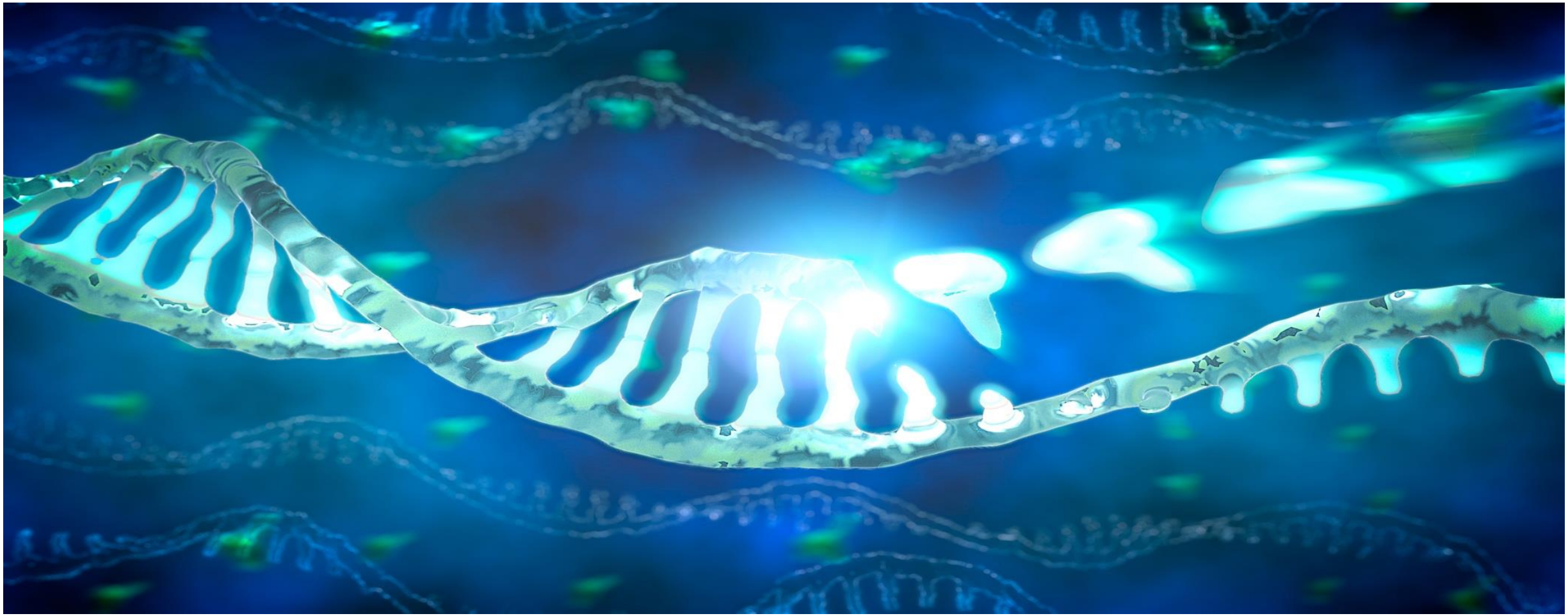
Clinical trials appendix
Q1 2020 results update

AstraZeneca
What science can do



Movement since Q4 2019 update

New to Phase I	New to Phase II	New to Pivotal trial	New to registration
NME **AZD2373** Podocyte health nephropathy **AZD7648**[#] DNAPK haematological and solid tumours **IPH5201**[#] CD39 solid tumours	**Lifecycle management** **Enhertu**[#] **DESTINY-Gastric02** HER2 targeting antibody drug conjugate HER2-positive gastric cancer that cannot be surgically removed or has spread		
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from registration**
	NME **MEDI3902** Psl/PcrV bispecific mAb prevention of nosocomial *Pseudomonas aeruginosa* pneumonia	**NME** **Imfinzi**[#] **+ tremelimumab DANUBE** PD-L1 mAb + CTLA-4 mAb 1st-line bladder cancer	**NME** ***Koselugo***[#] **(selumetinib) SPRINT**[¶ 1] MEK inhibitor paediatric neurofibromatosis type-1 **Lifecycle management** ***Imfinzi***[#] **+ SoC CASPIAN** [1] PD-L1 mAb + SoC 1st-line extensive-stage small cell lung cancer

¶ Registrational Phase II/III trial [#] Partnered and/or in collaboration [1] Submission approved

Q1 2020 new molecular entity (NME)[1] pipeline

Phase I

20 new molecular entities

- AZD0466 BCL2/xL haematological and solid tumours
- AZD1390 glioblastoma
- AZD4573 CDK9 haematological malignancies
- AZD5153 BRD4 haematological and solid tumours
- AZD5991 MCL1 haematological malignancies
- AZD7648# DNAPK solid and haematological tumours
- AZD9496 SERD ER+ breast
- *Calquence*+ceralasertib BTK+ATR haematological tumours
- *Calquence*+danvatirsen BTK+STAT3 haematological malignancies
- *Imfinzi*#+adavosertib# PD-L1+Wee1 solid tumours
- *Imfinzi*#+RT (platform) CLOVER PD-L1+RT HNSCC NSCLC SCLC
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 solid tumours
- *Imfinzi*#+tremelimumab+chemo PD-L1+CTLA-4 1L PDAC oesophageal SCLC
- *Imfinzi+Koselugo* (selumetinib)# PD-L1+MEK solid tumours
- IPH5201# CD39 solid tumours
- MEDI1191 IL12 mRNA solid tumours
- MEDI2228 BCMA ADC multiple myeloma
- MEDI5083 CD40 ligand fusion protein solid tumours
- MEDI5395 rNDV GMCSF solid tumours
- oleclumab+*Tagrisso* CD73+EGFR EGFRm NSCLC

Phase II

25 new molecular entities

- adavosertib# Wee1 ovarian cancer, solid tumours
- AZD2811 Aurora solid tumours, haematological malignancies
- AZD4635 A2aR inhibitor prostate cancer
- AZD9833 SERD ER+ breast
- capivasertib# AKT breast
- capivasertib# AKT prostate
- *Imfinzi*# (platform) COAST PD-L1+multiple novel ONC therapies NSCLC
- *Imfinzi*# (platform) NeoCOAST PD-L1++multiple novel ONC therapies NSCLC
- *Imfinzi*#+AZD4635 PD-L1+A2aR prostate cancer
- *Imfinzi*#+AZD5069 or Imfinzi#+ danvatirsen# PD-L1+(CXCR2 or STAT3) HNSCC bladder NSCLC
- *Imfinzi*#+*Lynparza*# ORION PD-L1+PARP 1L mNSCLC
- *Imfinzi*#+MEDI0457# PD-L1+DNA HPV vaccine HNSCC
- *Imfinzi*#+monalizumab# PD-L1+NKG2a solid tumours
- *Imfinzi*#+oleclumab PD-L1+CD73 solid tumours
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 gastric cancer
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 biliary tract oesophageal
- *Imfinzi+Lynparza*# BAYOU PD-L1+PARP bladder
- *Lynparza*#+adavosertib# PARP+Wee1 solid tumours
- *Lynparza*#+AZD6738 VIOLETTE PARP+ATR breast
- *Lynparza*#+*Imfinzi* MEDIOLA PARP+PD-L1 ovarian breast gastric SCLC
- MEDI5752 PD-1/CTLA-4 solid tumours
- oleclumab+AZD4635 CD73+A2aR prostate cancer
- oleclumab+chemo or Imfinzi#+ oleclumab+chemo CD73+chemo or PD-L1+CD73+chemo pancreatic
- *Tagrisso* combo# TATTON EGFR+PD-L1/MEK/MET NSCLC
- *Tagrisso*+savolitinib# SAVANNAH EGFR+MET advanced EGFRm NSCLC

Phase III

7 new molecular entities

- capivasertib+chemotherapy CAPItello-290 AKT+chemotherapy mTNBC 1L
- *Imfinzi*#+/-tremelimumab+chemo POSEIDON PD-L1+/-CTLA-4+SoC 1L NSCLC
- *Imfinzi*#+/-tremelimumab+CRT ADRIATIC PD-L1+/-CTLA-4+CRT LS-SCLC
- *Imfinzi*#+tremelimumab HIMALAYA PD-L1+CTLA-4 1L HCC
- *Imfinzi*#+tremelimumab KESTREL PD-L1+CTLA-4 1L HNSCC
- *Imfinzi*#+tremelimumab+SoC NILE PD-L1+CTLA-4+SoC 1L urothelial cancer
- *Lynparza*#+*Imfinzi*#+bevacizumab DUO-O PARP+PD-L1+VEGF 1L ovarian

Under review

0 new molecular entities

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

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

Oncology

Precision medicine approach being explored

Q1 2020 new molecular entity (NME)[1] pipeline

Phase I

17 new molecular entities

- AZD0284 RORg psoriasis / respiratory
- AZD0449 Inhaled JAK inhibitor asthma
- AZD1402# inhaled IL-4Ra asthma
- AZD2373 Podocyte health nephropathy
- AZD2693 nonalcoholic steatohepatitis
- AZD4041# orexin 1 receptor antagonist opioid use disorder
- AZD5634 inhaled ENaC cystic fibrosis
- AZD6615 hypercholesterolemia CV disease
- AZD8154 Inhaled PI3Kgd asthma
- AZD8233 hypercholesterolemia cardiovascular
- AZD9977 MCR cardiovascular
- MEDI0618# PAR2 antagonist mAb OA pain
- MEDI1341# alpha synuclein parkinson's disease
- MEDI1814# amyloidβ alzheimer's disease
- MEDI5117# China IL6 YTE rheumatoid arthritis
- MEDI6570 LOX-1 CV disease
- MEDI7219 anti-diabetic type-2 diabetes

Phase II

20 new molecular entities

- abediterol# LABA asthma / COPD
- anifrolumab# Type I IFN receptor SLE SC
- anifrolumab# Type I IFN receptor lupus nephritis
- AZD4831 MPO HFpEF
- AZD5718 FLAP coronary artery disease
- velsecorat (AZD7594) Inhaled SGRM asthma / COPD
- AZD7986# DPP1 COPD
- AZD8601# VEGF-A cardiovascular
- navafenterol (AZD8871)# MABA COPD
- AZD9567 SGRM RA / respiratory
- cotadutide GLP-1/glucagon type-2 diabetes / obesity / NASH
- MEDI3506 Diabetic kidney disease
- MEDI3506 IL33 AD / COPD
- MEDI5884# cholesterol modulation cardiovascular
- MEDI6012 LCAT cardiovascular
- MEDI7352 NGF/TNF OA pain / painful diabetic neuropathy
- suvratoxumab α-Toxin Staphylococcus pneumonia
- tezepelumab# TSLP atopic dermatitis
- tezepelumab# TSLP COPD
- verinurad URAT-1 chronic kidney disease

Phase III

4 new molecular entities

- anifrolumab# TULIP Type I IFN receptor SLE
- nirsevimab# RSV mAb-YTE passive RSV immunisation
- PT027 ICS/SABA asthma
- tezepelumab# NAVIGATOR SOURCE TSLP severe uncontrolled asthma

Under review

0 new molecular entities

[1] Includes novel combinations and additional indications for assets where the lead is not yet launched
Partnered and/or in collaboration; ¶ Registrational Phase II/III trial

BioPharmaceuticals

Precision medicine approach being explored

Q1 2020 lifecycle management (LCM)[1] pipeline

Phase I
1 Project

- *Imfinzi*#+azacitidine# PD-L1+azacitidine MDS

Phase II
9 Projects

- *Enhertu*# ADC NSCLC
- *Enhertu*# DESTINY-CRC-01 ADC colorectal cancer
- *Enhertu*# DESTINY-Gastric02 ADC gastric
- *Imfinzi*# PD-L1 solid tumours
- *Imfinzi*# (platform) BEGONIA PD-L1 1L mTNBC
- *Imfinzi*# (platform) MAGELLAN PD-L1 1L mNSCLC
- *Imfinzi*+FOLFOX+bevacizumab (platform) COLUMBIA1 PD-L1+chemo+VEGF+multiple novel ONC therapies 1L MSS-CRC
- *Lynparza*# (basket) MK-7339-002 / LYNK002 PARP HRRm cancer
- *Lynparza*#+cediranib CONCERTO PARP+VEGF recurrent Pt-R ovarian

Phase III
24 Projects

- *Calquence*# BTK inhibitor 1st line MCL
- *Calquence*# BTK inhibitor r/r CLL, high risk
- *Calquence*#+venetoclax+ obinutuzumab BTK+BCL-2+anti-CD20 1st line CLL
- *Enhertu*# DESTINY-Breast02 ADC breast
- *Enhertu*# DESTINY-Breast03 ADC breast
- *Enhertu*# DESTINY-Breast04 ADC breast
- *Enhertu*¶# DESTINY-Gastric01 ADC gastric
- *Imfinzi*# CALLA PD-L1 adj. locally advanced cervical cancer
- *Imfinzi*# PEARL PD-L1 1L metastatic NSCLC
- *Imfinzi*# post-SBRT PACIFIC-4 PD-L1 post-SBRT stage I/II NSCLC
- *Imfinzi*# POTOMAC PD-L1 non muscle invasive bladder cancer
- *Imfinzi*#+CRT PACIFIC-2 PD-L1+CRT NSCLC
- *Imfinzi*#+CRT PACIFIC-5 (China) PD-L1+CRT locally-advanced stage III NSCLC
- *Imfinzi*#+CTx neoadjuvant AEGEAN PD-L1+CTx locally-advanced stage I-III NSCLC
- *Imfinzi*#+CTx NIAGARA PD-L1+CTx muscle invasive bladder cancer
- *Imfinzi*#+CTx TOPAZ-1 PD-L1+CTx 1L biliary tract cancer
- *Imfinzi*#+VEGF EMERALD-2 PD-L1+VEGF adjuvant HCC
- *Imfinzi*#+VEGF+TACE EMERALD-1 PD-L1+VEGF+TACE locoregional HCC
- *Lynparza*# OlympiA PARP gBRCA adjuvant breast
- *Lynparza*# SOLO-3 PARP BRCAm PSR ovarian
- *Lynparza*+abiraterone# PROpel PARP+NHA prostate cancer
- *Tagrisso* ADAURA EGFR adj. EGFRm NSCLC
- *Tagrisso* LAURA EGFRm locally advanced unresectable NSCLC
- *Tagrisso*+chemo FLAURA2 EGFR+chemo 1L adv EGFRm NSCLC

Under review
1 Project

- *Lynparza*# PROfound PARP prostate cancer

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

Oncology

Precision medicine approach being explored

Q1 2020 lifecycle management (LCM)[1] pipeline

Phase I	Phase II	Phase III	Under review
0 Projects	2 Projects	10 Projects	4 Projects
	Breztri LABA/LAMA/ICS asthma	*Brilinta/Brilique* HESTIA P2Y12 paeds w/ sickle cell	*Brilinta/Brilique* THEMIS P2Y12 diabetes & CAD outcomes
	roxadustat# HIF-PH inhibitor chemo induced anaemia	*Brilinta/Brilique* THALES P2Y12 stroke	*Farxiga/Forxiga* DAPA-HF SGLT2 HFrEF
		Farxiga/Forxiga Dapa-CKD SGLT2 CKD	*Nexium* (CN only) stress ulcer prophylaxis
		Farxiga/Forxiga DELIVER SGLT2 HFpEF	*Symbicort* SYGMA as needed in mild asthma
		Farxiga/Forxiga DETERMINE-Preserved SGLT2 HFpEF	
		Farxiga/Forxiga DETERMINE-Reduced SGLT2 HFrEF	
		Fasenra MANDARA IL-5R EGPA	
		Fasenra# OSTRO, ORCHID IL-5R nasal polyposis	
		Fasenra# RESOLUTE IL-5R COPD	
		roxadustat# HIFPH anaemia MDS	

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

BioPharmaceuticals

Precision medicine approach being explored

Estimated key regulatory submission acceptances

	H1 2020	H2 2020	2021	2021+	
NME	*Imfinzi* +/- tremelimumab SCLC CASPIAN (China)	*Enhertu* DESTINY-Breast01 (EU)	*Imfinzi* +/- tremelimumab NSCLC POSEIDON	capivasertb + CTx 1L mTNBC CAPItello-290	*Lynparza* +*Imfinzi* + bevacizumab ovarian DUO-O
NME		anifrolumab SLE TULIP	*Imfinzi* + tremelimumab HNSCC KESTREL	nirsevimab passive RSV immunisation	*Imfinzi* + tremelimumab+ SoC urothelial NILE
NME			*Imfinzi* + tremelimumab HCC HIMALAYA	*Fasenra* severe asthma (China)	*Imfinzi* + tremelimumab + CRT LDS-SCLC ADRIATIC
NME			tezepelumab asthma NAVIGATOR		
NME			PT027 asthma		
LCM	*Enhertu* gastric cancer	*Lynparza* ovarian SOLO-3	*Brilinta* paeds w/ sickle cell HESTIA	*Calquence* 1L MCL ECHO	*Imfinzi* + CRT NSCLC PACIFIC-5 (China)
LCM	*Brilinta* stroke THALES	*Lynparza* pancreatic 1L POLO (China)	*Duaklir* Genuair COPD (China)	*Calquence* r/r CLL, high risk ELEVATE-RR	Imfinzi + VEGF + TACE locoregional HCC EMERALD-1
LCM	*Symbicort* mild astha (EU) SYGMA	*Tagrisso* EGFrm NSCLC ADAURA	*Fasenra* nasal polyposis OSTRO	*Calquence* + venetoclax + obinutuzumab 1L CLL AMPLIFY	*Imfinzi* + VEGF adjuvant HCC EMERALD-2
LCM			*Farxiga* CKD DAPA-CKD	*Enhertu* DESTINY-Breast03	*Tagrisso* locally adv. unresectable NSCLC LAURA
LCM			*Farxiga* HFrEF / HFpEF DETERMINE	*Enhertu* DESTINY-Breast04	*Tagrisso* + CTx EGFRm NSCLC FLAURA2
LCM			*Enhertu* DESTINY-Breast02	*Imfinzi* cervical CALLA	*Bydureon Bcise* type-2 diabetes (China)
LCM			*Imfinzi* adjuvant NSCLC BR.31	*Imfinzi* + CTx biliary tract TOPAZ-1	*Farxiga* HFpEF DELIVER
LCM			*Imfinzi* NSCLC PEARL	*Imfinzi* neoadjuvant NSCLC AEGEAN	*Fasenra* COPD RESOLUTE
LCM			*Imfinzi* + CRT NSCLC PACIFIC-2	*Imfinzi* non muscle invasive bladder POTOMAC	roxadustat anemia in MDS
LCM			*Lynparza* breast OLYMPIA	*Imfinzi* + chemo muscle invasive bladder NIAGARA	*Fasenra* nasal polyposis ORCHID (China / Japan)
LCM			*Lynparza* + abiraterone prostate PROPEL	*Imfinzi* post-SBRT NSCLC PACIFIC-4	*Fasenra* EGPA MANDARA

