154	<i>Imfinzi</i> following SBRT in unresected, Stage I/II NSCLC	630	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> IV Q4W following definitive SBRT (radiation therapy) Arm 2: placebo following 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: Q1 2019 Data anticipated: 2020+
Phase III PACIFIC-5 NCT03706690	Unresected, locally-advanced NSCLC	360	Arm 1: <i>Imfinzi</i> IV Q4W following chemo/RT (radiation therapy) 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: 2020+
Phase III AEGEAN NCT03800134	Neoadjuvant NSCLC patients Stage II and III resected NSCLC (incl. EGFR/ALK positive)	300	Arm 1: <i>Imfinzi</i> + platinum-based chemotherapy Arm 2: placebo + platinum-based chemotherapy	Primary endpoint: <ul style="list-style-type: none"> Major Pathological Response (mPR) Secondary endpoint: <ul style="list-style-type: none"> Pathological complete response (pCR) 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020



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

Lung cancer, advanced

Trial	Population	Patients	Design	Endpoints	Status
Phase III ADRIATIC NCT03703297	Limited disease- Small cell lung cancer (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: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2020+
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: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPD: Q1 2019 Data anticipated: 2020
Phase III NEPTUNE NCT02542293	NSCLC 1L	960	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: SoC 	<ul style="list-style-type: none"> Primary endpoint: OS Secondary endpoint: PFS 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPD: Q2 2017 Data anticipated: H2 2019
Phase III POSEIDON NCT03164616	NSCLC 1L	1,000	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + CTx Arm 2: <i>Imfinzi</i> + tremelimumab + chemotherapy Arm 3: SoC 	Primary endpoint: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPD: Q3 2018 Data anticipated: H2 2019
Phase III CASPIAN NCT03043872	SCLC 1L	795	<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: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPD: Q2 2018 Data anticipated: H2 2019
Phase II BALTIC NCT02937818	SCLC	80	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab Q4W Arm B: adavosertib and carboplatin BID Arm C: AZD6738 and <i>Lynparza</i> 	Primary endpoint: ORR	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: 2020+
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 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 	Primary endpoint: <ul style="list-style-type: none"> Safety & tolerability Secondary endpoint: <ul style="list-style-type: none"> ORR, DoR, PFS, OS, PK, ADA 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020+



Imfinzi (PD-L1 mAb) +/- treme (CTLA-4 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 (Bacillus Calmette–Guérin) (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: Q3 2018 Data anticipated: 2020+
Phase III NIAGARA	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 	Coprimary endpoints: <ul style="list-style-type: none"> pCR EFS 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020+
Phase III EMERALD-1 NCT03778957	Locoregional Hepatocellular Carcinoma	600	<ul style="list-style-type: none"> Arm A: Transarterial Chemoembolization (TACE) in combination with <i>Imfinzi</i> Arm B: Transarterial Chemoembolization (TACE) in combination with <i>Imfinzi</i> + Bevacizumab Arm C: Transarterial Chemoembolization (TACE) in combination with Placebos 	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: 2020+
Phase III EMERALD-2	Adjuvant Therapy in Hepatocellular Carcinoma	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 24 mos 	<ul style="list-style-type: none"> Initiating



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

Other cancers, late disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III DANUBE NCT02516241	Cis-eligible and ineligible bladder cancer 1L	1,005	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: <i>Imfinzi</i> Arm 3: SoC 	Primary endpoints: <ul style="list-style-type: none"> OS 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q1 2017 Data anticipated: H2 2019
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: Q3 2018 Data anticipated: 2020+
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 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD Q1 2017 Data anticipated: H2 2019
Phase III HIMALAYA NCT03298451	Unresectable Hepatocellular Carcinoma (HCC) 1L	1,310	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab (Regimen 1) Arm 2: <i>Imfinzi</i> + tremelimumab (Regimen 2) Arm 3: <i>Imfinzi</i> Arm 4: sorafenib 	Primary endpoint: <ul style="list-style-type: none"> OS Secondary endpoint: <ul style="list-style-type: none"> PFS, time to tumour progression (TTP), ORR 	<ul style="list-style-type: none"> FPCD: Q4 2017 Data anticipated: 2020+
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 Data readout: Q4 2018
Phase III TOPAZ-1 NCT03875235	Biliary Tract Carcinoma (BTC) 1L	474	<ul style="list-style-type: none"> Treatment Arm 1 Durvalumab + 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"> Initiating
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, PFS, CR rate, DoR, ORR, DoCR, safety/tolerability, PRO, PK/ADA 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020+



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

Other cancers

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: 2020+
Phase I Combination in Advanced Solid Tumours NCT02658214	Solid tumours	80	<ul style="list-style-type: none"> Arm 2 Small cell lung cancer (SCLC): <i>Imfinzi</i> + tremelimumab + carboplatin + etoposide Arm 3 TNBC (triple-negative breast cancer): <i>Imfinzi</i> + tremelimumab + chemo Arm 4 TNBC: <i>Imfinzi</i> + tremelimumab + chemo Arm 5 Gastric/gastro-Oesophageal junction (GEJ): <i>Imfinzi</i> + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin Arm 6 PDAC (pancreatic ductal adenocarcinoma): <i>Imfinzi</i> + tremelimumab + chemo Arm 7 ESSC (esophageal squamous cell carcinoma): <i>Imfinzi</i> + tremelimumab + chemo 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPD: Q1 2019 Data anticipated: 2020+
Phase I Immunotherapy in Combination With Chemoradiation in Patients With Advanced Solid Tumours CLOVER NCT03509012	Head and neck squamous-cell carcinoma (HNSCC), Non-small-cell lung cancer (NSCLC), Small-cell lung cancer (SCLC)	300	<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: 2020+
Phase II BEGONIA NCT03742102	mTNBC (metastatic triple negative breast cancer) 1L	100	<ul style="list-style-type: none"> Arm 1 <i>Imfinzi</i> + paclitaxel Arm 2 <i>Imfinzi</i> + paclitaxel + capivasertib Arm 3 <i>Imfinzi</i> + paclitaxel + selumetinib 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: 1Q2019 Data anticipated: 2020+



Lynparza (PARP inhibitor)

Ovarian and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III SOLO-1 NCT01844986	BRCAm maintenance ovarian cancer 1L	391	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg BID maintenance therapy for two years or until disease progression Arm 2: placebo Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPD: Q1 2015 Data readout: Q2 2018 Primary endpoint met
Phase III SOLO-3 NCT02282020	PSR gBRCAm ovarian cancer 3L+	266	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BID to progression Arm 2: physician's choice (single-agent chemotherapy) Global trial	<ul style="list-style-type: none"> Primary endpoint: ORR 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q2 2018 Data readout: Q4 2018 Primary endpoint met
Phase III OlympiA NCT02032823 Partnered	BRCAm adjuvant breast cancer	1,800	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg 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
Phase III OlympiAD NCT02000622	BRCAm metastatic breast cancer	302	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BiD, continuous to progression Arm 2: physician's choice: capecitabine 2500mg/m² x 14 q 21 vinorelbine 30mg/m² d 1, 8 q 21 eribulin 1.4mg/m² d 1, 8 q 21 to progression Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPD: Q4 2015 Data readout: Q1 2017 Primary endpoint met
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 LPD: 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> 300mg BID Arm 2: physician's choice: enzalutamide 160mg once daily 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 LPD: Q4 2018 Data anticipated : H2 2019



Lynparza (PARP inhibitor)

Imfinzi combinations, cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III DuO-O NCT03737643	Advanced ovarian cancer 1L	1,056	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 	<ul style="list-style-type: none"> • FPCD: Q1 2019 • Data anticipated: 2020+
Phase II DuO-L (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 	<ul style="list-style-type: none"> • FPCD Q1 2019 • Data anticipated: 2020+
Phase II BAYOU NCT03459846	Platinum-Ineligible unresectable Stage IV urothelial cancer	150	<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 	<ul style="list-style-type: none"> • FPCD: Q1 2018 • Data anticipated : 2020
Phase I / II MEDIOLA NCT02734004	gBRCAm ovarian cancer 2L+ gBRCAm HER2-negative breast cancer 1-3L Small cell lung cancer (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+	140	<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
Phase I / II MEDIOLA (Breast expansion) NCT02734004	HER2-negative BRCAm breast cancer HER2-negative non-BRCA HRRm breast cancer Non-HRRm triple negative breast cancer	140	<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"> • Initiating

Lynparza (PARP inhibitor)

Combinations, cancers

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 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q2 2018 Data anticipated: H2 2019
Phase III PROPEL NCT 03732820	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"> PFS 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: 2020+
Phase II VIOLETTE	Triple-negative breast cancer (TNBC)	450	<ul style="list-style-type: none"> Arm 1: AZD6738 + <i>Lynparza</i> Arm 2: adavosertib + <i>Lynparza</i> Arm 3: <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: 2020+
Phase III GY004 NCT02446600 Externally sponsored	Recurrent platinum sensitive ovarian cancer	549	<ul style="list-style-type: none"> Arm 1: chemotherapy Arm 2: <i>Lynparza</i> Arm 3: cediranib + <i>Lynparza</i> US/Canada/Japan sites	Primary endpoint: <ul style="list-style-type: none"> PFS Secondary endpoints: <ul style="list-style-type: none"> OS, QoL, safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2020+
Phase II/III GY005 NCT02502266 Externally sponsored	Recurrent platinum resistant/refractory ovarian cancer	680	<ul style="list-style-type: none"> Arm 1: chemotherapy 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: 2020+
Phase II LYNK-002 NCT03742895 Partnered	HRRm or HRD-positive advanced cancer	370	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> Trial conducted in 15 countries worldwide	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



Trastuzumab deruxtecan (DS-8201, HER2 ADC)

Breast and gastric cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II DESTINY-Breast01 NCT03248492 Partnered	HER2-positive, unresectable and/or metastatic breast cancer subjects previously treated With trastuzumab emtansine	230	Randomised, open label, sequential assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan 	Primary endpoint ORR Secondary end points DoR, CBR, CBR, PFS, OS	<ul style="list-style-type: none"> FPCD: Q3 2017 Data anticipated: H2 2019
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 <ul style="list-style-type: none"> Trastuzumab deruxtecan Physicians choice of <ul style="list-style-type: none"> Lapatinib + capecitabine Trastuzumab + capecitabine 	Primacy endpoint PFS Secondary endpoints OS, ORR, DoR, CBR	<ul style="list-style-type: none"> FPC Q3 2018 Data anticipated 2020+
Phase III DESTINY-Breast03 NCT03529110 Partnered	HER2-positive, unresectable and/or metastatic breast cancer subjects previously treated with trastuzumab and taxane	500	Randomised open label parallel assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan Ado-trastuzumab emtansine 	Primary endpoint PFS Secondary endpoints OS, ORR, DoR, CBR, PFS	<ul style="list-style-type: none"> FPCD Q3 2018 Data anticipated 2020+
Phase III DESTINY-Breast04 NCT03734029 Partnered	HER2-low, unresectable and/or metastatic breast cancer subjects	540	Randomised open label parallel assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan 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 2020+
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"> Trastuzumab deruxtecan SoC chemo 	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 Data anticipated 2020



Trastuzumab deruxtecan (DS-8201, HER2 ADC)

