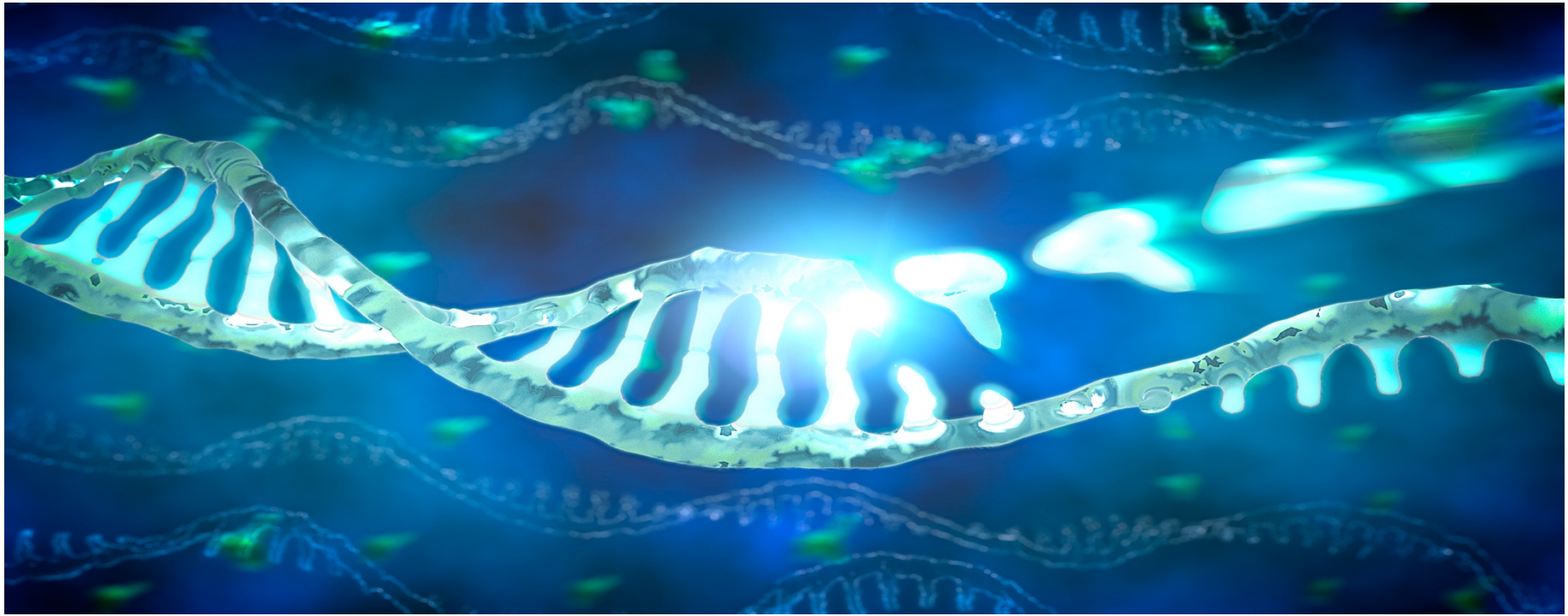
Clinical trials appendix
Q4 2018 results update

AstraZeneca
What science can do



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from clinicaltrials.gov to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 31 December 2018, unless otherwise specified.

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

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

List of abbreviations

ADA	Anti-Drug Antibody
ADC	Antibody-Drug Conjugate
AE	Adverse Event
AUC	Area Under Curve
BD/BID	Bis In Die (two times a day)
CE	Clinically Evaluable
CMAX	Maximum Concentration Absorbed
CNS	Central Nervous System
DCR	Disease Control Rate
DDI	Drug-Drug Interaction
DFS	Disease Free Survival
DLT	Dose-Limiting Toxicity
DoR	Duration of Response
DPI	Dry Powder Inhaler
FDC	Fixed-Dose Combination
FEV	Forced-Expiratory Volume
FPCD	First Patient Commenced Dosing
HRRm	Homologous Recombination Repair mutation
ICS	Inhaled Corticosteroid
IM	Intra Muscular
IR	Immediate Release
IV	Intravenous
LABA	Long Acting Beta Agonist
LAMA	Long Acting Muscarinic Agonist
LCM	Lifecycle Management
LPCD	Last Patient Commenced Dosing
MAD	Multiple Ascending Dose
MDI	Metered-Dose Inhaler
MTD	Maximum Tolerated Dose
NME	New Molecular Entity
OCS	Oral Corticosteroid
ORR	Objective Response Rate
OS	Overall Survival
PARP	Poly ADP Ribose Polymerase
PD	Pharmacodynamics
PFS	Progression-Free Survival
PK	Pharmacokinetics
pMDI	Pressurised Metered Dose Inhaler
PoC	Proof of Concept
PR	Partial Response
Q2W	Quaque (every) Two Weeks
Q3W	Quaque (every) Three Weeks
Q4W	Quaque (every) Four Weeks
Q8W	Quaque (every) Eight Weeks
QD	Quaque Die (one time a day)
QOD	Quaque Altera Die (every other day)
QoL	Quality of Life
SAD	Single Ascending Dose
SC	Subcutaneous
SoC	Standard of Care
TID	Ter In Die (three times a day)
VEGF	Vascular endothelial growth factor
XR	Extended release

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Movement since Q3 2018 update

New to Phase I

NME

MEDI6570
LOX-1 mAb cardiovascular disease

AZD0449
Inhales JAK inhibitor asthma

AZD9833
SERD ER+breast

New to Phase II

NME

***Imfinzi*# + oleclumab**
PD-L1 mAb + CD73 mAb solid tumours

***Imfinzi*# + monalizumab#**
PD-L1 mAb + NKG2a mAb solid tumours

AZD4831
myeloperoxidase heart failure with a preserved ejection fraction

MEDI7352
NGF/TF bi-specific mAb painful diabetic neuropathy

New to Pivotal Study

NME

PT027
ICSC/SABA asthma

Lifecycle Management

***Imfinzi*# + CRT PACIFIC-5 (China)**
PD-L1 mAb + CRT locally-advanced (stage III) NSCLC

***Imfinzi*# + CTx neoadjuvant AEGEAN**
PD-L1 mAb + CTx locally-advanced (stage III) NSCLC

***Imfinzi*# + CTx NIAGARA**
PD-L1 mAb + CTx muscle invasive bladder cancer

***Imfinzi*# + VEGF + TACE EMERALD-1**
PD-L1 mAb + VEGF + TACE locoregional hepatocellar carcinoma

***Lynparza*+abiraterone# PROpel**
PARP inhibitor + NHA prostate cancer

New to Registration

Removed from Phase I

Additional indications

***Imfinzi*# or *Imfinzi*# + (tremelimumab or danvatirsen)**
PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor) diffuse large B-cell lymphoma

***Imfinzi*# + MEDI0562#**
PD-L1 mAb + humanised OX40 agonist solid tumours

***Imfinzi*# + MEDI9197#**
PD-L1 mAb + TLR 7/8 agonist solid tumours

tremelimumab + MEDI0562#
CTLA-4 mAb + humanised OX40 agonist solid tumours

MEDI0562#
humanised OX40 agonist solid tumours

MEDI1873
GITR agonist fusion protein solid tumours

MEDI9197#
TLR 7/8 agonist solid tumours

Removed from Phase III

NME

***Imfinzi*#+tremelimumab MYSTIC**
PD-L1 mAb + CTLA-4 mAb 1st line NSCLC

Additional indications

***Imfinzi*#+tremelimumab EAGLE**
PD-L1 mAb + CTLA-4 mAb 2nd line HNSCC

Removed from Registration

NME

roxadustat# [CN] [2]
hypoxia-inducible factor prolyl hydroxylase inhibitor anaemia in chronic kidney disease/end stage renal disease

Lifecycle Management

***Lynparza*# SOLO-1 [US] [2]**
PARP inhibitor 1st-line *BRCA*m ovarian cancer

***Linzess* (linaclotide) [CN] [2]**
GC-C receptor peptide agonist irritable bowel syndrome with constipation

¶ Registrational Phase II/III study
# Partnered and/or in collaboration
[1] Submission Accepted [2] Submission Approved [3] Completed

Note: No projects removed from Phase II since last quarter

Q4 2018 New Molecular Entity (NME)[1] pipeline

Phase I
26 New Molecular Entities

- AZD0156 ATM solid tumours
- *Imfinzi*#+dabrafenib+trametinib PD-L1+BRAF+MEK melanoma
- AZD1390 glioblastoma
- *Imfinzi*#+*Iressa* PD-L1+EGFR NSCLC
- AZD4573 CDK9 haematalogical malignancies
- *Imfinzi*#+RT (platform) CLOVER PD-L1+RT HNSCC NSCLC SCLC
- AZD4785 KRAS solid tumours
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 solid tumours
- AZD5153 BRD4 solid tumours
- *Imfinzi*#+tremelimumab+chemo PD-L1+CTLA-4 1L PDAC oesophageal SCLC
- AZD5991 MCL1 haematalogical malignancies
- MEDI2228 BCMA ADC multiple myeloma
- AZD9496 SERD ER+ breast
- MEDI3726# PSMA ADC prostate
- AZD9833 SERD ER+ breast
- MEDI5083 CD40 ligand fusion protein solid tumours
- *Calquence*+AZD6738 BTK+ATR haematalogical tumours
- MEDI5752 PD-1/CTLA-4 solid tumours
- *Calquence*+danvatirsen BTK+STAT3 haematalogical malignancies
- MEDI7247 ASCT2 ADC haematological malignancies
- *Imfinzi*#+adavosertib# PD-L1+Wee1 solid tumours
- oleclumab CD73 solid tumours
- *Imfinzi*+selumetinib# PL-L1+MEK solid tumours
- oleclumab+AZD4635 CD73+A2aR EGFRm NSCLC
- *Imfinzi*#+azacitidine# PD-L1+azacitidine MDS
- oleclumab+*Tagrisso* CD73+EGFR EGFRm NSCLC

Phase II
20 New Molecular Entities

- adavosertib#+chemotherapy Wee1+chemo ovarian cancer
- *Imfinzi*#+MEDI0680 PD-L1+PD-1 solid tumours
- AZD2811# Aurora solid tumours
- *Imfinzi*#+monalizumab# PD-L1+NKG2a solid tumours
- AZD4547 FGFR solid tumours
- *Imfinzi*#+oleclumab PD-L1+CD73 solid tumours
- AZD4635 A2aR inhibitor solid tumours
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 gastric cancer
- AZD6738 ATR solid tumours
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 biliary tract oesophageal
- AZD8186 PI3Kβ solid tumours
- *Lynparza*#+adavosertib# PARP+Wee1 solid tumours
- capivasertib# AKT breast cancer
- *Lynparza*#+AZD6738 PARP+ATR gastric
- *Imfinzi*#+AZD5069 or *Imfinzi*#+danvatirsen# PD-L1+(CXCR2 or STAT3) HNSCC bladder NSCLC
- *Lynparza*#+AZD6738 or +adavosertib# VIOLETTE
- *Imfinzi*+*Lynparza*# BAYOU PD-L1+PARP bladder
- *Lynparza*#+*Imfinzi* MEDIOLA PARP+PD-L1 ovarian breast gastric SCLC
- *Imfinzi*#+MEDI0457# PD-L1+DNA HPV vaccine HNSCC
- *Tagrisso* combo# TATTON EGFR+PD-L1/MEK/MET NSCLC

Phase III
11 New Molecular Entities

- *Imfinzi*#+tremelimumab DANUBE PD-L1+CTLA-4 1L bladder
- *Imfinzi*#+tremelimumab HIMALAYA PD-L1+CTLA-4 1L HCC
- *Imfinzi*#+tremelimumab KESTREL PD-L1+CTLA-4 1L HNSCC
- *Imfinzi*#+tremelimumab NEPTUNE PD-L1+CTLA-4 1L NSCLC
- *Imfinzi*#+tremelimumab+CRT ADRIATIC PD-L1+CTLA-4+CRT LD-SCLC
- *Imfinzi*#+tremelimumab+SoC CASPIAN PD-L1+CTLA-4+SoC 1L SCLC
- *Imfinzi*#+tremelimumab+SoC NILE PD-L1+CTLA-4+SoC 1L urothelial cancer
- *Imfinzi*#+tremelimumab+SoC POSEIDON PD-L1+CTLA-4+SoC 1L NSCLC
- *Lynparza*#¶+cediranib CONCERTO PARP+VEGF recurrent Pt-R ovarian
- savolitinib# SAVOIR MET pRCC
- selumetinib#¶ SPRINT MEK paediatric neurofibromatosis type-1

Applications Under Review
0 New Molecular Entities

[1] Includes significant fixed-dose combination projects, and parallel indications and oncology combination projects
Partnered and/or in collaboration; ¶ Registrational P2/3 study

Oncology

Cardiovascular, Renal & Metabolism, Respiratory, Other

Oncology Q4 2018 Lifecycle Management (LCM)[1] pipeline

Phase I
0 Projects

Phase II
2 Projects

- *Calquence* BTK haematalogical malignancies
- *Imfinzi#* PD-L1 solid tumours

Phase III
18 Projects

- *Calquence#* BTK inhibitor 1st line MCL
- *Calquence#* BTK inhibitor 1st line CLL
- *Calquence#* BTK inhibitor r/r CLL, high risk
- *Calquence#* BTK inhibitor r/r CLL
- *Imfinzi#* PEARL (China) PD-L1 1L 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 mAb + CRT locally-advanced stage III
- *Imfinzi#*+CTx neoadjuvant AEGEAN PD-L1+CTx locally-advanced stage III NSCLC
- *Imfinzi#*+CTx NIAGARA PD-L1+CTx muscle invasive bladder cancer
- *Imfinzi#*+VEGF+TACE EMERALD-1 PD-L1 mAb + VEGF + TACE locoregional HCC
- *Lynparza#* OlympiA PARP gBRCA adjuvant breast
- *Lynparza#* POLO PARP pancreatic cancer
- *Lynparza#* PROfound PARP prostate cancer
- *Lynparza#* SOLO-3 PARP BRCAm PSR ovarian
- *Lynparza*+abiraterone# PROpel PARP + NHA prostate cancer
- *Tagrisso* ADAURA EGFR adj. EGFRm NSCLC
- *Tagrisso* LAURA EGFR adj. EGFRm NSCLC

Applications Under Review
0 Projects

[1] Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market

Partnered and/or in collaboration; ¶ Registrational P2/3 study

Oncology

Cardiovascular, Renal & Metabolism, Respiratory, Other

Cardiovascular, Renal & Metabolism, Respiratory, Other Q4 2018 New Molecular Entity (NME)[1] pipeline

Phase I
13 New Molecular Entities

- AZD0449 Inhaled JAK inhibitor asthma
- AZD1402# inhaled IL-4Ra asthma
- AZD5634 inhaled ENaC cystic fibrosis
- AZD8154 Inhaled PI3Kgd asthma
- MEDI3506 IL-33 COPD
- AZD8233 hypercholesterolemia cardiovascular
- AZD9977 MCR cardiovascular
- MEDI6570 LOX-1 CV disease
- MEDI7219 anti-diabetic type-2 diabetes
- AZD0284 RORg psoriasis/respiratory
- MEDI0700# BAFF/B7RP1 SLE
- MEDI1341 alpha synuclein Parkinson's disease
- MEDI1814# amyloidβ Alzheimer's disease