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

Oncology

BioPharmaceuticals

Designations

4 Accelerated approvals

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

13 Breakthrough / PRIME[1] / Sakigake[2]

- *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)
- nirsevimab (MEDI8897) RSV mAB (US)
- nirsevimab (MEDI8897) RSV mAB (EU)[1]
- selumetinib NFI type 1 SPRINT (US)
- *Enhertu* DESINTY-BREAST01 (US)
- *Calquence* CLL (US)
- *Enhertu* gastric cancer (JP)[2]

11 Fast Track

- MEDI3902 Psl-PcrV pneumo Px (US)
- savratoxumab Staph HAP (US)
- *Imfinzi* NSCLC (US)
- nirsevimab (MEDI8897) RSV mAB (US)
- *Imfinzi* HNSCC HAWK (US)
- anifrolumab SLE (US)
- *Lynparza* ovarian cancer SOLO-2 (US)
- *Tagrisso* EGFRm T790M NSCLC (CN)
- *Farxiga* HFrEF (US)
- *Farxiga* chronic kidney disease (US)
- cotadutide non-alcoholic steatohepatitis (US)

29 Priority Review / RTOR[3]

- *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)
- *Breztri Aerosphere* (PT010) COPD (CN)
- *Tagrisso* NSCLC 1L FLAURA (CN)
- *Breztri Aerosphere* (PT010) (CN)
- *Lokelma* hyperkalaemia (CN)
- *Lynparza* pancreatic 1L (US)
- *Enhertu* DESINTY-BREAST01 (US)
- *Farxiga* HF (DAPA-HF) (US)
- *Imfinzi* +/-treme+SOC SCLC 1L CASPIAN (US)
- *Lynparza* prostate PROfound (US)
- *Lynparza* +Avastin ovarian 1L PAOLA-1 (US)
- *Koselugo* (selumetinib) NFI type 1 SPRINT (US)
- *Calquence* CLL ELEVATE-TN, ASCEND[3] (US)

27 Orphan

- *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 1L (EU)
- selumetinib thyroid cancer ASTRA (US)
- *Lynparza* breast cancer OLYMPIAD (JP)
- *Lynparza* ovarian cancer SOLO-2 (JP)
- *Koselugo* (selumetinib) NFI type 1 SPRINT (US)
- *Koselugo* (selumetinib) NFI type 1 SPRINT (EU)
- *Lynparza* pancreatic cancer POLO (US)
- *Fasenra* EGPA (US)
- *Fasenra* HES (US)
- saracatinib IPF (US)
- *Imfinzi* +/-treme+SOC SCLC 1L CASPIAN (US)
- *Fasenra* EoE (US)
- *Imfinzi* +treme HCC 1L HIMALAYA (US)
- *Lynparza* pancreatic cancer POLO (JP)

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

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

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

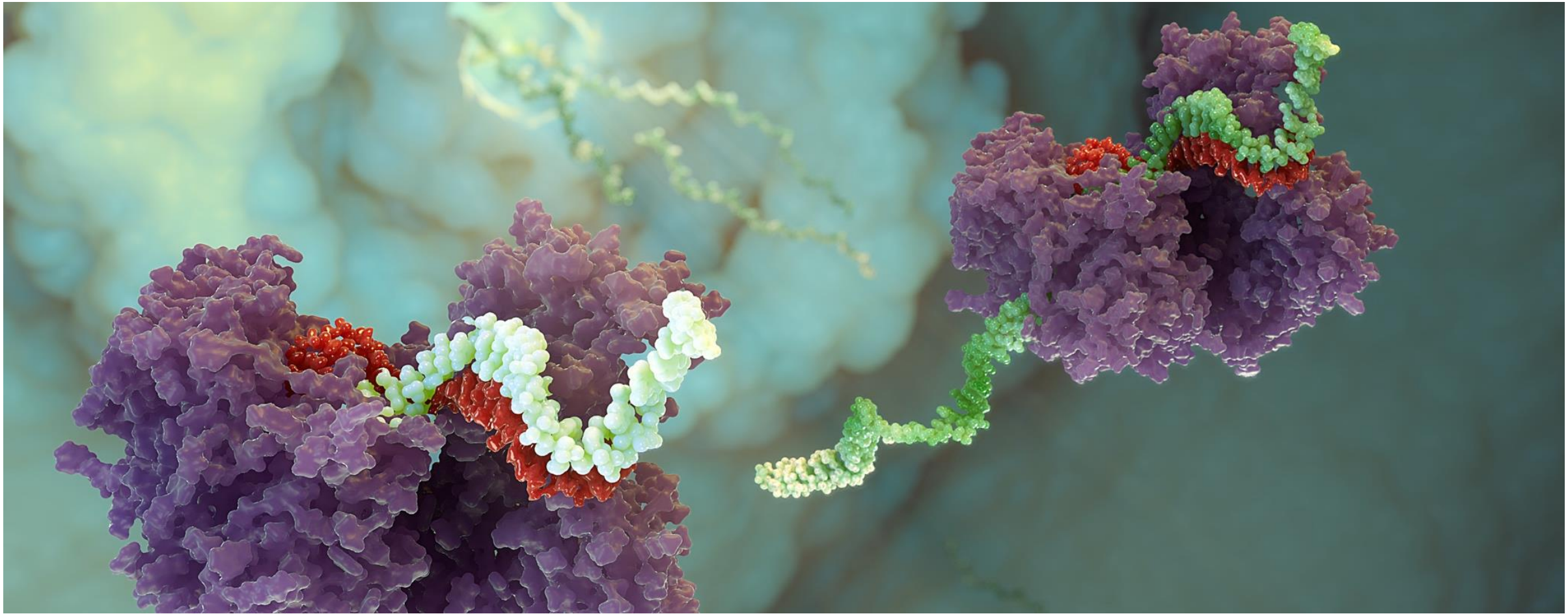
PRIORITY REVIEW DESIGNATION is the US FDA's goal to take action on an application within 6 months.

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

Oncology BioPharmaceuticals

AstraZeneca
What science can do

Oncology - approved medicines and late-stage pipeline



Tagrisso (highly-selective, irreversible EGFRi)

NSCLC

Trial	Population	Patients	Design	Endpoints	Status
Phase III ADAURA NCT02511106	Adjuvant EGFRm NSCLC	682	• Arm 1: *Tagrisso* QD following complete tumour resection, with or without chemo • Arm 2: placebo Global trial - 25 countries	• Primary endpoint: DFS • Secondary endpoints: DFS Rate, OS, OS Rate, QoL	• FPCD: Q4 2015 • LPCD: Q1 2019 • Data readout: Q1 2020 • Trial unblinded due to efficacy
Phase III LAURA NCT03521154	Maintenance therapy in patients with locally advanced, unresectable EGFRm Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy	200	• Arm 1: *Tagrisso* • Arm 2: placebo Global trial - 11 countries	• Primary endpoint: PFS (BICR) • Secondary endpoints: CNS PFS, OS, DoR, ORR, DCR	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III ASTRIS NCT02474355	Real world setting in adult patients with advanced or metastatic, EGFRm T790M+ NSCLC	3,020	Single-arm trial - *Tagrisso* Global trial - 16 countries	• Primary endpoints: OS and safety • Secondary endpoint: PFS	• FPCD: Q3 2015 • LPCD: Q4 2017
Phase II ELIOS NCT03239340	EGFR TKI treatment-naïve patients with locally-advanced or metastatic EGFRm NSCLC	150	Single arm trial - *Tagrisso* Global trial - five countries	• 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	• FPCD: Q2 2018
Phase I ODIN-BM NCT03463525	Patients with EGFRm NSCLC with brain metastases	8	Single-arm trial - *Tagrisso*	• Primary Endpoints: assessments of brain standard uptake value (SUV) and pharmacokinetics (PK) • Secondary endpoints: PK	• FPCD: Q4 2018

Tagrisso (highly-selective, irreversible EGFRi)

NSCLC, combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III **FLAURA2** **NCT04035486**	1st-line EGFRm NSCLC	586	Arm 1: *Tagrisso* plus Pemetrexed/Carboplatin or Pemetrexed/Cisplatin Arm 2: *Tagrisso* Global trial – 5+ countries	• Primary endpoint: PFS • Secondary endpoints: OS, LOS, ORR DoR, Depth of response, PFS2. QoL, PK	• FPCD: Q4 2019 • Data anticipated: 2021+
Phase II **ORCHARD** **NCT03944772**	Advanced EGFRm NSCLC patients who have progressed on first line *Tagrisso* treatment	150	Modular design platform trial: • Module 1: *Tagrisso* + savolitinib • Module 2: *Tagrisso* + gefitinib • Module 3: *Tagrisso* + necitumumab • Module 4: *carboplatin* + *pemetrexed* + *Imfinzi* • No intervention: observational cohort – Global trial - 8 countries	• Primary endpoint: ORR • Secondary endpoints: PFS, DoR, OS, safety and tolerability	• FPCD: Q3 2019 • Data anticipated: 2021+
Phase II **SAVANNAH** **NCT03778229**	EGFRm / MET+, locally advanced or metastatic NSCLC who have progressed following treatment with *Tagrisso*	172	• Single arm trial: *Tagrisso* + savolitinib Global trial	• Primary endpoint: ORR • Secondary endpoints include PFS, DoR and OS	• FPCD Q1 2019 • Data anticipated: 2021+
Phase Ib **TATTON** **NCT02143466**	Advanced EGFRm NSCLC TKI failure	344	• Arm 1: *Tagrisso* + *Imfinzi* • Arm 2: *Tagrisso* + savolitinib • Arm 3: *Tagrisso* + selumetinib Enrolment to *Tagrisso* + *Imfinzi* arm will not restart Global trial	• Safety, tolerability, pharmacokinetics and preliminary anti-tumour activity	• FPCD: Q3 2014 • Data anticipated: H2 2020

Imfinzi (PD-L1 mAb)

NSCLC, early disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III **AEGEAN** **NCT03800134**	Neoadjuvant NSCLC patients Stage II and III resected NSCLC (incl. EGFR/ALK positive)	800	• Arm 1: *Imfinzi* + platinum-based chemo • Arm 2: placebo + platinum-based chemo	Primary endpoint: • mPR, EFS Secondary endpoint • pCR	• FPCD: Q1 2019 • Data anticipated: 2021+
Phase III **ADJUVANT BR.31** **NCT02273375** **Partnered**	Adjuvant NSCLC patients Ib (≥4cm) – stage IIIa resected NSCLC (incl. EGFR/ALK positive)	1,360	• Arm 1: *Imfinzi* mg/kg i.v. Q4W x 12m • Arm 2: placebo Global trial	Primary endpoint: • DFS Secondary endpoint: • OS	• FPCD: Q1 2015 • LPCD Q1 2020 • Data anticipated: 2021
Phase III **PACIFIC-2** **NCT03519971**	Unresected, locally-advanced NSCLC	300	• Arm 1: *Imfinzi* i.v. Q4W + chemo/RT • Arm 2: placebo + chemo/RT ex US global trial	Primary endpoint: • PFS • ORR Secondary endpoint: • OS	• FPCD: Q2 2018 • LPCD: Q3 2019 • Data anticipated: H2 2020
Phase III **PACIFIC-4** **NCT03833154**	*Imfinzi* following SBRT in unresected, Stage I/II NSCLC	630	• Arm 1: *Imfinzi* i.v. Q4W following definitive SBRT • Arm 2: placebo following definitive SBRT	Primary endpoint: • PFS Secondary endpoint: • OS	•FPCD: Q2 2019 •Data anticipated: 2021+
Phase III **PACIFIC-5** **NCT03706690**	Unresected, locally-advanced NSCLC	360	• Arm 1: *Imfinzi* i.v. Q4W following chemo/RT • Arm 2: placebo following chemo/RT ex US global trial, China focus	Primary endpoint: • PFS Secondary endpoint: • OS	• FPCD: Q1 2019 • Data anticipated: 2021+
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: • Subtrial A: *Imfinzi* (non-match for other biomarker driven subtrials) i.v. Q2W single arm *Imfinzi* Phase II only • Subtrial B: PI3K inhibitor vs. docetaxel • Subtrial C: CDK4/6 inhibitor vs, docetaxel • Subtrial D: AZD4547 (FGFR inhibitor) vs. docetaxel • Subtrial E: C-MET/HGFR Inhibitor + erlotinib vs. erlotinib	Primary endpoints: • ORR • PFS • OS	• FPCD: Q2 2014 • Data anticipated: 2021+

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

Lung cancer, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III PEARL NCT03003962	NSCLC 1L	650	• Arm 1: *Imfinzi* Q4W • Arm 2: chemotherapy Asia trial	Primary endpoint: • OS	• FPCD: Q1 2017 • LPCD: Q1 2019 • Data anticipated: 2021+
Phase III POSEIDON NCT03164616	NSCLC 1L	1,000	• Arm 1: *Imfinzi* + chemo • Arm 2: *Imfinzi* + tremelimumab + chemo • Arm 3: SoC	Primary endpoint: • OS • PFS	• FPCD: Q2 2017 • LPCD: Q4 2018 • Data readout: Q4 2019 • PFS primary endpoint met • OS data anticipated: 2021
Phase II MAGELLAN NCT03819465	NSCLC 1L	200	• Arm A1: *Imfinzi* • Arm A2: *Imfinzi* + danvatirsen • Arm A3: *Imfinzi* + oleclumab • Arm B1: *Imfinzi* + Investigator's choice of chemo • Arm B2: *Imfinzi* + danvatirsen + Investigator's choice of chemo • Arm B3: *Imfinzi* + oleclumab + Investigator's choice of chemo	Primary endpoint: • Safety & tolerability Secondary endpoint: • ORR, DoR, PFS, OS, PK, ADA	• FPCD: Q1 2019 • Data anticipated: H2 2020
Phase III ADRIATIC NCT03703297	Limited stage SCLC 1L following platinum-based concurrent chemoradiation therapy	600	• Arm 1: *Imfinzi* + tremelimumab (4 doses) • Arm 2: *Imfinzi* • Arm 3: placebo	Primary endpoints: • PFS • OS	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III CASPIAN NCT03043872	Extensive stage SCLC 1L	795	• Arm 1: *Imfinzi* + tremelimumab + EP (carboplatin or cisplatin + etoposide) • Arm 2: *Imfinzi* + EP (carboplatin or cisplatin + etoposide) • Arm 3: EP (carboplatin or cisplatin + etoposide)	Primary endpoint: • OS	• FPCD: Q1 2017 • LPCD: Q2 2018 • Data readout: Q2 2019 • OS Primary endpoint met for *Imfinzi* monotherapy • OS primary endpoint not met for *Imfinzi* + tremelimumab
Phase II BALTIC NCT02937818	SCLC	80	• Arm A: *Imfinzi* + tremelimumab Q4W • Arm B: adavosertib and carboplatin BID • Arm C: AZD6738 and *Lynparza*	• Primary endpoint: ORR	• FPCD: Q4 2016 • Data anticipated: 2021

Imfinzi (PD-L1 mAb)

Other cancers, early disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III POTOMAC NCT03528694	Non-muscle invasive bladder cancer	975	• Arm 1: BCG (Induction + maintenance) • Arm 2: *Imfinzi* + BCG (Induction only) • Arm 3: *Imfinzi* + BCG (Induction + maintenance)	Primary endpoints: • DFS	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III NIAGARA NCT03732677	Muscle-invasive bladder cancer	960	• Arm 1: *Imfinzi* in combination with gemcitabine + cisplatin, *Imfinzi* maintenance • Arm 2: gemcitabine + cisplatin	Coprimary endpoints: • pCR • EFS	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III EMERALD-1 NCT03778957	Locoregional HCC	600	• Arm A: TACE in combination with *Imfinzi* • Arm B: TACE in combination with *Imfinzi* + bevacizumab • Arm C: TACE in combination with placebo	Primary endpoint PFS for Arm A vs Arm C Secondary endpoint PFS for Arm B vs Arm C , OS	• FPCD: Q1 2019 • Data anticipated: 2021
Phase III EMERALD-2 NCT03847428	Adjuvant therapy in HCC	888	• Arm 1: *Imfinzi* + bevacizumab • Arm 2: *Imfinzi* + placebo • Arm 3: placebo + placebo	Primary endpoint: • RFS for Arm 2 vs Arm 3 Secondary endpoint: • RFS Arm 1 vs Arm 3, OS, RFS at 24 mos	• FPCD: Q2 2019 • Data anticipated: 2021+

pCR = Pathologic Complete Response
EFS = event free survival

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

Other cancers, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III **DANUBE** **NCT02516241**	Cis-eligible and ineligible bladder cancer 1L	1,005	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: *Imfinzi* • Arm 3: SoC	Primary endpoints: • OS	• FPCD: Q4 2015 • LPCD: Q1 2017 • Data readout: Q1 2020 • Primary endpoints not met
Phase III **NILE** **NCT03682068**	Bladder cancer 1L	885	• Arm 1: *Imfinzi* + tremelimumab + SoC • Arm 2: *Imfinzi* + SoC • Arm 3: SoC	Primary endpoints: • PFS • OS	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III **KESTREL** **NCT02551159**	HNSCC 1L	823	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab • Arm 3: SoC	Primary endpoints: • OS	• FPCD: Q4 2015 • LPCD Q1 2017 • Data anticipated: 2021
Phase III **HIMALAYA** **NCT03298451**	HCC 1L	1,310	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: *Imfinzi* • Arm 3: sorafenib	Primary endpoint: • OS Secondary endpoint: • PFS, TTP, ORR	• FPCD: Q4 2017 • LPCD: Q4 2019 • Data anticipated: H2 2020
Phase II **NCT02527434**	Urothelial bladder cancer triple-negative breast cancer pancreatic ductal-adenocarcinoma	76	• Arm 1 tremelimumab (urothelial bladder cancer) • Arm 2 tremelimumab (triple-negative breast cancer) • Arm 3 tremelimumab (pancreatic ductal-adenocarcinoma)	Primary endpoint: • ORR Secondary endpoints: • Safety, DoR	• FPCD: Q4 2015 • Data readout: Q4 2018
Phase III **TOPAZ-1** **NCT03875235**	BTC 1L	474	• Treatment Arm 1 *Imfinzi* + gemcitabine + cisplatin • Treatment Arm 2 placebo + gemcitabine + cisplatin Global trial	Primary endpoint: • OS Secondary endpoint: • PFS, ORR, DoR	• FPCD Q2 2019 • Data anticipated: 2021+
Phase III **CALLA** **NCT03830866**	Locally advanced cervical cancer	714	• Arm 1 *Imfinzi* + EBRT + brachytherapy with platinum • Arm 2 placebo + EBRT + brachytherapy with platinum Global trial	Primary • PFS Secondary • OS, CR rate, DoR, ORR, safety/tolerability	• FPCD: Q1 2019 • Data anticipated: 2021+