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03384940 Partnered	HER2-expressing advanced colorectal cancer	90	Non randomised single group assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan 	Primary end point ORR Secondary end points PFS, OS, DoR, range of PK endpoints	<ul style="list-style-type: none"> FPCD Q1 2018 Data anticipated 2020
Phase II NCT03505710 Partnered	HER2-over-expressing or mutated, unresectable and/or metastatic NSCLC	80	Non randomised parallel group assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan 	Primary end point ORR Secondary end points DoR, PFS, OS	<ul style="list-style-type: none"> FPCD Q2 2018 Data anticipated 2020
Phase I NCT02564900 Partnered	Advanced solid malignant tumours	278	Non randomised single group assignment <ul style="list-style-type: none"> Trastuzumab deruxtecan 	Primary end points number of subjects with Aes, tumour response Secondary end points PK	<ul style="list-style-type: none"> FPCD Q3 2015 Data read out Q2 2018



Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III ACE-CL-007 (ELEVATE-TN) NCT02475681	Previously untreated chronic lymphocytic leukaemia (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 anticipated: H2 2019
Phase III ACE-CL-311	Previously untreated CLL fit	780	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> + venetoclax (AV) Arm B: <i>Calquence</i> + venetoclax + obinutuzumab (AVG) Arm C: fludarabine + cyclophosphamide + rituxumab (FCR) OR bendamustine + rituximab (BR) 	<ul style="list-style-type: none"> Primary - AV vs FCR/BR efficacy PFS Secondary AVG vs FCR/BR efficacy PFS; AV vs FCR/BR and AVG vs FCR/BR 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020+
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, patient reported outcomes (PROs) 	<ul style="list-style-type: none"> FPCD Q3 2016 Data anticipated: H2 2019
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: 2020+
Phase III ACE-LY-308 NCT02972840	Previously untreated mantle cell lymphoma (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 non-Hodgkin's Lymphoma (NHL) Secondary endpoints: Investigator-assessed (IA) PFS, ORR; IRC-assessed ORR, DoR, time to response; OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020+
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: 2020
Phase II 15-H-0016 NCT02337829	Relapsed/refractory and treatment naive/del17p CLL/small lymphocytic lymphoma (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: 2020+
Phase I/II ACE-CL-001 NCT02029443	CLL/SLL/Richter's transformation (RT)	286	<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: 2020+



Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I/II ACE-LY-001 NCT02328014	B-cell Malignancies	126	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: 2020
Phase I/II ACE-LY-005 NCT02362035	Haematological Malignancies	159	<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: 2020+
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: Q1 2018
Phase Ib ACE-LY-002 NCT02112526	Relapsed/refractory de novo activated B-cell diffuse large B-cell lymphoma (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	Mantle Cell Lymphoma (MCL)	76	<i>Calquence</i> in combination with bendamustine and rituximab <ul style="list-style-type: none"> Arm A: Treatment naïve Arm B: Relapsed/refractory Arm C: Treatment naïve: <i>Calquence</i>+venetoclax+Rituxan 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2020+
Phase Ib ACE-MY-001 NCT02211014	Relapsed/refractory Multiple Myeloma	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: Q4 2018
Phase I ACE-LY-003 NCT02180711	Relapsed/refractory Follicular Lymphoma	126	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: <i>Calquence</i> + rituximab 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2020+
Phase I ACE-CL-002 NCT02157324	Relapsed/refractory CLL/ small lymphocytic lymphoma (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: 2020
Phase I ACE-CL-003 NCT02296918	CLL/SLL/Prolymphocytic Leukaemia (PLL)	69	<i>Calquence</i> + obinutuzumab <ul style="list-style-type: none"> Arm A: Relapsed/refractory Arm B: Treatment naïve <i>Calquence</i> + venetoclax + rituximab Arm C: Relapsed/refractory 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: 2020+

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I NCT03198650	Japanese Adults with Advanced B-cell Malignancies	25	<ul style="list-style-type: none"> • <i>Calquence</i> monotherapy • Dose confirmation and expansion 	<ul style="list-style-type: none"> • Safety 	<ul style="list-style-type: none"> • FPCD: Q2 2017 • Data anticipated: 2020+
Phase I/II CL-110 NCT03328273	CLL (chronic lymphocytic leukaemia) R/R	62	<ul style="list-style-type: none"> • Arm A: AZD6738 monotherapy • Arm B: <i>Calquence</i> + AZD6738 	<ul style="list-style-type: none"> • Identify dose of AZD 6738 and safety of co-administration of <i>Calquence</i> + AZD6738 	<ul style="list-style-type: none"> • FPCD: Q1 2018 • Data anticipated: H1 2020
Phase I/II LY-110 NCT03205046	B-cell malignancies R/R	25	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 	<ul style="list-style-type: none"> • FPCD: Q3 2017 • Data anticipated: 2020



Calquence (BTK inhibitor)

Other cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II ACE-ST-006 NCT02454179	≥ 2L advanced or metastatic Head and neck squamous-cell carcinoma (HNSCC)	74	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: <i>Calquence</i> + pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q2 2018
Phase II ACE-ST-007 NCT02448303	≥ 2L advanced or metastatic Non-small-cell lung cancer (NSCLC)	74	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: <i>Calquence</i> + pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: 2017
Phase II ACE-ST-208 NCT02537444	Recurrent ovarian cancer	76	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: <i>Calquence</i> + pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q4 2015 Data readout: Q3 2018
Phase II ACE-ST-003 NCT02362048	≥ 2L advanced or metastatic pancreatic cancer	73	<ul style="list-style-type: none"> Arm A: <i>Calquence</i> Arm B: <i>Calquence</i> + pembrolizumab 	• Safety	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q3 2017
Phase II ACE-ST-005 NCT02351739	Platinum-resistant urothelial bladder cancer	75	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: <i>Calquence</i> + pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q1 2018
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 	• Safety, ORR	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: H1 2019



Selumetinib (MEK inhibitor)

Paediatric neurofibromatosis type 1

Trial	Population	Patients	Design	Endpoints	Status
Phase II SPRINT NCT01362803 Partnered	Paediatric neurofibromatosis type 1 (NF1)	50 (stratum 1)	<ul style="list-style-type: none"> Single arm: selumetinib 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
Phase Ib Selumetinib + MK-8353 (ERK inhibitor) NCT03745989 Partnered (Merck Lead study)	Advanced solid tumours	80 (dose escalation trial)	Phase Ib open-label trial of MK-8353 in combination with selumetinib in participants with advanced solid tumours	<ul style="list-style-type: none"> Dose-limiting toxicities (DLTs) Adverse Events (AEs) Study drug discontinuations due to an AE 	<ul style="list-style-type: none"> FPCD: Q1 2019



Savolitinib (MET inhibitor)

Papillary renal cell, NSCLC and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT03091192 Partnered	MET-driven, papillary renal cell cancer	180	<ul style="list-style-type: none"> Arm 1: savolitinib 600mg QD Arm 2: sunitinib 50mg QD (4 weeks on / 2 weeks off) Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints include ORR, DoR and OS 	<ul style="list-style-type: none"> FPCD: Q4 2017 Data anticipated: 2020
Phase I NCT01985555 Partnered	Advanced cancer (all comers)	~70	<ul style="list-style-type: none"> Dose escalation trial Conducted in China	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: 2020+
Phase I NCT02374645	NSCLC	64	<ul style="list-style-type: none"> Dose escalation trial Conducted in China	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q4 2018
Phase II NCT02897479 Partnered	Lung Pulmonary Sarcomatoid Carcinoma (PSC) and other NSCLC	92	<ul style="list-style-type: none"> Single arm trial: savolitinib 600mg QD Conducted in China	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020+



Cediranib (VEGF receptor inhibitor)

Ovarian cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

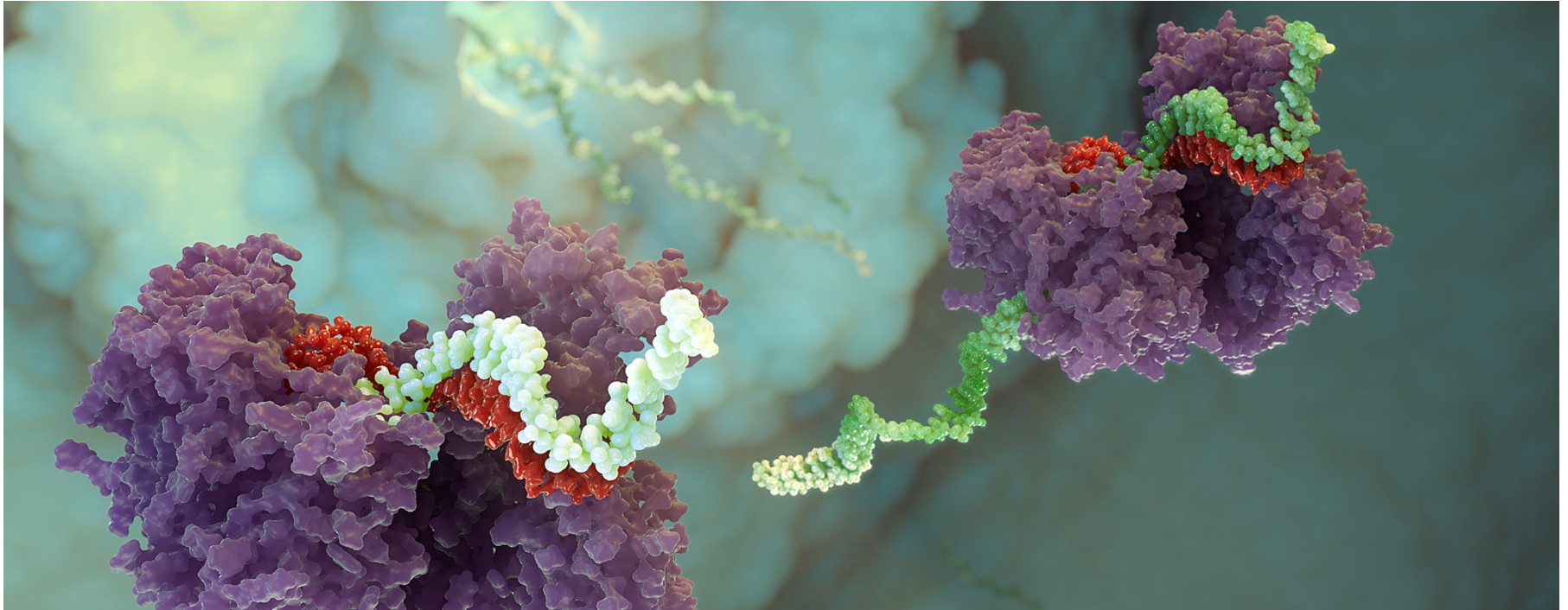
Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CONCERTO NCT02889900	Recurrent platinum resistant (PRR) ovarian cancer - heavily pre-treated <i>BRC</i> Awt	62	<ul style="list-style-type: none">Cediranib 30mg + <i>Lynparza</i> 200mg bd	<ul style="list-style-type: none">ORR DoR, DCR, QoL, OS; Safety	<ul style="list-style-type: none">FPCD: Q1 2017LPCD: Q1 2019



Oncology – early-stage development



AZD1390 (ATM inhibitor, blood brain barrier)

Cancer

Trial	Population	Subjects	Design	Endpoints	Status
Phase I NCT03215381	Healthy volunteers	8	<ul style="list-style-type: none"> Positron-Emission Tomography (PET) trial [11C]AZD1390 microdose administered by IV bolus Trial conducted in a single centre in Sweden	<ul style="list-style-type: none"> Brain distribution of AZD1390 to assess if [11C]AZD1390 crosses the blood brain barrier in healthy volunteers 	<ul style="list-style-type: none"> FPCD: Q4 2017 Data anticipated: H2 2019
Phase I NCT03423628	Recurrent Glioblastoma eligible for re-irradiation, brain metastases and leptomeningeal disease, newly-diagnosed glioblastoma patients	c. 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 tumours Dose 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 2018 Data anticipated: 2020+