Phase II
23 New Molecular Entities

- abediterol# LABA asthma/COPD
- AZD1419# inhaled TLR9 asthma
- AZD7594 Inhaled SGRM asthma/COPD
- AZD7986# DPP1 COPD
- AZD8871# MABA COPD
- AZD9567 SGRM RA/respiratory
- PT010 LABA/LAMA/ICS asthma
- tezepelumab# TSLP atopic dermatitis
- AZD4831 MPO HFpEF
- AZD5718 FLAP coronary artery disease
- AZD8601# VEGF-A cardiovascular
- verinurad URAT-1 chronic kidney disease
- cotadutide (MEDI0382) GLP-1/glucagon type-2 diabetes
- MEDI5884# cholesterol modulation cardiovascular
- MEDI6012 LCAT cardiovascular
- anifrolumab# Type I IFN receptor SLE SC
- anifrolumab# Type I IFN receptor lupus nephritis
- MEDI3902 PsI/PcrV Pseudomonas pneumonia
- MEDI7352 NGF/TNF painful diabetic neuropathy / osteoarthritis pain
- MEDI8852 influenza A treatment
- MEDI8897# passive RSV prophylaxis
- prezalumab# primary Sjögren's syndrome
- suvratoxumab α-Toxin Staphylococcus pneumonia

Phase III
3 New Molecular Entities

- PT027 ICS/SABA asthma
- tezepelumab# NAVIGATOR SOURCE TSLP severe uncontrolled asthma
- anifrolumab# TULIP Type I IFN receptor SLE

Applications Under Review
1 New Molecular Entity

- PT010 LABA/LAMA/ICS COPD

[1] Includes significant fixed-dose combination projects, and parallel indications
Partnered and/or in collaboration; ¶ Registrational P2/3 study

Oncology

Cardiovascular, Renal & Metabolism, Respiratory, Other

Cardiovascular, Renal & Metabolism, Respiratory, Other Q4 2018 Lifecycle Management (LCM)[1] pipeline

Phase I	Phase II	Phase III	Applications Under Review
0 Projects	0 Projects	11 Projects	4 Projects
		Fasenra# IL-5R COPD	*Symbicort* SYGMA as needed in mild asthma
		Fasenra# OSTRO IL-5R nasal polyposis	*Farxiga/Forxiga* DEPICT type-1 diabetes
		Brilinta/Brilique HESTIA P2Y12 paeds w/ sickle cell	saxagliptin/dapagliflozin metformin DPP4 type-2 diabetes
		Brilinta/Brilique THALES P2Y12 stroke	*Nexium* (CN only) stress ulcer prophylaxis
		Brilinta/Brilique THEMIS P2Y12 diabetes & CAD outcomes	
		Epanova STRENGTH outcomes	
		Farxiga/Forxiga SGLT2 HFrEF	
		Farxiga/Forxiga SGLT2 CKD	
		Farxiga/Forxiga DECLARE outcomes	
		Farxiga/Forxiga DELIVER SGLT2 HFpEF	
		roxadustat# HIFPH anaemia MDS	

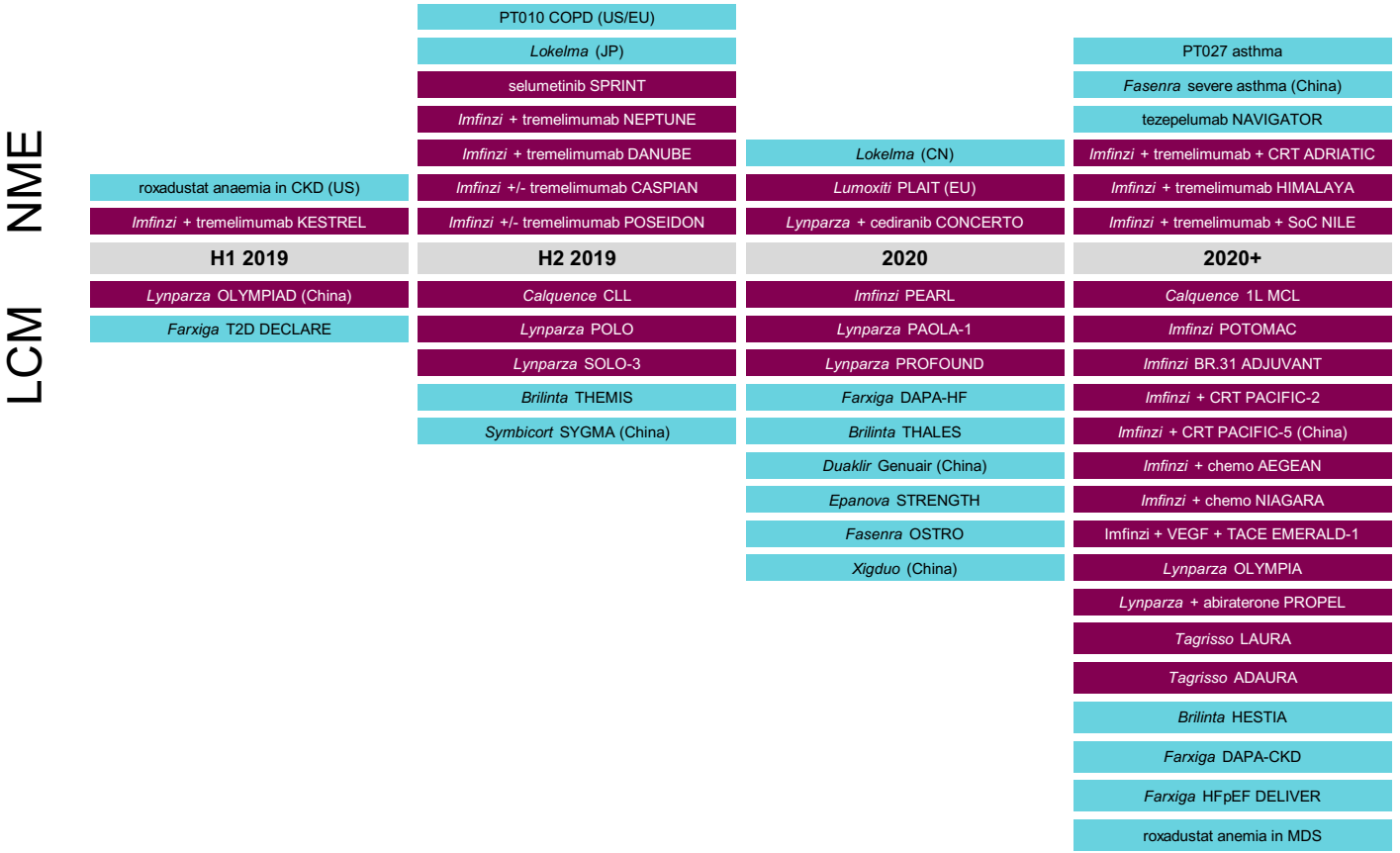
[1] Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market

Partnered and/or in collaboration; ¶ Registrational P2/3 study

Oncology

Cardiovascular, Renal & Metabolism, Respiratory, Other

Estimated key regulatory submission acceptances



Designations

4 Accelerated approvals

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

8 Breakthrough Therapy

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

8 Fast Track

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

20 Priority Review / PRIME

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

22 Orphan Drug

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

Fast track is a process designed to facilitate the development, and expedite the review of medicines to treat serious conditions and fill an unmet medical need.
Breakthrough therapy is a process designed to expedite the development and review of medicines which may demonstrate substantial improvement over available therapy.
Accelerated approval, these regulations allowed medicines for serious conditions that addressed an unmet medical need to be approved based on a surrogate endpoint.
Priority Review designation is the US FDA's goal to take action on an application within 6 months. PRIME is a scheme launched by the EMA to enhance support for the development of medicines that target an unmet medical need
Orphan Drug Designation, intended for treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 patients in the US, or that affect more than 200,000 patients but are not expected to recover the costs of developing and marketing a treatment drug.

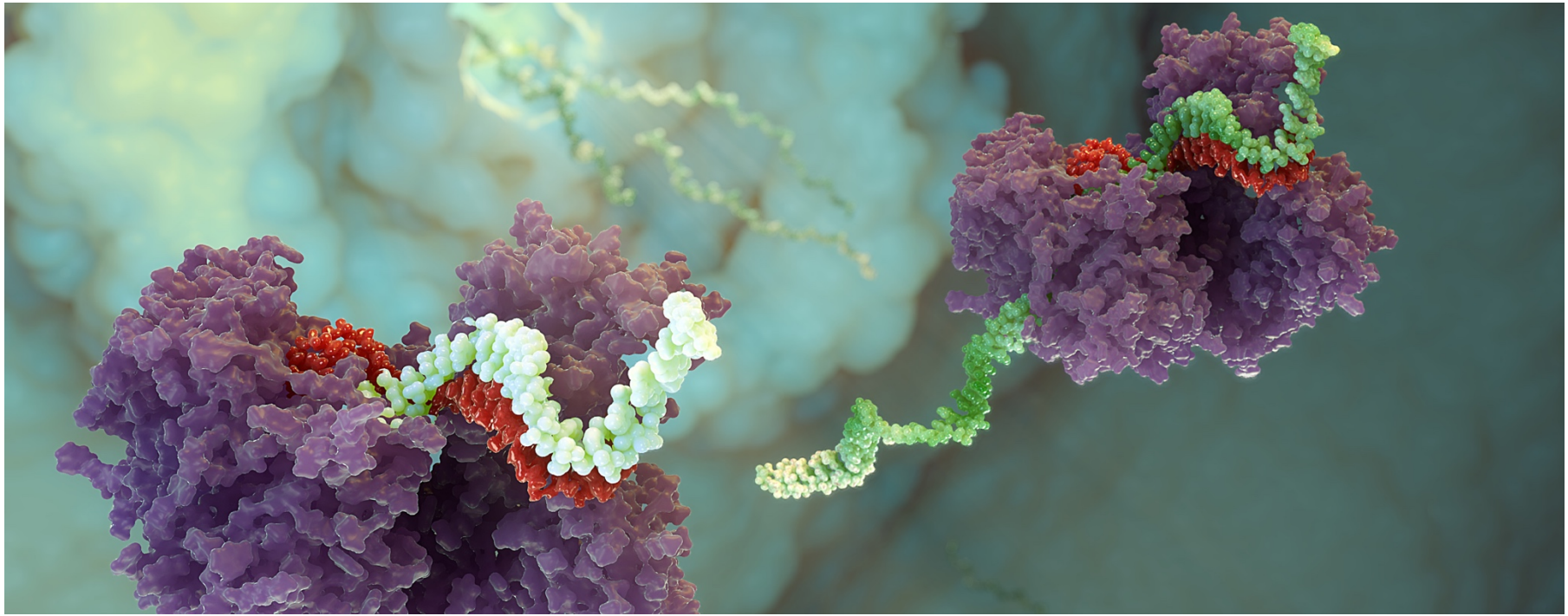
Oncology

Cardiovascular, Renal & Metabolism, Respiratory, Other

AstraZeneca

AstraZeneca
What science can do

Oncology – approved medicines and late-stage pipeline



Tagrisso (highly-selective, irreversible EGFRi)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ADAURA** **NCT02511106**	Adjuvant EGFRm	700	• Arm 1: *Tagrisso* 80mg QD following complete tumour resection, with or without chemotherapy • Arm 2: Placebo Global trial - 25 countries	• Primary endpoint: Disease Free Survival (DFS) • Secondary endpoints: DFS Rate, OS, OS Rate, QoL	• FPCD: Q4 2015 • Data anticipated: 2020+
Phase III **LAURA** **NCT03521154**	Maintenance therapy in patients with locally advanced, unresectable EGFRm+ Stage III whose disease has not progressed following platinum-based chemoradiation therapy	200	• Arm 1: *Tagrisso* 80mg • Arm 2: placebo Global trial - 11 countries	• Primary endpoint: PFS (via blinded independent central review (BICR)) • Secondary endpoints: CNS PFS, OS, DoR, ORR, DCR	• FPCD: Q3 2018 • Data anticipated: 2020+
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	• Data anticipated: 2020+
Phase Ib **TATTON** **NCT02143466**	Advanced EGFRm TKI failure	308	• Arm 1: *Tagrisso* + *Imfinzi* • Arm 2: *Tagrisso* + savolitinib • Arm 3: *Tagrisso* + selumetinib Enrolment to *Imfinzi* combination arms will not restart Global trial	• Safety, tolerability, pharmacokinetics and Preliminary anti-tumour activity	• FPCD: Q3 2014
Phase III **ASTRIS** **NCT02474355**	Real world setting in adult patients with advanced or metastatic, EGFR T790M+	3,515	Single-arm trial - *Tagrisso* 80mg 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+	100	Single arm trial – *Tagrisso* 80 mg 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: Q3 2018

Imfinzi (PD-L1 mAb)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ADJUVANT BR.31** **NCT02273375** **Partnered**	Adjuvant NSCLC patients IB (≥4cm) – stage IIIA resected NSCLC (incl. EGFR/ALK positive)	1,360	• Arm 1: *Imfinzi* mg/kg IV Q4W x 12m • Arm 2: placebo Global trial	Primary endpoint: • DFS Secondary endpoint: • OS	• FPCD: Q1 2015 • Data anticipated: 2020+
Phase II/III Lung Master Protocol **NCT02154490** **Partnered**	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	140	Umbrella trial with five arms based on biomarker expression: • Substudy A: *Imfinzi* (non-match for other biomarker driven substudies) IVQ2W single arm *Imfinzi* Phase II only • Substudy B: PI3K inhibitor vs. docetaxel • Substudy C: CDK4/6 inhibitor vs, docetaxel • Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel • Substudy E: C-MET/HGFR Inhibitor + erlotinib vs. erlotinib	Primary endpoints: • ORR • PFS • OS	• FPCD: Q2 2014 • Data anticipated: 2020+
Phase III **PACIFIC-2** **NCT03519971**	Unresected, locally-advanced NSCLC	300	• Arm 1: *Imfinzi* IV Q4W + chemo/RT (radiation therapy) • Arm 2: placebo + chemo/RT ex US global trial	Primary endpoint: • PFS • ORR Secondary endpoint: • OS	• FPCD: Q2 2018 • Data anticipated: 2020+
Phase III **PACIFIC-4** **NCT03833154**	Imfinzi following SBRT in unresected, Stage I/II NSCLC	630	•Arm 1: *Imfinzi* IV Q4W following definitive SBRT (radiation therapy) •Arm 2: placebo following definitive SBRT	Primary endpoint: •PFS Secondary endpoint: •OS	•FPCD: Q1 2019 •Data anticipated: 2020+
Phase III **PACIFIC-5** **NCT03706690**	Unresected, locally-advanced NSCLC	360	Arm 1: *Imfinzi* IV Q4W following chemo/RT (radiation therapy) Arm 2: placebo following chemo/RT ex US global trial, China focus	Primary endpoint: • PFS Secondary endpoint: • OS	• FPCD: Q3 2018 • Data anticipated: 2020+
Phase III **AEGEAN** **NCT03800134**	Neoadjuvant NSCLC patients Stage II and III resected NSCLC (incl. EGFR/ALK positive)	300	Arm 1: *Imfinzi* + platinum-based chemotherapy Arm 2: Placebo + platinum-based chemotherapy	Primary endpoint: • Major Pathological Response (mPR) Secondary endpoint • Pathological complete response (pCR)	• FPCD: Q1 2019 • Data anticipated: 2020

Imfinzi (PD-L1 mAb)

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02301130** **Partnered**	Solid tumours	108	• Dose escalation: N=36, three cohorts receiving Treatment A (mogamulizumab + *Imfinzi*) and three cohorts receiving Treatment B (mogamulizumab + tremelimumab), in parallel • Dose expansion: N=72, Multiple solid tumour types (NSCLC HNSCC (head and neck squamous-cell carcinoma), Pancreatic), Treatment A or B (12 subjects per treatment per disease type, in parallel)	• Safety and tolerability • MTD • ORR, DoR, DCR, PFS, OS	• FPCD: Q4 2014 • LPCD: Q3 2017 • Data readout: Q4 2018
Phase I **NCT01938612**	Solid tumours (all-comers)	176	• Dose escalation: Three cohorts at Q2W and 1 cohort at Q3W • Dose expansion: biliary tract cancer, oesophageal cancer and SCCNH, Q2, and Q4 schedule • Dose expansion of combination: Biliary Tract Cancer and Oesophageal Cancer, *Imfinzi* Q4W 20mg/kg + tremelimumab Q4W 1mg/kg Trial conducted in Japan	• Safety • Optimal biologic dose	• FPCD: Q3 2013 • LPCD: Q1 2017 • Data readout: Q4 2018