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

Other cancers, advanced disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III STRONG **NCT03084471**	Advanced solid malignancies	1,200	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab	• Primary endpoint: Safety	• FPCD: Q2 2017 • Data anticipated: 2021+
Phase I Combination in Advanced Solid Tumours **NCT02658214**	Solid tumours	80	• Arm 2 SCLC: *Imfinzi* + tremelimumab + carboplatin + etoposide • Arm 3 TNBC: *Imfinzi* + tremelimumab + chemo • Arm 4 TNBC: *Imfinzi* + tremelimumab + chemo • Arm 5 GEJ: *Imfinzi* + tremelimumab + oxaliplatin + 5-FU + leucovorin • Arm 6 PDAC: *Imfinzi* + tremelimumab + chemo • Arm 7 ESSC: *Imfinzi* + tremelimumab + chemo	• Safety	• FPCD: Q1 2016 • LPCD: Q1 2019 • Data anticipated: 2021+
Phase I Immunotherapy in Combination With Chemoradiation in Patients With Advanced Solid Tumours **CLOVER** **NCT03509012**	HNSCC, NSCLC, SCLC	300	• HNSCC Arm 1 • NSCLC Arm 1 • NSCLC Arm 2 • NSCLC Arm 3 • SCLC Arm 2 • SCLC Arm 3 • SCLC Arm 4	• Safety	• FPCD: Q2 2018 • Data anticipated: 2021+
Phase II BEGONIA **NCT03742102**	mTNBC 1L	110	• Arm 1 *Imfinzi* + paclitaxel • Arm 2 *Imfinzi* + paclitaxel + capivasertib • Arm 4 *Imfinzi* + paclitaxel + danvatirsen • Arm 5 *Imfinzi* + paclitaxel + oleclumab Global trial	Primary endpoint: • Safety and tolerability Secondary endpoint: • ORR, PFS, DoR, OS, PK, ADA	• FPCD: Q1 2019 • Data anticipated: 2021

Lynparza (PARP inhibitor)

Ovarian and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III OlympiA NCT02032823 Partnered	*BRCA*m adjuvant breast cancer	1,836	• Arm 1: *Lynparza* BiD 12 month duration • Arm 2: placebo 12-month duration Global trial partnership with BIG and NCI/NRG	• Primary endpoint: invasive disease-free survival (IDFS) • Secondary endpoint: distant disease-free survival and OS	• FPCD: Q2 2014 • LPCD: Q2 2019 • Data anticipated: 2021
Phase III POLO NCT02184195	g*BRCA*m pancreatic cancer	154	• Arm 1: *Lynparza* tablets 300mg twice daily as maintenance therapy until progression • Arm 2: placebo tablets BID Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q1 2015 • LPCD: Q1 2019 • Data readout: Q1 2019 • Primary endpoint met
Phase III PROfound NCT02987543	Metastatic castration-resistant prostate cancer HRRm, 2L+	387	• Arm 1: *Lynparza* BID • Arm 2: physician's choice: enzalutamide 160mg once daily or abiraterone acetate 1,000mg once daily Global trial	• Primary endpoint: radiologic PFS • Secondary endpoints: ORR, Time to Pain Progression, OS	• FPCD: Q2 2017 • LPCD: Q4 2018 • Data readout : Q3 2019 • Primary endpoint met

Lynparza (PARP inhibitor)

Imfinzi combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III **DuO-O** **NCT03737643**	Advanced ovarian cancer 1L	1,056	Non t*BRCA*m (tumour BRCA) patients • Arm 1: bevacizumab • Arm 2: bevacizumab + *Imfinzi* • Arm 3: bevacizumab + *Imfinzi* + *Lynparza* tBRCAm patients • bevacizumab (optional) + *Imfinzi* + *Lynparza* Global trial	Primary endpoint: • PFS Secondary endpoints: • OS, PFS2	• FPCD: Q1 2019 • Data anticipated: 2021+
Phase II **ORION** **NCT03775486**	Stage IV NSCLC whose disease has not progressed following SoC chemo + *Imfinzi* Maintenance therapy 1L	250	• Arm 1: *Imfinzi* + *Lynparza* • Arm 2: *Imfinzi* + placebo Global trial	Primary endpoint: • PFS Secondary enpoints: • OS, ORR, DoR, PFS in HRRm, PK, ADA	• FPCD Q1 2019 • Data anticipated: 2021+
Phase II **BAYOU** **NCT03459846**	Platinum-Ineligible unresectable Stage IV urothelial cancer	154	• Arm 1: *Imfinzi* + *Lynparza* • Arm 2: *Imfinzi* + placebo Global trial	• Primary endpoint: PFS • Secondary endpoints: OS, DoR, ORR, PFS in HRRm, PFS6, PK, ADA, PRO	• FPCD: Q2 2018 • Data anticipated : H1 2020
Phase I / II **MEDIOLA** **NCT02734004**	g*BRCA*m ovarian cancer 2L+ g*BRCA*m HER2-negative breast cancer 1-3L SCLC 2L+ Gastric cancer 2L+	148	• Arm 1: *Lynparza* + *Imfinzi* • Dose until progression Global trial	Primary endpoints: • DCR at 12 weeks • Safety and tolerability	• FPCD: Q2 2016 • LPCD: Q2 2017
Phase I / II **MEDIOLA** **(Ovarian expansion)** **NCT02734004**	g*BRCA*m ovarian cancer 2L+ Non-g*BRCA*m ovarian cancer 2L+ Non-g*BRCA*m ovarian cancer 2L+	140	• Arm 1: *Lynparza* + *Imfinzi* • Arm 2: *Lynparza* + *Imfinzi* • Arm 3: *Lynparza* + *Imfinzi* + bevacizumab • Dose until progression Global trial	Primary endpoints: • DCR at 12 weeks • ORR • Safety and tolerability	• FPCD: Q2 2018

Lynparza (PARP inhibitor)

Other combinations

Trial	Population	Patients	Design	Endpoints	Status
Phase III **PAOLA-1** **NCT02477644** **Externally sponsored**	Advanced ovarian cancer 1L maintenance	806	• Arm 1: *Lynparza* maintenance therapy for two years or until disease progression • Arm 2: placebo for two years or until disease progression Global trial	Primary endpoint: • PFS Secondary endpoints: • OS, PFS2	• FPCD: Q2 2015 • LPCD: Q2 2018 • Data readout: Q3 2019 • Primary endpoint met
Phase III **PROpel** **NCT03732820**	Metastatic castration-resistant prostate cancer 1L	720	• Arm 1: *Lynparza* + abiraterone • Arm 2: placebo + abiraterone Global trial	Primary Endpoint: • rPFS Secondary endpoints: • TFST, TTPP, OS	• FPCD: Q4 2018 • Data anticipated: 2021
Phase II **VIOLETTE** **NCT03330847**	TNBC	450	• Arm 1: AZD6738 + *Lynparza* • Arm 2: *Lynparza* Trial conducted in 15 countries: North America, Europe and Asia	• PFS • ORR / OS • Safety and tolerability	• FPCD: Q2 2018 • Data anticipated: 2021
Phase III **GY004** **NCT02446600** **Externally sponsored**	Recurrent platinum sensitive ovarian cancer	549	• Arm 1: chemo • Arm 2: *Lynparza* • Arm 3: cediranib + *Lynparza* US/Canada/Japan sites	Primary endpoint: • PFS Secondary endpoints: • OS, QoL, safety	• FPCD: Q1 2016 • LPCD: Q4 2017 • Data readout: Q1 2020 • Primary endpoint not met
Phase II/III **GY005** **NCT02502266** **Externally sponsored**	Recurrent platinum resistant/refractory ovarian cancer	680	• Arm 1: chemo • Arm 2: cediranib + *Lynparza* • Arm 3: cediranib • Arm 4: *Lynparza* • US/Canada sites	Primary endpoints: • PFS, OS Secondary endpoints: • ORR, QoL, safety	• FPCD: Q2 2016 • Data anticipated: 2021+
Phase II **LYNK-002** **NCT03742895** **Partnered**	HRRm or HRD-positive advanced cancer	370	• Arm 1: *Lynparza* Trial conducted in 15 countries worldwide	Primary endpoints: • ORR Secondary endpoints: • DOR, OS, PFS, AE, Prog by CA-125	• FPCD: Q1 2019

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III **ACE-CL-007 (ELEVATE-TN)** **NCT02475681**	Previously untreated CLL	535	• Arm A: chlorambucil + obinutuzumab • Arm B: *Calquence* + obinutuzumab • Arm C: *Calquence*	• 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)	• FPCD: Q2 2015 • Data readout: Q2 2019 • Primary endpoint met
Phase III **ACE-CL-311** **NCT03836261**	Previously untreated CLL fit	780	• Arm A; *Calquence* + venetoclax • Arm B: *Calquence* + venetoclax + obinutuzumab • Arm C: FCR or BR	• Primary – IRC assessed PFS (arm A vs arm C) • Secondary - IRC assessed PFS (arm B vs arm C); INV assessed PFS (arm A vs arm C; arm B vs arm C)	• FPCD: Q1 2019 • Data anticipated: 2021+
Phase III **ACE-CL-309 (ASCEND)** **NCT02970318**	Relapsed/refractory CLL	306	• Arm A: *Calquence* • Arm B: rituximab + idelalisib or bendamustine (investigator's choice)	• Primary endpoint: IRC assessed PFS (arm A vs. Arm B) • Secondary endpoints: INV-assessed ORR, OS, DoR, PROs	• FPCD Q3 2016 • Data readout: Q2 2019 • Primary endpoint met
Phase III **ACE-CL-006 (ELEVATE-RR)** **NCT02477696**	Relapsed/refractory high risk CLL	533	• Arm A: *Calquence* • Arm B: ibrutinib	• Primary endpoint: PFS • Secondary endpoints: comparison of incidence of infections, RTs (Richter's Transformation) and atrial fibrillation, OS	• FPCD: Q2 2015 • Data anticipated: 2021+
Phase III **ACE-LY-308** **NCT02972840**	Previously untreated MCL	546	• Arm A: *Calquence* + bendamustine + rituximab • Arm B: bendamustine + rituximab	• Primary endpoint: PFS by Lugano Classification for NHL • Secondary endpoints: IA, PFS, ORR; IRC-assessed ORR, DoR, time to response, OS	• FPCD: Q1 2017 • Data anticipated: 2021+
Phase II **ACE-CL-208** **NCT02717611**	Relapsed/ refractory CLL, intolerant to ibrutinib	60	*Calquence* monotherapy	• ORR at 36 cycles	• FPCD: Q1 2016 • Data anticipated: H1 2020
Phase II **15-H-0016** **NCT02337829**	Relapsed/refractory and treatment naïve/del17p CLL/SLL	48	*Calquence* monotherapy • Arm A: lymph node biopsy • Arm B: bone marrow biopsy	• ORR	• FPCD: Q4 2014 • Data anticipated: 2021+
Phase I/II **ACE-CL-001** **NCT02029443**	CLL/SLL/Richter's transformation	306	*Calquence* monotherapy Dose escalation and expansion	• Safety, PK, PD	• FPCD: Q1 2014 • Data anticipated: 2021

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I/II **ACE-LY-001** **NCT02328014**	B-cell malignancies	40	Dose escalation and expansion trial of the combination of *Calquence* and ACP-319 (Pi3K inhibitor)	• Safety • ORR	• FPCD: Q1 2015 • Data anticipated: H1 2020
Phase I/II **ACE-LY-005** **NCT02362035**	Haematological malignancies	161	*Calquence* + pembrolizumab	• Safety • Secondary endpoints: ORR, DoR, PFS, OS, TTNT (time to next therapy)	• FPCD: Q1 2015 • Data anticipated: 2021
Phase I/II **ACE-WM-001** **NCT02180724**	Waldenstrom microglobulinaemia	106	*Calquence* monotherapy	• ORR	• FPCD: Q3 2014 • Data readout: Q4 2019
Phase Ib **ACE-LY-002** **NCT02112526**	Relapsed/refractory de novo activated B-cell DLBCL	21	*Calquence* monotherapy	• Safety	• FPCD: Q3 2014 • Data anticipated: H2 2019
Phase Ib **ACE-LY-106** **NCT02717624**	MCL	70	*Calquence* in combination with bendamustine and rituxumab • Arm A: treatment naive • Arm B: relapsed/refractory • Arm C: treatment naïve: *Calquence* + venetoclax + rituxumab	• Safety	• FPCD: Q1 2016 • Data anticipated: 2021+
Phase Ib **ACE-MY-001** **NCT02211014**	Relapsed/refractory MM	28	• Arm A: *Calquence* • Arm B: *Calquence* + dexamethasone	• Safety	• FPCD: Q1 2015 • Data readout: Q2 2019
Phase I **ACE-LY-003** **NCT02180711**	Relapsed/refractory follicular lymphoma	80	• Arm A: *Calquence* • Arm B: *Calquence* + rituximab • Arm C: *Calquence* + rituximab + lenolidomide	• Safety	• FPCD: Q1 2015 • Data anticipated: 2021+
Phase I **ACE-CL-002** **NCT02157324**	Relapsed/refractory CLL/ SLL	12	*Calquence* in combination with ACP-319 dose escalation	• Safety, PK, PD	• FPCD: Q3 2014 • Data anticipated: H2 2020
Phase I **ACE-CL-003** **NCT02296918**	CLL/SLL/PLL	69	*Calquence* + obinutuzumab • Arm A: relapsed/refractory • Arm B: treatment naïve *Calquence* + venetoclax + rituxumab • Arm C: relapsed/refractory • Arm D: treatment naïve	• Safety, ORR • Secondary endpoints: PD, PFS, TTNT, OS	• FPCD: Q4 2014 • Data anticipated: 2021+

Calquence (BTK inhibitor)

Blood and other cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I **NCT03198650**	Japanese adults with advanced B-cell malignancies	34	• *Calquence* monotherapy • Dose confirmation and expansion • *Calquence* + obinutuzumab	• Safety • PK	• FPCD: Q2 2017 • Data anticipated: 2021+
Phase I/II **CL-110** **NCT03328273**	CLL r/r	62	• Arm A: ceralasertib (AZD6738) monotherapy • Arm B: *Calquence* + ceralasertib (AZD6738)	• Identify dose of ceralasertib and safety of co-administration of *Calquence* + ceralasertib	FPCD: Q1 2018 Data anticipated: H1 2020
Phase I/II **LY-110** **NCT03205046**	B-cell malignancies r/r	25	• Part 1: *Calquence* daily + vistusertib daily • Part 2: *Calquence* daily + vistusertib 5 days on/2 days off	• MTD and optimal dosing schedule • Safety	FPCD: Q3 2017 Data anticipated: H2 2020
Phase III **CL-312** **NCT04008706**	CLL TN and r/r	600	• Arm A: treatment naïve • Arm B: relapsed/refractory • Arm C: prior BTKi therapy • Arm D: concomitant vitamin K antagonists	• Safety	Data anticipated: 2021+
Phase Ib/II **PRISM** **NCT03527147**	Relapsed/refractory aggressive NHL	88	• Arm 1: *Calquence* + danvatirsen • Arm 2: *Calquence* + AZD6738 • Arm 3: *Calquence* + Hu5F9G4 + Rituxan • Arm 4: *Calquence* + AZD5153 An open-label platform trial with trial centres in US and UK	• Primary outcome; safety & tolerability • Secondary outcomes; ORR, DOR, PFS, OS	FPCD: Q2 2018 Data anticipated: 2021
Phase Ib/II **ACE-ST-209** **NCT02586857**	≥ 2L glioblastoma multiforme	52	• Arm A: *Calquence* 200mg BID • Arm B: *Calquence* 400mg QD	• Safety, ORR	• FPCD: Q1 2016 • Data anticipated: H2 2019