Adavosertib (AZD1775, WEE-1 inhibitor)

Ovarian cancer, triple-negative breast cancer, small cell lung cancer (SCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02272790	Platinum-resistant (PR) ovarian cancer	97	<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, Disease Control Rate, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q2 2018
Phase I NCT02511795	Advanced solid tumours	102	<ul style="list-style-type: none"> Dose escalation trial to determine MTD (adavosertib + <i>Lynparza</i>) followed by an expansions in SCLC Conducted in US, Canada	<ul style="list-style-type: none"> Safety and tolerability Secondary endpoints: Overall response rate, Disease Control Rate, Duration of Response, PFS 	<ul style="list-style-type: none"> FPCD: Q3 2015
Phase I NCT02617277	Advanced solid tumours	55	<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
Phase I D6014C00006 NCT03333824	Advanced solid tumours	30	Part A: caffeine (200mg), omeprazole (20mg) and midazolam (1mL of 2mg/mL syrup) followed 7-14 days later by adavosertib 225mg bid for 2.5 days plus caffeine (200mg), omeprazole (20mg) and midazolam (1mL of 2mg/mL syrup) on day 3. Part B: 7-14 days after end of Part A, adavosertib 225mg BID for 2.5 days. Conducted in US	<ul style="list-style-type: none"> Primary endpoints: Part A: Plasma AUC, AUC_{0-t} and C_{MAX} for cocktail parent compounds (midazolam, omeprazole and caffeine) Part B: dECG (Differentiated ECG) intervals (QTcF) for absolute values and time-matched change from baseline 	<ul style="list-style-type: none"> FPCD: Q4 2017
Phase I D6014C00007 NCT03313557	Advanced solid tumours	54	adavosertib monotherapy once daily. Conducted in US and Europe	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2017



Capivasertib (AZD5363, AKT inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT01226316	Breast and gynaecological cancers with PIK pathway mutation	12-24 per arm (Parts E & F)	AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant [initially 12 patients per arm with option to expand to 24 patients in one or more arms] <ul style="list-style-type: none"> Part E arm 1: ER+ Breast with AKT-1 mutation (prior <i>Faslodex</i> resistance) Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to <i>Faslodex</i>) Part F arm 1: ER+ Breast with PTEN mutation (prior <i>Faslodex</i> resistance) Part F arm 2: ER+ Breast with PTEN mutation (first exposure to <i>Faslodex</i>) 	<ul style="list-style-type: none"> Safety and tolerability ORR Clinical Benefit Rate at 24 weeks (CBR24) [Parts E & F only] 	<ul style="list-style-type: none"> Data anticipated: H2 2019
Phase II (ESR) NCT02423603 PAKT	Advanced / metastatic triple negative breast cancer receiving 1L chemotherapy with paclitaxel	140	Randomised comparative ARM1: Paclitaxel + capivasertib ARM 2: Paclitaxel + placebo	<ul style="list-style-type: none"> Progression Free Survival Overall survival Overall population and in sub-group with tumours harbouring PIK3CA/AKT1/PTEN alterations	<ul style="list-style-type: none"> Data readout: Q2 2018 Final OS data awaited
Phase II (ESR) NCT01992952 FAKTION	Post menopausal women with advanced ER+/Her2- breast cancer previously treated with aromatase inhibition	140	Randomised comparative ARM 1: <i>Faslodex</i> + capivasertib ARM 2: <i>Faslodex</i> + placebo	<ul style="list-style-type: none"> Progression Free Survival Overall survival Overall population and sub-group with activation of the tumour PI3K/Akt/PTEN pathway (eg. PIK3CA/AKT1/PTEN alterations)	<ul style="list-style-type: none"> Data anticipated: H1 2019
Phase II (ESR) NCT02121639 PROCAID	Metastatic castration resistant prostate cancer eligible for treatment with docetaxel chemotherapy	150	Randomised comparative ARM 1: Docetaxel + prednisolone + capivasertib ARM 2: Docetaxel + prednisolone + placebo	<ul style="list-style-type: none"> Progression Free Survival 	<ul style="list-style-type: none"> Data anticipated: 2020



Imfinzi (PD-L1 mAb)

Cancer

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase I/II STUDY 1108 NCT01693562	Imfinzi	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 anticipated: H2 2019
Phase I NCT02117219	Imfinzi, azacitidine (Vidaza)	Myelodysplastic syndrome	79	<p>Dose escalation and dose expansion trial</p> <ul style="list-style-type: none"> Part 1: Imfinzi Part 2 Arm 1: Imfinzi and tremelimumab Part 2 Arm 2: Imfinzi, 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, OS, PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2014 Data anticipated: 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 Data anticipated: H2 2019
Phase II HUDSON NCT03334617	Imfinzi Lynparza Vistusertib AZD6738 Danvatirsen Oleclumab	Non-small-cell lung cancer (NSCLC)	260	<p>5 modules encompassing 13 cohorts</p> <p>Module 1; Imfinzi and Lynparza Module 2; Imfinzi and danvatirsen Module 3; Imfinzi and AZD6738 Module 4; Imfinzi and vistusertib Module 5; Imfinzi and oleclumab</p> <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 	<ul style="list-style-type: none"> FPCD: Q1 2018 Data anticipated: 2020+
Phase II COAST NCT03822351	Imfinzi	Stage III NSCLC Unresectable	300	<p>Arm A: Control (Imfinzi) Arm B: Imfinzi + oleclumab Arm C: Imfinzi + monalizumab</p>	<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: 2020+
Phase II NeoCOAST NCT03794544	Imfinzi	Resectable, Early Stage NSCLC	160	<p>Arm A: Control (Imfinzi) Arm B: Imfinzi + oleclumab Arm C: Imfinzi + monalizumab Arm D: Imfinzi + danvatirsen</p>	<p>Primary</p> <ul style="list-style-type: none"> Major pathological response rate 	<ul style="list-style-type: none"> FPCD: Q1 2019 Data anticipated: 2020+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II STUDY 21 NCT02340975	Gastric/gastro-Oesophageal junction (GEJ) adenocarcinoma	114	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab 2L Arm B: <i>Imfinzi</i> 2L Arm C: tremelimumab 2L Arm D: <i>Imfinzi</i> + tremelimumab 3L Arm E: <i>Imfinzi</i> + tremelimumab 2L & 3L <p>US and ROW trial centres</p>	<ul style="list-style-type: none"> Primary endpoints: Safety & tolerability, ORR, PFS Secondary endpoints: DCR, OS, DoR, PD-L1 Expression 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data anticipated: H2 2019
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, ORR, PFS Secondary endpoints: DCR, OS, DoR, PD-L1 Expression 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2020
Phase Ib STUDY 006 NCT02000947	Non-small-cell lung cancer (NSCLC) (Immunob naïve and Immunob pretreated patient cohorts)	459	<ul style="list-style-type: none"> Dose Escalation: minimum 5 cohorts exploring various treme Q4W and <i>Imfinzi</i> IV 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 Secondary endpoints include antitumour activity, PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2013 LPD: Q4 2016 Data anticipated: H1 2019
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 Secondary endpoints include anti-tumour activity, PK/PD and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPD: Q2 2017 Data anticipated: H2 2019
Phase Ib STUDY 23 NCT02549651	Diffuse Large B cell Lymphoma	32	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> Arm B: <i>Imfinzi</i> + tremelimumab Arm C: <i>Imfinzi</i> + AZD9150 <p>US and European trial centres</p>	<ul style="list-style-type: none"> Primary endpoint: Safety & tolerability Secondary endpoints: OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers 	<ul style="list-style-type: none"> FPCD: Q3 2016 Data readout: Q2 2019



Imfinzi (PD-L1 mAb) + monalizumab (NKG2a mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II NCT02671435	Advanced solid tumours	501	<p>Escalation phase</p> <ul style="list-style-type: none"> monalizumab + <i>Imfinzi</i> IV <p>Expansion phase</p> <ul style="list-style-type: none"> monalizumab + <i>Imfinzi</i> IV recommended dose <p>Exploration phase</p> <ul style="list-style-type: none"> monalizumab + <i>Imfinzi</i> IV recommended dose + SoC systemic therapy with or without biologic agent in adult subjects with CRC (Colorectal cancer) and monalizumab in combination with biologic agent in adult subjects with colorectal cancer <p>Global trial</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Optimal biologic dose for the combination <p>• Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics</p>	<ul style="list-style-type: none"> FPCD: Q2 2016 Data anticipated: 2020+



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

Squamous cell carcinoma of the Head and Neck (SCCHN)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/Ia NCT03162224	Human papillomavirus (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: 2020



Oleclumab (MEDI9447, CD73 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02503774	Advanced malignancies	310	<p>Dose escalation phase</p> <ul style="list-style-type: none"> oleclumab IV oleclumab IV + <i>Imfinzi</i> IV <p>Dose expansion phase</p> <ul style="list-style-type: none"> oleclumab IV recommended dose + <i>Imfinzi</i> IV <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, pharmacokinetics, pharmacodynamics, and immunogenicity</p>	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: 2020
Phase Ib/II NCT03611556	Pancreatic 1L and 2L with prior gemcitabine-based chemotherapy	204	<ul style="list-style-type: none"> Arm A1: Gemcitabine and nab Paclitaxel IV Arm A2: Gemcitabine and nab Paclitaxel IV + oleclumab IV Arm A3: Gemcitabine and nab Paclitaxel IV + oleclumab IV + <i>Imfinzi</i> IV Arm B1: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV Arm B2: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV + oleclumab IV Arm B3: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV + oleclumab IV + <i>Imfinzi</i> IV <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 pharmacokinetics, pharmacodynamics, immunogenicity, and safety</p>	<ul style="list-style-type: none"> FPCD: Q2 2018 Data anticipated: 2020+
Phase I/II NCT03381274	Non-small-cell lung cancer (NSCLC)	98	<ul style="list-style-type: none"> Arm A: oleclumab IV + <i>Tagrisso</i> Arm B: oleclumab IV + AZD4635 <p>PoC for future registrational studies</p> <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: 2020+



AZD2811 (AURN)

Cancer

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02579226	Solid tumours	72	<ul style="list-style-type: none">• Arm 1: AZD2811 dose escalation• Arm 2: AZD2811 dose expansion	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetics and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: H2 2019
Phase I NCT03217838	Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome	130	<ul style="list-style-type: none">• Part A: AZD2811 single agent dose escalation cohorts• Part B: AZD2811 single agent and azacytidine combination dose expansions to further explore the tolerability, PK and clinical activity.	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetics and efficacy	<ul style="list-style-type: none">• FPCD: Q3 2017• Data anticipated: 2020+

Oncology

CVRM

Respiratory

Other



AZD4573 (CDK9 inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03263637	Relapsed/refractory haematologic malignancies	42	Dose escalation in relapsed/refractory haematological malignancies AZD4573 will be administered 2 parallel arms of (1-6 cohorts of dose escalations) based on the haematological malignancy	Primary: • safety/PK; Secondary: • efficacy	<ul style="list-style-type: none">• FPCD: Q4 2017• Data anticipated: H2 2019