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

Lung cancer, advanced

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ADRIATIC** **NCT03703297**	Limited disease- Small cell lung cancer (SCLC) 1L following platinum-based concurrent chemoradiation therapy	600	• Arm 1: *Imfinzi* + tremelimumab (4 doses) • Arm 2: *Imfinzi* • Arm 3: placebo	Primary endpoints: • PFS • OS	• FPCD: Q4 2018 • Data anticipated: 2020+
Phase III **PEARL** **NCT03003962**	NSCLC 1L	650	• Arm 1: *Imfinzi* Q4W • Arm 2: chemotherapy Asia trial	Primary endpoint: • OS	• FPCD: Q1 2017 • Data anticipated: 2020
Phase III **NEPTUNE** **NCT02542293**	NSCLC 1L	960	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: SoC	• Primary endpoint: OS • Secondary endpoint: PFS	• FPCD: Q4 2015 • LPCD: Q2 2017 • Data anticipated: H2 2019
Phase III **POSEIDON** **NCT03164616**	NSCLC 1L	1,000	• Arm 1: *Imfinzi* + CTx • Arm 2: *Imfinzi* + tremelimumab + chemotherapy • Arm 3: SoC	Primary endpoint: • OS	• FPCD: Q2 2017 • LPCD: Q3 2018 • Data anticipated: H2 2019
Phase III **CASPIAN** **NCT03043872**	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 anticipated: H2 2019
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: 2020+
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: 2020+

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

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **POTOMAC** **NCT**03528694	Non-muscle invasive bladder cancer	975	• Arm 1: BCG (Bacillus Calmette–Guérin) (Induction + Maintenance) • Arm 2: *Imfinzi* + BCG (Induction only) • Arm 3: *Imfinzi* + BCG (Induction + Maintenance)	Primary endpoints: • DFS	• FPCD: Q3 2018 • Data anticipated: 2020+
Phase III **NIAGARA**	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: 2020+
Phase III **EMERALD-1** **NCT03778957**	Locoregional Hepatocellular Carcinoma	600	• Arm A: Transarterial Chemoembolization (TACE) in combination with *Imfinzi* • Arm B: Transarterial Chemoembolization (TACE) in combination with *Imfinzi* + Bevacizumab • Arm C:Transarterial Chemoembolization (TACE) in combination with Placebos	Primary endpoint PFS for Arm A vs Arm C Secondary endpoint PFS for Arm B vs Arm C , OS	• FPCD: Q4 2018 • Data anticipated: 2020+
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 anticipated: H2 2019
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: 2020+
Phase III **KESTREL** **NCT02551159**	HNSCC 1L	823	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab • Arm 3: Standard of care	Primary endpoints: • OS	• FPCD: Q4 2015 • LPCD Q1 2017 • Data anticipated: H1 2019
Phase III **HIMALAYA** **NCT03298451**	Unresectable Hepatocellular Carcinoma (HCC) 1L	1,200	• Arm 1: *Imfinzi* + tremelimumab (Regimen 1) • Arm 2: *Imfinzi* + tremelimumab (Regimen 2) • Arm 3: *Imfinzi* • Arm 4: sorafenib	Primary endpoint: • OS Secondary endpoint: • PFS, time to tumour progression (TTP), ORR	• FPCD: Q4 2017 • Data anticipated: 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

pCR = Pathologic Complete Response
EFS = event free survival

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

Other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **STRONG** **NCT03084471**	Advanced solid malignancies	1,200	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab	• Primary endpoint: Safety	• FPCD: Q2 2017 • Data anticipated: 2020+
Phase I Combination in Advanced Solid Tumours **NCT02658214**	Solid tumours	80	• Arm 2 Small cell lung cancer (SCLC). *Imfinzi* + tremelimumab + carboplatin + etoposide • Arm 3 TNBC (triple-negative breast cancer): *Imfinzi* + tremelimumab + chemo • Arm 4 TNBC: *Imfinzi* + tremelimumab + chemo • Arm 5 Gastric/gastro-Oesophageal junction (GEJ): *Imfinzi* + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin Arm 6 PDAC (pancreatic ductal adenocarcinoma): *Imfinzi* + tremelimumab + chemo • Arm 7 ESSC (esophageal squamous cell carcinoma): *Imfinzi* + tremelimumab + chemo	• Safety	• FPCD: Q1 2016 • LPCD: Q4 2016 • Data anticipated: H2 2019
Phase I Immunotherapy in Combination With Chemoradiation in Patients With Advanced Solid Tumours **CLOVER** **NCT03509012**	Head and neck squamous-cell carcinoma (HNSCC), Non-small-cell lung cancer (NSCLC), Small-cell lung cancer (SCLC)	300	• 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: 2020+
Phase II **BEGONIA** NCT03742102	mTNBC (metastatic triple negative breast cancer) 1L	100	• Arm 1 *Imfinzi* + paclitaxel • Arm 2 *Imfinzi* + paclitaxel + capivasertib • Arm 3 *Imfinzi* + paclitaxel + selumetinib • 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: 1Q2019 • Data anticipated: 2020+

Lynparza (PARP inhibitor)

Ovarian and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **SOLO-1** **NCT01844986**	*BRCA*m maintenance ovarian cancer 1L	391	• Arm 1: *Lynparza* tablets 300mg BID maintenance therapy for two years or until disease progression • Arm 2: placebo Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q3 2013 • LPCD: Q1 2015 • Data readout: Q2 2018 • Primary endpoint met
Phase III **SOLO-3** **NCT02282020**	PSR g*BRCA*m ovarian cancer 3L+	266	• Arm 1: *Lynparza* 300mg BID to progression • Arm 2: physician's choice (single-agent chemotherapy) Global trial	• Primary endpoint: ORR	• FPCD: Q1 2015 • LPCD: Q2 2018 • Data readout: Q4 2018 • Primary endpoint met
Phase III **OlympiA** **NCT02032823** **Partnered**	*BRCA*m adjuvant breast cancer	1,500	• Arm 1: *Lynparza* 300mg 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
Phase III **OlympiAD** **NCT02000622**	*BRCA*m metastatic breast cancer	302	• Arm 1: *Lynparza* 300mg BiD, continuous to progression • Arm 2: physician's choice: capecitabine 2500mg/m2 x 14 q 21 vinorelbine 30mg/m2 d 1, 8 q 21 eribulin 1.4mg/m2 d 1, 8 q 21 to progression Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q2 2014 • LPCD: Q4 2015 • Data readout: Q1 2017 • Primary endpoint met
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 anticipated: H1 2019
Phase III **PROfound** **NCT02987543**	Metastatic castration-resistant prostate cancer HRRm, 2L+	387	• Arm 1: *Lynparza* 300mg BID • Arm 2: physician's choice: enzalutamide 160mg once daily abiraterone acetate 1000mg once daily Global trial	• Primary endpoint: radiologic PFS • Secondary endpoints: ORR, Time to Pain Progression, OS	• FPCD: Q2 2017 • LPCD: Q4 2018 • Data anticipated : H2 2019

Lynparza (PARP inhibitor)

Imfinzi combinations, cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **DuO-O** **NCT03737643**	Advanced ovarian cancer 1L	1,056	Non t*BRCA*m (tumour *BRCA*) patients • Arm 1: bevacizumab • Arm 2: bevacizumab + *Imfinzi* • Arm 3: bevacizumab + *Imfinzi* + *Lynparza* t*BRCA*m patients • bevacizumab (optional) + *Imfinzi* + *Lynparza* Global trial	Primary endpoint: • PFS	• FPCD: Q1 2019 • Data anticipated: 2020+
Phase II **DuO-L** **(ORION)**	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	• FPCD Q4 2018 • Data anticipated: 2020+
Phase II **BAYOU** **NCT03459846**	Platinum-Ineligible unresectable Stage IV urothelial cancer	150	• Arm 1: *Imfinzi* + *Lynparza* • Arm 2: *Imfinzi* + placebo Global trial	• Primary endpoint: PFS	• FPCD: Q1 2018 • Data anticipated : 2020
Phase I / II **MEDIOLA** **NCT02734004**	g*BRCA*m ovarian cancer 2L+ g*BRCA*m HER2-negative breast cancer 1-3L Small cell lung cancer (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-gBRCAm ovarian cancer 2L+ Non-gBRCAm 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
Phase I / II **MEDIOLA** **(Breast expansion)** **NCT02734004**	HER2 negative BRCAm breast cancer HER2 negative non-BRCA HRRm breast cancer Non-HRRm triple negative breast cancer	140	• 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	• Initiating

Lynparza (PARP inhibitor)

Combinations, cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **PAOLA-1** **NCT02477644** **Externally sponsored**	Advanced ovarian cancer 1L	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	• FPCD: Q2 2015 • LPCD: Q2 2018 • Data anticipated: H2 2019
Phase III **PROPEL** **NCT 03732820**	Metastatic castration-resistant prostate cancer 1L	720	• Arm 1: *Lynparza* + abiraterone • Arm 2: placebo + abiraterone Global trial	Primary Endpoint: • PFS	• FPCD: Q4 2018 • Data anticipated: 2020+
Phase II **VIOLETTE**	Triple-negative breast cancer (TNBC)	450	• Arm 1: AZD6738 + *Lynparza* • Arm 2: adavosertib + *Lynparza* • Arm 3: *Lynparza* Trial conducted in 15 countries: North America, Europe and Asia	• PFS • ORR / OS • Safety and Tolerability	• FPCD: Q2 2018 • Data anticipated: 2020+
Phase II/III **GY005** **NCT02502266** **Externally sponsored**	Recurrent platinum resistant/refractory ovarian cancer	680	• Arm 1: chemotherapy • 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: 2020+

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III **ACE-CL-007 (ELEVATE-TN)** **NCT02475681**	Previously untreated chronic lymphocytic leukaemia (CLL)	535	• 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 anticipated: H2 2019
Phase III **ACE-CL-311**	Previously untreated CLL fit	780	• Arm A; *Calquence* + venetoclax (AV) • Arm B: *Calquence* + venetoclax + obinutuzumab (AVG) • Arm C: fludarabine + cyclophosphamide + rituximab (FCR) OR bendamustine + rituximab (BR)	• Primary - AV vs FCR/BR efficacy PFS • Secondary AVG vs FCR/BR efficacy PFS; AV vs FCR/BR and AVG vs FCR/BR	Initiating Data anticipated: 2020+
Phase III **ACE-CL-309** **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, patient reported outcomes (PROs)	• FPCD Q3 2016 • Data anticipated: H2 2019
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: 2020+
Phase III **ACE-LY-308** **NCT02972840**	Previously untreated mantle cell lymphoma (MCL)	546	• Arm A: *Calquence* + bendamustine + rituximab • Arm B: bendamustine + rituximab	• Primary endpoint: PFS by Lugano Classification for non-Hodgkin's Lymphoma (NHL) • Secondary endpoints: Investigator-assessed (IA) PFS, ORR; IRC-assessed ORR, DoR, time to response; OS	• FPCD: Q1 2017 • Data anticipated: 2020+
Phase II **ACE-CL-208** **NCT02717611**	Relapsed/ refractory CLL, intolerant to ibrutinib	60	*Calquence* monotherapy	• ORR at 36 cycles	• FPCD: Q1 2016 • Data anticipated: 2020
Phase II **15-H-0016** **NCT02337829**	Relapsed/refractory and treatment naïve/del17p CLL/small lymphocytic lymphoma (SLL)	48	*Calquence* monotherapy • Arm A: Lymph node biopsy • Arm B: Bone marrow biopsy	• ORR	• FPCD: Q4 2014 • Data anticipated: 2020+
Phase I/II **ACE-CL-001** **NCT02029443**	CLL/SLL/Richter's transformation (RT)	286	*Calquence* monotherapy Dose escalation and expansion	• Safety, PK, PD	• FPCD: Q1 2014 • Data anticipated: 2020+

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I/II **ACE-LY-001** **NCT02328014**	B-cell Malignancies	126	Dose escalation and expansion trial of the combination of *Calquence* and ACP-319 (Pi3K inhibitor)	• Safety • ORR	• FPCD: Q1 2015 • Data anticipated: 2020
Phase I/II **ACE-LY-005** **NCT02362035**	Haematological Malignancies	159	*Calquence* + pembrolizumab	• Safety • Secondary endpoints: ORR, DoR, PFS, OS, TTNT (time to next therapy)	• FPCD: Q1 2015 • Data anticipated: 2020+
Phase I/II **ACE-WM-001** **NCT02180724**	Waldenstrom Microglobulinaemia	106	*Calquence* monotherapy	• ORR	• FPCD: Q3 2014 • Data readout: Q1 2018
Phase Ib **ACE-LY-002** **NCT02112526**	Relapsed/refractory de novo activated B-cell diffuse large B-cell lymphoma (DLBCL)	21	*Calquence* monotherapy	• Safety	• FPCD: Q3 2014 • Data anticipated: H2 2019
Phase Ib **ACE-LY-106** **NCT02717624**	Mantle Cell Lymphoma (MCL)	48	*Calquence* in combination with bendamustine and rituximab • Arm A: Treatment naive • Arm B: Relapsed/refractory	• Safety	• FPCD: Q1 2016 • Data anticipated: 2020+
Phase Ib **ACE-MY-001** **NCT02211014**	Relapsed/refractory Multiple Myeloma	28	• Arm A: *Calquence* • Arm B: *Calquence* + dexamethasone	• Safety	• FPCD: Q1 2015 • Data readout: Q4 2018
Phase I **ACE-LY-003** **NCT02180711**	Relapsed/refractory Follicular Lymphoma	80	• Arm A: *Calquence* • Arm B: *Calquence* + rituximab	• Safety	• FPCD: Q1 2015 • Data anticipated: 2020+
Phase I **ACE-CL-002** **NCT02157324**	Relapsed/refractory CLL/ small lymphocytic lymphoma (SLL)	12	*Calquence* in combination with ACP-319 Dose escalation	• Safety, PK, PD	• FPCD: Q3 2014 • Data anticipated: 2020
Phase I **ACE-CL-003** **NCT02296918**	CLL/SLL/Prolymphocytic Leukaemia (PLL)	72	*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: 2020+

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I **NCT03198650**	Japanese Adults with Advanced B-cell Malignancies	28	• *Calquence* monotherapy • Dose confirmation and expansion	• Safety	• FPCD: Q2 2017 • Data anticipated: 2020+
Phase I/II **CL-110** **NCT03328273**	CLL (chronic lymphocytic leukaemia) R/R	62	• Arm A: AZD6738 monotherapy • Arm B: *Calquence* + AZD6738	• Identify dose of AZD 6738 and safety of co-administration of *Calquence* + AZD6738	FPCD: Q1 2018 Data anticipated: 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 2019

Calquence (BTK inhibitor)

Other cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II **ACE-ST-006** **NCT02454179**	≥ 2L advanced or metastatic Head and neck squamous-cell carcinoma (HNSCC)	74	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q2 2015 • Data readout: Q2 2018
Phase II **ACE-ST-007** **NCT02448303**	≥ 2L advanced or metastatic Non-small-cell lung cancer (NSCLC)	74	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q2 2015 • Data readout: Q2 2018
Phase II **ACE-ST-208** **NCT02537444**	Recurrent ovarian cancer	76	• Arm A: *Calquence* • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q4 2015 • Data readout: Q4 2018
Phase II **ACE-ST-003** **NCT02362048**	≥ 2L advanced or metastatic pancreatic cancer	73	• Arm A: *Calquence* • Arm B: *Calquence* + pembrolizumab	• Safety	• FPCD: Q2 2015 • Data readout: Q3 2017
Phase II **ACE-ST-005** **NCT02351739**	Platinum-resistant urothelial bladder cancer	75	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q2 2015 • Data readout: Q1 2018
Phase Ib/II **ACE-ST-209** **NCT02586857**	≥ 2L glioblastoma multiforme	72	• Arm A: *Calquence* 200 mg BID • Arm B: *Calquence* 400 mg QD	• Safety, ORR	• FPCD: Q1 2016 • Data anticipated: H1 2019