Enhertu (trastuzumab deruxtecan, 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 patients previously treated with trastuzumab emtansine	230	Randomised, open label, sequential assignment • *Enhertu*	Primary endpoint ORR Secondary end points DoR, CBR, CBR, PFS, OS	• FPCD: Q4 2017 • LPCD: Q4 2018 • Data readout: Q2 2019 • Primary objective met
Phase III **DESTINY-Breast02** **NCT03523585** **Partnered**	HER2-positive, unresectable and/or metastatic breast cancer pretreated with prior standard of care HER2 therapies, including trastuzumab emtansine	600	Randomised open label parallel assignment • *Enhertu* Physicians choice of • Lapatinib + capecitabine • Trastuzumab + capecitabine	Primacy endpoint PFS Secondary endpoints OS, ORR, DoR, CBR	• FPCD: Q4 2018 • Data anticipated 2021
Phase III **DESTINY-Breast03** **NCT03529110** **Partnered**	HER2-positive, unresectable and/or metastatic breast cancer patients previously treated with trastuzumab and taxane	500	Randomised open label parallel assignment • *Enhertu* • Ado-trastuzumab emtansine	Primary endpoint PFS Secondary endpoints OS, ORR, DoR, CBR	• FPCD: Q4 2018 • Data anticipated 2021
Phase III **DESTINY-Breast04** **NCT03734029** **Partnered**	HER2-low, unresectable and/or metastatic breast cancer patients	540	Randomised open label parallel assignment • *Enhertu* • Physicians choice of SoC chemo (choice of capecitabine, eribulin, gemcitabine, paclitaxel or nab-paclitaxel)	Primary end point PFS Secondary end points OS, DoR, ORR	• FPCD: Q4 2018 • Data anticipated 2021
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 • *Enhertu* • SoC chemo	Primary end point ORR Secondary end points PFS, OS, DoR, DCR, TTF, range of PK endpoints	• FPCD: Q4 2017 • LPCD: Q2 2019 • Data readout Q1 2020 • Primary endpoint met
Phase II **DESTINY-Gastric02** **NCT04014075** **Partnered**	HER2-positive gastric cancer that cannot be surgically removed or has spread	72	Open label single group assignment • *Enhertu*	Primary endpoint ORR Secondary endpoints PFS, ORR, OS, DoR	• FPCD: Q3 2019 • Data anticipated: H2 2020

Enhertu (trastuzumab deruxtecan, HER2 ADC)

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase II **DESTINY-CRC01** **NCT03384940** **Partnered**	HER2-expressing advanced colorectal cancer	90	Non randomised single group assignment • *Enhertu*	Primary end point ORR Secondary end points PFS, OS, DoR, range of PK endpoints	• FPCD Q1 2018 • Data anticipated H2 2020
Phase II **NCT03505710** **Partnered**	HER2-over-expressing or mutated, unresectable and/or metastatic NSCLC	130	Non randomised parallel group assignment • *Enhertu*	Primary end point ORR Secondary end points DoR, PFS, OS	• FPCD Q2 2018 • Data anticipated H2 2020
Phase I **NCT02564900** **Partnered**	Advanced solid malignant tumours	278	Non randomised single group assignment • *Enhertu*	Primary end points number of subjects with AEs, tumour response Secondary end points PK	• FPCD Q3 2015 • Data read out Q3 2018

Koselugo (Selumetinib, MEK inhibitor)

Paediatric neurofibromatosis type 1, solid tumours

Trial	Population	Patients	Design	Endpoints	Status

Phase II
SPRINT
 	
NCT01362803
 	
Partnered
	Paediatric NF1	50 (stratum 1)
		25 (Stratum 2)
			• Single arm: *Koselugo* 25mg/m^2 BID with 2 strata:
			  • Stratum 1: PN related morbidity present at enrolment
			  • Stratum 2: no PN related morbidity present at enrolment
				• Complete partial and complete response rate measured by volumetric MRI;
				• Duration of response and functional outcomes/QoL
					• FPCD: Q3 2015
					• LPCD: Q4 2016
					• Data readout: Q1 2019
					• Primary endpoint met

Phase Ib ***Koselugo* + MK-8353 (ERK inhibitor)** **NCT03745989** **Partnered (Merck Lead trial)**	Advanced solid tumours	80 (dose escalation trial)	Phase Ib open-label trial of MK-8353 in combination with *Koselugo* in participants with advanced solid tumours	• DLTs • AEs • Trial drug discontinuations due to an AE	• FPCD: Q1 2019

Lumoxiti (moxetumomab pasudotox,CD22 mAb)

Blood cancer

Trial	Population	Patients	Design	Endpoints	Status

Phase III
PLAIT
NCT01829711
 	
Partnered
	Adults with relapsed or refractory HCL	80	• Multicentre, single-arm, open-label Phase III trial
			• *Lumoxiti* i.v. at the recommended dose
				• Primary endpoint: rate of durable CR (complete response): CR maintained for > 180 days
				• Secondary endpoints
				  • Efficacy: CR rate, ORR, Duration of CR and ORR, TTR, PFS
				  • Safety and tolerability
				  • PK and immunogenicity
					• FPCD: Q2 2013
					• Data readout: Q3 2017
					• Primary endpoint met

Savolitinib (MET inhibitor)

NSCLC and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT01985555** **Partnered**	Advanced NSCLC (all comers)	85	• Dose escalation trial Conducted in China	• Primary endpoint: safety and tolerability • Secondary endpoint: PK profile	• FPCD: Q2 2013 • Data anticipated: H2 2020
Phase II **NCT02897479** **Partnered**	Lung PSC and other NSCLC	65	• Single arm trial: savolitinib QD Conducted in China	• Primary endpoint: ORR • Secondary endpoint: PFS, safety parameters	• FPCD: Q1 2017 • Data anticipated: H1 2020

Cediranib (VEGF receptor inhibitor)

Ovarian cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CONCERTO **NCT02889900**	PRR ovarian cancer - heavily pre-treated BRCAwt	62	• Cediranib 30mg + *Lynparza* 200mg BID	Primary endpoint: • ORR Secondary endpoints: • PFS, DoR, DCR, QoL, OS	• FPCD: Q1 2017 • LPCD: Q1 2019 • Data readout: Q4 2019

Capivasertib (AKT inhibitor)

Breast cancer, prostate cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT03997123** **CAPItello-290**	Locally advanced or metastatic TNBC	800	Double-blind randomised comparative trial • Arm 1: capivasertib + paclitaxel • Arm 2: placebo + paclitaxel	• PFS • OS	• FPCD Q3 2019 • Data anticipated: 2021+
Phase 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	• PFS	• FPCD Q1 2014 • Data anticipated: H1 2020

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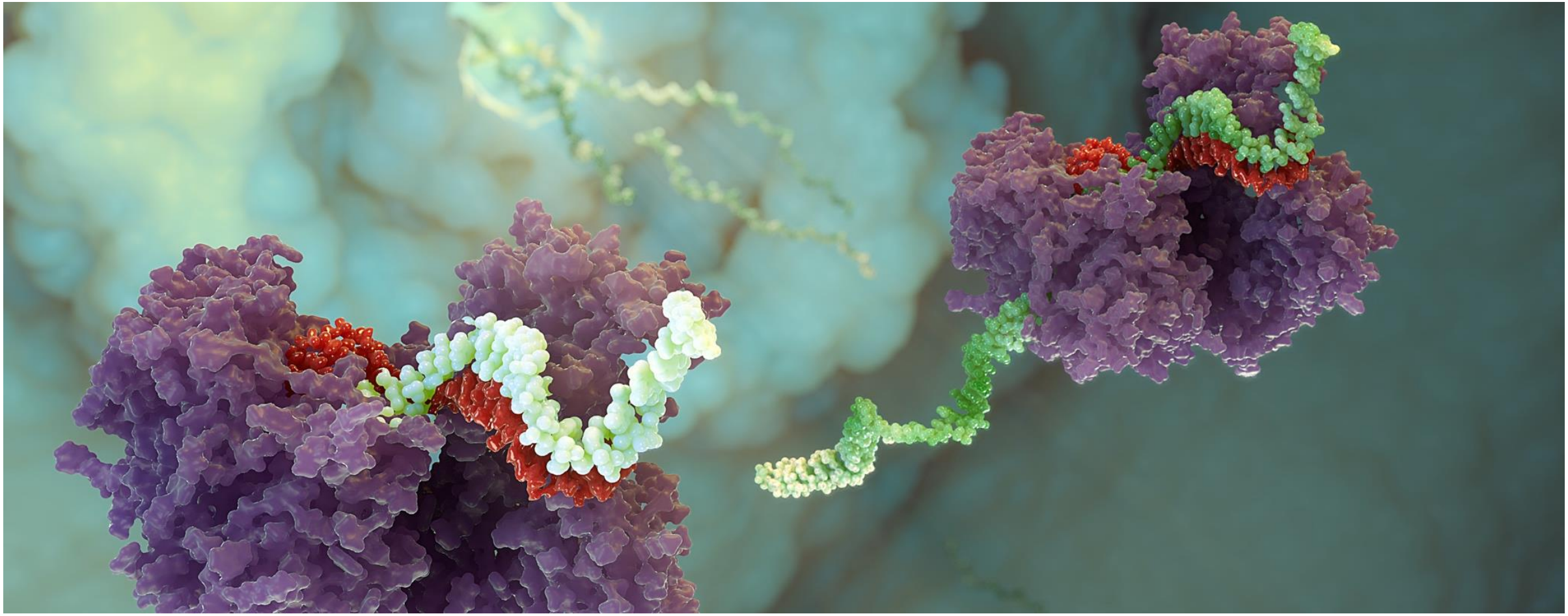
Oncology - early-stage development



Imfinzi (PD-L1 mAb)

Cancer

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase I/II STUDY 1108 NCT01693562	*Imfinzi*	Solid tumours	1,022	• 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 Global trial - nine countries	• Safety • Optimal biologic dose • Secondary endpoints include PK, immunogenicity and antitumour activity	• FPCD: Q3 2012 • LPCD: Q4 2016 • Data anticipated: H1 2020
Phase I NCT02117219	*Imfinzi*, azacitidine	Myelodysplastic syndrome	79	Dose escalation and dose expansion trial • Part 1: *Imfinzi* • Part 2 Arm 1: *Imfinzi* and tremelimumab • Part 2 Arm 2: *Imfinzi,* tremelimumab and azacitidine Global trial - four countries	• Safety and tolerability of monotherapy and combination • Secondary endpoints include duration of response, PFS and OS, PK and immunogenicity	• FPCD: Q2 2014 • Data anticipated: H2 2020
Phase I NCT02900157	MEDI9090	Solid tumours	42	Multi-centre, open-label, single-arm trial for adult subjects US and Japan trial centers	• Safety, PK, number of subjects reporting infusion related reaction	• FPCD: Q3 2016 • Data anticipated: H1 2020
Phase II HUDSON NCT03334617	*Imfinzi* *Lynparza* vistusertib ceralasertib (AZD6738) danvatirsen oleclumab *Enhertu* cediranib	NSCLC	320	5 modules encompassing 13 cohorts • Module 1; *Imfinzi* and *Lynparza* • Module 2; *Imfinzi* and danvatirsen • Module 3; *Imfinzi* and ceralasertib (AZD6738) • Module 4; *Imfinzi* and vistusertib • Module 5; *Imfinzi* and oleclumab • Module 6; *Imfinzi* and *Enhertu* • Module 7; *Imfinzi* and cedirinib 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	• Primary outcome; ORR • Secondary outcomes; efficacy including OS, PFS, DCR, and safety and tolerability, DoR	• FPCD: Q1 2018 • Data anticipated: 2021+
Phase II COAST NCT03822351	*Imfinzi*	Stage III NSCLC unresectable	300	• Arm A: *Imfinzi* • Arm B: *Imfinzi* + oleclumab • Arm C: *Imfinzi* + monalizumab	Primary • OR per RECIST v1.1	• FPCD: Q4 2018 • Data anticipated: H2 2020
Phase II NeoCOAST NCT03794544	*Imfinzi*	Resectable, early stage NSCLC	160	• Arm A: *Imfinzi* • Arm B: *Imfinzi* + oleclumab • Arm C: *Imfinzi* + monalizumab • Arm D: *Imfinzi* + danvatirsen	Primary • Major pathological response rate	• FPCD: Q1 2019 • Data anticipated: H2 2020

Imfinzi (PD-L1 mAb)

Cancer

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase Ib/II **COLUMBIA 1** **NCT04068610**	*Imfinzi*	1L metastatic MSS-CRC	112	• Part 1 S1 FOLFOX + bevacizumab + *Imfinzi* + oleclumab • Part 2 Control 1 FOLFOX + bevacizumab • Part 2 E1 FOLFOX + bevacizumab + *Imfinzi* + oleclumab	Primary • Part 1: Safety • Part 2: Efficacy - OR Secondary • Part 1: Efficacy – OR, BOR, DoR, PFS • Part 2: Safety and Efficacy (BOR, DoR, DC, PFS, OS)	• FPCD: Q3 2019 • Data anticipated: H2 2020
Phase II **COLUMBIA 2**	*Imfinzi*	High risk adjuvant MSS-CRC	160	• Control mFOLFOX6 • E1-COC mFOLFOX6 + *Imfinzi* • E2 mFOLFOX6 + *Imfinzi* + oleclumab • E3 mFOLFOX6 + *Imfinzi* + monalizumab	Primary • Efficacy: ctDNA clearance – ctDNA status change from positive at baseline to negative post baseline. Secondary • Safety, efficacy (DFS, DFS-12, and OS), PK, ADA,	• FPCD: 2020 • Data anticipated: 2021+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **STUDY 22** **NCT02519348**	Hepatocellular carcinoma	545	• Arm A: *Imfinzi* + tremelimumab • Arm B: *Imfinzi* 2L • Arm C: tremelimumab 2L • Arm D: Imfinzi + tremelimumab • Arm E: *Imfinzi* in combination with bevacizumab	• Primary endpoints: Safety & tolerability, DLTs • Secondary endpoints: ORR, DoR, OS	• FPCD: Q4 2015 • Data anticipated: H2 2020
Phase Ib **STUDY 006** **NCT02000947**	NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	459	• Dose escalation: minimum 5 cohorts exploring various treme Q4W and *Imfinzi* i.v. Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment • Dose expansion: MTD for the combination in escalation to be explored in expansion North American, EU and ROW trial centres	Primary endpoints: • Safety • Optimal biologic dose for the combination • OR • Secondary endpoints include antitumour activity, PK and immunogenicity	• FPCD: Q4 2013 • LPCD: Q4 2016 • Data anticipated: H1 2020
Phase I **STUDY 10** **NCT02261220**	Solid tumours (basket trial)	380	• 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 *Imfinzi* dose combinations and 2 cohorts exploring various Q2W treme and *Imfinzi* dose combinations North American, EU and ROW trial centres	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints include anti-tumour activity, PK/PD and immunogenicity	• FPCD: Q4 2014 • LPCD: Q2 2017 • Data anticipated: H1 2020

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II **NCT02671435**	Advanced solid tumours	381	Escalation phase • monalizumab + *Imfinzi* i.v. Expansion phase • monalizumab + *Imfinzi* i.v. recommended dose Exploration phase • monalizumab + *Imfinzi* i.v. recommended dose + SoC systemic therapy with or without biologic agent and monalizumab in combination with a biologic agent in adult subjects with CRC Global trial	Primary endpoints: • Safety • Exploration Phase: Objective Response per RECIST • Secondary endpoints include tumour response (OR, DC, DoR, PFS and OS), immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2021+

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

Head and neck squamous cell carcinoma (HNSCC)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/IIa **NCT03162224**	HPV associated recurrent/metastatic head and neck cancer	50	Multi-centre, open label trial to evaluate the safety and efficacy of combination treatment with MEDI0457 and *Imfinzi*	Primary endpoints: Safety & Tolerability, ORR Secondary endpoints: PK, ADA, DCR, OS, PFS	• FPCD: Q3 2017 • Data anticipated: H2 2020

AZD0466 (Bcl2/xL inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT04214093**	Advanced hematologic malignancies or solid tumours	102	Monotherapy dose escalation, consisting of two arms: • Arm A: Patients with low risk for tumour lysis syndrome (solid tumours, lymphomas, myelomas) • Arm B: Patients with high risk for tumour lysis syndrome (relapsed/refractory haem malignancies)	• Primary: safety • Secondary: PK, anti-tumour activity	• FPCD: Q4 2019 • Data anticipated: 2021+

MEDI1191 (IL12 modRNA)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03946800**	Advanced solid tumours	87	First-time-in-human Phase I, open-label, dose-escalation and expansion trial of MEDI1191 administered intratumourally as monotherapy and in combination with *Imfinzi*	• Primary endpoint: safety and tolerability • Secondary endpoints: PK, immunogenicity and efficacy	• FPCD: Q2 2019 • Data anticipated: 2021+

AZD1390 (ATM inhibitor)

Cancer

Trial	Population	Subjects	Design	Endpoints	Status
Phase I **NCT03423628**	Recurrent glioblastoma eligible for re-irradiation, brain metastases and leptomeningeal disease, newly-diagnosed glioblastoma patients	132	• 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	• Primary: investigate the safety, tolerability, and MTD of AZD1390 administered in combination with radiation therapy in brain malignancies	• FPCD Q2 2018 • Data anticipated: 2021

Adavosertib (AZD1775, WEE-1 inhibitor)

Ovarian cancer, solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase II **D6010C00004** **NCT02272790**	Platinum-resistant (PR) ovarian cancer	96	• Arm B: paclitaxel + adavosertib • Arm C: carboplatin + adavosertib Global trial	• Primary endpoint: ORR • Secondary endpoints: DoR, PFS, OS, DCR, safety and tolerability	• FPCD: Q1 2015 • LPCD: Q2 2018 • Data readout: Q3 2019
Phase I **D6010C00005** **NCT02511795**	Advanced solid tumours	130	• Dose escalation trial to determine MTD (adavosertib + *Lynparza*) followed by an expansions in SCLC Conducted in US, Canada	• Safety and tolerability • Secondary endpoints: ORR, DCR, DoR, PFS	• FPCD: Q3 2015 • LPCD: Q4 2018 • Data readout Q4 2019
Phase I **D6015C00002** **NCT02617277**	Advanced solid tumours	56	• Dose escalation trial to determine MTD (adavosertib + *Imfinzi*) Conducted in US	• Safety and tolerability	• FPCD: Q4 2015 • LPCD: Q4 2018 • Data readout Q4 2019
Phase I **D6014C00006** **NCT03333824**	Advanced solid tumours	33	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	• Primary endpoints: • Part A: Plasma AUC, AUC0-t and CMAX for cocktail parent compounds (midazolam, omeprazole and caffeine) • Part B: dECG (differentiated ECG) intervals (QTcF) for absolute values and time-matched change from baseline	• FPCD: Q4 2017 • LPCD: Q4 2018 • Data readout Q4 2019
Phase I **D6014C00007** **NCT03313557**	Advanced solid tumours	48	adavosertib monotherapy once daily. Conducted in US and Europe	• Safety and tolerability	• FPCD: Q4 2017 • LPCD: Q1 2019 • Data readout Q4 2019