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 metastatic castrate-resistant prostate carcinoma (mCRPC) Immune checkpoint-naïve colorectal carcinoma (CRC) Other immune checkpoint-naïve solid tumours	104-118 190	<ul style="list-style-type: none"> Phase Ia: dose escalation to determine the MTD of AZD4635 given as monotherapy and in combination with <i>Imfinzi</i> in patients with solid malignancies. Also, to determine the MTD of AZD4635 in combination with abiraterone or with enzalutamide in patients with metastatic castrate-resistant prostate carcinoma (mCRPC). When the combination MTD is determined, additional patients with advanced solid malignancies and mCRPC will be enrolled to a dose expansion cohort to explore further the safety, tolerability, PK, and biological activity. Phase Ia: will also enroll patients to a capsule formulation of AZD4635 to determine the PK of the capsule formulation and the MTD in combination with <i>Imfinzi</i> plus oleclumab or with docetaxel. Phase Ib will consist of additional expansions in NSCLC, mCRPC, CRC and other post-immunotherapy and immune checkpoint-naïve solid tumours at the combination and/or monotherapy MTD or maximum feasible dose <p>Both parts conducted at sites in the US</p>	Primary outcome measure: <ul style="list-style-type: none"> Safety and tolerability Secondary outcome measures: <ul style="list-style-type: none"> PK of AZD4635 as monotherapy and combination with <i>Imfinzi</i> abiraterone and enzalutamide. Preliminary assessment of anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q2 2016 Data anticipated: 2020
Phase I NCT03710434	Healthy male volunteers	20	<ul style="list-style-type: none"> Part A is a 2-period randomised crossover study of single doses of AZD4635. Subjects will be randomised to receive 50mg AZD4635 nano-suspension (reference) or 50mg AZD4635 solid oral formulation, in the fasted state. Part B is a 4-period, open-label, randomised, crossover study of single doses of AZD4635 in the same subjects from Part A. The treatments selected for Part B will depend on the outcome of interim analyses of AZD4635 exposure. <p>Both parts conducted at a site in the UK</p>	Primary outcome measures: <ul style="list-style-type: none"> Maximum observed plasma concentration (C_{max}) of AZD4635 solid oral formulation and nano-suspension Exposure to AZD4635 solid oral formulation and nano-suspension 	<ul style="list-style-type: none"> FPCD: Q4 2018 Data anticipated: H1 2019



AZD5069 (CXCR2 antagonist)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II NCT02583477	Metastatic pancreatic ductal carcinoma	16	Dose escalation and expansion arms: <i>Imfinzi</i> in combination with nab-paclitaxel and gemcitabine <i>Imfinzi</i> in combination with AZD5069	<ul style="list-style-type: none">Safety/efficacy trial	<ul style="list-style-type: none">FPCD: Q1 2016Data anticipated: H2 2019



AZD5153 (BRD4 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II NCT03205176	Relapsed/refractory solid tumours, lymphomas	54	Dose Escalation advanced solid and lymphomas Six dose escalation cohorts of AZD5153 Dose and schedule from dose escalation will be applied in dose expansion Phase in platinum-resistant or platinum-refractory high grade serous (HGS) ovarian cancer	<ul style="list-style-type: none"> Primary: safety Secondary: efficacy 	<ul style="list-style-type: none"> FPCD: Q2 2017 Data anticipated: H2 2019



AZD5991 (MCL1 inhibitor)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03218683	Relapsed/refractory haematologic malignancies	48	Dose escalation in relapsed/refractory haematological malignancies Five dose escalation cohorts of AZD5991	<ul style="list-style-type: none">Primary: safetySecondary: efficacy	<ul style="list-style-type: none">FPCD: Q3 2017Data anticipated: H2 2019



AZD6738 (ATR inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02264678	Solid tumours	160	<ul style="list-style-type: none"> Arm 1: AZD6738 + carboplatin Arm 2: AZD6738 dose escalation, AZD6738 + <i>Lynparza</i> Arm 3: AZD6738 + <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: H2 2019
Phase I NCT03022409	SCCHN	40	<p>Window of opportunity</p> <ul style="list-style-type: none"> Arm 1: AZD6738 Arm 2: <i>Lynparza</i> <ul style="list-style-type: none"> Trial conducted in US, France, Taiwan and the UK 	<ul style="list-style-type: none"> Biomarker change 	<ul style="list-style-type: none"> FPCD: Q4 2017 Data anticipated: 2020



AZD9150 (STAT3 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II NCT02499328	Head and neck squamous-cell carcinoma (HNSCC)	405	Dose escalation advanced solid and blood cancers <ul style="list-style-type: none"> • Arm A1: AZD9150/<i>Imfinzi</i> • Arm A2: AZD5069/<i>Imfinzi</i> • Arm A4: AZD9150/<i>Imfinzi</i>/treme • Arm A5: AZD5069/<i>Imfinzi</i>/treme Dose expansion 2L HNSCC: <ul style="list-style-type: none"> • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/<i>Imfinzi</i> • Arm B4: AZD5069/<i>Imfinzi</i> • Arm B5: AZD9150 mono • Arm B6: AZD5069 mono • Arm B7: AZD9150/<i>Imfinzi</i> (1L HNSCC) • Arm B8: AZD9150 Q2W/<i>Imfinzi</i> (1L HNSCC) 	<ul style="list-style-type: none"> • Safety/efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • Data anticipated: H2 2020
Phase Ib/II NCT03421353	NSCLC, advanced solid tumours	213	Dose escalation advanced solid and blood cancers <ul style="list-style-type: none"> • Arm A1: AZD9150 alternate week/<i>Imfinzi</i> • Arm A2-A5: AZD9150/<i>Imfinzi</i> + SoC chemotherapy Dose Expansion 1L HNSCC: <ul style="list-style-type: none"> • Arm D1/D2/D3: AZD9150 IV vs SC formulations/<i>Imfinzi</i> (advanced solid tumours) 	<ul style="list-style-type: none"> • Safety/efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q1 2018 • Data anticipated: 2020



AZD9496 (selective estrogen receptor degrader)

Breast cancer

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 oestrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (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: Pharmacodynamics changes to estrogen receptor (ER) expression following treatment with AZD9496 or <i>Faslodex</i> Secondary Outcome Measures: Pharmacodynamics changes to Ki67 and progesterone receptor (PgR) expression following treatment with AZD9496 or <i>Faslodex</i> 	<ul style="list-style-type: none"> FPCD: Q4 2017 Data anticipated: H2 2019
Phase I NCT02248090	ER+ Breast Cancer	c. 50	<ul style="list-style-type: none"> This is a Phase I open label multicentre trial of AZD9496 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. In addition, expansion cohort(s) at potential therapeutic dose(s) in patients with or without ESR1 mutations will be enrolled to further determine the safety, tolerability, pharmacokinetics and biological activity of AZD9496 	<ul style="list-style-type: none"> Primary Outcome Measures: Safety and tolerability Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood Anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2016 Data readout: Q2 2017
Phase I NCT02780713	Healthy subjects	14	<ul style="list-style-type: none"> This is a Phase I open label single centre trial to assess the pharmacokinetics and safety of different forms and formulations of AZD9496 in healthy subjects 	<ul style="list-style-type: none"> Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites Secondary Outcome Measures: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q3 2016 Data readout: Q2 2017



AZD9833 (selective estrogen receptor degrader)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03616587	ER+ breast cancer	240	<ul style="list-style-type: none"> This is a Phase I 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 pharmacokinetics of AZD9833 alone and in combination with palbociclib. Antitumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2018



MEDI2228 (BCMA antibody drug conjugate)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03489525	Relapsed/Refractory Multiple Myeloma	129	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: pharmacokinetics, immunogenicity, ORR, DoR, PFS, OS	<ul style="list-style-type: none">• FPCD: Q2 2018• Data anticipated: 2020+



MEDI3726 (PSMA antibody drug conjugate)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib NCT02991911	Subjects with metastatic castration resistant prostate cancer	224	Open-label, Dose-escalation and Dose-expansion <ul style="list-style-type: none"> Three arm trial <ul style="list-style-type: none"> Post-chemo Pre-chemo MEDI3726+Enzalutamide 	Primary endpoint: <ul style="list-style-type: none"> Safety Secondary endpoints <ul style="list-style-type: none"> RECIST response PSA50 response CTC response Pharmacokinetics, and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020+



MEDI5083 (CD40 Ligand fusion protein) + *Imfinzi* (PD-L1 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03089645	Advanced solid tumours	204	Dose-escalation phase <ul style="list-style-type: none"> Part 1: MEDI5083 Part 2: MEDI5083 + <i>Imfinzi</i> IV Dose expansion phase <ul style="list-style-type: none"> Part 3: MEDI5083 recommended dose + <i>Imfinzi</i> IV US and Australian trial centres	Primary endpoints: <ul style="list-style-type: none"> Safety Determination of MTD Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020+



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

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03530397	Advanced solid tumour	263	Open-label, Dose-escalation and Dose-expansion Dose-escalation: MEDI5752 IV Dose-expansion : 2 cohorts with 2 arms each	Primary endpoints: <ul style="list-style-type: none">Dose-escalation: Safety & determination of MTDDose-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, DC, PFS, OS,	<ul style="list-style-type: none">FPCD: Q2 2018Data anticipated: 2020+



MEDI7247 (PBD ADC mAb)

Cancer

Approved medicines

Late-stage development

Early development

Oncology

CVRM

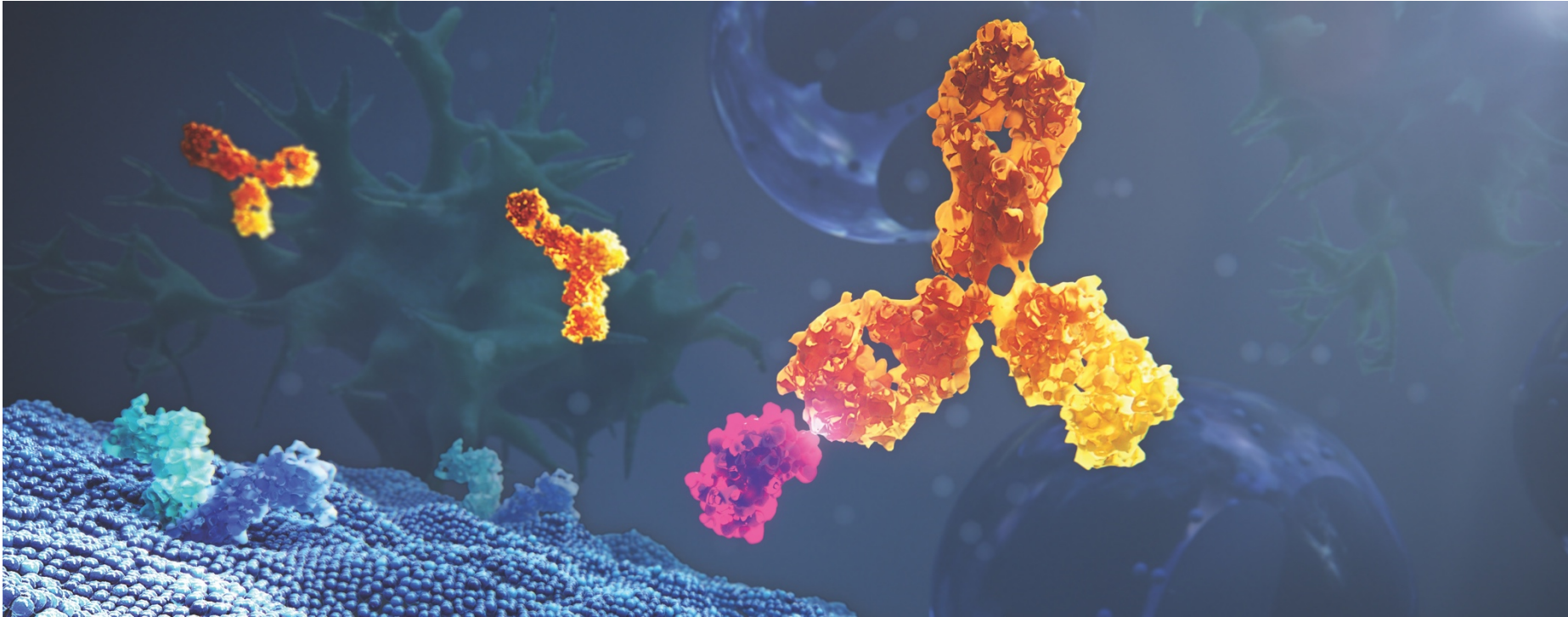
Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03106428	Relapsed/Refractory Haematological Malignancies	408	First-time-in-human Phase I, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	<ul style="list-style-type: none">• Primary endpoint: safety• Secondary endpoints: Pharmacokinetics, immunogenicity and antitumour activity	<ul style="list-style-type: none">• FPCD: Q2 2017• Data anticipated: 2020+
Phase I/Ib NCT03811652	Advanced or metastatic solid tumours	336	Open-label, dose-escalation and dose-expansion.	<ul style="list-style-type: none">• Primary endpoint: safety• Secondary endpoints: Pharmacokinetics, immunogenicity and antitumour activity	<ul style="list-style-type: none">• FPCD: Q4 2018• Data anticipated: 2020+