Lumoxiti (moxetumomab pasudotox,CD22 mAb)

Blood cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase III PLAIT **NCT01829711**	Adults with relapsed or refractory hairy cell leukaemia (HCL)	77	• Multicentre, single-arm, open-label Phase III trial • *Lumoxiti* IV at the recommended dose	• Primary endpoint: Rate of durable CR (complete response): CR maintained for > 180 days • Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS • Safety and tolerability • PK and immunogenicity	• FPCD: Q2 2013 • Data readout: Q3 2017 • Primary endpoint met
Phase I **NCT00586924**	Adults with relapsed refractory HCL	49	• Open-label dose escalation Phase I trial • *Lumoxiti* IV	• MTD and efficacy	• FPCD: Q2 2007 • LPCD: Q1 2014 • Data readout: Q2 2015

Selumetinib (MEK inhibitor)

Paediatric neurofibromatosis type 1

Trial	Population	Patients	Design	Endpoints	Status

Phase II
SPRINT
 	
NCT01362803
 	
Partnered
	Paediatric neurofibromatosis type 1 (NF1)	50 (stratum 1)	• Single arm: selumetinib 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

Savolitinib (MET inhibitor)

Papillary renal cell and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT03091192** **Partnered**	MET-Driven, Papillary renal cell cancer	180	• Arm 1: savolitinib 600mg QD • Arm 2: sunitinib 50mg QD (4 weeks on / 2 weeks off) Global trial	• Primary endpoint: PFS • Secondary endpoints include ORR, DoR and OS	• FPCD: Q4 2017 • Data anticipated: 2020
Phase I **NCT01985555** **Partnered**	Advanced cancer (all comers)	~70	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPCD: Q2 2013 • Data anticipated: 2020+
Phase I **NCT02374645**	NSCLC	64	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPCD: Q2 2015 • Data readout: Q4 2018
Phase II **NCT02897479** **Partnered**	Lung Pulmonary Sarcomatoid Carcinoma (PSC) and other NSCLC	92	• Single arm trial: savolitinib 600mg QD Conducted in China	• ORR	• FPCD: Q1 2017 • Data anticipated: 2020+

Cediranib (VEGF receptor inhibitor)

Ovarian cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CONCERTO **NCT02889900**	Recurrent platinum resistant (PRR) ovarian cancer - heavily pre-treated *BRCA*wt	62	• Cediranib 30 mg + *Lynparza* 200 mg bd	• ORR DoR, DCR, QoL. OS; Safety	• FPCD: Q1 2017 • LPCD: Q1 2019

AstraZeneca

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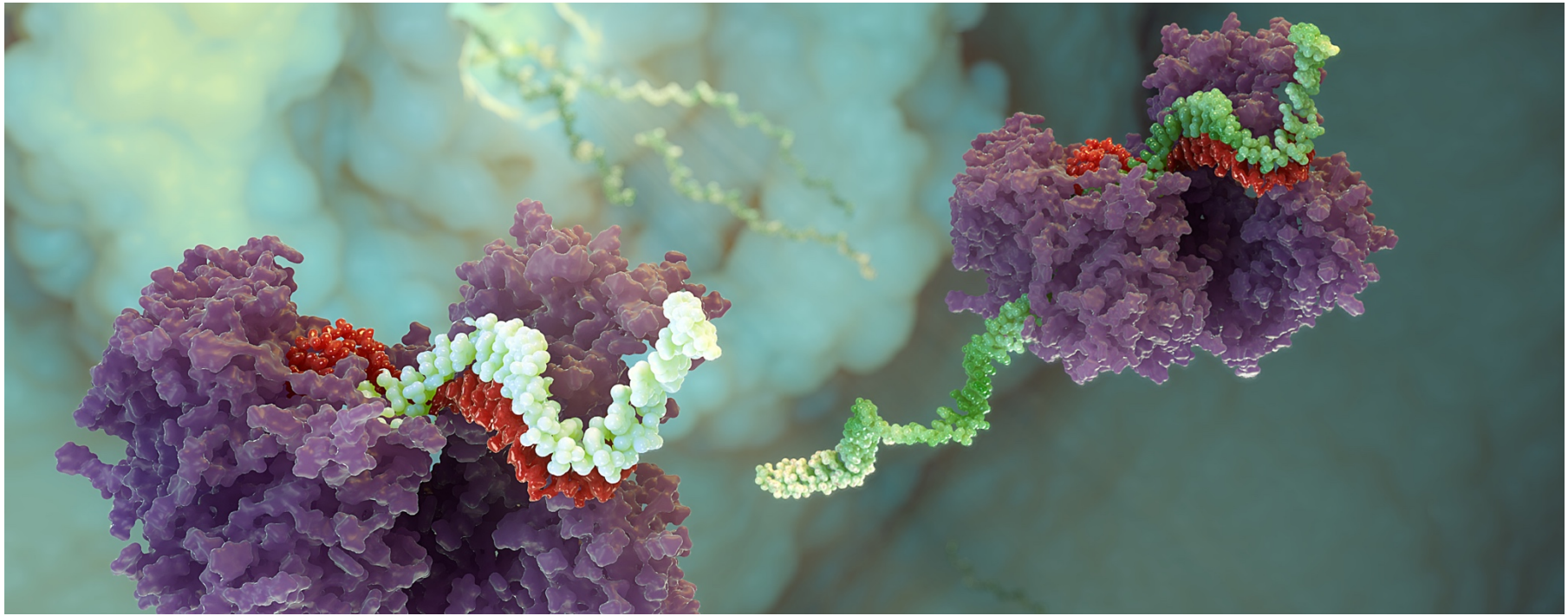
What science can do

Oncology – early-stage development



AZD0156 (ATM inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02588105**	Solid tumours	130	• Arm 1: AZD0156 + *Lynparza* • Arm 2: AZD0156 + irinotecan Trial conducted in North America, Europe and South Korea	• Safety, tolerability, PK and efficacy	• FPCD: Q4 2015 • Data anticipated: H2 2019

AZD1390 (ATM inhibitor, blood brain barrier)

Cancer

Trial	Population	Subjects	Design	Endpoints	Status
Phase I **NCT03215381**	Healthy volunteers	8	• Positron-Emission Tomography (PET) trial • [11C]AZD1390 microdose administered by IV bolus Trial conducted in a single centre in Sweden	• Brain distribution of AZD1390 to assess if [11C]AZD1390 crosses the blood brain barrier in healthy volunteers	• FPCD: Q4 2017 • Data anticipated: H2 2019
Phase I **NCT03423628**	Recurrent Glioblastoma eligible for re-irradiation, brain metastases and leptomeningeal disease, newly-diagnosed glioblastoma patients	c. 132	• 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: 2020+

Adavosertib (AZD1775, WEE-1 inhibitor)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT02272790**	Platinum-resistant (PR) ovarian cancer	97	• Arm B: paclitaxel + adavosertib • Arm C: carboplatin + adavosertib Global trial	• Primary endpoint: ORR • Secondary endpoints: DoR, PFS, OS, Disease Control Rate, safety and tolerability	• FPCD: Q1 2015 • LPCD: Q2 2018
Phase I/II **NCT02482311**	Advanced solid tumours	97	• Monotherapy Safety Run-in (part A, N=12); solid tumours Expansions into specific tumour types, inc. ovarian cancer (*BRCA*m PARP failures and *BRCA*wt with three or more prior lines of treatment), triple negative breast cancer (TNBC) and SCLC Conducted in US, Canada	• Safety and tolerability • Secondary endpoints: Overall response rate, DCR, DoR, PFS	• FPCD: Q3 2015 • LPCD: Q4 2016
Phase I **NCT02610075**	Advanced solid tumours	78	• Monotherapy adavosertib Dose escalation trial to determine MTD Conducted in US	• Safety and tolerability	• FPCD: Q4 2015 • LPCD: Q3 2017
Phase I **NCT02511795**	Advanced solid tumours	102	• Dose escalation trial to determine MTD (adavosertib + *Lynparza*) followed by an expansions in SCLC Conducted in US, Canada	• Safety and tolerability • Secondary endpoints: Overall response rate, Disease Control Rate, Duration of Response, PFS	• FPCD: Q3 2015
Phase I **NCT02617277**	Advanced solid tumours	55	• Dose escalation trial to determine MTD (adavosertib + *Imfinzi*) Conducted in US	• Safety and tolerability	• FPCD: Q4 2015

Adavosertib (AZD1775, WEE-1 inhibitor)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase I **D6014C00005** **NCT03315091**	Advanced solid tumours	24	Open-label, randomised, 2-period crossover design: • Fasted (Treatment A): Single dose 300 mg adavosertib • Fed (Treatment B): Single dose 300 mg adavosertib Conducted in Europe	• Primary endpoints: Plasma AUC, AUC0-t and CMAX • Secondary endpoints: Plasma tmax, λz , t½, CL/F and Vz/F • Safety and tolerability	• FPCD: Q4 2017 • LPCD: Q2 2018
Phase I **D6014C00006** **NCT03333824**	Advanced solid tumours	30	Part A: caffeine (200mg), omeprazole (20mg) and midazolam (1mL of 2mg/mL syrup) followed 7-14 days later by adavosertib 225mg bid for 2.5 days plus caffeine (200mg), omeprazole (20mg) and midazolam (1mL of 2mg/mL syrup) on day 3. Part B: 7-14 days after end of Part A, adavosertib 225mg BID for 2.5 days. Conducted in US	• 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
Phase I **D6014C00007** **NCT03313557**	Advanced solid tumours	54	adavosertib monotherapy once daily. Conducted in US and Europe	• Safety and tolerability	• FPCD: Q4 2017

Capivasertib (AZD5363, AKT inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT01226316**	Breast and gynaecological cancers with PIK pathway mutation	12-24 per arm (Parts E & F)	AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant [initially 12 patients per arm with option to expand to 24 patients in one or more arms] • Part E arm 1: ER+ Breast with AKT-1 mutation (prior *Faslodex* resistance) • Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to *Faslodex*) • Part F arm 1: ER+ Breast with PTEN mutation (prior *Faslodex* resistance) • Part F arm 2: ER+ Breast with PTEN mutation (first exposure to *Faslodex*)	• Safety and tolerability • ORR • Clinical Benefit Rate at 24 weeks (CBR24) [Parts E & F only]	• Data anticipated: H2 2019
Phase II (ESR) **NCT02423603** **PAKT**	Advanced / metastatic triple negative breast cancer receiving 1L chemotherapy with paclitaxel	140	Randomised comparative ARM1: Paclitaxel + capivasertib ARM 2: Paclitaxel + placebo	• Progression Free Survival • Overall survival Overall population and in sub-group with tumours harbouring PIK3CA/AKT1/PTEN alterations	• Data readout: Q2 2018 • Final OS data awaited
Phase II (ESR) **NCT01992952** **FAKTION**	Post menopausal women with advanced ER+/Her2- breast cancer previously treated with aromatase inhibition	140	Randomised comparative ARM 1: *Faslodex* + capivasertib ARM 2: *Faslodex* + placebo	• Progression Free Survival • Overall survival Overall population and sub-group with activation of the tumour PI3K/Akt/PTEN pathway (eg. PIK3CA/AKT1/PTEN alterations)	• Data anticipated: H1 2019
Phase II (ESR) **NCT02121639** **PROCAID**	Metastatic castration resistant prostate cancer eligible for treatment with docetaxel chemotherapy	150	Randomised comparative ARM 1: Docetaxel + prednisolone + capivasertib ARM 2: Docetaxel + prednisolone + placebo	• Progression Free Survival	• Data anticipated: 2020

Imfinzi (PD-L1 mAb) + dabrafenib (BRAF inhibitor) / trametinib (MEK inhibitor)

Melanoma

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II **NCT02027961**	Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&C)	68	Dose Escalation: • Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ *Imfinzi* IV • Cohort B trametinib 2mg QD/ *Imfinzi* IV • Cohort C trametinib 2mg QD/ *Imfinzi* IV Dose Expansion: • Each cohort will be expanded at the MTD to enrol a total of 20 subjects per cohort Global trial - four countries	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints include objective response and disease control, duration of response, progression-free survival and OS, pharmacokinetics and immunogenicity	• FPCD: Q1 2014 • LPCD: Q2 2015 • Data readout: Q2 2018

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 2019
Phase I **NCT02117219**	*Imfinzi*, azacitidine (Vidaza)	Myelodysplastic syndrome	72	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: 2020
Phase I **NCT02900157**	*Imfinzi*	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: H2 2019
Phase II **HUDSON** **NCT03334617**	*Imfinzi* *Lynparza* Vistusertib AZD6738 Danvatirsen Oleclumab	Non-small-cell lung cancer (NSCLC)	260	5 modules encompassing 13 cohorts Module 1; *Imfinzi* and *Lynparza* Module 2; *Imfinzi* and danvatirsen Module 3; *Imfinzi* and AZD6738 Module 4; *Imfinzi* and vistusertib Module 5; *Imfinzi* and oleclumab 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	• FPCD: Q1 2018 • Data anticipated: 2020+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **STUDY 21** **NCT02340975**	Gastric/gastro-Oesophageal junction (GEJ) adenocarcinoma	114	• Arm A: *Imfinzi* + tremelimumab 2L • Arm B: *Imfinzi* 2L • Arm C: tremelimumab 2L • Arm D: *Imfinzi* + tremelimumab 3L • Arm E: *Imfinzi* + tremelimumab 2L & 3L US and ROW trial centres	• Primary endpoints: Safety & tolerability, ORR, PFS • Secondary endpoints: DCR, OS, DoR, PD-L1 Expression	• FPCD: Q2 2015 • Data anticipated: H1 2019
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, ORR, PFS • Secondary endpoints: DCR, OS, DoR, PD-L1 Expression	• FPCD: Q4 2015 • Data anticipated: 2020
Phase Ib **STUDY 006** **NCT02000947**	Non-small-cell lung cancer (NSCLC) (Immunotx naïve and Immunotx pretreated patient cohorts)	459	• Dose Escalation: minimum 5 cohorts exploring various treme Q4W and *Imfinzi* IV Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment • Dose Expansion: MTD for the combination in escalation to be explored in expansion 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 2019
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 2019
Phase Ib **STUDY 23** **NCT02549651**	Diffuse Large B cell Lymphoma	32	• Arm A: *Imfinzi* • Arm B: *Imfinzi* + tremelimumab • Arm C: *Imfinzi* + AZD9150 US and European trial centres	• Primary endpoint: Safety & tolerability • Secondary endpoints: OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers	• FPCD: Q3 2016 • Data anticipated: 2020+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II **NCT02671435**	Advanced solid tumours	50	Escalation phase • monalizumab + *Imfinzi* IV Expansion phase • monalizumab + *Imfinzi* IV recommended dose Exploration phase • monalizumab + *Imfinzi* IV recommended dose + SoC systemic therapy with or without biologic agent in adult subjects with CRC (Colorectal cancer) Global trial	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2020+

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

Squamous cell carcinoma of the Head and Neck (SCCHN)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/IIa **NCT03162224**	Human papillomavirus (HPV) Associated Recurrent/Metastatic Head and Neck Cancer	50	Multi-centre, open label trial to evaluate the safety and efficacy of combination treatment with MEDI0457 and *Imfinzi*	Primary endpoints: Safety & Tolerability, ORR Secondary endpoints: PK, ADA, DCR, OS, PFS	• FPCD: 3Q 2017 • Data anticipated: 2020