MEDI2228 (BCMA antibody drug conjugate)

Cancer

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: • Safety • Determination of MTD • Secondary endpoints: pPK, immunogenicity, ORR, DCR, DoR, PFS, OS	• FPCD: Q2 2018 • Data anticipated: 2021+

AZD2811NP (AURN)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02579226**	Solid tumours	72	• Arm 1: AZD2811NP dose escalation • Arm 2: AZD2811NP dose expansion SCLC	• Safety and tolerability • PK and efficacy	• FPCD: Q4 2015 • Data anticipated: H2 2020
Phase I **NCT03217838**	AML/high-risk MDS	130	• Part A: AZD2811NP monotherapy / azacitidine combination / venetoclax combination dose escalation cohorts • Part B: AZD2811NP monotherapy / azacitidine combination / venetoclax combination dose expansions to further explore the tolerability, PK and clinical activity	• Safety and tolerability • PK and efficacy	• FPCD: Q3 2017 • Data anticipated: 2021+

AZD4573 (CDK9 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03263637**	Relapsed/refractory haematologic malignancies	45	Dose escalation in relapsed/refractory haematological malignancies AZD4573 will be administered in 2 parallel arms (1-6 cohorts of dose escalations) based on the haematological malignancy	Primary: • safety/PK; Secondary: • efficacy	• FPCD: Q4 2017 • Data anticipated: H2 2020

AZD4635 ($A_{2A}R$ inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02740985**	Phase Ia: patients with advanced solid tumours Phase Ib: Post-immunotherapy NSCLC Other post-immunotherapy solid tumours Immune checkpoint-naïve mCRPC Immune checkpoint-naïve CRC Other immune checkpoint-naïve solid tumours	3067	Phase Ia – solid tumours or mCPRC: • AZD4635 monotherapy • AZD4635 + *Imfinzi* • AZD4635 + abiraterone • AZD4635 + enzalutamide • *AZD4635* + *Imfinzi* + oleclumab • AZD4635 + docetaxel. Phase Ib: AZD4635 monotherapy or AZD4635 + *Imfinzi* dose expansions in NSCLC, mCRPC, CRC and other post-immunotherapy and immune checkpoint-naïve solid tumours Conducted at sites in the US	Primary outcome measure: • Safety and tolerability Secondary outcome measures: • Preliminary assessment of anti-tumour activity	• FPCD: Q2 2016
Phase I **NCT03710434**	Healthy male volunteers	21	• Part A 2-period randomised crossover trial of single doses of AZD4635, nanosuspension or solid oral formulation in fasted state • Part B, 4-period, open-label, randomised, crossover trial of single doses of AZD4635 in the same subjects from Part A to assess food effect, pH effect and formulation variants Both parts conducted at a site in the UK	Primary outcome measures: • Cmax and exposure (AUC) of AZD4635 solid oral formulation and nano-suspension	• FPCD: Q4 2018 • LPCD: Q2 2019
Phase II **NCT04089553**	Prostate cancer	60	ARM 1: AZD4635 + *Imfinzi* ARM 2: AZD4635 + oleclumab Conducted at sites in the US	• Primary outcome measure: Efficacy; (ORR and PSA response) • Secondary outcome measure: Efficacy, PK, safety and tolerability	• FPCD: Q3 2019
Phase I **NCT03980821**	Japanese patients with advanced solid malignancies	12	AZD4635 dose escalation Conducted at sites in Japan	Primary outcome measure: • Safety and tolerability Secondary outcome measure: • PK and preliminary anti-tumour activity	• FPCD: Q3 2019

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 • Part 1: MEDI5083 • Part 2: MEDI5083 + *Imfinzi* i.v. Dose expansion phase • Part 3: MEDI5083 recommended dose + *Imfinzi* i.v. US and Australian trial centres	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	• FPCD: Q1 2017 • Data anticipated: H1 2020

AZD5153 (BRD4 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib **NCT03205176**	Relapsed/refractory solid tumours, lymphomas	60	Monotherapy dose escalation in advanced solid tumours and lymphomas Dose escalation of AZD5153 in combination with *Lynparza* in platinum resistant/refractory HGS patients.	• Primary: safety • Secondary: efficacy, PK	• FPCD: Q2 2017 • Data anticipated: H2 2020

MEDI5395 (rNDV GMCSF)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03889275**	Select advanced solid tumours	164	First-time-in-human Phase I, open-label, dose-escalation and expansion arm of MEDI5395 in combination with *Imfinzi*	• Primary endpoint: safety and tolerability • Secondary endpoints: PK, PD, immunogenicity and efficacy	• FPCD: Q4 2019 • Data anticipated: 2021+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03530397**	Advanced solid tumours	272	Open-label, dose-escalation and dose-expansion: • Dose-escalation: MEDI5752 i.v. • Dose-expansion arm: MEDI5752 i.v. in combination with chemotherapy	Primary endpoints: • dose-escalation: safety & determination of MTD • dose-expansion: assessment of antitumour activity based on OR Secondary endpoints: • PK, ADA, tumoural baseline PD-L1, assessment of antitumour activity based on OR, DoR, DC, PFS, OS	• FPCD: Q2 2018 • Data anticipated: 2021+

AZD5991 (MCL1 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib/IIa **NCT03218683**	Relapsed/refractory haematologic malignancies	177	• Arm1: monotherapy dose escalation & expansions in relapsed/refractory haematological malignancies • Arm2: combination dose escalation (AZD5991+venetoclax) in relapsed/refractory AML/MDS;. • i.v. route of administration • US only	• Primary: safety • Secondary: PK, efficacy	• FPCD: Q3 2017 • Data anticipated: 2021

Ceralasertib (AZD6738, ATR inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02264678**	Solid tumours	250	• Arm 1: ceralasertib + carboplatin • Arm 2: ceralasertib dose escalation, ceralasertib + *Lynparza* • Arm 3: ceralasertib + *Imfinzi* Trial conducted in North America, Europe and South Korea	• Safety and tolerability • PK and efficacy	• FPCD: Q4 2014 • Data anticipated: 2021+
Phase I **NCT03022409**	HNSCC	44	Window of opportunity • Arm 1: ceralasertib • Arm 2: *Lynparza* Trial conducted in US, France, Taiwan and the UK	• Biomarker change	• FPCD: Q4 2017 • Data anticipated: H2 2020

AZD7648 (selective DNA-PK inhibitor)

Advanced solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03907969**	Advanced Malignancies	234	• This is a modular Phase I/IIa, open-label, multi-centre, trial of AZD7648 administered orally, either as a monotherapy, or in combination with either cytotoxic chemotherapies or novel anti-cancer agents in participants with advanced malignancies. The modular design allows for an escalation of the dose of AZD7648 alone or in combination with either cytotoxic chemotherapies or novel anti-cancer agents, with intensive safety monitoring to ensure the safety of the participants.	• Primary outcome measures: safety and tolerability • Secondary outcome measures: Cmax, AUC, Cytochromes P450, ORR	• Initiating

Danvatirsen (AZD9150, STAT3 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	HNSCC	339	Dose escalation advanced solid and blood cancers • Arm A1: AZD9150/*Imfinzi* • Arm A2 : AZD5069/*Imfinzi* • Arm A4: AZD9150/*Imfinzi*/treme • Arm A5: AZD5069/*Imfinzi*/treme Dose expansion 2L HNSCC: • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/*Imfinzi* • Arm B4: AZD5069/*Imfinzi* • Arm B5: AZD9150 mono • Arm B6: AZD5069 mono • Arm B7: AZD9150/*Imfinzi* (1L HNSCC) • Arm B8: AZD9150 Q2W/*Imfinzi* (1L HNSCC)	• Safety/efficacy trial	• FPCD: Q3 2015 • LPCD: Q2 2019 • Data anticipated: 2021
Phase Ib/II **NCT03421353**	NSCLC, advanced solid tumours	76	Dose escalation advanced solid and blood cancers • Arm A1: AZD9150 alternate week/*Imfinzi* • Arm A2-A5 : AZD9150/*Imfinzi* + SoC chemo Dose expansion 1L HNSCC: • Arm D1/D2/D3: AZD9150 i.v. vs s.c. formulations/*Imfinzi* (advanced solid tumours)	• Safety/efficacy trial	• FPCD: Q1 2018 • Data anticipated: 2021

Oleclumab (MEDI9447, CD73 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02503774**	Advanced malignancies	348	Dose escalation phase • oleclumab i.v. • oleclumab i.v. + *Imfinzi* i.v. Dose expansion phase • oleclumab i.v. recommended dose + *Imfinzi* i.v. US, South Korean and Australian trial centres	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints include preliminary anti-tumour activity, PK, PD, immunogenicity and biomarker activity	• FPCD: Q3 2015 • Data anticipated: 2021+
Phase Ib/II **NCT03611556**	Pancreatic 1L and 2L with prior gemcitabine-based chemotherapy	339	• Arm A1: gemcitabine and nab paclitaxel i.v. • Arm A2: gemcitabine and nab paclitaxel i.v. + oleclumab i.v. • Arm A3: gemcitabine and nab paclitaxel i.v. + oleclumab i.v. + Imfinzi i.v. • Arm B1: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. • Arm B2: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. + oleclumab i.v. • Arm B3: mFOLFOX (oxaliplatin, leucovorin, 5-FU) i.v. + oleclumab i.v. + *Imfinzi* i.v. US, Norway, Spain and Australian trial centres	Primary endpoints: • Safety and anti-tumour activity • Secondary endpoints include PFS, PK, immunogenicity, safety and anti-tumour activity	• FPCD: Q2 2018 • Data anticipated: 2021
Phase Ib/II **NCT03381274**	NSCLC	98	• Arm A: oleclumab i.v. + *Tagrisso* US, South Korean and Taiwan trial centres	Primary endpoints: • Safety • ORR Secondary endpoints: • DoR, DCR, PFS, OS, PK and immunogenicity	• FPCD: Q2 2018 • Data anticipated: 2021+

AZD9496 (SERD, oral)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03236974**	ER+ breast cancer	c. 50	• This is an open label randomised multicentre pre-surgical pharmacodynamics trial to compare and assess the biological effects of AZD9496 and *Faslodex* in postmenopausal women with ER+, HER2- primary breast cancer. Patients will receive AZD9496 or *Faslodex* and will have a pre-dose and an on-treatment core biopsy after 5-14 days of commencing treatment.	• Primary outcome measures: PD changes to ER expression following treatment with AZD9496 or *Faslodex* • Secondary outcome measures: pharmacodynamics changes to Ki67 and PgR expression following treatment with AZD9496 or *Faslodex* • Safety, tolerability + pharmacokinetics	• FPCD: Q4 2017 • Data readout: Q1 2020

AZD9833 (SERD, oral)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03616587**	ER+ breast cancer	240	• 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	• Primary outcome measures: safety and tolerability • Secondary outcome measures: multiple dose PK of AZD9833 alone and in combination with palbociclib antitumour activity	• FPCD: Q4 2018
Phase II **NCT04214288**	ER+ breast cancer	288	• This is a Phase II randomised, open-label, parallel-group, multicentre trial aimed to compare the efficacy and safety of oral AZD9833 versus intramuscular (IM) *Faslodex* in women with advanced breast cancer.	• Primary outcome measure: mPFS	• Initiating

IPH5201 (CD39 mAb)

Solid Tumour

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT04261075** **Partnered**	Advanced Solid tumours	204	• First time in human Phase I, open-label, dose-escalation trial to determine MTD of IPH5201 as monotherapy, or in combination with *Imfinzi* +/- oleclumab. • Part 1: IPH5201 monotherapy dose escalation to MTD • Part 2: IPH5201 + *Imfinzi* dose escalation to MTD • Part 3: IPH5201 + *Imfinzi* + Oleclumab dose escalation to MTD • Route of Administration: IV • Geographical Regions: 4 countries - US and 3 in EU.	Primary endpoints: AE, SAE, DLT Secondary endpoints: OR, DC, PK, ADA	• FPCD: Q1 2020 • Data anticipated: 2021+

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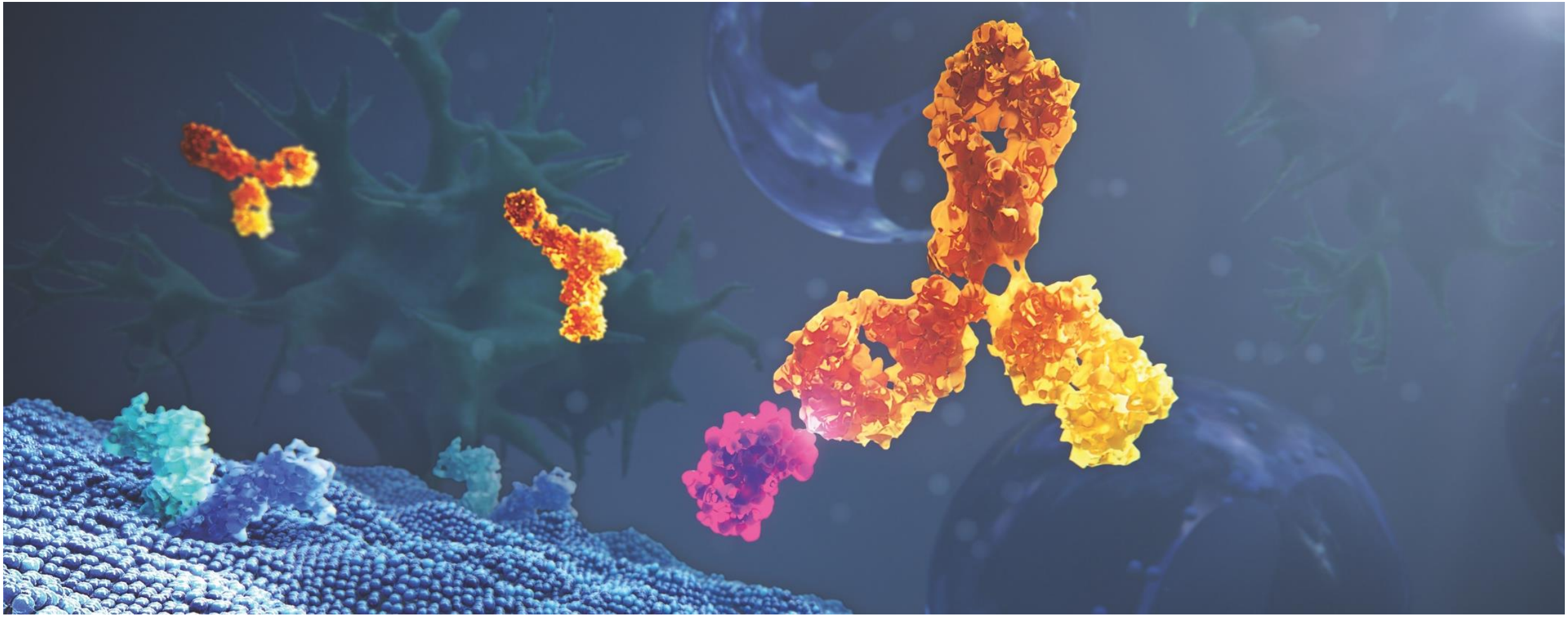
BioPharmaceuticals - approved medicines and late-stage pipeline



Farxiga (SGLT2 inhibitor)

Heart failure and chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III **Dapa-HF** **NCT03036124**	CHF patients with HFrEF	4,744	• Arm 1: *Farxiga* 10mg or 5 mg QD + SoC therapy • Arm 2: placebo + SoC therapy • Global trial - 20 countries	• Primary endpoint: time to the first occurrence of any of the components of the composite: CV death or hospitalisation for HF or an urgent HF visit	• FPCD: Q1 2017 • LPCD Q4 2018 • Data readout: Q3 2019 • Primary endpoint met
Phase III **Dapa-CKD** **NCT03036150**	Patients With CKD	4,000	• Arm 1: *Farxiga* 10mg or 5 mg QD • Arm 2: placebo Global trial - 21 countries	• Primary endpoint: time to the first occurrence of any of the components of the composite: ≥50% sustained decline in eGFR or reaching ESRD or CV death or renal death	• FPCD: Q1 2017 • LPCD: Q1 2020 • Data readout: Q1 2020 • Trial stopped early based on IDMC recommendation
Phase III **DELIVER** **NCT03619213**	CHF patients with HFpEF	6,100	• Arm 1: *Farxiga* 10mg QD • Arm 2: placebo • Global trial - 21 countries	• Primary endpoint: time to the first occurrence of any of the components of the composite: CV death or hospitalisation for HF or an urgent HF visit	• FPCD: Q4 2018 • Data anticipated: 2021+
Phase III **DETERMINE-preserved** **NCT03877224**	CHF patients with HFpEF	500	• Arm 1: *Farxiga* 10mg QD • Arm 2: placebo • Global trial - 12 countries	Family of primary endpoints: • Change from baseline in the KCCQ-TSS at Week 16. • Change from baseline in the KCCQ-PLS at Week 16. • Change from baseline in 6 min walking distance at Week 16	• FPCD: Q2 2019 • Data anticipated: H1 2020
Phase III **DETERMINE-reduced** **NCT03877237**	CHF patients with HFrEF	300	• Arm 1: *Farxiga* 10mg QD • Arm 2: placebo • Global trial - 9 countries	Family of primary endpoints: • Change from baseline in the KCCQ-TSS at Week 16. • Change from baseline in the KCCQ-PLS at Week 16. • Change from baseline in 6 min walking distance at Week 16	• FPCD: Q2 2019 • Data anticipated: H1 2020

Brilinta (P2Y12 receptor antagonist)

Cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints (primary)	Status
Phase III **THEMIS** **NCT01991795**	Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	19,000	• Arm 1: *Brilinta* 60mg BiD • Arm 2: placebo BID on a background of acetylsalicylic acid if not contra-indicated or not tolerated Global trial – 42 countries	• Primary endpoint: composite of CV death, non-fatal MI and non-fatal stroke Secondary endpoints: • Prevention of CV death • Prevention of MI • Prevention of ischaemic stroke • Prevention of all-cause death	• FPCD: Q1 2014 • LPCD: Q2 2016 • Data readout: Q1 2019 • Primary endpoint met
Phase III **THALES** **NCT03354429**	Patients with acute ischaemic stroke or transient ischaemic attack	11,000	• Arm 1: *Brilinta* 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: • Prevention of the composite of subsequent stroke and death at 30 days Secondary endpoints include: • Prevention of subsequent ischaemic stroke at 30 days • Reduction of overall disability at 30 days	• FPCD: Q1 2018 • LPCD: Q4 2019 • Data readout: Q1 2020 • Primary endpoint met
Phase III **HESTIA3** **NCT03615924**	Paediatric patients (2-18 years old) with sickle cell disease	182	• Arm 1: *Brilinta* 15, 30 or 45mg (dose based on subject weight) • Arm 2: placebo Global trial – 18 countries	• Primary endpoint: the number of vaso-occlusive crisis which is the composite of painful crisis and/or acute chest pain	• FPCD: Q3 2018 • Data anticipated: 2021

Lokelma (sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase IIIb **DIALIZE** **NCT03303521**	Patients on haemodialysis with persistent pre-dialysis hyperkalaemia	180	• Arm 1: *Lokelma* 5g QD for 8 weeks on non-dialysis days. Option to uptitrate to 10 and15g QD. • Arm 2: placebo QD for 8 weeks on non-dialysis days Global trial – four countries	• 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	• FPCD: Q4 2017 • LPCD: Q4 2018 • Data readout: Q1 2019 • Primary endpoint met
Phase II **PRIORITIZE HF** **NCT03532009**	Patients with chronic heart failure and hyperkalaemia or at high risk of developing hyperkalaemia	280	• Arm 1: *Lokelma* 5g QD for 12 weeks. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD • Arm 2: placebo QD for 12 weeks Global trial – nine countries	• Primary endpoint: difference between *Lokelma* and placebo in RAAS (renin–angiotensin–aldosterone system) blockade treatment.	• FPCD: Q3 2018 • Data readout: H2 2020

Roxadustat (HIF-PH inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ANDES** **NCT01750190** **Partnered**	Anaemia in CKD in patients not receiving dialysis	922	• Arm 1: roxadustat • Arm 2: placebo Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2012 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III **ALPS** **NCT01887600** **Partnered**		597	• Arm 1: roxadustat • Arm 2: placebo Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q2 2013 • LPCD: Q4 2017 • Data readout: Q3 2018 • Primary endpoint met Sponsored by Astellas
Phase III **DOLOMITES** **NCT02021318** **Partnered**		616	• Arm 1: roxadustat • Arm 2: darbepoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q1 2014 • Data anticipated: H1 2020 Sponsored by Astellas
Phase III **OLYMPUS** **NCT02174627**		2,781	• Arm 1: roxadustat • Arm 2: placebo Global trial	• Primary efficacy endpoint: Haemoglobin response • Primary safety objective: Contribute CV safety data to pooled safety • analyses across the Phase III program	• FPCD: Q3 2014 • LPCD: Q4 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by AstraZeneca
Phase III **ROCKIES** **NCT02174731**	Anaemia in CKD in patients receiving dialysis	2,133	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	• Primary efficacy endpoint: Haemoglobin response • Primary safety objective:Contribute CV safety data to pooled safety • analyses across the Phase III program	• FPCD: Q3 2014 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by AstraZeneca
Phase III **SIERRAS** **NCT02273726** **Partnered**		741	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2014 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III **PYRENEES** **NCT02278341** **Partnered**		838	• Arm 1: roxadustat • Arm 2: epoetin alfa or darbepoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2014 • LPCD: Q3 2018 • Data readout: Q3 2018 • Primary endpoint met Sponsored by Astellas

Roxadustat (HIF-PH inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III **HIMALAYAS** **NCT02052310** **Partnered**	Anaemia in newly initiated dialysis patients	1,043	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2013 • LPCD: Q3 2018 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III **NCT03263091** **Partnered**	Anaemia in lower risk MDS patients	184	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo US/global trial	• Primary endpoint: Proportion of patients achieving transfusion independence	• FPCD: Q3 2017 • Data anticipated: 2021 Sponsored by FibroGen
Phase II/III **NCT03303066** **Partnered**	Anaemia in lower risk MDS patients	175	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo China	• Primary endpoint: Haemoglobin response	• FPCD: Q2 2018 • Data anticipated: 2021 Sponsored by FibroGen
Phase II **NCT04076943** **Partnered**	Anemia in patients receiving chemotherapy treatment for non-myeloid malignancies	100	US	• Primary endpoint: Maximum change in hemoglobin within 16 weeks from baseline without RBC transfusion	• FPCD: Q3 2019 • Data anticipated: H2 2020 Sponsored by FibroGen

Eklira / Tudorza (LAMA, DPI)

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 • Arm 1: aclidinium bromide 200 µg DPI • Arm 2: aclidinium bromide 400 µg DPI • Arm 3: aclidinium bromide 800 µg DPI Global trial – one Country	• To investigate the PK of aclidinium bromide and its metabolites after single and multiple doses (BID) of aclidinium bromide 200 µg, 400 µg and 800 µg • To evaluate the safety, and tolerability of aclidinium bromide 200 µg, 400 µg and 800 µg after single and multiple dose administration (BID)	• FPCD: Q2 2018 • Data anticipated: 2021

Duaklir Genuair (LAMA/LABA, DPI)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III **AVANT** **NCT03022097**	Patients with stable COPD	1,060	• Arm 1: *Duaklir Genuair* 400/12 µg DPI • Arm 2: aclidinium bromide 400 µg DPI • Arm 3: formoterol fumarate 12 µg DPI • Arm 4: tiotropium 18 µg DPI Global trial – five countries	Primary endpoints: • Change from baseline in one hour morning post-dose dose FEV1 *Duaklir Genuair* 400/12 µg compared to Aclidinium bromide at Week 24 • Change from baseline in morning pre-dose (trough) FEV1 of *Duaklir Genuair* 400/12 µg compared to Formoterol fumarate at Week 24 • Change from baseline in trough FEV1 of Aclidinium bromide 400 µg compared to placebo at Week 24	• FPCD: Q1 2017 • Data anticipated: 2021

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

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT02536508**	Moderate to very severe COPD	500	Treatments (52-week treatment period) • 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: • Bone mineral density sub-trial endpoint. change from baseline in BMD of the lumbar spine measured using DXA (dual energy X-ray absorptiometry) scans of L1-L4 at week 52 • Ocular sub-trial safety endpoint change from baseline in LOCS III at week 52	• FPCD: Q3 2015 • LPCD: Q3 2016 • Data readout: Q1 2018 • Primary endpoints met
Phase III **ETHOS** **NCT02465567**	Moderate to very severe COPD	8,588	Treatments (1-year treatment period) • 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	• Primary endpoint: rate of moderate or severe COPD exacerbations • Secondary endpoint: time to first moderate or severe COPD exacerbation	• FPCD: Q3 2015 • LPCD: Q3 2018 • Data readout: Q3 2019 • Primary endpoint met
Phase III **KRONOS** **NCT02497001**	Moderate to very severe COPD	1,800	Treatments (24-week treatment period) • BGF MDI 320/14.4/9.6µg BID pMDI • GFF MDI 14.4/9.6µg BID pMDI • BFF MDI 320/9.6µg BID pMDI • *Symbicort Turbuhaler* 400/12µg BID DPI Randomised, double-blind, parallel-group, and chronic dosing and multi-centre Multi-country	Primary Endpoints: • FEV_1 area under curve from 0 to 4 hours (AUC0-4) over 24 weeks (BGF MDI vs. BFF MDI and BGF MDI vs. *Symbicort Turbuhaler*) • Change from baseline in morning pre-dose trough FEV_1 over 24 weeks (BGF MDI vs. GFF MDI) • TDI focal score over 24 weeks (BGF MDI vs. BFF MDI and BGF MDI vs. GFF MDI)	• 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) • BGF MDI 320/14.4/9.6µg BID pMDI • GFF MDI 14.4/9.6µg BID pMDI • BFF MDI 320/9.6µg BID pMDI • *Symbicort Turbuhaler* 400/12µg BID DPI Randomised, double-blind, parallel-group, chronic dosing, multicenter Country: Japan	Primary outcome measures: • Long-term safety and tolerability (52 weeks): adverse events, 12-lead ECG, laboratory tests, vital signs	• FPCD Q3 2016 • LPCD Q4 2017 • Data readout: Q3 2018 • Primary safety endpoint met

Daliresp/Daxas (PDE4 inhibitor, oral)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Post Launch PASS **NCT03381573**	COPD	124,080	• 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).	• Primary endpoint: all-cause mortality (up to five years)	• Data anticipated: 2021+

Fasenra (IL5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III MELTEMI NCT02808819	A multi-centre, open-label, safety extension trial with *Fasenra* for asthmatic adults on ICS plus LABA2 Agonist Age 18-75 years	770	• Arm 1: *Fasenra* 30mg Q4W s.c. • Arm 2: *Fasenra* 30mg Q8W s.c. Global trial - 15 countries	• Primary endpoint: safety and tolerability	• FPCD: Q2 2016 • LPCD: Q3 2019 • Data anticipated: H2 2020
Phase IIIb PONENTE NCT03557307	Severe eosinophilic asthmatics receiving HD ICS + LABA and chronic OCS with or without additional asthma controller(s). Age 18 Years and older	600	Arm 1: *Fasenra* 30mg Q8W s.c. 38-week trial Global trial – 16 countries	• Primary endpoint: reduction of oral corticosteroid dose	• FPCD: Q3 2018 • LPCD: Q3 2019 • Data anticipated: H2 2020
D3250C00036 China ICS/LABA Trial (MIRACLE) NCT03186209	Severe, uncontrolled asthma, despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	666	• Arm 1: *Fasenra* 30mg Q8W s.c. • Arm 2: placebo s.c. 56-week trial Global trial – 4 countries	• Primary endpoint: annual asthma exacerbation rate • Secondary endpoints: assess pulmonary function, asthma symptoms, other asthma control metrics	• FPCD: Q4 2017 • Data readout: 2021+

Fasenra (IL5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	2,550	• Arm 1: *Fasenra* 30mg Q4W s.c. • Arm 2: *Fasenra* 30mg Q8W s.c.* • placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial – 24 countries	• Primary endpoint: safety and tolerability	• 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	• Arm 1: *Fasenra* 30mg Q4W s.c. 28-week (adults) Global trial – two countries	• Primary endpoint: functionality, reliability, and performance of a pre-filled syringe with *Fasenra* administered at home	• 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 *Fasenra* on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years	38	• Arm 1 : *Fasenra* 30mg Q4W s.c. • Arm 2: placebo s.c. 37-week trial	• Primary endpoint: safety and tolerability • Primary endpoint: the effect of *Fasenra* on allergen induced eosinophil changes in sputum and allergen-induced late asthmatic response	• FPCD Q4 2016 • Data anticipated: H1 2020
Phase III **ALIZE** **NCT02814643**	A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of *Fasenra* on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years	100	• Arm 1: *Fasenra* 30mg Q4W s.c. with one dose of seasonal influenza virus vaccine IM at week eight • Arm 2: placebo Q4W s.c. with one dose of seasonal influenza virus vaccine intra muscular at week 12-week trial	Primary endpoints: • Post-dose strain-specific HAI) antibody GMFRs • Post-dose strain-specific serum HAI antibody GMTs • Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer	• FPCD: Q3 2016 • Data readout: Q3 2017 • Primary endpoint met

Fasenra (IL5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **GRECO** **NCT02918071**	Severe asthma on ICS-LABA Age 18-75 years	120	Open label *Fasenra* 30mg Q4w 28-week trial Global trial - two countries	• Primary endpoint: percentage of patients/ caregivers who successfully self administer at home	• 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 *Fasenra* 30 mg s.c. in patients with severe asthma uncontrolled on SoC treatment. Age 18-75	800	• Arm 1: *Fasenra* 30mg Q8W s.c. • Arm 2: placebo s.c. 24-week trial Global trial – 15 countries	• Primary endpoint: rate of asthma exacerbations • Secondary outcome measures: Saint George Respiratory Questionnaire (SGRQ)	• FPCD: Q3 2017 • LPCD: Q1 2019 • Data readout: Q4 2019 • Primary endpoint met
Phase I **AMES** **NCT02968914**	Healthy volunteers age 18-55 years	162	Open label trial to compare 30 mg *Fasenra* PK administered by APFS or AI device 8-week trial Global trial – two countries	• Primary endpoint: PK comparability	• FPCD: Q1 2017 • Data readout: Q3 2017

Fasenra (IL5R mAb)

Nasal polyposis and other eosinophilic diseases

Trial	Population	Patients	Design	Endpoints	Status
Phase III OSTRO **NCT03401229**	Patients with severe bilateral nasal polyposis who are still symptomatic despite standard of care therapy Age 18-75 years	400	• Arm 1: *Fasenra* 30mg Q8W s.c. • Arm 2: placebo s.c. 56-week trial Global trial- 8 countries	• Primary endpoint: effect of *Fasenra* on nasal polyp burden and on patient reported nasal blockage	• FPCD: Q1 2018 • LPCD: Q2 2019 • Data anticipated: H2 2020
Phase III ORCHID **NCT04157335**	Patients with eosinophilic chronic rhinosinusitis with severe nasal polyposis Age 18-75 years	148	Arm 1: *Fasenra* 30mg Q8W s.c. Arm 2: placebo Q8W s.c. 56-week trial Asian countries (4 countries)	• Primary endpoint: Change in endoscopic total nasal polyp score and Change in mean nasal blockage score	• FPCD: Q4 2019 • Data anticipated: 2021+
Phase III MANDARA **NCT04157348**	Patients with relapsing or refractory EGPA on corticosteroid therapy with or without stable immunosuppressive therapy Age 18 years and older	140	• Arm 1: *Fasenra* 30mg Q4W s.c. • Arm 2: mepolizumab 300mg Q4W s.c. 52-week trial with a minimum 1 year open label extension Global trial- 9 countries	• Primary endpoint: Proportion of patients achieving remission (BVAS=0 and OCS dose ≤ 4mg/day) at both weeks 36 and 48.	• FPCD: Q4 2019 • Data anticipated: 2021+
Phase III NATRON **NCT04191304**	Patients with HES (history of persistent eosinophilia >1500 cells/µL with evidence of end organ manifestations attributable to eosinophilia) and signs or symptoms of HES worsening/flare at Visit 1 Age 12 years and older	120	• Arm 1: *Fasenra* 30mg Q4W s.c. • Arm 2: placebo Q4W s.c. 24-week trial with a minimum 1 year open label extension Global trial- 9-12 countries	• Primary endpoint: Time to first HES worsening/flare.	• FPCD Q4 2019 • Data anticipated: 2021+
Phase III MESSINA	Documented diagnosis of EoE Age 12 to 65 years	170	• Arm 1: *Fasenra* 30mg Q4W s.c. • Arm 2: placebo Q4W s.c. 24-week double blind treatment period and open label period(s)	• Primary endpoints: Histologic response at week 24 Change from baseline in DSQ score at week 24	• Initiating • Data anticipated: 2021+

Fasenra (IL5R mAb)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase III **RESOLUTE** **NCT04053634**	Patients with moderate to very severe COPD with a history of frequent exacerbations on a background triple therapy (ICS/LABA/LAMA) Age 40-85 years	1216	• Double-blind, placebo controlled, single dose (100mg q8w) • 56-week treatment • Global trial	• Primary endpoint: annualized rate of moderate or severe exacerbations over 56 weeks	• FPCD Q4 2019 • Data anticipated: 2021+

PT027 (SABA/ICS, pMDI)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **MANDALA** **NCT03769090** **Managed by Avillion**	Moderate to severe asthma	3,100	Treatments (minimum 24-week treatment period) • 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: • Time to first severe asthma exacerbation Secondary endpoints: • Severe exacerbation rate (annualised) • Total corticosteroid exposure over the treatment period • Asthma Control Questionnaire -5 change from baseline and responder analysis at Week 24 • Asthma quality of life questionnaire for 12 years and older/paediatric asthma quality of life questionnaire change from baseline and responder analysis at week 24	• FPCD: Q4 2018 • Data anticipated: 2021
Phase III **DENALI** **NCT03847896** **Managed by Avillion**	Mild to moderate asthma	600	Treatments (12 week treatment period) • 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: • Change from baseline in FEV1 AUC0-6 hours over 12 weeks • Change from baseline in trough FEV1 at week 12	• FPCD: Q2 2019 • Data anticipated: H2 2020
Phase III **TYREE** **NCT04234464** **Managed by Avillion**	Asthma with exercise induced bronchoconstriction	60	Treatments (single dose) • BDA MDI 160/180 µg • placebo MDI QID Randomised, double-blind, multi-centre crossover Country: US	Primary endpoint: • The maximum percentage fall from post-dose, pre-exercise baseline in forced expiratory volume in 1 second (FEV1) observed up to 60 minutes post-exercise challenge	• FPCD Q1 2019 • FPCD: Q1 2020 • Data anticipated: H2 2020

Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III NAVIGATOR **NCT03347279** **Partnered**	Severe asthma Age 12-80 years	1,061	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 52 week trial Global trial – 18 countries	• 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)	• FPCD: Q1 2018 • LPCD: Q3 2019 • Data anticipated: H2 2020
Phase III SOURCE **NCT03406078** **Partnered**	Severe asthma Age 18-80 years	150	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 48 week trial Global trial – seven countries	• Primary endpoint: Reduction from baseline in daily OCS dose while not losing asthma control • Secondary endpoint: Annual asthma exacerbation rate	• FPCD: Q2 2018 • LPCD: Q4 2019 • Data anticipated: H2 2020
Phase III DESTINATION **NCT03706079** **Partnered**	Severe asthma Age 12-80 years	~975	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. Extension trial to NAVIGATOR and SOURCE. 52 week trial (subjects from NAVIGATOR); 56 week trial (subjects from SOURCE) Global trial – ~ 20 countries	• Primary endpoint: Exposure adjusted rates of AEs/SAEs Secondary endpoints: Annual asthma exacerbation rate	• FPCD: Q1 2019 • Data anticipated: 2021+
Phase III PATH-HOME **NCT03968978** **Partnered**	Severe asthma Age 12-80 years	216	• Arm 1: tezepelumab s.c. via autoinjector (AI) • Arm 2: tezepelumab s.c. via accessorized pre-filled syringe (APFS) 24 week trial Global trial – 4 countries	Primary endpoint: Proportion of health care professionals and subjects /caregivers who successfully administrated tezepelumab in clinic and at home with an APFS or an AI, respectively	• FPCD: Q2 2019 • LPCD: Q3 2019 • Data anticipated: H2 2020

Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase II CASCADE **NCT03688074** **Partnered**	Severe asthma Age 18-75 years	116	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 28 week trial Global trial – five countries	• Primary endpoint: number of airway submucosal inflammatory cells/mm2 of bronchoscopic biopsies	• FPCD: Q4 2018 • LPCD: Q4 2019
Phase III DIRECTION **NCT03927157** **Partnered**	Severe asthma Age 18-80 years	396	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 52 week trial Regional Asia trial – three countries	• 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)	• FPCD: Q3 2019
Phase III NOZOMI **NCT04048343** **Partnered**	Severe asthma 12-80 years	66	Arm 1: tezepelumab s.c. 52 week trial Local study - Japan	• Primary endpoint: Number of subjects with adverse events	• FPCD: Q2 2019

Tezepelumab (TSLP mAb)

Atopic dermatitis, COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb **NCT03809663** **Partnered**	Patients with chronic atopic dermatitis	300	A dose-ranging, double-blind, placebo-controlled study to evaluate the safety and efficacy of tezepelumab alone or combined with topical corticosteroids in moderate-to-severe atopic dermatitis • Arm 1: tezepelumab HD, s.c. Q2W • Arm 2: tezepelumab MD, s.c. Q4W • Arm 3: tezepelumab LD, s.c. Q2W • Arm 4: placebo, s.c. Q2W or Q4W	The effect of tezepelumab compared with placebo, assessed using the IGA and EASI	• FPCD: Q1 2019 • Data anticipated: 2021
Phase IIa COURSE **NCT04039113** **Partnered**	Moderate to very severe COPD Age 40-80	282	• Arm 1: tezepelumab s.c. • Arm 2: placebo s.c. 52 week trial Global trial – 10 countries	• Primary endpoint: Rate of moderate or severe COPD exacerbations	• FPCD Q3 2019 • Data anticipated: 2021+

Anifrolumab (type I interferon receptor mAb)

Lupus (SLE / LN)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **TULIP SLE 1** **NCT02446912**	Moderate to severe SLE	450	• Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks • Arm 2: 150mg i.v. anifrolumab Q4W for 48 weeks • Arm 3: placebo i.v. Q4W for 48 weeks	• Primary endpoint: response in SLE responder index at week 52	• FPCD: Q4 2015 • LPCD: Q4 2017 • Data readout: Q3 2018 • Primary endpoint not met
Phase III **TULIP SLE 2** **NCT02446899**	Moderate to severe SLE	360	• Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks • Arm 2: placebo i.v. Q4W for 48 weeks	• Primary endpoint: response in SLE responder index at week 52 BICLA at week 52	• FPCD: Q4 2015 • LPCD: Q4 2017 • Data readout: Q3 2019 • Primary endpoint met
Phase III **TULIP LTE** **NCT02794285**	Moderate to severe SLE	630	• Arm 1: 300mg i.v. anifrolumab Q4W for 152 weeks • Arm 2: placebo i.v. Q4W for 152 weeks	• Primary endpoint: extension to evaluate long-term safety and tolerability	• FPCD: Q2 2016 • LPCD: Q4 2018 • Data anticipated: 2021
Phase II **NCT01438489**	Moderate to severe SLE patients	307	• Arm 1: 300mg i.v. anifrolumab Q4W for 48 weeks • Arm 2: 1000mg i.v. anifrolumab Q4W for 48 weeks • Arm 3: placebo i.v. Q4W for 48 weeks	• Primary endpoint: response in SLE responder index at 6 months	• FPCD: Q1 2012 • LPCD: Q1 2015 • Data readout: Q3 2014
Phase II **NCT01753193**	Moderate to severe SLE patients	218	• Arm 1: anifrolumab, i.v. Q4W for 104 weeks	• Primary endpoint: open-label extension to evaluate long-term safety and tolerability	• FPCD: Q1 2013 • Data readout: Q4 2018
Phase II **NCT02962960**	Moderate to severe SLE patients	32	• Arm 1: 150mg s.c. every other week • Arm 2: 300mg s.c. every other week • Arm 3: placebo s.c. every other week	• PK/PD, safety, tolerability, primary analysis at week 12, secondary analysis at week 52	• FPCD: Q1 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
Phase II **TULIP-LN1** **NCT02547922**	Active Proliferative LN	150	• Arm 1: 900 mg i.v. Q4W for 12 weeks then 300mg i.v. anifrolumab Q4W for 36 weeks • Arm 2: 300 mg i.v. anifrolumab Q4W for 48 weeks • Arm 3: placebo i.v. Q4W for 48 weeks	• Response in proteinuria at week 52	• FPCD: Q4 2015 • LPCD: Q4 2018 • Data anticipated: 2021

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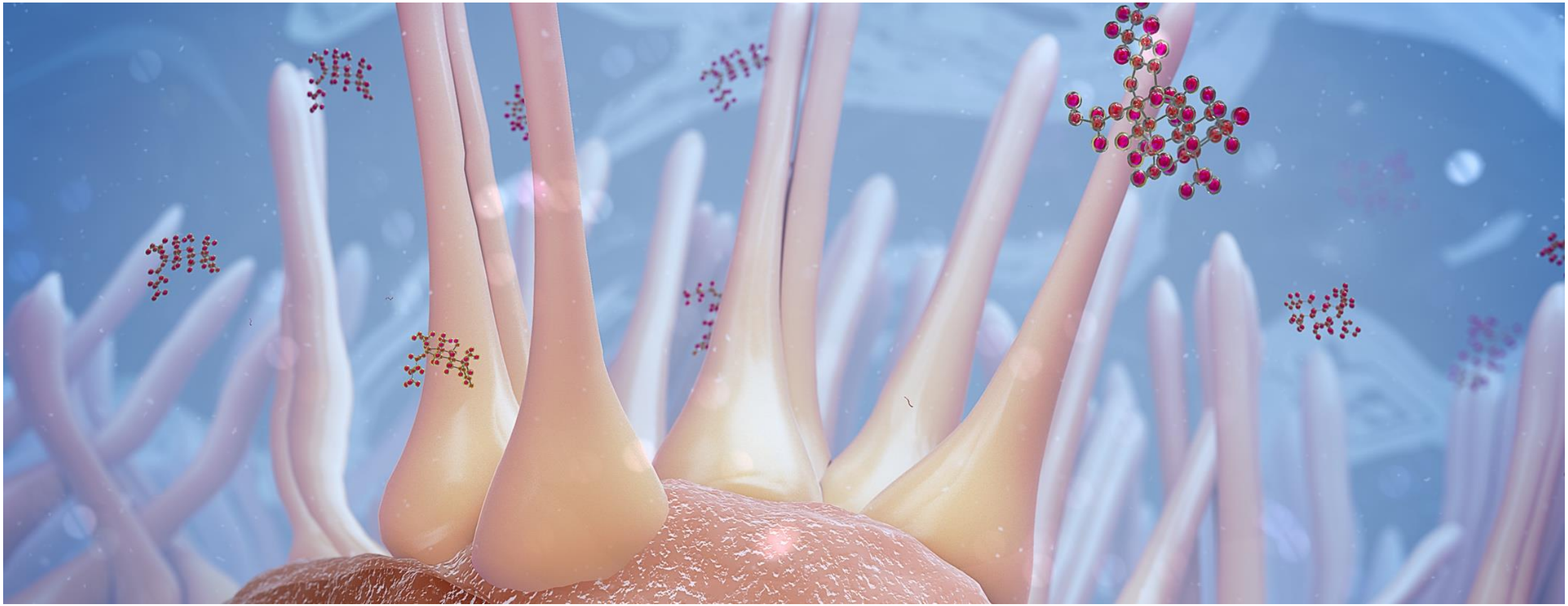
What science can do

BioPharmaceuticals - early-stage development



Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT03244800**	Adults with type-2 diabetes	65	• Arm1: cotadutide s.c. or placebo • Arm2: cotadutide s.c. or placebo • Germany	• Primary: efficacy MMT glucose AUC, body weight loss • Secondary: efficacy HbA1c, fasting plasma glucose • Secondary: safety profile in terms of adverse events, heart rate, blood pressure, vital signs, ECG, lab variables	• FPCD: Q3 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
Phase II **NCT03235050**	Overweight and Obese subjects with type-2 diabetes	834	• Arm1: cotadutide low dose s.c. + metformin • Arm2: cotadutide mid dose s.c. + metformin • Arm3: cotadutide high dose s.c. + metformin • Arm4: placebo s.c. + metformin • Arm5: liraglutide s.c. + metformin US, Canada, Bulgaria, Czech Rep, Germany, Mexico, Russia, Slovakia	• Primary: efficacy HbA1c, body weight loss • Secondary: percentage of subjects achieving weight loss of ≥5% and ≥10% • Secondary: proportion of subjects rescued or discontinued for lack of glycaemic control • Secondary: PK and immunogenicity	• FPCD: Q3 2017 • LPCD: Q1 2018 • Data readout Q3 2019
Phase II **NCT03444584**	Overweight/obese subjects with type-2 diabetes	49	• Arm1: cotadutide + dapagliflozin • Arm2: placebo + dapagliflozin • Germany, Hungary	• Primary: efficacy MMT glucose AUC • Secondary: safety • Secondary: PK • Secondary: immunogenicity	• FPCD: Q3 2018 • LPCD: Q4 2018 • Data readout: Q1 2019
Phase II **NCT03550378**	Adults with type-2 diabetes and renal impairment	41	• Cotadutide or placebo s.c. • Germany, UK	• Primary: efficacy MMT glucose AUC • Secondary: safety • Secondary: tolerability • Secondary: PK • Secondary: immunogenicity	• FPCD Q2 2018 • LPCD; Q4 2018 • Data readout: Q1 2019
Phase II **NCT03555994**	Adults with type-2 diabetes	44	• Part A: cotadutide or placebo s.c. • Part B: cotadutide s.c. or placebo s.c. or liraglutide s.c. • Sweden	• Primary: change in hepatic glycogen concentration postprandially, adjusted by liver volume • Secondary: safety • Secondary: tolerability • Secondary: immunogenicity	• FPCD: Q2 2018 • Part A LPCD: Q4 2018 • Data readout: Q1 2019 • Part B FPCD: Q1 2020

Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity, NASH

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03596177	Overweight and obese subjects with type-2 diabetes	27	• Cotadutide or placebo s.c. • UK	• 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	• FPCD: Q4 2018 • LPCD: Q4 2019 • Data anticipated: H2 2020
Phase I NCT03625778	Non-diabetic obese subjects	51	• Cotadutide or placebo s.c. with 7 week, 10 week or 16 week titration period • US	• Primary: safety, tolerability • Secondary: PK • Secondary: immunogenicity	• FPCD: Q3 2018 • LPCD: Q2 2019 • Data readout Q3 2019
Phase II NCT03745937	Overweight and obese subjects with type-2 diabetes	20	• Cotadutide or placebo s.c. • Germany	• Primary: safety, tolerability • Secondary: PK • Secondary: immunogenicity • Secondary: glucose control	• FPCD: Q1 2019 • LPCD: Q2 2019 • Data readout: Q3 2019
Phase II NCT03645421	Japanese preobese or obese subjects with type-2 diabetes	61	• MAD s.c. administration • Japan	• Primary: safety, glucose AUC, body weight • Secondary: HbA1c, FPG, fructosamine • Secondary: glucose control • Secondary: PK, immunogenicity	• FPCD: Q3 2018 • LPCD: Q3 2018 • Data readout: Q2 2019
Phase II NCT04019561	Obese subjects with non-alcoholic fatty liver disease (NAFLD)/non-alcoholic steatohepatitis (NASH)	72	• Arm1: cotadutide high dose s.c. • Arm2: placebo high dose s.c. • Arm3: cotadutide low dose s.c. • Arm4: placebo low dose s.c. • US	• Primary: safety and tolerability • Secondary: change in hepatic fat fraction, • Secondary: change in liver fat volume • Secondary: change in visceral adipose tissue	• FPCD: Q4 2019
Phase I NCT04091373	Healthy adult subjects	36		• Primary: to evaluate exposure following a single s.c of cotadutide at each of 3 different sites of injection • Secondary: immunogenicity • Secondary: safety and tolerability	• FPCD: Q4 2019 • LPCD: Q1 2020

Verinurad (RDEA3170, URAT1 inhibitor)

CKD

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT03118739**	CKD patients with hyperuricaemia, albuminuria, and Type 2 diabetes	60	• 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	• FPCD: Q2 2017 • LPCD: Q3 2018 • Data readout: Q4 2018
Phase II **NCT03316131**	Asymptomatic hyperuricaemic subjects (sUA (serum uric acid levels) > 6.0 mg/dL)	36	• 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.	• FPCD: Q4 2017 • LPCD: Q3 2018 • Data readout: Q4 2019
Phase II **NCT04024501**	Healthy volunteers	25	• Verinurad ER8 capsule formulation (fasted) • Verinurad capsule A formulation (fasted) • Verinurad capsule A formulation (fed) • Verinurad capsule B formulation (fasted) • Verinurad capsule B formulation (fed) This trial is a single centre trial conducted in Germany	Relative bioavailability (AUC, Cmax) between the ER8 capsule formulation given under fasted conditions and 2 new capsule formulation of verinurad (A-capsule and B-capsule) given under fed or fasted conditions	• FPCD: Q3 2019 • LPCD: Q3 2019 • Data readout: Q4 2019
Phase II **NCT03836599**	Healthy volunteers of Asian descent	23	• Arm A: verinurad 24 mg + allopurinol 300 mg • Arm B; verinurad 12 mg + allopurinol 300 mg • Arm C: Placebo This trial is a single centre trial conducted in the US	Safety analyses (AEs, ECG abnormalities, vital sign abnormalities, laboratory abnormalities) PK outcomes (AUC, Cmax, tmax)	• FPCD: Q1 2019 • LPCD: Q2 2019 • Data readout: Q4 2019
Phase II **NCT03990363**	Patients with: • sUA ≥6.0 mg/dL • eGFR ≥25 mL/min/1.73 m2 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI formula) • Mean UACR between 30 mg/g and 5000 mg/g	725	• Arm A; Verinurad 12 mg + allopurinol 300 mg • Arm B Verinurad 7.5 mg + allopurinol 300 mg • Arm C; Verinurad 3 mg + allopurinol 300 mg • Arm D; Verinurad placebo + allopurinol 300 mg • Arm E; Verinurad placebo + allopurinol placebo This trial is multi-centre trial conducted in USA, China, Czech Republic, France, Hungary, Israel, Italy, Mexico, Poland, Romania, Slovakia, South Africa, Spain	Ratio of urinary albumin to urinary creatinine Changes in eGFR, Cystatin C, and uric acid	• FPCD: Q3 2019 • LPCD: Q3 2021 • Data anticipated: 2021

AZD2373

Chronic Kidney Disease

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

AZD2693 (resolution of NASH)

NASH

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT04142424**	Healthy subjects	48	SAD 6 cohorts with 6 subjects receiving AZD2693 and 2 subjects receiving placebo in each cohort Route of administration: subcutaneous injections Trial conducted in the US.	Primary: • Safety and tolerability Secondary; • PK	• FPCD: Q4 2019 • Data anticipated: H2 2020

MEDI3506 (IL33 ligand mAb)

Diabetic Kidney Disease (DKD)

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT04170543**	Adult subjects with diabetic kidney disease	168	Randomized, double-blind, placebo-controlled, multicenter trial to evaluate the efficacy, safety, PK, and immunogenicity of MEDI3506 in adult subjects with diabetic kidney disease	• Efficacy and safety	• FPCD: Q4 2019

AZD4831 (MPO inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
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
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
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
Phase I NCT04232345	Healthy Subjects	40	SAD trial in Japanese and Chinese subjects	• Safety and tolerability	• FPCD Q1 2020 • LPCD Q3 2020

AZD5718 (FLAP inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT03317002**	CAD	129	• Arm 1: AZD5718 Dose A • Arm 2: AZD5718 Dose B • Arm 3: placebo Global trial – three countries in Europe	• Primary endpoint: PD effect of AZD5718 by assessment of u-LTE4	• FPCD: Q4 2017 • LPCD: Q4 2019
Phase I **NCT03948451**	Healthy subjects	6	hADME trial (one trial site in UK) • Oral administration Open-label trial to characterize the absorption, distribution, metabolism and excretion following a single oral dose of [14C]AZD5718 in healthy male volunteers	• Mass balance, with routes and rates of elimination of [14C]AZD5718. • Metabolite profiling and structural identification • PK and total radioactivity	• FPCD: Q2 2019 • LPCD: Q2 2019
Phase I **NCT04087187**	Healthy subjects	14	BA trial (one trial site in UK) An open-label, randomized, 3-period, 3-treatment, crossover trial to assess the drug absorption into the blood after administration of 3 doses of AZD5718	• To evaluate the pharmacokinetics and exposure of 3 different doses of AZD5718 • Safety and tolerability	• FPCD: Q4 2019 • LPCD: Q4 2019
Phase I **NCT04210388**	Healthy subjects	12	BA trial (one trial site in UK) The trial is a randomized, single-dose, open-label, combined 2x2 dose and 3x3 dose crossover design in fixed sequence.	To evaluate: • The relative bioavailability of different formulations • Safety and tolerability	• FPCD: Q1 2020 • LPCD: Q1 2020

AZD6615 (anti-hypercholesterolemia)

Hypercholesterolemia

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

MEDI7219 (anti-diabetic)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03362593**	Healthy Volunteers	130	• 5 part trial • Part A : SAD • Part B, C & E : open label, single dose studies • Part D : MAD	• Safety and tolerability • Pharmacokinetics	• FPCD: Q1 2018 • Data anticipated: H1 2020

AZD8233 (anti-hypercholesterolemia)

Hypercholesterolemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03593785**	Healthy subjects	56	SAD 7 cohorts with 6 subjects receiving AZD8233 and 2 subjects receiving placebo in each cohort Trial conducted in the US.	Primary: • Safety and tolerability Secondary; • PK and PD parameters	• FPCD: Q3 2018 • LPCD: Q3 2019
Phase I **NCT04155645**	T2DM	33	MAD Up to 3 cohorts with 8 subjects receiving AZD8233 and 3 subjects receiving placebo in each cohort Trial conducted in the US	Primary: • Safety and tolerability Secondary; • PK and PD parameters	• FPCD Q1 2020

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**	HF	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

AZD9977

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 • Data readout: Q3 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 • LPCD: Q2 2019 • Data readout: Q3 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 • Data readout: Q3 2019

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	• Cohort A: 2-dose regimen 300 mg of MEDI6012 or placebo on day 1 (loading dose) prior to pPCI followed by a second inpatient dose of 150 mg or placebo on Day 3 by i.v. push. • Cohort B: 6-dose regimen 300 mg of MEDI6012 or placebo on day 1 prior to pPCI followed by a second inpatient dose of 150 mg or placebo on day 3 and outpatient maintenance doses of 100 mg or placebo on days 10, 17, 24, and 31 by i.v. push.	Primary endpoints: Infarct size as a percentage of left ventricle (LV) mass at 10-12 weeks post-MI (myocardial infarction) compared to placebo Secondary endpoints: • Ejection Fraction at 10-12 weeks post-MI compared to placebo. • Change in NCPV in the coronary arteries from at10-12 weeks post-MI compared with placebo • Myocardial mass and LV volumes at end-systole and end-diastole • Incidence of TEAEs and treatment-emergent SAEs. • LCAT mass and ADAs	• FPCD: Q2 18 • Data anticipated: 2021+
Phase IIa **NCT03351738**	MEDI5884 cholesterol modulation	Adults with stable CHD	133	• MEDI5884 (5 dose cohorts) vs. placebo in stable CHD patients	• Safety profile in terms of AEs, vital signs, ECG, lab variables • Changes in HDL-C over time • PK, immunogenicity, and Apolipoprotein B	• FPCD Q4 2017 • Data readout: Q4 2018
Phase I **NCT03654313**	MEDI6570	Atherosclerotic cardiovascular disease	88	• SAD followed by multi ascending dose with 3 monthly doses in T2DM subjects	• Primary endpoints: Safety and tolerability	• FPCD: Q4 2018 • Data anticipated: 2021

Velsecorat (AZD7594, SGRM, inhaled)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03976869**	Adolescent asthma patients	24	An open-label, multi-centre, Phase I trial to assess the PK, PD and safety of 2-week treatment with inhaled velsecorat in adolescents (12 to 17 years) with asthma	Primary endpoint: • PK, safety and tolerability following 2 weeks treatment with velsecorat Secondary endpoints • Changes from baseline in lung function, asthma control and plasma cortisol on day 15	• FPCD: Q3 2019 • Data readout: H2 2020

AZD0449 (inhaled JAK-1 inhibitor)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03766399**	Healthy subjects and patients with mild asthma	156	SAD/MAD/Bridge trial (UK) Part 1 SAD • Dose escalation in 6 cohorts with 6 subjects receiving AZD0449 and 2 subjects receiving placebo in each cohort • i.v. cohort with 8 subjects Part 2 MAD: • 3 cohorts of (6, 6, 18) subjects receiving three different doses of AZD0449 and (3,3, 12) subjects receiving placebo in each cohort Part 3 bridge • 18 subjects will receive AZD0449 and 6 subjects receiving placebo Trial conducted in the UK	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters • FENO	• FPCD: Q4 2018

AZD1402 (IL4 receptor antagonist)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib **NCT03574805** **Partnered**	Patients with mild asthma	75	PoM. A dose-escalating, single blind trial to assess the safety, tolerability, and pharmacokinetics of multiple doses of PRS-060 administered by oral Inhalation In subjects with mild asthma Australia	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters • Potential immunogenicity • Change in FENO	• FPCD: Q3 2018

MEDI3506 (IL33 ligand mAb)

COPD, atopic dermatitis

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SAD / MAD) **NCT03096795**	SAD: healthy subjects with mild atopy J-SD: healthy Japanese subjects MAD: GOLD I-II COPD	SAD: 56 J-SD: 8 MAD: 24	SAD: • 7 sequential placebo-controlled single dose cohorts by either SC or IV route (active N=6 / placebo N = 2 within each cohort) J-SD: • single placebo-controlled single dose cohort by IV route (active N=6 / placebo N = 2 within cohort) MAD: • 3 sequential placebo-controlled multiple dosing cohorts by SC route (active N=6 / placebo N = 2 within each cohort) Conducted in UK	• Safety and tolerability	• FPCD: Q2 2017 • LPCD: Q2 2019 • Data anticipated: H2 2020
Phase II **NCT04212169**	Adult subjects with atopic dermatitis	152	Randomised, blinded, placebo-controlled trial to determine the efficacy and safety of different strengths of MEDI3506 by SC route Conducted in US, Australia, Germany & Poland	• Efficacy and safety	• FPCD: Q4 2019

AZD7986 (DPP1)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02653872**	Healthy volunteers	15	This is a phase I, non-randomised, fixed sequence, 3-period, drug-drug interaction trial to assess the PK of AZD7986 in healthy subjects when administered alone and in combination with multiple doses of verapamil and itraconazole or diltiazem • Arm 1: AZD7986 (alone) treatment period 1 • Arm 2: verapamil (with AZD7986) treatment period 2 • Arm 3: itraconazole (with AZD7986) treatment Period 3 • Arm 4: diltiazem (with AZD7986) treatment period 3	• Safety and tolerability • PK/PD and DDI	• FPCD: Q1 2016 • Data readout: Q2 2016
Phase I **NCT02303574**	Healthy volunteers	89	A phase I, randomised, single-blind, placebo-controlled, 2-part trial to assess the safety, tolerability, PK and food effect of single and multiple oral doses of AZD7986 in healthy volunteers. • Arm 1: AZD7986, single and multiple oral doses • Arm 2: placebo, single and multiple doses	• Safety and tolerability • PK/PD • Bioavailability	• FPCD: Q4 2014 • Data readout: Q3 2016

AZD8154 (PI3Kγδ inhibitor)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03436316**	Healthy subjects	78	SAD/MAD A Phase I trial to assess the safety, tolerability and PK of AZD8154 following single dose administration and multiple dose administration in healthy subjects	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters	• FPCD: Q3 2018 • LPCD: Q3 2019 • Data readout: Q4 2019

AZD8871 (MABA, inhaled)

Respiratory

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT03645434**	Patients with COPD	73	Randomised, double-blind, placebo and active-controlled crossover trial. Eligible patients will be randomised in 1:1:1:1:1:1 ratio to 1 of 6 treatment sequences and will receive 1 of the following 3 treatments sequence in the form of dry powder inhalation: • AZD8871 600 µg once daily • Anoro® Ellipta® (55 µg umeclidinium [UMEC]/ 22 µg vilanterol [VI]) once daily • Placebo	Primary endpoint: • Change from baseline in trough FEV_1 on day 15 Secondary endpoints: • To characterize the pharmacokinetics of AZD8871 following multiple inhaled doses • To assess safety and tolerability of AZD8871	• FPCD: Q4 2018 • LPCD: Q2 2019 • Data anticipated: Q3 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: • 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: • 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	• FPCD: Q2 2016 • Data readout: Q2 2018
Phase IIa **NCT03368235**	Patients with active RA	40	A randomised, double-blind, parallel trial to assess the efficacy, safety and tolerability of AZD9567 compared to prednisolone 20 mg in patients with active rheumatoid arthritis	Primary endpoint: To assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active RA in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs (Disease-modifying antirheumatic drugs) Secondary endpoints: • 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	• FPCD: Q1 2018

AZD0284 (RORγ inverse agonist)

Plaque psoriasis vulgaris

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02976831**	Healthy subjects	80	Part 1 (SAD) • Seven different dose levels investigated vs. placebo • Oral administration	• 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	• FPCD: Q3 2016 • LPCD: Q2 2017
			Part 2 (MAD) • Three different dose levels investigated vs. placebo in healthy subjects • Oral administration	• Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses • PoM confirmed by demonstrating that oral dosing of AZD0284 reduces IL-17 secretion by ex vivo stimulated whole blood T cells	• FPCD: Q1 2017 • LPCD: Q1 2017
Phase I **NCT03029741**	Healthy subjects	6	A single centre, open-label, non-randomised, single dose trial performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The trial will assess the absolute bioavailability of a single oral dose of AZD0284 and the pharmacokinetics (PK) of a single intravenous (IV) microdose of [14C] AZD0284 in healthy male and female subjects. Oral AZD0284 and [14C] AZD0284 intravenous solution are referred to as the investigational products in this trial	• Determination of absolute bioavailability of AZD0284 • Safety and tolerability of AZD0284	• FPCD: Q1 2017 • LPCD: Q1 2017
Phase Ib **NCT03310320**	Moderate to severe plaque psoriasis	25 planned 5 completed 9 dosed	A randomised, double-blind, placebo-controlled, multi-centre, parallel group Phase Ib trial, 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	• 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 PASI compared to placebo • Safety and tolerability and PK following 4 weeks oral administration with single ascending dose	• 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 trial, in the meantime, and for portfolio and prioritisation reasons, a decision was taken in Q3 2018 to end the trial.

MEDI0618 (PAR2 antagonist mAb)

Osteoarthritis pain

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02508155**	Painful osteoarthritis of the knee	64 (healthy volunteers)	• SAD • Up to 8 i.v. cohorts are planned vs. placebo • 1 s.c. cohortis planned vs. placebo Europe only	• Safety, tolerability and PK	• FPCD: Q4 2019

MEDI1341 (alpha-synuclein mAb)

Parkinson's Disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03272165**	Healthy volunteers	48	• SAD • Up to 6 i.v. cohorts are planned vs. placebo US only	• Safety, tolerability, PK, PD	• FPCD: Q4 2017 • Data anticipated: H2 2020

AZD4041 (orexin 1 receptor antagonist)

Opioid use disorder

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT04076540** **Partnered with Eolas Therapeutics Inc and NIH.**	Healthy volunteers	48 healthy volunteers	• Randomised, double blind, single ascending dose • Up to 6 cohorts are planned vs. placebo Single centre in US only	• Safety, tolerability, PK, PD	• FPCD: Q4 2019 • Data anticipated: H2 2020

AZD5634 (ENaC, inhaled)

Cystic Fibrosis

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02679729**	Healthy volunteers	56	A randomised, single-blind, placebo-controlled trial to assess the safety, tolerability and pharmacokinetics of AZD5634 following single-ascending inhaled doses (Part A) and after single inhaled and intravenous doses (Part B) in healthy subjects • Arm 1: AZD5634 following inhaled administration of SAD (Part A) and following administration of single inhaled and i.v. doses (Part B) • Arm 2: placebo	• Safety and tolerability • PK/PD	• FPCD: Q1 2016 • Data readout: Q4 2016
Phase Ib **NCT02679729**	Patients with cystic fibrosis	9	A randomised blinded placebo-controlled, cross-over trial to assess the effect of AZD5634 on mucociliary clearance as well as safety, tolerability, and PK parameters following single inhaled dose administration to patients with cystic fibrosis • Arm 1: subjects were administered single dose of placebo in period 1 and AZD5634 in period 2 • Arm 2: subjects were administered single dose of AZD5634 in period 1 and placebo in period 2	• Safety and tolerability • PK/PD	• FPCD: Q2 2017 • Data readout: Q2 2018

MEDI7352 (NGF TNF bispecific mAb)

Osteoarthritis pain

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02508155**	Painful osteoarthritis of the knee	160	• SAD & MAD • Up to 12 i.v. cohorts are planned vs. placebo • 1 s.c. cohorts are planned vs. placebo Europe only	• Safety, tolerability, PK, PD	• FPCD: Q1 2016 • Data anticipated: H1 2020
Phase II **NCT03755934**	Painful diabetic neuropathy	271	• Multiple dose trial • Up to 4 i.v. cohorts are planned vs. placebo Europe only	• Dose response, safety, tolerability, PK, PD	• FPCD Q4 2018 • Data anticipated: 2021

Other biologics

Infections

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II **EudraCT 2014-001097-34**	Anti-Staph AT (suvratoxumab, MEDI4893)	Intubated ICU	213	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and safety	• FPCD: Q4 2014 • Data readout: Q4 2018
Phase IIb **NCT02878330**	Anti-Respiratory Syncytial Virus mAb-YTE nirsevimab (MEDI8897)	29-35 WK GA (Gestational age) infants	1,453	• Randomised, double-blind, placebo-controlled trial • Route of administration: intramuscular	• Safety and efficacy	• FPCD: Q4 2016 • Data readout: Q4 2018
Phase II **NCT02696902**	Anti-Pseudomonas A mAb (MEDI3902)	Intubated ICU	195	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and safety	• FPCD: Q2 2016 • Data anticipated: H2 2020

List of abbreviations

14C	Radioactive isotope of carbon, Carbon 14
1L, 2L, 3L	1st, 2nd or 3rd line
5-FU	5-fluorouracil
A2AR	Adenosine A2A receptor
ACQ	Asthma control questionnaire
ACR	American college of rheumatology response scoring system
ADA	Anti-drug antibodies
ADC	Antibody-drug conjugate
ADP	Adenosine diphosphate
AE	Adverse Event
AI	Auto-injector
AKT	Protein kinase B
ALK	Anaplastic large-cell lymphoma kinase
APFS	Accessorised pre-filled syringe
AQLQ	Asthma quality of life questionnaire
AS	Albuterol sulphate
ATM	Ataxia-telangiectasia mutated kinase
ATR	Ataxia telangiectasia and rad3-related protein
AUC	Area under curve
B7RP	B7-related protein-1
BA	Bioavailability
BAFF	B-cell activating factor
BCG	Bacillus Calmette–Guérin
BCMA	B-cell maturation antigen
BDA	Budesonide albuterol
BFF	Budesonide and formoterol fumarate
BGF	Budesonide, glycopyrronium and formoterol fumarate
BICR	Blinded independent central review
BID	Bis in die (twice per day)
BIG	Big ten cancer research consortium
BMD	Bone mineral density
BMI	Body mass index
BRCAwt	Breast cancer wild-type gene
BRD4	Bromodomain-containing protein 4
BTC	Biliary tract carcinoma
BTK	Bruton's tyrosine kinase
CA-125	Cancer antigen 125
CAD	Coronary artery disease
CBR	Clinical benefit rate
CCL20	Chemokine (C-C motif) ligand 20
CD	Cluster of differentiation
CDK	Cyclin-dependent kinase
CE	Clinically evaluable
CHD	Coronary heart disease
Chemo	Chemotherapy
CHF	Chronic heart failure
CKD	Chronic kidney disease
CLL	Chronic lymphocytic leukaemia
CMAX	Maximum observed plasma concentration
C-MET	Tyrosine-protein kinase Met
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
CR	Complete response
CRC	Colorectal cancer
CrCl	Creatinine clearance
CRR	Complete response rate
CTC	Circulating tumour cell
CTLA-4	Cytotoxic T-lymphocyte–associated antigen 4
CV	Cardiovascular
CVOT	Cardiovascular outcomes trial
CVRM	Cardiovascular renal and metabolism
CXCR2	C-X-C Motif chemokine receptor 2
DB	Double blind
DC	Disease control
DCR	Disease control rate
DDI	Drug-drug Interaction
dECG	Differentiated electrocardiogram
DFS	Disease free survival
DLBCL	Diffuse large B-cell lymphoma
DLT	Dose-limiting toxicity
DMARDs	Disease-modifying antirheumatic drugs
DNA	Deoxyribonucleic acid
DoCR	Durability of complete response
DoR	Duration of response
DPI	Dry powder inhaler
DXA	Dual energy X-ray absorptiometry
EBRT	External beam radiation therapy
ECG	Electrocardiogram
EFS	Event-free survival
eGFR	Estimated glomerular filtration rate
EGFR	Epidermal growth factor receptor
ER	Oestrogen receptor
ERK	Extracellular signal-regulated kinase
ESR	Externally sponsored trial
ESR1	Oestrogen receptor 1
ESSC	Esophageal squamous cell carcinoma
FDC	Fixed-dose combination
FeNO	Fractional nitric oxide concentration in exhaled breath
FEV	Forced-expiratory volume
FGFR	Fibroblast growth factor receptor
FLAP	5-lipoxygenase-activating protein
FPDC	First patient commenced dosing
FPG	Fasting plasma glucose
GA	Gestational age
GBM	Glioblastoma
gBRCAm or tBRCAm	Germline or tumour BRCA mutation somatic
GEJ	Gastric/gastro-oesophageal junction
GFF	Glycopyrronium and formoterol fumarate
GLP-1	Glucagon-like peptide-1
GMFRs	Geometric mean fold rises
GMTs	Geometric mean titers
HAI	Haemagglutination-inhibition
HbA1c	Hemoglobin A1c
HCC	Hepatocellular carcinoma
HD	High dose
HDL-C	High-density lipoprotein cholesterol
HER2	Human epidermal growth factor receptor 2
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HFrEF	Heart failure with reduced ejection fraction
HGFR	Met/hepatocyte growth factor receptor
HGSC	High grade serous carcinoma
hHF	Hospitalisation for heart failure
HIF-PHI	Hypoxia inducible factor - prolyl hydroxylase inhibitor
HNSCC	Head and neck squamous-cell carcinoma
HPV	Human papillomavirus
HRD	Homologous recombination deficiency
HRRm	Homologous recombination repair mutation
i	inhibitor
IA	Investigator-assessed
ICS	Inhaled corticosteroid
ICU	Intensive care unit
IDFS	Invasive disease-free survival
IL	Interleukin
i.m.	Intramuscular
IRC	Independent review committee
ISS	Investigator-sponsored studies
i.v.	Intraveneous
J-SD	Japanese single dose
Ki67	Protein that is encoded by the MKI67 gene in human

List of abbreviations

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

Clinical trials appendix
Q1 2020 results update

AstraZeneca
What science can do