CVRM, Respiratory and Other medicines – approved medicines and late-stage pipeline



Farxiga (SGLT2 inhibitor)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III/IV DECLARE NCT01730534	Type-2 diabetes with high risk for CV event	17,190	<ul style="list-style-type: none"> • Arm 1: <i>Farxiga</i> 10mg QD + SoC therapy QD • Arm 2: Placebo + SoC therapy for type-2 Diabetes Global trial – 33 countries	<ul style="list-style-type: none"> • Primary endpoints: Superiority for major adverse cardiac events (MACE) (CV death, non-fatal MI (myocardial infarction) or non-fatal stroke). Superiority for the composite endpoint of CV death or hospitalisation for heart failure. 	<ul style="list-style-type: none"> • FPCD: Q2 2013 • LPCD: Q2 2015 • Data Readout: Q3 2018 • Met primary safety endpoint and one of two primary efficacy endpoints (hHF or CV death)
Phase III DERIVE NCT02413398	Patients with type-2 diabetes and moderate renal impairment	302	<ul style="list-style-type: none"> • Arm 1: <i>Farxiga</i> 10mg QD for 24 weeks • Arm 2: Placebo 10mg QD for 24 weeks Global trial – eight countries	<ul style="list-style-type: none"> • Primary endpoint: Change from baseline in HbA1c at week 24 	<ul style="list-style-type: none"> • FPCD: Q2 2015 • LPCD: Q2 2017 • Data readout: Q1 2018 • Primary endpoint met
Phase III DEPICT 1 NCT02268214 Partnered	Type-1 diabetes	833	<ul style="list-style-type: none"> • Arm 1: <i>Farxiga</i> 5mg QD 52 weeks + insulin • Arm 2: <i>Farxiga</i> 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 17 countries	<ul style="list-style-type: none"> • Primary endpoint: : Adjusted Mean Change From Baseline in HbA1c at week 24 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • LPCD Q2 2016 • Data readout: Q1 2017 • Primary endpoint met
Phase III DEPICT 2 NCT02460978 Partnered	Type-1 diabetes	813	<ul style="list-style-type: none"> • Arm 1: <i>Farxiga</i> 5mg QD 52 weeks + insulin • Arm 2: <i>Farxiga</i> 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 14 countries	<ul style="list-style-type: none"> • Primary endpoint: Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • LPCD: Q1 2017 • Data readout: Q4 2017 • Primary endpoint met



Farxiga (SGLT2 inhibitor)

Diabetes / cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints	Status
Phase III Dapa-HF NCT03036124	Chronic Heart Failure (CHF) patients with reduced ejection fraction (HFrEF)	4,744	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg or 5 mg QD + standard of care therapy Arm 2: Placebo + standard of care therapy <ul style="list-style-type: none"> 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 heart failure (HF) or an urgent HF visit 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q3 2018 Data anticipated: H2 2019
Phase III Dapa-CKD NCT03036150	Patients With Chronic Kidney Disease (CKD)	4,000	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg or 5 mg QD Arm 2: Placebo <ul style="list-style-type: none"> 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: $\geq 50\%$ sustained decline in estimated glomerular filtration rate (eGFR) or reaching end stage renal disease (ESRD) or CV death or renal death 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2019 Data anticipated: 2020+
Phase III DELIVER NCT03619213	Chronic Heart Failure (CHF) patients with preserved ejection fraction (HFpEF)	4,700	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD Arm 2: Placebo <ul style="list-style-type: none"> 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 heart failure (HF) or an urgent HF visit 	<ul style="list-style-type: none"> FPCD: Q3 2018 Data anticipated: 2020+



Brilinta (ADP 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 myocardial infarction (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 cardiovascular (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 LPD: Q2 2016 Data readout: Q1 2019 Primary endpoint met
Phase III THALES NCT03354429	Patients with acute ischaemic stroke or transient ischaemic attack	13,000	<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 Data anticipated: 2020
Phase III HESTIA3 NCT03615924	Pediatric patients (2-18 years old) with sickle cell disease	182	<ul style="list-style-type: none"> Arm 1: <i>Brilinta</i> 15, 30 or 45mg (dose based on subject weight) Arm 2: Placebo Global trial – 18 countries	<ul style="list-style-type: none"> Primary endpoint: The number of vaso-occlusive crisis which is the composite of painful crisis and/or acute chest pain 	<ul style="list-style-type: none"> FPCD: Q3 2018 Data anticipated: 2020+



Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III STRENGTH (CVOT) NCT02104817	Patients with hypertriglyceridaemia and high cardiovascular disease risk	13,000	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 4g QD + statin Arm 2: Placebo (corn oil) + statin Global trial – 22 countries	<ul style="list-style-type: none"> Primary endpoint: Composite of Major Adverse Cardiac Events (MACE) 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2017 Data anticipated: 2020
Phase III NCT02463071	Japanese patients with hypertriglyceridaemia	375	<ul style="list-style-type: none"> <i>Epanova</i> 2g and 4g vs. Placebo (after meal) daily for 52 weeks Global trial – one country	Primary endpoints: <ul style="list-style-type: none"> Safety in Japanese patients percentage change in triglycerides 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q1 2016 Data readout: Q2 2017
Phase III EVOLVE II NCT02009865	Severe hypertriglyceridaemia	162	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 2g QD Arm 2: Placebo (olive oil) Global trial – seven countries	<ul style="list-style-type: none"> Primary endpoint: Change in serum triglycerides over 12 weeks 	<ul style="list-style-type: none"> FPCD: Q4 2013 LPCD: Q4 2014 Data readout: Q4 2015 Primary endpoint met
Phase I China PK NCT03574142	Healthy Chinese subjects	14	Open-label trial to evaluate the pharmacokinetics of single and multiple doses of <i>Epanova</i> 4 g/day in Chinese healthy subjects Local trial – China	<ul style="list-style-type: none"> Primary endpoints: Plasma concentrations versus time profile of EPA and DHA to assess PK parameters 	<ul style="list-style-type: none"> FPCD: Q2 2018 LPCD: Q2 2018 Data readout: Q4 2018



Lokelma (sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III Harmonize Global NCT02875834	Hyperkalaemia	248	Open-label <i>Lokelma</i> 10g TID for 48 hours followed by: <ul style="list-style-type: none"> • Arm 1: <i>Lokelma</i> 5g QD for 28 days • Arm 2: <i>Lokelma</i> 10g QD for 28 days • Arm 3: Placebo QD for 28 days <p>Global trial – four countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Maintenance of normokalaemia 	<ul style="list-style-type: none"> • FPCD: Q1 2017 • LPCD: Q1 2018 • Data readout: Q4 2018 • Primary endpoint met
Phase II/III NCT03127644	Hyperkalaemia	103	<p>Arm 1: <i>Lokelma</i> 5g TID for 48 hours</p> <p>Arm 2: <i>Lokelma</i> 10g TID for 48 hours</p> <p>Arm 3: Placebo TID for 48 hours</p> <p>Japan</p>	<ul style="list-style-type: none"> • Primary endpoint: Exponential rate of change in serum potassium 	<ul style="list-style-type: none"> • FPCD: Q2 2017 • LPCD: Q1 2018 • Data readout: Q3 2018 • Primary endpoint met
Phase III NCT03172702	Hyperkalaemia	150	<p>Arm 1: Open-label <i>Lokelma</i> 10g TID for up to 72 hrs followed by <i>Lokelma</i> 5g QD for 12 months. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD (or 2.5g QD)</p> <p>Japan</p>	<ul style="list-style-type: none"> • Primary endpoint: Safety and tolerability as measured by adverse events reporting, vital signs, ECGs, physical examinations and safety laboratory measurements 	<ul style="list-style-type: none"> • FPCD: Q3 2017
Phase I NCT03283267	Healthy Subjects	22	<p>Arm 1: Open-label <i>Lokelma</i> 5g QD for 4 days</p> <p>Arm 2: Open-label <i>Lokelma</i> 10g QD for 4 days</p> <p>China</p>	<ul style="list-style-type: none"> • Primary endpoint: Mean change from baseline to <i>Lokelma</i> treatment period in urine potassium excretion 	<ul style="list-style-type: none"> • FPCD: Q4 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
Phase IIIb DIALIZE NCT03303521	Patients on haemodialysis with persistent pre-dialysis hyperkalaemia	180	<p>Arm 1: <i>Lokelma</i> 5g QD for 8 weeks on non-dialysis days. Option to uptitrate to 10 and 15g QD.</p> <p>Arm 2: Placebo QD for 8 weeks on non-dialysis days</p> <p>Global trial – four countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Proportion of patients who maintain a pre-dialysis serum K between 4.0-5.0 mmol/L on 3 out of 4 dialysis treatments following the long interdialytic interval 	<ul style="list-style-type: none"> • FPCD: Q4 2017 • LPCD: Q4 2018 • Primary endpoint met
Phase II ENERGIZE NCT03337477	Hyperkalaemia	132	<p>Arm 1: <i>Lokelma</i> 10g TID for 24 hours on top off SoC (insulin and glucose)</p> <p>Arm 2: Placebo TID for 24 hours on top off SoC (insulin and glucose)</p> <p>Global trial – four countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Mean absolute change in S-K from baseline until 4h after start of dosing 	<ul style="list-style-type: none"> • FPCD: Q1 2018 • LPCD: Q4 2018
Phase II PRIORITIZE HF NCT03532009	Patients with chronic heart failure and hyperkalaemia or at high risk of developing hyperkalaemia	280	<p>Arm 1: <i>Lokelma</i> 5g QD for 12 weeks. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD</p> <p>Arm 2: Placebo QD for 12 weeks</p> <p>Global trial – six countries</p>	<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