Imfinzi (PD-L1 mAb) + MEDI0680 (PD-1 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II **NCT02118337**	Advanced malignancies (escalation phase) Renal cell carcinoma (RCC) (expansion phase)	97	Dose escalation phase • *Imfinzi* IV + MEDI0680 IV Dose expansion phase at selected dose from dose-escalation phase • *Imfinzi* IV + MEDI0680 IV recommended dose	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, OS, immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2014 • Data anticipated: 2020+

Oleclumab (MEDI9447, CD73 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02503774**	Advanced malignancies	310	Dose escalation phase • oleclumab IV • oleclumab IV + *Imfinzi* IV Dose expansion phase • oleclumab IV recommended dose + *Imfinzi* IV US, South Korean and Australian trial centres	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	• FPCD: Q3 2015 • Data anticipated: 2020+
Phase Ib/II **NCT03611556**	Pancreatic 1L and 2L with prior gemcitabine-based chemotherapy	204	• Arm A1: Gemcitabine and nab Paclitaxel IV • Arm A2: Gemcitabine and nab Paclitaxel IV + oleclumab IV • Arm A3: Gemcitabine and nab Paclitaxel IV + oleclumab IV + *Imfinzi* IV • Arm B1: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV • Arm B2: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV + oleclumab IV • Arm B3: mFOLFOX (oxaliplatin, leucovorin, 5-FU) IV + oleclumab IV + *Imfinzi* IV US, Norway, Spain and Australian trial centres	Primary endpoints: • Safety and anti-tumour activity • Secondary endpoints include pharmacokinetics, pharmacodynamics, immunogenicity, and safety	• FPCD: Q2 2018 • Data anticipated: 2020+
Phase I/II **NCT03381274**	Non-small-cell lung cancer (NSCLC)	98	• Arm A: oleclumab IV + *Tagrisso* • Arm B: oleclumab IV + A2AR • PoC for future registrational studies US, South Korean trial centres	Primary endpoints: • Safety (AEs & serious adverse events (SAEs)) • ORR Secondary endpoints: • DoR, DCR, PFS, OS, PK and immunogenicity	• FPCD: Q2 2018 • Data anticipated: 2020+

AZD2811 (AURN)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02579226**	Solid tumours	72	• Arm 1: AZD2811 dose escalation • Arm 2: AZD2811 dose expansion	• Safety and tolerability • Pharmacokinetics and efficacy	• FPCD: Q4 2015 • Data anticipated: H2 2019
Phase I **NCT03217838**	Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome	130	• Part A: AZD2811 single agent dose escalation cohorts • Part B: AZD2811 single agent and azacytidine combination dose expansions to further explore the tolerability, PK and clinical activity.	• Safety and tolerability • Pharmacokinetics and efficacy	• FPCD: Q3 2017 • Data anticipated: 2020+

AZD4547 (FGFR inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status

Phase II
GLOW
 	
NCT01202591
	Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy	40	• Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane
			• Part B:
			  • Arm 1: AZD4547 (dose from part A) + *Faslodex*
			  • Arm 2: placebo + *Faslodex*
			Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients)
			
			Conducted in eight countries in Europe
				• Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547
				• Part B Interim analysis: Tumour size analysis on 30 FGFR amplified patients
				• Part B Final analysis: PFS
					• FPCD: Q4 2010
					• LPCD: Q1 2014
					• Data readout: Q3 2014

Phase II **SHINE** **NCT01457846**	Advanced gastro-oesophageal cancer	71	• Arm 1 (FGFR2 polysomy): AZD4547 vs. paclitaxel randomised 1:1 (30 to 80 patients) • Arm 2 (FGFR 2 low gene amplification: AZD4547 vs. paclitaxel randomised 3:2 (25 to 80 patients) • Arm 3 (FGFR2 high gene amplification: AZD4547 vs. paclitaxel randomised 3:2 (25 to 80 patients) Conducted in 16 countries across Europe and Asia	• Primary endpoint: PFS • Secondary endpoint: OS/Tumour size	• FPCD: Q4 2011 • LPCD: Q2 2013 • Data readout: Q1 2015
Phase I **NCT01213160**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	33	• Part A: AZD4547 in ascending multiple doses given bd and QD (c. 30 patients) • Part B: AZD4547 in patients whose tumours have FGFR amplification (c. eight patients) Conducted in Japan	• Part A: MTD and recommended dose for Parts B and C • Part B: Safety and tolerability and preliminary anti-tumour activity	• FPCD: Q4 2010 • LPCD: Q4 2012 • Data readout: Q2 2013
Phase I **NCT00979134**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	94	• Part A: Ascending oral doses of AZD4547 to define MTD and /or continuous, tolerable recommended dose (RD) • Part B: Dose expansion phase at RD defined in Part A • Part C: Expansion phase in patients with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A Conducted in seven countries across North America and Europe	• Part A: MTD and recommended dose for Parts B and C • Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity	• FPCD: Q4 2009 • LPCD: Q4 2013 • Data readout: Q1 2015
Phase I **BISCAY** **NCT02546661**	2L muscle-invasive metastatic bladder cancer in patients who have failed prior therapy	110	• Multi-drug biomarker-directed trial • Arm 1: AZD4547 • Arm 2: AZD4547 + *Imfinzi* • Arm 3: *Lynparza* + *Imfinzi* • Arm 4: adavosertib + *Imfinzi* • Arm 5: *Imfinzi* • Arm 6: vistusertib + *Imfinzi* • Arm 7: AZD9150 + *Imfinzi* • *Arm 8:* selumetinib + *Imfinzi* North America and Europe	• Safety and tolerability of the combinations • PK and preliminary anti-tumour activity	• FPCD: Q4 2016 • Data anticipated: H1 2019

AZD4573 (CDK9 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03263637**	Relapsed/refractory haematologic malignancies	42	Dose escalation in relapsed/refractory haematological malignancies AZD4573 will be administered 2 parallel arms of (1-6 cohorts of dose escalations) based on the haematological malignancy	Primary: • safety/PK; Secondary: • efficacy	• FPCD: Q4 2017 • Data anticipated: H2 2019

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02740985**	Phase Ia: patients with advanced solid tumours Phase Ib: Post-immunotherapy NSCLC Other post-immunotherapy solid tumours Immune checkpoint-naïve metastatic castrate-resistant prostate carcinoma (mCRPC) Immune checkpoint-naïve colorectal carcinoma (CRC) Other immune checkpoint-naïve solid tumours	48-90 190	• Phase Ia: dose escalation to determine the MTD of AZD4635 given as monotherapy and in combination with *Imfinzi* in patients with solid malignancies. Also, to determine the MTD of AZD4635 in combination with abiraterone or with enzalutamide in patients with metastatic castrate-resistant prostate carcinoma (mCRPC). When the combination MTD is determined, additional patients with advanced solid malignancies and mCRPC will be enrolled to a dose expansion cohort to explore further the safety, tolerability, PK, and biological activity. • Phase Ib will consist of additional expansions in NSCLC, mCRPC, CRC and other post-immunotherapy and immune checkpoint-naïve solid tumours at the combination and/or monotherapy MTD or maximum feasible dose Both parts conducted at sites in the US	Primary outcome measure: • Safety and tolerability Secondary outcome measures: • PK of AZD4635 as monotherapy and combination with *Imfinzi* abiraterone and enzalutamide. • Preliminary assessment of anti-tumour activity	• FPCD: Q2 2016 • Data anticipated: H2 2019
Phase I **NCT03710434**	Healthy male volunteers	20	• Part A is a 2-period randomised crossover study of single doses of AZD4635. Subjects will be randomised to receive 50mg AZD4635 nano-suspension (reference) or 50mg AZD4635 solid oral formulation, in the fasted state. • Part B is a 4-period, open-label, randomised, crossover study of single doses of AZD4635 in the same subjects from Part A. The treatments selected for Part B will depend on the outcome of interim analyses of AZD4635 exposure. Both parts conducted at a site in the UK	Primary outcome measures: • Maximum observed plasma concentration (Cmax) of AZD4635 solid oral formulation and nano-suspension • Exposure to AZD4635 solid oral formulation and nano-suspension	• FPCD: Q4 2018 • Data anticipated: H1 2019

AZD4785 (KRAS antisense oligonucleotide)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03101839**	Phase Ia: patients with advanced solid tumours which harbour mutations of KRAS Phase Ib: patients with advanced NSCLC with tumours harbouring mutations of KRAS	30 (estimated) 20	• Phase Ia: dose escalation to determine the MTD of AZD4785 given as monotherapy. When the MTD is determined, additional patients with advanced solid malignancies may be enrolled to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity • Phase Ib will consist of an expansion phase in patients with KRASm NSCLC at the MTD or maximum feasible dose. To be conducted at sites in the US and UK	Primary outcome measure: safety and tolerability Secondary outcome measures: • Pharmacokinetics of AZD4785 • Change in KRAS mRNA from baseline • Objective clinical response	• FPCD: Q2 2017 • Data anticipated: H2 2019

AZD5069 (CXCR2 antagonist)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **NCT02583477**	Metastatic pancreatic ductal carcinoma	16	Dose escalation and expansion arms: *Imfinzi* in combination with nab-paclitaxel and gemcitabine *Imfinzi* in combination with AZD5069	• Safety/efficacy trial	• FPCD: Q1 2016 • Data anticipated: H2 2019

AZD5153 (BRD4 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I/Ib **NCT03205176**	Relapsed/refractory solid tumours, lymphomas	54	Dose Escalation advanced solid and lymphomas Six dose escalation cohorts of AZD5153 Dose and schedule from dose escalation will be applied in dose expansion Phase in platinum-resistant or platinum-refractory high grade serous (HGS) ovarian cancer	• Primary: safety • Secondary: efficacy	• FPCD: Q2 2017 • Data anticipated: H2 2019

AZD5991 (MCL1 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03218683**	Relapsed/refractory haematologic malignancies	48	Dose escalation in relapsed/refractory haematological malignancies Five dose escalation cohorts of AZD5991	• Primary: safety • Secondary: efficacy	• FPCD: Q3 2017 • Data anticipated: H2 2019

AZD6738 (ATR inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02264678**	Solid tumours	160	• Arm 1: AZD6738 + carboplatin • Arm 2: AZD6738 dose escalation, AZD6738 + *Lynparza* • Arm 3: AZD6738 + *Imfinzi* Trial conducted in North America, Europe and South Korea	• Safety and tolerability • PK and efficacy	• FPCD: Q4 2014 • Data anticipated: H2 2019
Phase I **NCT03022409**	SCCHN	40	Window of opportunity • Arm 1: AZD6738 • Arm 2: *Lynparza* • Trial conducted in US, France, Taiwan and the UK	• Biomarker change	• FPCD: Q4 2017 • Data anticipated: H2 2019

AZD8186 (PI3Kb/d inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT01884285**	Advanced castrate resistant prostate Cancer /sqNSCLC /TNBC (triple-negative breast cancer) and patients with known PTEN-deficient/ mutated or PIK3CM mutated/ amplified advanced solid malignancies	153	• Part A: AZD8186 monotherapy in ascending intermittent doses in 3 schedules • Part B: AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer • Part C: combination AZD8186 added to abiraterone acetate (with prednisone) in PTEN deficient metastatic castrate resistant prostate cancer (mCRPC) patients. Initial dose/ schedule confirmation phase using AZD8186 monotherapy recommended dose/ schedule from Part A and the labelled dose of abiraterone followed by an expansion cohort to explore clinical activity • Part D: combination AZD8186 and AZD2014 (a novel dual mTORC ½ inhibitor). Initial dose/ schedule determination phase in same patient population as Part A followed by an expansion cohort in PTEN deficient TNBC patients to explore clinical activity Trial conducted in Canada, US, Spain & the UK	• Part A: PK, MTD and recommended dose and schedule(s) for Part B • Part B: Safety, tolerability and preliminary assessment of anti-tumour activity (PoM) • Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of anti-tumour activity of AZD8186 in combination with abiraterone • Part D: PK, safety, tolerability and recommended dose and schedule of AZD8186 in combination with AZD2014. Preliminary assessment of anti-tumour activity of AZD8186 in combination with AZD2014	• FPCD: Q2 2013 • Data anticipated: H2 2019

AZD9150 (STAT3 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Head and neck squamous-cell carcinoma (HNSCC)	405	Dose escalation advanced solid and blood cancers • 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 • Data anticipated: H2 2020
Phase Ib/II **NCT03421353**	NSCLC, advanced solid tumours	213	Dose escalation advanced solid and blood cancers • Arm A1: AZD9150 alternate week/*Imfinzi* • Arm A2-A5 : AZD9150/*Imfinzi* + SoC chemotherapy Dose Expansion 1L HNSCC: • Arm D1/D2/D3: AZD9150 IV vs SC formulations/*Imfinzi* (advanced solid tumours)	• Safety/efficacy trial	• FPCD: Q1 2018 • Data anticipated: 2020

AZD9496 (selective estrogen receptor degrader)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03236974**	ER+ Breast Cancer	c. 50	• 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 oestrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (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: Pharmacodynamics changes to estrogen receptor (ER) expression following treatment with AZD9496 or *Faslodex* • Secondary Outcome Measures: Pharmacodynamics changes to Ki67 and progesterone receptor (PgR) expression following treatment with AZD9496 or *Faslodex*	• FPCD: Q4 2017 • Data anticipated: H2 2019
Phase I **NCT02248090**	ER+ Breast Cancer	c. 50	• This is a Phase I open label multicentre trial of AZD9496 administered orally in patients with advanced ER+ HER2 negative breast cancer. The trial design allows an escalation of dose with intensive safety monitoring to ensure the safety of patients. The trial will determine the maximum tolerated dose. In addition, expansion cohort(s) at potential therapeutic dose(s) in patients with or without ESR1 mutations will be enrolled to further determine the safety, tolerability, pharmacokinetics and biological activity of AZD9496	• Primary Outcome Measures: Safety and tolerability • Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood • Anti-tumour activity	• FPCD: Q4 2014 • LPCD: Q2 2016 • Data readout: Q2 2017
Phase I **NCT02780713**	Healthy subjects	14	• This is a Phase I open label single centre trial to assess the pharmacokinetics and safety of different forms and formulations of AZD9496 in healthy subjects	• Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites • Secondary Outcome Measures: Safety and tolerability	• FPCD: Q2 2016 • LPCD: Q3 2016 • Data readout: Q2 2017

AZD9833 (selective estrogen receptor degrader)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03616587**	ER+ breast cancer	240	• 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 pharmacokinetics of AZD9833 alone and in combination with palbociclib. Antitumour activity	• FPCD: Q4 2018

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: pharmacokinetics, immunogenicity, ORR, DoR, PFS, OS	• FPCD: Q2 2018 • Data anticipated: 2020+

MEDI3726 (PSMA antibody drug conjugate)

Cancer

Trial	Population	Patients	Design	Endpoints	Status

Phase I/Ib
 	
NCT02991911
	Subjects with metastatic castration resistant prostate cancer	224	Open-label, Dose-escalation and Dose-expansion
			• Three arm trial
			  • Post-chemo
			  • Pre-chemo
			  • MEDI3726+Enzalutamide
				Primary endpoint:
				• Safety
				Secondary endpoints
				• RECIST response
				• PSA50 response
				• CTC response
				• Pharmacokinetics, and immunogenicity
					• FPCD: Q1 2017
					• Data anticipated: 2020+

MEDI4276 (HER2 ADC)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02576548**	Advanced HER2+ metastatic breast and gastric cancer	47	• First-time-in-human Phase I, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	• Primary endpoint: safety • Secondary endpoints: anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size	• FPCD: Q4 2015 • Data anticipated: H2 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* IV Dose expansion phase • Part 3: MEDI5083 recommended dose + *Imfinzi* IV 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: 2020+