Roxadustat (China: 艾瑞卓) (HIF-PHI inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III ANDES NCT01750190 Partnered	Anaemia in CKD (Chronic Kidney Disease) 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 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 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 Data anticipated: H1 2019 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 Data readout: Q4 2018 Primary endpoint met Sponsored by AstraZeneca
Phase III ROCKIES NCT02174731		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 Data readout: Q4 2018 Primary endpoint met Sponsored by AstraZeneca
Phase III SIERRAS NCT02273726 Partnered		820	<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 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: erythropoiesis stimulating agent Arm 3: darbepoetin alfa Global trial	<ul style="list-style-type: none"> Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: H2 2018 Sponsored by Astellas

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor



Roxadustat (China: 爱瑞卓) (HIF-PHI inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III HIMALAYAS NCT02052310 Partnered	Anaemia in newly initiated dialysis patients	900	<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 Data readout: Q4 2018 Primary endpoint met Sponsored by FibroGen
Phase III NCT02652819 Partnered	Anaemia in CKD (Chronic Kidney Disease) patients not receiving dialysis	154	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: placebo China trial	<ul style="list-style-type: none"> Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2016 Data readout: Q2 2017 Primary endpoint met Sponsored by FibroGen
Phase III NCT02652806 Partnered	Anaemia in CKD patients receiving dialysis	305	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: epoetin alfa China trial	<ul style="list-style-type: none"> Primary endpoint: Haemoglobin response 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q2 2016 Data readout: Q2 2017 Primary endpoint met Sponsored by FibroGen
Phase III NCT03263091 Partnered	Anaemia in lower risk Myelodysplastic Syndrome (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 	FPCD: Q3 2017 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 	Sponsored by FibroGen

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor



Ekliral/Tudorza (LAMA, DPI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Number of patients	Design	Endpoints	Status
Phase I NCT03276052	Healthy Chinese subjects	18	Open-label, 2-period ascending dose incomplete block, cross-over trial <ul style="list-style-type: none"> Arm 1: Acclidinium bromide 200 µg DPI Arm 2: Acclidinium bromide 400 µg DPI Arm 3: Acclidinium bromide 800 µg DPI Global trial – one Country	<ul style="list-style-type: none"> To investigate the pharmacokinetics (PK) of aclidinium bromide and its metabolites after single and multiple doses (twice-daily [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 (twice-daily [BID]) 	<ul style="list-style-type: none"> FPCD: Q2 2018 Data anticipated: H2 2019



Duaklir Genuair (LAMA/LABA, DPI)

Chronic obstructive pulmonary disease (COPD)

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 Acridinium 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 Acridinium bromide 400 µg compared to placebo at Week 24 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020



Bevespi Aerosphere (LAMA/LABA, pMDI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design (G = glycopyrronium, F = formoterol fumarate)	Endpoints	Status
Phase IIIb AERISTO NCT03162055	Moderate to very severe COPD	1,000	Treatments (24-week treatment period) <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BID pMDI Umeclidinium/vilanterol DPI 62.5/25µg QD Randomised, double-blind, double-dummy, multi-centre, parallel group US, Canada, Bulgaria, France, Hungary, Russia, Ukraine	Co-primary endpoints: <ul style="list-style-type: none"> Change from baseline in morning pre-dose trough FEV1 over 24 weeks Peak change from baseline in FEV1 within two hours post-dosing over 24 weeks 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q4 2017 Data readout: Q3 2018



Daliresp/Daxas (PDE4 inhibitor, oral)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IV RESPOND NCT01443845	COPD	2,354	<ul style="list-style-type: none"> 52W, randomised, DB with <i>Daliresp</i> 500µg OD vs. placebo, in COPD on top of ICS/LABA 	<ul style="list-style-type: none"> Primary endpoint: Rate of moderate or severe COPD exacerbations per subject per year 	<ul style="list-style-type: none"> FPCD: Q4 2011 LPCD: Q1 2016 Data readout: Q4 2016
Phase IV OPTIMIZE NCT02165826	COPD	1,323	<ul style="list-style-type: none"> 12W, randomised, DB to evaluate tolerability and PK of <i>Daliresp</i> 500µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg <i>Daliresp</i> OD in patients not tolerating 500µg OD 	<ul style="list-style-type: none"> Primary endpoint: Percentage of participants prematurely discontinuing trial treatment for any reason during the main period 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q3 2015 Data readout: Q4 2016
Phase IIIb ROBERT NCT01509677	COPD	158	<ul style="list-style-type: none"> 16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of <i>Daliresp</i> in COPD 	<ul style="list-style-type: none"> Primary endpoint: Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period 	<ul style="list-style-type: none"> FPCD: Q1 2012 LPCD: Q1 2016 Data readout: Q4 2016
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: 2020+



Fasenra (IL-5R 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	770	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W SC Arm 2: <i>Fasenra</i> 30mg Q8W SC Global trial - 15 countries	<ul style="list-style-type: none"> Primary endpoint: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2016 Data anticipated: 2020
Phase IIIb PONENTE NCT03557307	Severe eosinophilic asthmatics receiving HD (high dose) ICS + LABA and chronic OCS with or without additional asthma controller(s). Age: 18 Years and older	600	Arm 1: <i>Fasenra</i> 30mg Q8W SC 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 Data anticipated: 2020
D3250C00036 China ICS/LABA Trial (MIRACLE) NCT03186209	Severe, uncontrolled asthma, despite background controller medication, medium dose (MD) & high dose (HD) ICS + LABA ± chronic OCS Age 12-75 years	666	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q8W SC Arm 2: Placebo SC 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: Q3 2017 Data readout: 2020+



Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III BORA NCT02258542	Severe asthma, inadequately controlled despite background controller medication, MD (medium dose) & HD (high dose) ICS + LABA ± chronic OCS Age 12-75 years	2,550	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W SC Arm 2: <i>Fasenra</i> 30mg Q8W SC* <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	120	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W SC 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	38	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W SC Arm 2: placebo SC 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 Data anticipated: H2 2019
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	100	<ul style="list-style-type: none"> Arm1 <i>Fasenra</i> 30mg Q4W SC with one dose of seasonal influenza virus vaccine Intramuscular (IM) at week eight Arm1 Placebo Q4W SC with one dose of seasonal influenza virus vaccine intra muscular at week 12-week trial	Primary endpoints: <ul style="list-style-type: none"> Post-dose strain-specific haemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs) Post-dose strain-specific serum HAI antibody geometric mean titers (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 (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III SOLANA NCT02869438	Severe uncontrolled asthma despite background controller medication HD ICS + LABA with or without controllers Age 18-75 years	230	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q4W SC Arm 2: Placebo SC 16-week trial Global trial – six countries	<ul style="list-style-type: none"> Primary endpoint: Onset and maintenance of effect on lung function 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: Q3 2018 Primary endpoint not met
Phase III GRECO NCT02918071	Severe asthma on ICS-LABA Age 18-75 years	120	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 sc in patients with severe asthma uncontrolled on SoC treatment. Age 18-75	800	<ul style="list-style-type: none"> Arm 1: <i>Fasenra</i> 30mg Q8W SC Arm 2: placebo SC 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 Data anticipated: 2020
Phase I AMES NCT02968914	Healthy Volunteer Age 18-55 years	162	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



Fasenra (IL-5R mAb)

Nasal polyps

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase III OSTRO NCT03401229	Patients with severe bilateral nasal polyps who are still symptomatic despite standard of care therapy Age 18-75 years	400	<ul style="list-style-type: none">• Arm 1: <i>Fasenra</i> 30mg Q8W SC• Arm 2: Placebo SC 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">• FPCC: Q1 2018• Data anticipated: 2020

Oncology

CVRM

Respiratory

Other



PT010 (LAMA/LABA/ICS, pMDI)

Chronic obstructive pulmonary disease (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-study 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-study 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
Phase III ETHOS NCT02465567	Moderate to very severe COPD	8,000 (possible increase by 4,000 after blinded sample size re-assessment)	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 anticipated: H2 2019
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) Transition dyspnoea index (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



PT027 (ICS/SABA, 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/Pediatric 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: 2020+
Phase III DENALI 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 	Initiating



Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III NAVIGATOR NCT03347279 Partnered	Severe asthma Age 12-80 years	1,060	<ul style="list-style-type: none"> Arm 1: tezepelumab SC Arm 2: placebo SC 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 Data anticipated: 2020
Phase III SOURCE NCT03406078 Partnered	Severe asthma Age 18-80 years	152	<ul style="list-style-type: none"> Arm 1: tezepelumab SC Arm 2: placebo SC 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
Phase III DESTINATION NCT03706079 Partnered	Severe asthma Age 12-80 years	~975	<ul style="list-style-type: none"> Arm 1: tezepelumab SC Arm 2: placebo SC Extension Study to NAVIGATOR and SOURCE. 52 week trial (subjects from NAVIGATOR); 56 week trial (subjects from SOURCE) Global trial – ~ 20 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



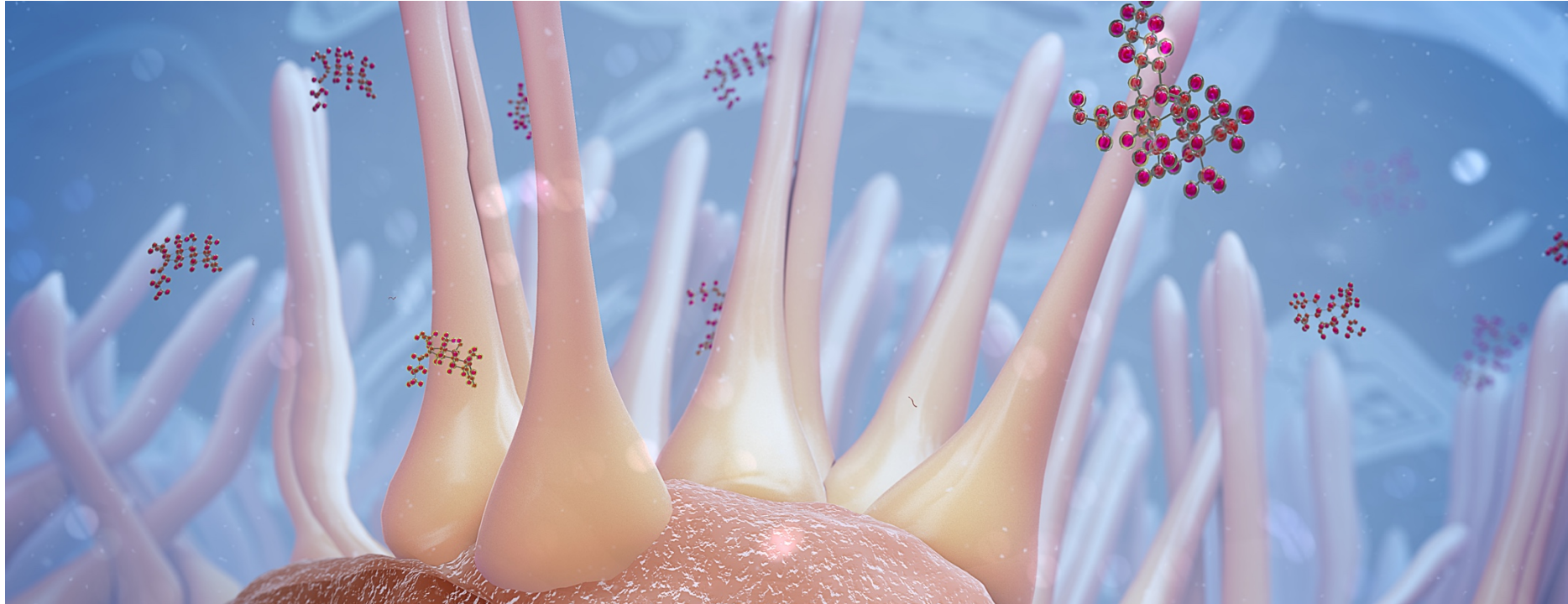
Anifrolumab (type I IFN receptor mAb)