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03530397**	Advanced solid tumour	263	Open-label, Dose-escalation and Dose-expansion Dose-escalation: MEDI5752 IV Dose-expansion : 2 cohorts with 2 arms each	Primary endpoints: • 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: 2020+

MEDI7247 (PBD ADC mAb)

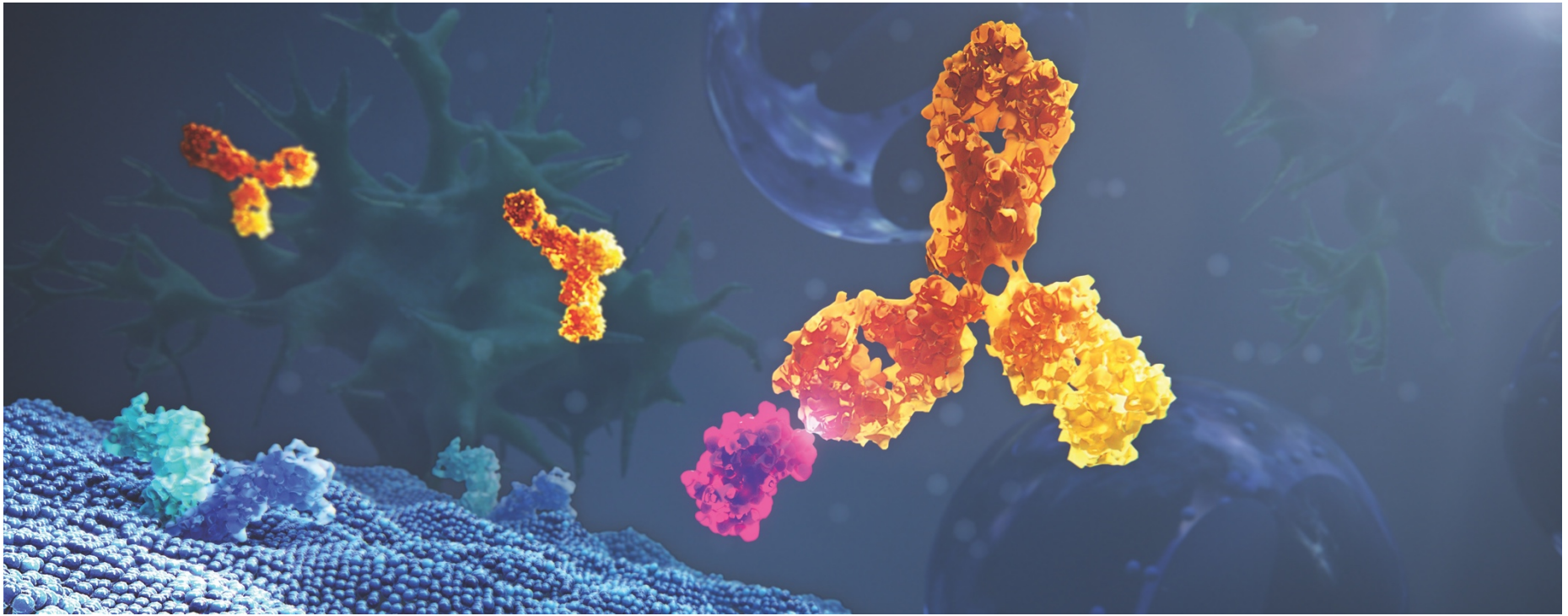
Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03106428**	Relapsed/Refractory Haematological Malignancies	408	First-time-in-human Phase I, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	• Primary endpoint: safety • Secondary endpoints: Pharmacokinetics, immunogenicity and antitumour activity	• FPCD: Q2 2017 • Data anticipated: 2020+
Phase I/Ib **NCT03811652**	Advanced or metastatic solid tumours	336	Open-label, dose-escalation and dose-expansion.	• Primary endpoint: safety • Secondary endpoints: Pharmacokinetics, immunogenicity and antitumour activity	• FPCD: Q4 2018 • Data anticipated: 2020+

AstraZeneca

AstraZeneca
What science can do

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



Farxiga (SGLT2 inhibitor)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III/IV **DECLARE** **NCT01730534**	Type-2 diabetes with high risk for CV event	17,190	• Arm 1: *Farxiga* 10mg QD + SoC therapy QD • Arm 2: Placebo + SoC therapy for type-2 Diabetes Global trial – 33 countries	• Primary endpoints: Superiority for major adverse cardiac events (MACE) (CV death, non-fatal MI (myocardial infarction) or non-fatal stroke). Superiority for the composite endpoint of CV death or hospitalisation for heart failure.	• FPCD: Q2 2013 • LPCD: Q2 2015 • Data Readout: Q3 2018 • Met primary safety endpoint and one of two primary efficacy endpoints (hHF or CV death)
Phase III **DERIVE** **NCT02413398**	Patients with type-2 diabetes and moderate renal impairment	302	• Arm 1: *Farxiga* 10mg QD for 24 weeks • Arm 2: Placebo 10mg QD for 24 weeks Global trial – eight countries	• Primary endpoint: Change from baseline in HbA1c at week 24	• FPCD: Q2 2015 • LPCD: Q2 2017 • Data readout: Q1 2018 • Primary endpoint met
Phase III **DEPICT 1** **NCT02268214** **Partnered**	Type-1 diabetes	833	• Arm 1: *Farxiga* 5mg QD 52 weeks + insulin • Arm 2: *Farxiga* 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 17 countries	• Primary endpoint: : Adjusted Mean Change From Baseline in HbA1c at week 24	• FPCD: Q4 2014 • LPCD Q2 2016 • Data readout: Q1 2017 • Primary endpoint met
Phase III **DEPICT 2** **NCT02460978** **Partnered**	Type-1 diabetes	813	• Arm 1: *Farxiga* 5mg QD 52 weeks + insulin • Arm 2: *Farxiga* 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 14 countries	• Primary endpoint: Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24	• FPCD: Q3 2015 • LPCD: Q1 2017 • Data readout: Q4 2017 • Primary endpoint met

Farxiga (SGLT2 inhibitor)

Diabetes / cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints	Status
Phase III **Dapa-HF** **NCT03036124**	Chronic Heart Failure (CHF) patients with reduced ejection fraction (HFrEF)	4,744	• Arm 1: *Farxiga* 10mg or 5 mg QD + standard of care therapy • Arm 2: Placebo + standard of care 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 heart failure (HF) or an urgent HF visit	• FPCD: Q1 2017 • LPCD Q3 2018 • Data anticipated: 2020
Phase III **Dapa-CKD** **NCT03036150**	Patients With Chronic Kidney Disease (CKD)	4,000	• Arm 1: *Farxiga* 10mg or 5 mg QD • Arm 2: Placebo Global trial - 20 countries	• Primary endpoint: Time to the first occurrence of any of the components of the composite: ≥50% sustained decline in estimated glomerular filtration rate (eGFR) or reaching end stage renal disease (ESRD) or CV death or renal death	• FPCD: Q1 2017 • Data anticipated: 2020
Phase III **DELIVER** NCT03619213	Chronic Heart Failure (CHF) patients with preserved ejection fraction (HFpEF)	4,700	• 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 heart failure (HF) or an urgent HF visit	• FPCD: Q3 2018 • Data anticipated: 2020+

Brilinta (ADP receptor antagonist)

Cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints (primary)	Status
Phase III **THEMIS** **NCT01991795**	Patients with type-2 diabetes and coronary artery disease without a previous history of myocardial infarction (MI) or stroke	19,000	• 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 cardiovascular (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 anticipated: H1 2019
Phase III **THALES** **NCT03354429**	Patients with acute ischaemic stroke or transient ischaemic attack	13,000	• 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 • Data anticipated: 2020
Phase III **HESTIA3** **NCT03615924**	Pediatric 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: 2020+

Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III **STRENGTH (CVOT)** **NCT02104817**	Patients with hypertriglyceridaemia and high cardiovascular disease risk	13,000	• Arm 1: *Epanova* 4g QD + statin • Arm 2: Placebo (corn oil) + statin Global trial – 22 countries	• Primary endpoint: Composite of Major Adverse Cardiac Events (MACE)	• FPCD: Q4 2014 • LPCD: Q2 2017 • Data anticipated: 2020
Phase III **NCT02463071**	Japanese patients with hypertriglyceridaemia	375	• *Epanova* 2g and 4g vs. Placebo (after meal) daily for 52 weeks Global trial – one country	Primary endpoints: • Safety in Japanese patients • percentage change in triglycerides	• FPCD: Q2 2015 • LPCD: Q1 2016 • Data readout: Q2 2017
Phase III **EVOLVE II** **NCT02009865**	Severe hypertriglyceridaemia	162	• Arm 1: *Epanova* 2g QD • Arm 2: Placebo (olive oil) Global trial – seven countries	• Primary endpoint: Change in serum triglycerides over 12 weeks	• FPCD: Q4 2013 • LPCD: Q4 2014 • Data readout: Q4 2015 • Primary endpoint met
Phase I **China PK** **NCT03574142**	Healthy Chinese subjects	14	Open-label trial to evaluate the pharmacokinetics of single and multiple doses of *Epanova* 4 g/day in Chinese healthy subjects Local trial – China	• Primary endpoints: Plasma concentrations versus time profile of EPA and DHA to assess PK parameters	• FPCD: Q2 2018 • LPCD: Q2 2018 • Data readout: Q4 2018

Lokelma (sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III **Harmonize Global** **NCT02875834**	Hyperkalaemia	248	Open-label *Lokelma* 10g TID for 48 hours followed by: • Arm 1: *Lokelma* 5g QD for 28 days • Arm 2: *Lokelma* 10g QD for 28 days • Arm 3: Placebo QD for 28 days Global trial – four countries	• Primary endpoint: Maintenance of normokalaemia	• FPCD: Q1 2017 • LPCD: Q1 2018 • Data readout: Q4 2018 • Primary endpoint met
Phase II/III **NCT03127644**	Hyperkalaemia	103	Arm 1: *Lokelma* 5g TID for 48 hours Arm 2: *Lokelma* 10g TID for 48 hours Arm 3: Placebo TID for 48 hours Japan	• Primary endpoint: Exponential rate of change in serum potassium	• FPCD: Q2 2017 • LPCD: Q1 2018 • Data readout: Q3 2018 • Primary endpoint met
Phase III **NCT03172702**	Hyperkalaemia	150	Arm 1: Open-label *Lokelma* 10g TID for up to 72 hrs followed by *Lokelma* 5g QD for 12 months. Option to uptitrate to 10 and15g QD or downtitrate to 5g QOD (or 2.5g QD) Japan	• Primary endpoint: Safety and tolerability as measured by adverse events reporting, vital signs, ECGs, physical examinations and safety laboratory measurements	• FPCD: Q3 2017
Phase I **NCT03283267**	Healthy Subjects	22	Arm 1: Open-label *Lokelma* 5g QD for 4 days Arm 2: Open-label *Lokelma* 10g QD for 4 days China	• Primary endpoint: Mean change from baseline to *Lokelma* treatment period in urine potassium excretion	• FPCD: Q4 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
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
Phase II **ENERGIZE** **NCT03337477**	Hyperkalaemia	132	Arm 1: *Lokelma* 10g TID for 24 hours on top off SoC (insulin and glucose) Arm 2: Placebo TID for 24 hours on top off SoC (insulin and glucose) Global trial – four countries	• Primary endpoint: Mean absolute change in S-K from baseline until 4h after start of dosing	• FPCD: Q1 2018 • LPCD: Q4 2018
Phase II **PRIORITIZE HF** **NCT03532009**	Patients with chronic heart failure and hyperkalaemia or at high risk of developing hyperkalaemia	280	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 – six countries	• Primary endpoint: Difference between *Lokelma* and placebo in RAAS (renin–angiotensin–aldosterone system) blockade treatment.	• FPCD: Q3 2018

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

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III ANDES **NCT01750190** **Partnered**	Anaemia in CKD (Chronic Kidney Disease) patients not receiving dialysis	922	• Arm 1: roxadustat • Arm 2: placebo Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2012 • 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 • 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 2019 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 • 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 • Data readout: Q4 2018 • Primary endpoint met Sponsored by AstraZeneca
Phase III SIERRAS **NCT02273726** **Partnered**		820	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2014 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III PYRENEES **NCT02278341** **Partnered**		838	• Arm 1: roxadustat • Arm 2: erythropoiesis stimulating agent • Arm 3: darbepoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2014 • Data anticipated: H2 2018 Sponsored by Astellas

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor

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

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III HIMALAYAS **NCT02052310** **Partnered**	Anaemia in newly initiated dialysis patients	900	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2013 • Data readout: Q4 2018 • Primary endpoint met Sponsored by FibroGen
Phase III **NCT02652819** **Partnered**	Anaemia in CKD (Chronic Kidney Disease) patients not receiving dialysis	154	• Arm 1: roxadustat • Arm 2: placebo China trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2015 • LPCD: Q4 2016 • Data readout: Q2 2017 • Primary endpoint met Sponsored by FibroGen
Phase III **NCT02652806** **Partnered**	Anaemia in CKD patients receiving dialysis	305	• Arm 1: roxadustat • Arm 2: epoetin alfa China trial	• Primary endpoint: Haemoglobin response	• FPCD: Q4 2015 • LPCD: Q2 2016 • Data readout: Q2 2017 • Primary endpoint met Sponsored by FibroGen
Phase III **NCT03263091** **Partnered**	Anaemia in lower risk Myelodysplastic Syndrome (MDS) patients	184	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo US/global trial	• Primary endpoint: Proportion of patients achieving transfusion independence	FPCD: Q3 2017 Sponsored by FibroGen
Phase II/III **NCT03303066** **Partnered**	Anaemia in lower risk MDS patients	175	Open label roxadustat lead-in Arm 1: roxadustat Arm 2: placebo China	• Primary endpoint: Haemoglobin response	Sponsored by FibroGen

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor

Ekliral/*Tudorza* (LAMA, DPI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Number of patients	Design	Endpoints	Status
Phase I **NCT03276052**	Healthy Chinese subjects	18	Open-label, 2-period ascending dose incomplete block, cross-over trial • 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 pharmacokinetics (PK) of aclidinium bromide and its metabolites after single and multiple doses (twice-daily [BID]) of aclidinium bromide 200 µg, 400 µg and 800 µg • To evaluate the safety, and tolerability of aclidinium bromide 200 µg, 400 µg and 800 µg after single and multiple dose administration (twice-daily [BID])	• FPCD: Q2 2018 • Data anticipated: H2 2019

Duaklir Genuair (LAMA/LABA, DPI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **AVANT** **NCT03022097**	Patients with stable COPD	1,060	• 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: 2020

Bevespi Aerosphere (LAMA/LABA, pMDI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **PINNACLE 1** **NCT01854645**	Moderate to very severe COPD	2,103	Treatment (24-week Treatment Period) • Arm 1: GFF (Glycopyrronium and Formoterol Fumarate) MDI (*Bevespi Aerosphere*) 14.4/9.6µg BID pMDI • Arm 2: GP (Glycopyrrolate) MDI (PT001) 14.4µg BID • Arm 3: FF MDI (PT005) 9.6µg BID • Arm 4: Open-label tiotropium bromide inhalation powder 18µg QD • Arm 5: Placebo MDI BID Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active- controlled US, Australia, New Zealand	• Primary endpoint: Change from baseline in morning pre-dose trough FEV_1	• FPCD: Q2 2013 • LPCD: Q3 2014 • Data readout: Q1 2015 • Primary endpoint met
Phase III **PINNACLE 2** **NCT01854658**	Moderate to very severe COPD	1,615	Treatment (24-week treatment period) • Arm 1: GFF MDI (*Bevespi Aerosphere)* 14.4/9.6µg BID pMDI • Arm 2: GP MDI (PT001) 14.4µg BID • Arm 3: FF MDI (PT005) 9.6µg BID • Arm 4: Placebo MDI BID Multicentre, randomised, double-blind, parallel group, chronic dosing and placebo-controlled US	• Primary endpoint: Change from baseline in morning pre-dose trough FEV_1	• FPCD: Q3 2013 • LPCD: Q3 2014 • Data readout: Q1 2015 • Primary endpoint met
Phase III **PINNACLE 3** **NCT01970878**	Moderate to very severe COPD	893	Treatment (28-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere*) 14.4/9.6µg BID pMDI • Arm 2: GP MDI (PT001) 14.4µg BID • Arm 3: FF MDI (PT005) 9.6µg BID • Arm 4: Open-label tiotropium bromide inhalation powder 18µg QD Multi-centre, randomised, double-blind, parallel-group and active-controlled US, Australia, New Zealand	• Primary endpoint: Change from baseline in morning pre-dose trough FEV_1	• FPCD: Q4 2013 • LPCD: Q2 2014 • Data readout: Q1 2015 • Primary endpoint met

Bevespi Aerosphere (LAMA/LABA, pMDI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design (G = glycopyrronium, F = formoterol fumarate)	Endpoints	Status
Phase III **PINNACLE 4** **NCT02343458**	Moderate to very severe COPD	1,614	Treatments (24-week Treatment Period) • GFF (Glycopyrronium and Formoterol Fumarate) MDI (*Bevespi Aerosphere*) 14.4/9.6µg BID (N=514) pMDI • GP (Glycopyrrolate) MDI 14.4µg BID (N=440) • FF MDI 9.6µg BID (N=440) • Placebo MDI BID (N=220) • US/China: Trough FEV1 at week 24 of treatment • EU/Hybrid: Co-primary = Trough FEV_1 over week 24 of treatment and TDI score over 24 weeks randomised, double-blind, chronic-dosing , placebo-controlled, parallel-group and multi-centre US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan	• Primary endpoint: change from baseline in morning pre-dose trough FEV1 of treatment [Time Frame: At Week 24] Assessed at week 24 for US/China and over weeks 12-24 for Japan, and over 24 weeks for EU/South Korea/Taiwan • Secondary endpoint: TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 weeks]	• FPCD: Q2 2015 • LPCD: Q1 2017 • Data readout: Q3 2017
Phase IIIb **AERISTO** **NCT03162055**	Moderate to very severe COPD	1,000	Treatments (24-week treatment period) • GFF MDI (*Bevespi Aerosphere*) 14.4/9.6µg BID pMDI • Umeclidinium/vilanterol DPI 62.5/25µg QD Randomised, double-blind, double-dummy, multi-centre, parallel group US, Canada, Bulgaria, France, Hungary, Russia, Ukraine	Co-primary endpoints: • Change from baseline in morning pre-dose trough FEV1 over 24 weeks • Peak change from baseline in FEV1 within two hours post-dosing over 24 weeks	• FPCD: Q2 2017 • LPCD: Q4 2017 • Data readout: Q3 2018

Daliresp/*Daxas* (PDE4 inhibitor, oral)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IV RESPOND **NCT01443845**	COPD	2,354	• 52W, randomised, DB with *Daliresp* 500µg OD vs. placebo, in COPD on top of ICS/LABA	• Primary endpoint: Rate of moderate or severe COPD exacerbations per subject per year	• FPCD: Q4 2011 • LPCD: Q1 2016 • Data readout: Q4 2016
Phase IV OPTIMIZE **NCT02165826**	COPD	1,323	• 12W, randomised, DB to evaluate tolerability and PK of *Daliresp* 500µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg *Daliresp* OD in patients not tolerating 500µg OD	• Primary endpoint: Percentage of participants prematurely discontinuing trial treatment for any reason during the main period	• FPCD: Q2 2014 • LPCD: Q3 2015 • Data readout: Q4 2016
Phase IIIb ROBERT **NCT01509677**	COPD	158	• 16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of *Daliresp* in COPD	• Primary endpoint: Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period	• FPCD: Q1 2012 • LPCD: Q1 2016 • Data readout: Q4 2016
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: 2020+

Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

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

Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD (medium dose) & HD (high dose) ICS + LABA ± chronic OCS Age 12-75 years	2,550	• Arm 1: *Fasenra* 30mg Q4W SC • Arm 2: *Fasenra* 30mg Q8W SC* • Placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial	• 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 SC 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 SC • Arm 2: placebo SC	• Primary endpoint: Safety and tolerability	• FPCD Q4 2016 • Data anticipated: H2 2019
Phase III **ALIZE** **NCT02814643**	A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of *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	• Arm1 *Fasenra* 30mg Q4W SC with one dose of seasonal influenza virus vaccine Intramuscular (IM) at week eight • Arm1 Placebo Q4W SC with one dose of seasonal influenza virus vaccine intra muscular at week	Primary endpoints: • Post-dose strain-specific haemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs) • Post-dose strain-specific serum HAI antibody geometric mean titers (GMTs) • Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer	• FPCD: Q3 2016 • Data readout: Q3 2017 • Primary endpoint met

Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **SOLANA** **NCT02869438**	Severe asthma Age 18-75 years	230	• Arm 1: *Fasenra* 30mg Q4W SC • Arm 2: Placebo SC 16-week trial Global trial – six countries	• Primary endpoint: Onset and maintenance of effect on lung function	• FPCD: Q4 2016 • Data anticipated: Q3 2018 • Primary endpoint not met
Phase III **GRECO** **NCT02918071**	Severe asthma 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 sc in patients with severe asthma uncontrolled on SoC treatment. Age 18-75	800	• Arm 1: *Fasenra* 30mg Q8W SC • Arm 2: placebo SC	• Primary endpoint: rate of asthma exacerbations • Secondary outcome measures: Saint George Respiratory Questionnaire (SGRQ)	• FPCD: Q3 2017 • Data anticipated: 2020
Phase I **AMES** **NCT02968914**	Healthy Volunteer 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 (IL-5R mAb)

Nasal polyps

Trial	Population	Patients	Design	Endpoints	Status
Phase III **OSTRO** **NCT03401229**	Patients with severe bilateral nasal polyps who are still symptomatic despite standard of care therapy	400	• Arm 1: *Fasenra* 30mg Q8W SC • Arm 2: Placebo SC 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 • Data anticipated: 2020

PT010 (LAMA/LABA/ICS, pMDI)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT02536508**	Moderate to very severe COPD	500	Treatments (52-week Treatment Period) • 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-study Endpoint. Change from baseline in BMD of the lumbar spine measured using DXA (dual energy X-ray absorptiometry) scans of L1-L4 at week 52 • Ocular Sub-study Safety Endpoint Change from baseline in LOCS III at week 52.	• FPCD: Q3 2015 • LPCD: Q3 2016 • Data readout: Q1 2018
Phase III **ETHOS** **NCT02465567**	Moderate to very severe COPD	8,000 (possible increase by 4,000 after blinded sample size re-assessment)	Treatments (1-year Treatment Period) • 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 anticipated: H2 2019
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) • Transition dyspnoea index (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

PT027 (ICS/SABA, pMDI)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **MANDALA** **NCT03769090** **Managed by Avillion**	Moderate to severe asthma	3,100	Treatments (minimum 24-week treatment period) • 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 (annualized) • Total corticosteroid exposure over the treatment period • Asthma Control Questionnaire -5 change from baseline and responder analysis at Week 24 • Asthma Quality of Life Questionnaire for 12 years and older/Pediatric Asthma Quality of Life Questionnaire change from baseline and responder analysis at Week 24	• FPCD: Q4 2018 • Data anticipated: 2020+
Phase III **DENALI** **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	Initiating

Tezepelumab (TSLP mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III NAVIGATOR **NCT03347279** **Partnered**	Severe asthma Age 12-80 years	1,060	• Arm 1: tezepelumab SC • Arm 2: placebo SC 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 • Data anticipated: 2020
Phase III SOURCE **NCT03406078** **Partnered**	Severe asthma Age 12-80 years	140	• Arm 1: tezepelumab SC • Arm 2: placebo SC 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
Phase III DESTINATION **NCT03706079** **Partnered**	Severe asthma Age 12-80 years	~975	• Arm 1: tezepelumab SC • Arm 2: placebo SC Extension Study to NAVIGATOR and SOURCE. 52 week trial (subjects from NAVIGATOR); 56 week trial (subjects from SOURCE) Global trial – ~ 20 countries	• Primary endpoint: Exposure adjusted rates of AEs/SAEs Secondary endpoints: Annual asthma exacerbation rate	• FPCD: Q1 2019

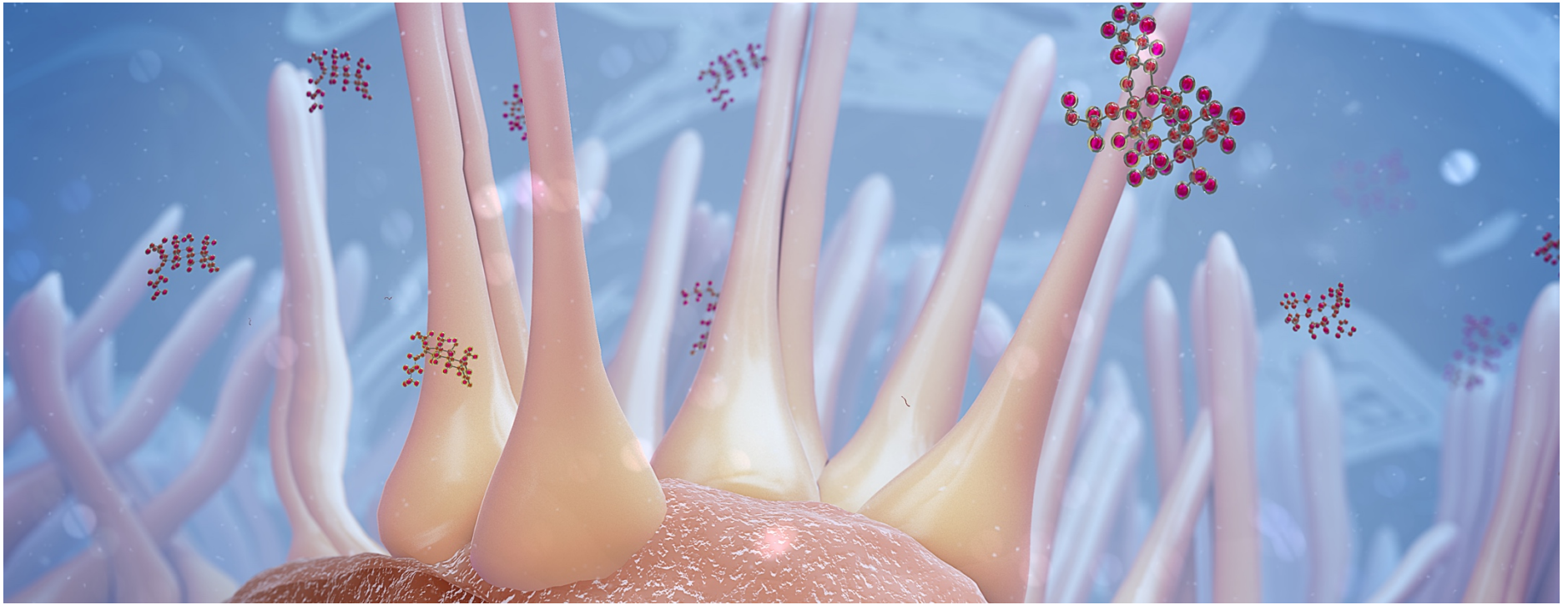
Anifrolumab (type I IFN receptor mAb)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT02446912**	Moderate to severe SLE TULIP SLE 1	450	• Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: 150mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV Q4W for 48 weeks	• Primary endpoint: Response in SLE responder index at week 52	• FPCD: Q3 2015 • Data readout: Q2 2018 • Primary endpoint not met
Phase III **NCT02446899**	Moderate to severe SLE TULIP SLE 2	360	• Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: placebo IV Q4W for 48 weeks	• Primary endpoint: Response in SLE responder index at week 52	• FPCD: Q3 2015 • Data anticipated: H2 2019
Phase III **NCT02794285**	Moderate to severe SLE TULIP LTE	630	• Arm 1: 300mg IV anifrolumab Q4W for 152 weeks • Arm 2: placebo IV Q4W for 152 weeks	• Primary endpoint: Extension to evaluate long-term safety and tolerability	• FPCD: Q2 2016 • Data anticipated: 2020
Phase II **NCT01438489**	Moderate to severe SLE patients	307	• Arm 1: 300mg IV anifrolumab Q4W for 48 weeks • Arm 2: 1000mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV Q4W for 48 weeks	• 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, IV 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 SC every other week • Arm 2: 300mg SC every other week • Arm 3: placebo SC every other week	• PK/PD, Safety, tolerability, Primary analysis at week 12, Secondary analysis at week 52	• FPCD: Q1 2017 • Data readout: Q1 2018
Phase II **NCT02547922**	Active Proliferative LN (TULIP-LN1)	150	• Arm 1: 900 mg IV Q4W for 12 weeks then 300mg IV anifrolumab Q4W for 36 weeks • Arm 2: 300 mg IV anifrolumab Q4W for 48 weeks • Arm 3: placebo IV Q4W for 48 weeks	• Response in proteinuria at week 52	• FPCD: Q4 2015 • Data anticipated: 2020

AstraZeneca
What science can do

CVRM, Respiratory and Other – early-stage development



Verinurad (RDEA3170, URAT1 inhibitor)

Chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT03118739**	CKD (Chronic Kidney Disease) patients with hyperuricaemia, albuminuria, and Type 2 diabetes	60	• Arm A: verinurad 9 mg and febuxostat 80 mg • Arm B: Placebo The trial is a multi-centre trial conducted in the US	To assess the effects of intensive uric acid lowering therapy with RDEA3170 and febuxostat on UACR (urine albumin creatinine ratio)	• FPCD: Q2 2017 • LPCD: Q3 2018 • Data readout: Q4 2018
Phase II **NCT03316131**	Asymptomatic hyperuricemic subjects (sUA (serum uric acid levels) > 6.0 mg/dL)	36	• 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 2018

AZD4831 (MPO inhibitor)

Cardiovascular disease

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

AZD5718 (FLAP inhibitor)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
AZD5718 (FLAP) **Phase I** **NCT02632526**	Healthy subjects	96	SMAD trial (one trial site in UK) SAD • Oral administration MAD	• Safety and tolerability • PK parameters, bioavailability	• FPCD: Q1 2016 • LPCD: Q3 2016 • Data readout: Q4 2016
AZD5718 (FLAP) **Phase I** **NCT02963116**	Healthy subjects	12	DDI/BA trial (one trial site in UK) A randomised, 5-period, 5-treatment, single-dose, crossover trial to estimate the effect of AZD5718 on the PK of rosuvastatin, and to assess the relative BA of different formulations of AZD5718 as well as the food effect of AZD5718	• PK and bioavailability • To further assess the safety of single doses of AZD5718 in healthy subjects	• FPCD: Q2 2016 • LPCD: Q1 2017 • Data readout Q2 2017
AZD5718 (FLAP) **Phase IIa** **NCT03317002**	Coronary Artery Disease (CAD)	138	Phase IIA trial • Arm 1: AZD5718 Dose A • Arm 2: AZD 5718 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
AZD5718 (FLAP) **Phase I** **NCT03400488**	Healthy subjects	48	Combined SAD and MAD trial in Japanese subjects (one trial site in USA)	• Safety and tolerability • PK and PD parameters	• FPCD: Q1 2018 • LPCD: Q2 2018 • Data readout: Q4 2018
AZD5718 (FLAP) **Phase I** **NCT03420092**	Healthy subjects	14	BA trial (one trial site in UK) A randomised, 6-period, 6-treatment, single-dose, open-label, crossover trial to assess the relative bioavailability of different formulations of AZD5718 and the food effect	• PK and bioavailability • Safety and tolerability	• FPCD: Q1 2018 • LPCD: Q2 2018 • Data readout: Q3 2018