Systemic lupus erythematosus (SLE) / Lupus nephritis (LN)

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02446912	Moderate to severe SLE TULIP SLE 1	450	<ul style="list-style-type: none"> • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: 150mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV 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: Q3 2015 • Data readout: Q3 2018 • Primary endpoint not met
Phase III NCT02446899	Moderate to severe SLE TULIP SLE 2	360	<ul style="list-style-type: none"> • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: placebo IV 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: Q3 2015 • Data anticipated: H2 2019
Phase III NCT02794285	Moderate to severe SLE TULIP LTE	630	<ul style="list-style-type: none"> • Arm 1: 300mg IV anifrolumab Q4W for 152 weeks • Arm 2: placebo IV 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 • Data anticipated: 2020+
Phase II NCT01438489	Moderate to severe SLE patients	307	<ul style="list-style-type: none"> • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: 1000mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV 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, IV 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 SC every other week • Arm 2: 300mg SC every other week • Arm 3: placebo SC 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 • Data readout: Q1 2018
Phase II NCT02547922	Active Proliferative LN (TULIP-LN1)	150	<ul style="list-style-type: none"> • Arm 1: 900 mg IV Q4W for 12 weeks then 300mg IV anifrolumab Q4W for 36 weeks • Arm 2: 300 mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV 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 • Data anticipated: 2020



CVRM, Respiratory and Other medicines – early-stage development



Verinurad (RDEA3170, URAT1 inhibitor)

Chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03118739	CKD (Chronic Kidney Disease) patients with hyperuricaemia, albuminuria, and Type 2 diabetes	60	<ul style="list-style-type: none"> Arm A: verinurad 9 mg and febuxostat 80 mg Arm B: Placebo The trial is a multi-centre trial conducted in the US	To assess the effects of intensive uric acid lowering therapy with RDEA3170 and febuxostat on UACR (urine albumin creatinine ratio)	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: Q3 2018 Data readout: Q4 2018
Phase II NCT03316131	Asymptomatic hyperuricemic subjects (sUA (serum uric acid levels) > 6.0 mg/dL)	36	<ul style="list-style-type: none"> Arm A: 9 mg verinurad + 80 mg febuxostat + 10 mg dapagliflozin Arm B: 9 mg verinurad + 80 mg febuxostat + placebo The trial is a two-centre trial conducted in the US	Primary: Peak uric acid excretion during the first 8 hours) on Day 7 of treatment Secondary: serum uric acid levels after 7 days of treatment.	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q3 2018 Data readout: Q4 2018



AZD4831 (MPO inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
AZD4831 (MPO) Phase I NCT02712372	Healthy subjects	c. 96	SAD trial (one trial site in Germany) • Planned to investigate 6 different dose levels vs. placebo but up to 10 cohort may be used	• Safety and tolerability • PK parameters	• FPCD: Q3 2016 • LPCD: Q4 2016 • Data readout Q2 2017
AZD4831 (MPO) Phase I NCT03136991	Healthy subjects	c. 40	MAD (one trial site in USA) • The planned number of cohorts is four but up to five cohorts may be included	• Safety and tolerability • PK parameters	• FPCD: Q2 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
AZD4831 (MPO) Phase IIa NCT03756285	HFpEF	96	Arm 1: AZD4831 Arm 2: Placebo Global trial – five countries	• Primary Endpoint: The change from baseline in MPO activity in % after AZD4831 treatment	• FPCD: Q4 2018



AZD5718 (FLAP inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
AZD5718 (FLAP) Phase I NCT02632526	Healthy subjects	96	SMAD trial (one trial site in UK) SAD • Oral administration MAD	<ul style="list-style-type: none"> Safety and tolerability PK parameters, bioavailability 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q3 2016 Data readout: Q4 2016
AZD5718 (FLAP) Phase I NCT02963116	Healthy subjects	12	DDI/BA trial (one trial site in UK) A randomised, 5-period, 5-treatment, single-dose, crossover trial to estimate the effect of AZD5718 on the PK of rosuvastatin, and to assess the relative BA of different formulations of AZD5718 as well as the food effect of AZD5718	<ul style="list-style-type: none"> PK and bioavailability To further assess the safety of single doses of AZD5718 in healthy subjects 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q1 2017 Data readout Q2 2017
AZD5718 (FLAP) Phase IIa NCT03317002	Coronary Artery Disease (CAD)	138	Phase IIa trial <ul style="list-style-type: none"> Arm 1: AZD5718 Dose A Arm 2: AZD 5718 Dose B Arm 3: Placebo Global trial – three countries in Europe	<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
AZD5718 (FLAP) Phase I NCT03400488	Healthy subjects	48	Combined SAD and MAD trial in Japanese subjects (one trial site in USA)	<ul style="list-style-type: none"> Safety and tolerability PK and PD parameters 	<ul style="list-style-type: none"> FPCD: Q1 2018 LPCD: Q2 2018 Data readout: Q4 2018
AZD5718 (FLAP) Phase I NCT03420092	Healthy subjects	14	BA trial (one trial site in UK) A randomised, 6-period, 6-treatment, single-dose, open-label, crossover trial to assess the relative bioavailability of different formulations of AZD5718 and the food effect	<ul style="list-style-type: none"> PK and bioavailability Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2018 LPCD: Q2 2018 Data readout: Q3 2018



AZD8233 (anti-hypercholesterolemia)

Hypercholesterolemia

Approved medicines

Late-stage development

Early development

Oncology

CVRM

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03593785	Healthy subjects	40	SAD Dose escalation in 5 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



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) • Planned to investigate 3 different dose levels vs. placebo but up to 5 cohort may be used	• Safety and tolerability	• FPCD: Q1 2017 • LPCD: Q3 2017 • Data readout: Q1 2018
Phase IIa NCTT03370887	Heart Failure	Up to 33	Phase IIa trial (two trial sites in Finland) • Arm 1: AZD8601 Dose A • Arm 2: AZD 8601 Dose B • Arm 3: Placebo	• Safety and tolerability	• FPCD: Q1 2018



Heart failure with preserved ejection fraction

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03435276	Healthy subjects	27	MAD Dose escalation in 3 cohorts with 6 subjects receiving AZD9977 and 3 subjects receiving placebo in each cohort Trial conducted in the UK.	Primary: • Safety and tolerability Secondary; • PK parameters	• FPCD: Q1 2018 • LPCD: Q2 2018 • Data readout: Q3 2018
Phase I NCT03450759	Healthy subjects	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	• FPCD: Q2 2018 • LPCD: Q2 2018 • Data readout: Q3 2018
Phase I NCT03682497	HFpEF	60	Proof of differentiation To compare the effect of AZD9977 with spironolactone on serum potassium	Primary: • serum potassium	• FPCD Q4 2018 • LPCD Q1 2019
Phase I NCT03843060	Healthy subjects	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	• FPCD: Q1 2019 • LPCD: Q1 2019
Phase I NCT03801967	Healthy subjects	45	JSMAD Single and multiple-ascending dose administration in Japanese healthy volunteers. Trial conducted in the UK	Primary: • Safety and tolerability Secondary; • PK parameters	• FPCD: Q1 2019
Phase I NCT03804645	Healthy subjects	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	• FPCD: Q1 2019 • LPCD: Q2 2019



Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02394314	Healthy adult subjects	64	<ul style="list-style-type: none"> SAD SC administration Germany 	<ul style="list-style-type: none"> Primary: Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q4 2015 Data readout: Q4 2015
Phase II NCT02548585 Completed	Adults with type-2 diabetes	113	<ul style="list-style-type: none"> MAD SC administration Germany 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination Efficacy: MMT glucose AUC, HbA1c, fructosamine and body weight loss 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q1 2017 Data readout: Q1 2017
Phase II NCT03244800	Adults with type-2 diabetes	65	<ul style="list-style-type: none"> Arm1: MEDI0382 SC or placebo Arm2: MEDI0382 SC or placebo Germany 	<ul style="list-style-type: none"> Efficacy: MMT glucose AUC, body weight loss, HbA1c, fasting plasma glucose Safety profile in terms of adverse events (AE), heart rate, blood pressure, vital signs, ECG, lab variables 	<ul style="list-style-type: none"> FPCD: Q3 2017 LPCD: Q4 2017 Data readout: Q1 2018
Phase II NCT03235050	Overweight and Obese subjects with type-2 diabetes	834	<ul style="list-style-type: none"> Arm1: MEDI0382 low dose SC + metformin Arm2: MEDI0382 mid dose SC + metformin Arm3: MEDI0382 high dose SC + metformin Arm4: placebo SC + metformin Arm5: liraglutide SC + metformin <p>US, Canada, Bulgaria, Czech Rep, Germany, Mexico, Russia, Slovakia</p>	<ul style="list-style-type: none"> Efficacy; HbA1c, body weight loss Percentage of subjects achieving weight loss of $\geq 5\%$ and $\geq 10\%$ Proportion of subjects rescued or discontinued for lack of glycaemic control PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2017 LPCD: Q1 2018 Data anticipated H2 2019
Phase I NCT03235375	Adults with renal impairment	37	<ul style="list-style-type: none"> ARM1: Subjects with CrCl < 20ml/min MEDI0382 SC ARM2: Subjects with CrCl 20-30ml/min MEDI0382 SC ARM3: Subjects with CrCl > 90ml/min MEDI0382 SC 	<ul style="list-style-type: none"> PK, safety, tolerability and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2017 LPCD: Q1 2018



Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03347968	Healthy adult subjects	22	<ul style="list-style-type: none"> Open label, one sequence, cross-over MEDI0382 with warfarin and esmolol US 	<ul style="list-style-type: none"> Effect of MEDI0382 on PK & PD of warfarin & esmolol Safety profile Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q1 2018
Phase I NCT03341013	Healthy adult subjects	24	<ul style="list-style-type: none"> Open label, cross-over, two period Single dose MEDI0382 formulation 2 SC Single dose MEDI0382 formulation 3 SC US 	<ul style="list-style-type: none"> PK Safety profile Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q4 2017 Data readout: Q2 2018
Phase I NCT03385369	Overweight/obese subjects of Japanese or Chinese descent	32	<ul style="list-style-type: none"> Arm1: Single low dose of MEDI0382 or placebo (Japanese) Arm2: Single intermediate-low dose of MEDI0382 or placebo (Japanese) Arm3: Single intermediate-high dose of MEDI0382 or placebo (Japanese) Arm4: Single high dose of MEDI0382 or placebo (Japanese) Arm5: Single intermediate-low dose of MEDI0382 or placebo US 	<ul style="list-style-type: none"> Safety profile Tolerability PK Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q1 2018 LPCD: Q2 2018
Phase II NCT03444584	Overweight/obese subjects with type-2 diabetes	46	<ul style="list-style-type: none"> Arm1: MEDI0382 + dapagliflozin Arm2: placebo + Dapagliflozin 	<ul style="list-style-type: none"> Efficacy: MMT glucose AUC Safety PK Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2018 LPCD: Q4 2018 Data readout: Q1 2019
Phase II NCT03550378	Adults with type-2 diabetes and renal impairment	40	<ul style="list-style-type: none"> MEDI0382 or placebo SC Germany, UK 	<ul style="list-style-type: none"> Efficacy: MMT glucose AUC Safety Tolerability PK Immunogenicity 	<ul style="list-style-type: none"> FPCD Q2 2018 LPCD: Q4 2018 Data readout: Q1 2019
Phase II NCT03555994	Adults with type-2 diabetes	40	<ul style="list-style-type: none"> Part A: MEDI0382 or placebo SC Part B: MEDI0382 SC or placebo SC or liraglutide SC 	<ul style="list-style-type: none"> Change in hepatic glycogen concentration postprandially, adjusted by liver volume Safety Tolerability Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2018 Part A LPCD: Q4 2018 Data readout: Q1 2019



Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03596177	Overweight and obese subjects with type-2 diabetes	26	<ul style="list-style-type: none"> MEDI0382 or placebo SC 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
Phase I NCT03625778	Non-diabetic obese subjects	51	<ul style="list-style-type: none"> MEDI0382 or placebo SC with 7 week, 10 week or 16 week titration period US 	<ul style="list-style-type: none"> Primary: safety, tolerability Secondary: PK Secondary: Immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2018
Phase II NCT03745937	Overweight and obese subjects with type-2 diabetes	20	<ul style="list-style-type: none"> MEDI0382 or placebo SC Germany 	<ul style="list-style-type: none"> Primary: Safety, tolerability Secondary: PK Secondary: Immunogenicity Secondary: Glucose control 	<ul style="list-style-type: none"> FPCD: Q1 2019
Phase II NCT03645421	Japanese preobese or obese subjects with type-2 diabetes	61	<ul style="list-style-type: none"> MAD SC administration Japan 	<ul style="list-style-type: none"> Primary: Safety, glucose AUC, body weight Secondary: HbA1c, FPG, fructosamine Secondary: glucose control Secondary: PK, immunogenicity 	<ul style="list-style-type: none"> FPCD: Q3 2018 LPCD: Q3 2018



MEDI7219 (anti-diabetic)

Diabetes

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03362593	Healthy Volunteers	104	<ul style="list-style-type: none">• 4 part trial• Part A : SAD• Part B & C : open label, single dose studies• Part D : MAD	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetics	<ul style="list-style-type: none">• FPCD: Q1 2018• Data anticipated: H2 2019

Oncology

CVRM

Respiratory

Other



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	414	<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 IV 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 IV push. 	<p>Primary endpoints: Infarct size as a percentage of left ventricle (LV) mass at 10-12 weeks post-MI (myocardial infarction) compared to placebo.</p> <p>Secondary endpoints:</p> <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 treatment-emergent adverse events (TEAEs) and treatment-emergent serious adverse events (SAEs). Lecithin-cholesterol acyltransferase (LCAT) mass and ADAs. 	<ul style="list-style-type: none"> FPCD: Q2 18 Data anticipated: 2020+
Phase IIa NCT03351738	MEDI5884 Cholesterol modulation	Adults With Stable Coronary Heart Disease (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 adverse events (AE), 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	72	<ul style="list-style-type: none"> Single Ascending Dose 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: 2020



AZD1402 (IL4 receptor antagonist)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03384290 Partnered	Healthy subjects	Inhaled: 56 IV: 16	SAD. A dose escalating single blind trial to assess the safety, tolerability and pharmacokinetics of single dose of PRS-060 administered by oral inhalation or IV infusion in healthy subjects <ul style="list-style-type: none"> ARM 1-7 (Inhaled (nebulizer) PRS-060 and matched placebo ARM8-9 (IV) PRS-060 and matched placebo Australia	Primary endpoint: <ul style="list-style-type: none"> Safety and tolerability Secondary endpoint: <ul style="list-style-type: none"> PK parameters 	<ul style="list-style-type: none"> FPCD: Q4 2017 LPCD: Q3 2018 Data readout: Q1 2019
Phase Ib NCT03574805 Partnered	Patients with mild asthma	70	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 <ul style="list-style-type: none"> ARM 1-4 (ARM 5 optional) (inhaled nebulizer) and matched placebo 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 fractional nitric oxide concentration in exhaled breath (FeNO) 	<ul style="list-style-type: none"> FPCD: Q3 2018 LPCD Q2 2019 Data anticipated: H2 2019



AZD1419 (TLR9 agonist)

Asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa INCONTRO NCT02898662	Adults with eosinophilic, moderate to severe asthma on ICS + LABA background treatment	81	<ul style="list-style-type: none">• Arm 1: AZD1419, once-weekly adaptive dosing (4mg, 1mg, 8mg)• Arm 2: placebo Inhaled (nebulised) administration Trial conducted in EU	<ul style="list-style-type: none">• Time to loss of asthma control	<ul style="list-style-type: none">• FPCD: Q4 2016• LPCD: Q4 2017• Data readout: Q4 2018

Oncology

CVRM

Respiratory

Other



AZD8154 (PI3K γ δ inhibitor)

Asthma

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03436316	Healthy subjects	54	SAD A Phase 1 trial to assess the safety, tolerability and pharmacokinetics of AZD8154 following single dose administration in healthy subjects	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters	• FPCD: Q3 2018

Oncology

CVRM

Respiratory

Other



AZD8871 (MABA, inhaled)

Respiratory

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa NCT03645434	Patients with chronic obstructive pulmonary disease (COPD)	72	Randomised, double-blind, placebo and active-controlled crossover trial. Eligible patients will be randomized 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 Data anticipated: H2 2019



AZD9567 (SGRM, oral)

Respiratory

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 Rheumatoid Arthritis (RA)	40	A Phase II, 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: <p>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 sc/i.v. biological DMARDs (Disease-modifying antirheumatic drugs)</p> 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



MEDI3506 (IL-33 mAb) ligand

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SDE / MDE) NCT03096795	SDE: Healthy subjects with mild atopy	SDE: 56	SDE: <ul style="list-style-type: none"> 7 sequential placebo-controlled single dose cohorts (active N=6 / placebo N = 2 within each cohort) Dose levels: 1mg SC, 3 mg SC, 10 mg SC, 30 mg SC, 100 mg SC, 300 mg SC and 300 mg IV 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2017 LPCD: H1 2019 Data anticipated: H2 2019
	J-SD: Healthy Japanese subjects	J-SD: 8	J-SD <ul style="list-style-type: none"> A single placebo-controlled single dose cohort (active N=6 / placebo N = 2 within cohort) Dose level: 300 mg IV 		
	MDE: COPD	MAD: 24	MDE: <ul style="list-style-type: none"> 3 sequential placebo-controlled multiple dosing cohorts (active N=6 / placebo N = 2 within each cohort) Dose levels: 30 mg SC, 100 mg SC and 300 mg SC 		



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 Proof of Mechanism (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 Phase I, 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	Moderate to severe plaques psoriasis	25 Planned 5 Completed 9 Dosed	A randomised, double-blind, placebo-controlled, multi-centre, parallel group Phase 1b study, designed to evaluate the pharmacodynamic effects, clinical efficacy and safety of AZD0284 compared with placebo as measured by the relative change from baseline in Psoriasis Area Severity Index (PASI score), other disease assessments of involved body surface area (BSA), static physicians global assessment score (sPGA), pruritis and biomarkers associated with the mechanism of disease and AZD0284	<ul style="list-style-type: none"> Reduction from baseline to the end of 4 weeks treatment, in gene expression level of IL-17A and CCL20 relative to placebo Change (percent improvement) in Psoriasis Area and Severity Index score(PASI) compared to placebo Safety and tolerability and PK following 4 weeks oral administration with single ascending dose 	<ul style="list-style-type: none"> FPCD:Q4 2017 LPCD: Q2 2018 The trial was temporarily suspended ~5 months due to preclinical findings. However, whilst the intention was to re-open the DERMIS study, in the meantime, and for portfolio and prioritization reasons, a decision was taken in Q3 2018 to end the study.



AZD5634 (epithelial NaC inhibitor)

Cystic fibrosis

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02679729	Healthy subjects	Part A: 57 Part B: 6	SAD A Phase I, 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	Primary endpoint: <ul style="list-style-type: none">• Safety and tolerability Secondary endpoint: <ul style="list-style-type: none">• PK parameters	<ul style="list-style-type: none">• FPCD: Q1 2016• LPCD: Q3 2016• Data readout: Q2 2017
Phase Ib NCT02950805	Patients with cystic fibrosis	10	PoM A Phase Ib, randomised, blinded, placebo-controlled cross-over trial to assess the effect of AZD5634 on mucociliary clearance as well as safety, tolerability and pharmacokinetic parameters following single inhaled dose administration to patients with cystic fibrosis	Primary endpoint: <ul style="list-style-type: none">• Mucociliary clearance (MCC) Secondary endpoint: <ul style="list-style-type: none">• PK parameters• Safety and tolerability	<ul style="list-style-type: none">• FPCD: Q2 2017• LPCD Q1 2018• Data readout: Q2 2018

Oncology

CV/RM

Respiratory

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 Intensive Care Unit (ICU)	213	<ul style="list-style-type: none">Placebo-controlled, single-dose, dose-rangingRoute of administration: intravenous	<ul style="list-style-type: none">Efficacy and safety	<ul style="list-style-type: none">FPCD: Q4 2014Data readout: Q4 2018
Phase IIb NCT02878330	Anti-Respiratory Syncytial Virus mAb-YTE (MEDI8897)	29-35 WK GA (Gestational age) infants	1,453	<ul style="list-style-type: none">Randomised, double-blind, placebo-controlled trialRoute of administration: IM	<ul style="list-style-type: none">Safety and efficacy	<ul style="list-style-type: none">FPCD: Q4 2016Data 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-rangingRoute of administration: intravenous	<ul style="list-style-type: none">Efficacy and safety	<ul style="list-style-type: none">FPCD: Q2 2016Data anticipated: 2020

Oncology

CVRM

Respiratory

Other



MEDI0700 - AMG 570 (Anti-B7RP-1 mAb/BAFF)

Systemic lupus erythematosus (SLE)

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase Ia NCT02618967 Partnered	Healthy volunteers	56	Single Ascending Dose <ul style="list-style-type: none">• Arm 1: MEDI0700 administered as single SC dose• Arm 2: Dose levels of Placebo administered as single SC dose	<ul style="list-style-type: none">• Safety and tolerability• PK/PD	<ul style="list-style-type: none">• FPCD: Q1 2016• Data readout: Q3 2018

Oncology

CVRM

Respiratory

Other



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	40	<ul style="list-style-type: none">SADUp to 5 IV 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 2017Data anticipated: H2 2019

Oncology

CVRM

Respiratory

Other



MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Approved medicines

Late-stage development

Early development

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02036645	Alzheimer's disease & healthy elderly	121	<ul style="list-style-type: none">SAD & MADUp to 10 IV cohorts are planned vs. placebo2 SC cohorts are planned vs. placebo US only	<ul style="list-style-type: none">Safety, tolerability	<ul style="list-style-type: none">FPCD: Q2 2014LPCD: Q2 2016Data readout: Q4 2016

Oncology

CVRM

Respiratory

Other



MEDI7352 (NGF TNF bispecific mAb)

Osteoarthritis pain

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02508155	Painful osteoarthritis of the knee	160	<ul style="list-style-type: none"> SAD & MAD Up to 10 IV cohorts are planned vs. placebo 2 SC 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 2016 Data anticipated: H2 2019
Phase II NCT03755934	Painful diabetic neuropathy	271	<ul style="list-style-type: none"> Multiple dose study Up to 4 IV cohorts are planned vs. placebo Europe and Russia only	<ul style="list-style-type: none"> Dose response, safety, tolerability, PK, PD 	<ul style="list-style-type: none"> FPCD Q4 2018 Data anticipated: 2020+



Clinical trials appendix

Q1 2019 results update