AZD8233 (anti-hypercholesterolemia)

Hypercholesterolemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03593785**	Healthy subjects	40	SAD Dose escalation in 5 cohorts with 6 subjects receiving AZD8233 and 2 subjects receiving placebo in each cohort Trial conducted in the US.	Primary: • Safety and tolerability Secondary: • PK and PD parameters	• FPCD: Q3 2018

AZD8601 (VEGF-A modified RNA)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02935712**	Type 2 diabetic patients	c. 60	SAD trial (one trial site in Germany) • Planned to investigate 3 different dose levels vs. placebo but up to 5 cohort may be used	• Safety and tolerability	• FPCD: Q1 2017 • LPCD: Q3 2017 • Data readout: Q1 2018
Phase IIa **NCTT03370887**	Heart Failure	Up to 33	Phase IIa trial (two trial sites in Finland) • Arm 1: AZD8601 Dose A • Arm 2: AZD 8601 Dose B • Arm 3: Placebo	• Safety and tolerability	• FPCD: Q1 2018

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

Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02394314**	Healthy adult subjects	64	• SAD SC administration • Germany	• Primary: Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination	• FPCD: Q1 2015 • LPCD: Q4 2015 • Data readout: Q4 2015
Phase II **NCT02548585** **Completed**	Adults with type-2 diabetes	113	• MAD SC administration • Germany	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination • Efficacy: MMT glucose AUC, HbA1c, fructosamine and body weight loss	• FPCD: Q1 2016 • LPCD: Q1 2017 • Data readout: Q1 2017
Phase II **NCT03244800**	Adults with type-2 diabetes	65	• Arm1: MEDI0382 SC or placebo • Arm2: MEDI0382 SC or placebo • Germany	• Efficacy: MMT glucose AUC, body weight loss, HbA1c, fasting plasma glucose • Safety profile in terms of adverse events (AE), heart rate, blood pressure, vital signs, ECG, lab variables	• FPCD: Q3 2017 • LPCD: Q4 2017 • Data readout: Q1 2018
Phase II **NCT03235050**	Overweight and Obese subjects with type-2 diabetes	834	• Arm1: MEDI0382 low dose SC + metformin • Arm2: MEDI0382 mid dose SC + metformin • Arm3: MEDI0382 high dose SC + metformin • Arm4: placebo SC + metformin • Arm5: liraglutide SC + metformin US, Canada, Bulgaria, Czech Rep, Germany, Mexico, Russia, Slovakia	• Efficacy; HbA1c, body weight loss • Percentage of subjects achieving weight loss of ≥5% and ≥10% • Proportion of subjects rescued or discontinued for lack of glycaemic control • PK and immunogenicity	• FPCD: Q3 2017 • LPCD: Q1 2018 • Data anticipated H2 2019
Phase I **NCT03235375**	Adults with renal impairment	37	• ARM1: Subjects with CrCl <20ml/min MEDI0382 SC • ARM2: Subjects with CrCl 20-30ml/min MEDI0382 SC • ARM3: Subjects with CrCl >90ml/min MEDI0382 SC	• PK, safety, tolerability and immunogenicity	• FPCD: Q3 2017 • LPCD: Q1 2018

Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03347968	Healthy adult subjects	22	• Open label, one sequence, cross-over MEDI0382 with warfarin and esmolol US	• Effect of MEDI0382 on PK & PD of warfarin & esmolol • Safety profile • Immunogenicity	• FPCD: Q4 2017 • LPCD: Q1 2018
Phase I NCT03341013	Healthy adult subjects	24	• Open label, cross-over, two period • Single dose MEDI0382 formulation 2 SC • Single dose MEDI0382 formulation 3 SC US	• PK • Safety profile • Immunogenicity	• FPCD: Q4 2017 • LPCD: Q4 2017 • Data readout: Q2 2018
Phase I NCT03385369	Overweight/obese subjects of Japanese or Chinese descent	32	• Arm1: Single low dose of MEDI0382 or placebo (Japanese) • Arm2: Single intermediate-low dose of MEDI0382 or placebo (Japanese) • Arm3: Single intermediate-high dose of MEDI0382 or placebo (Japanese) • Arm4: Single high dose of MEDI0382 or placebo (Japanese) • Arm5: Single intermediate-low dose of MEDI0382 or placebo US	• Safety profile • Tolerability • PK • Immunogenicity	• FPCD: Q1 2018 • LPCD: Q2 2018
Phase II NCT03444584	Overweight/obese subjects with type-2 diabetes	46	• Arm1: MEDI0382 + dapagliflozin • Arm2: placebo + Dapagliflozin	• Efficacy: MMT glucose AUC • Safety • PK • Immunogenicity	• FPCD: Q3 2018
Phase II NCT03550378	Adults with type-2 diabetes and renal impairment	40	• MEDI0382 or placebo SC Germany, UK	• Efficacy: MMT glucose AUC • Safety • Tolerability • PK • Immunogenicity	• FPCD Q2 2018 • LPCD; Q4 2018 • Data anticipated: H1 2019
Phase II NCT03555994	Adults with type-2 diabetes	40	• Part A: MEDI0382 or placebo SC • Part B: MEDI0382 SC or placebo SC or liraglutide SC	• Change in hepatic glycogen concentration postprandially, adjusted by liver volume • Safety • Tolerability • Immunogenicity	• FPCD: Q2 2018 • Part A LPCD: Q4 2018

Cotadutide (MEDI0382, GLP-1-glucagon agonist)

Diabetes/obesity

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03596177	Overweight and obese subjects with type-2 diabetes	24	• MEDI0382 or placebo SC • 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
Phase I NCT03625778	Non-diabetic obese subjects	15	• MEDI0382 or placebo SC • US	• Primary: safety, tolerability • Secondary: PK • Secondary: Immunogenicity	• FPCD: Q3 2018
Phase II NCT03745937	Overweight and obese subjects with type-2 diabetes	20	• MEDI0382 or placebo SC • Germany	• Primary: Safety, tolerability • Secondary: PK • Secondary: Immunogenicity • Secondary: Glucose control	• initiating
Phase II NCT03645421	Japanese preobese or obese subjects with type-2 diabetes	61	• MAD SC administration • Japan	• Primary: Safety, glucose AUC, body weight • Secondary: HbA1c, FPG, fructosamine • Secondary: glucose control • Secondary: PK, immunogenicity	• FPCD: Q3 2018 • LPCD: Q3 2018

MEDI7219 (anti-diabetic)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03362593**	Healthy Volunteers	104	• 4 part trial • Part A : SAD • Part B & C : open label, single dose studies • Part D : MAD	• Safety and tolerability • Pharmacokinetics	• FPCD: Q1 2018 • Data anticipated: H1 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 IV push. • Cohort B: 6-Dose Regimen 300 mg of MEDI6012 or placebo on Day 1 prior to pPCI followed by a second inpatient dose of 150 mg or placebo on Day 3 and outpatient maintenance doses of 100 mg or placebo on Days 10, 17, 24, and 31 by IV push.	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 treatment-emergent adverse events (TEAEs) and treatment-emergent serious adverse events (SAEs). • Lecithin-cholesterol acyltransferase (LCAT) mass and ADAs.	• FPCD: Q2 18 • Data anticipated: 2020+
Phase IIa **NCT03351738**	MEDI5884 Cholesterol modulation	Adults With Stable Coronary Heart Disease (CHD)	133	• MEDI5884 (5 dose cohorts) vs. placebo in stable CHD patients	• Safety profile in terms of adverse events (AE), 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	72	• Single Ascending Dose followed by Multi Ascending dose with 3 monthly doses in T2DM subjects	• Primary Endpoints: Safety and tolerability	• FPCD: Q4 2018 • Data anticipated: H2 2019

AZD1402 (IL4 receptor antagonist)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03384290** **Partnered**	Healthy subjects	Inhaled: 56 IV: 16	SAD. A dose escalating single blind trial to assess the safety, tolerability and pharmacokinetics of single dose of PRS-060 administered by oral Inhalation or IV Infusion in healthy subjects • ARM 1-7 (Inhaled (nebulizer) PRS-060 and matched placebo • ARM8-9 (IV) PRS-060 and matched placebo Australia	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters	• FPCD: Q4 2017 • LPCD: Q3 2018 • Data readout: Q1 2019
Phase Ib **NCT03574805** **Partnered**	Patients with mild asthma	70	PoM. A dose-escalating, single blind trial to assess the safety, tolerability, and pharmacokinetics of multiple doses of PRS-060 administered by oral Inhalation In subjects with mild asthma • ARM 1-4 (ARM 5 optional) (inhaled nebulizer) and matched placebo Australia	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters • Potential immunogenicity • Change in fractional nitric oxide concentration in exhaled breath (FeNO)	• FPCD: Q3 2018 • LPCD Q2 2019 • Data anticipated: H2 2019

AZD1419 (TLR9 agonist)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa INCONTRO **NCT02898662**	Adults with eosinophilic, moderate to severe asthma on ICS + LABA background treatment	81	• Arm 1: AZD1419, once-weekly adaptive dosing (4mg, 1mg, 8mg) • Arm 2: placebo Inhaled (nebulised) administration Trial conducted in EU	• Time to loss of asthma control	• FPCD: Q4 2016 • LPCD: Q4 2017 • Data readout: Q4 2018

AZD8154 (PI3Kγδ inhibitor)

Asthma

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

AZD8871 (MABA, inhaled)

Respiratory

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT03645434**	Patients with chronic obstructive pulmonary disease (COPD)	72	Randomised, double-blind, placebo and active-controlled crossover trial. Eligible patients will be randomized in 1:1:1:1:1:1 ratio to 1 of 6 treatment sequences and will receive 1 of the following 3 treatments sequence in the form of dry powder inhalation: • 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 • Data anticipated: H2 2019

AZD9567 (SGRM, oral)

Respiratory

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02760316**	Healthy subjects	71	MAD trial with a total of 6 dose levels of AZD9567: 10 mg, 20mg, 40mg, 80mg and 125 mg as well as with 3 dose levels of prednisolone: 5 mg, 20 mg and 40 mg	Primary endpoint: • 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 Rheumatoid Arthritis (RA)	40	A Phase II, randomised, double-blind, parallel trial to assess the efficacy, safety and tolerability of AZD9567 compared to prednisolone 20 mg in patients with active rheumatoid arthritis	Primary endpoint: To assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active RA in spite of stable treatment with conventional and/or sc/i.v. biological DMARDs (Disease-modifying antirheumatic drugs) 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

MEDI3506 (IL-33 mAb) ligand

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SDE / MDE) **NCT03096795**	SDE: Healthy subjects with mild atopy	SDE: 56	SDE: • 7 sequential placebo-controlled single dose cohorts (active N=6 / placebo N = 2 within each cohort) • Dose levels: 1mg SC, 3 mg SC, 10 mg SC, 30 mg SC, 100 mg SC, 300 mg SC and 300 mg IV	• Safety and tolerability	• FPCD: Q2 2017 • LPCD: H1 2019 • Data anticipated: 2020
	J-SD: Healthy Japanese subjects	J-SD: 8	J-SD • A single placebo-controlled single dose cohort (active N=6 / placebo N = 2 within cohort) • Dose level: 300 mg IV		
	MDE: COPD	MAD: 24	MDE: • 3 sequential placebo-controlled multiple dosing cohorts (active N=6 / placebo N = 2 within each cohort) • Dose levels: 30 mg SC, 100 mg SC and 300 mg SC		

AZD0284 (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 • Proof of Mechanism (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 Phase I, single centre, open-label, non-randomised, single dose trial performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The trial will assess the absolute bioavailability of a single oral dose of AZD0284 and the pharmacokinetics (PK) of a single intravenous (IV) microdose of [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 • The trial is temporarily suspended due to preclinical findings that are currently under evaluation

AZD5634 (epithelial NaC inhibitor)

Cystic fibrosis

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02679729**	Healthy subjects	Part A: 57 Part B: 6	SAD A Phase I, randomised, single-blind, placebo-controlled trial to assess the safety, tolerability and pharmacokinetics of AZD5634 following single-ascending inhaled doses (Part A) and after single inhaled and intravenous doses (Part B) in healthy subjects	Primary endpoint: • Safety and tolerability Secondary endpoint: • PK parameters	• FPCD: Q1 2016 • LPCD: Q3 2016 • Data readout: Q2 2017
Phase Ib **NCT02950805**	Patients with cystic fibrosis	10	PoM A Phase Ib, randomised, blinded, placebo-controlled cross-over trial to assess the effect of AZD5634 on mucociliary clearance as well as safety, tolerability and pharmacokinetic parameters following single inhaled dose administration to patients with cystic fibrosis	Primary endpoint: • Mucociliary clearance (MCC) Secondary endpoint: • PK parameters • Safety and tolerability	• FPCD: Q2 2017 • LPCD Q1 2018 • Data readout: Q2 2018

Other biologics

Infections

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II **EudraCT 2014-001097-34**	Anti-Staph AT (suvratoxumab, MEDI4893)	Intubated Intensive Care Unit (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 (MEDI8897)	29-35 WK GA (Gestational age) infants	1,453	• Randomised, double-blind, placebo-controlled trial • Route of administration: IM	• 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: 2020+

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

Systemic lupus erythematosus (SLE)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ia **NCT02618967** **Partnered**	Healthy volunteers	56	Single Ascending Dose • Arm 1: MEDI0700 administered as single SC dose • Arm 2: Dose levels of Placebo administered as single SC dose	• Safety and tolerability • PK/PD	• FPCD: Q1 2016 • Data readout: Q3 2018

MEDI1341 (alpha-synuclein mAb)

Parkinson's Disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03272165**	Healthy volunteers	40	• SAD • Up to 5 IV cohorts are planned vs placebo US only	• Safety, tolerability, PK, PD	• FPCD: Q4 2017 • Data anticipated: H1 2019

MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02036645**	Alzheimer's disease & healthy elderly	121	• SAD & MAD • Up to 10 IV cohorts are planned vs. placebo • 2 SC cohorts are planned vs. placebo US only	• Safety, tolerability	• FPCD: Q2 2014 • LPCD: Q2 2016 • Data readout: Q4 2016

Prezalumab (MEDI5872, B7RP-1 mAb)

Systemic lupus erythematosus (SLE)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT02334306** **Partnered**	Primary Sjögren's syndrome	32	• Arm 1: MEDI5872 210mg SC QW for 3 weeks and then Q2W for 9 weeks • Arm 2: placebo SC QW for 3 weeks and then Q2W for 9 weeks Global trial – five countries	• Safety and tolerability • Change in the ESSDAI (EULAR Sjögren's syndrome (SS) disease activity index) score from baseline to Day 99	• FPCD: Q3 2015 • Data readout: Q3 2018
Phase I **NCT01683695** **Partnered**	SLE and lupus related inflammatory arthritis	20	Dose escalation trial: • Arm 1: MEDI5872 SC • Arm 2: placebo SC Global trial – eight countries	• Safety and tolerability • Lupus Arthritis Response Rate	• FPCD: Q2 2012 • LPCD: Q4 2015 • Data readout: Q2 2016

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 10 IV cohorts are planned vs. placebo • 2 SC cohorts are planned vs. placebo Europe only	• Safety, tolerability, PK, PD	• FPCD: Q1 2016 • Data anticipated: H1 2019
Phase II **NCT03755934**	Painful diabetic neuropathy	271	• Multiple dose study • Up to 4 IV cohorts are planned vs.placebo Europe and Russia only	• Dose response, safety, tolerability, PK, PD	• FPCD Q4 2018 • Data anticipated: 2020+

Clinical trials appendix
Q4 2018 results update

AstraZeneca
What science can do