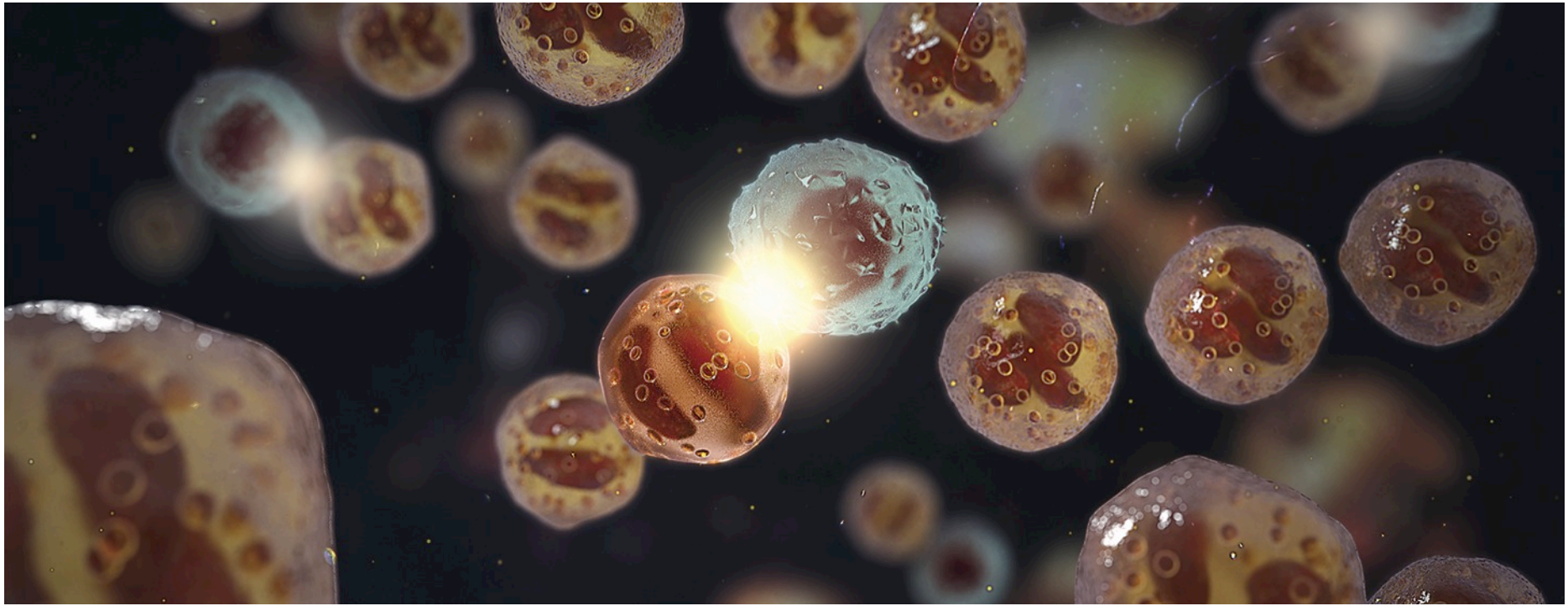
Clinical trials appendix
Q1 2018 Results update

AstraZeneca
What science can do



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

List of abbreviations

AE	Adverse Event
AUC	Area Under Curve
BID	Bis In Die (two times a day)
CE	Clinically Evaluable
CMAX	Maximum Concentration Absorbed
cMITT	Clinical-Modified Intent To Treat
CNS	Central Nervous System
DLT	Dose-Limiting Toxicity
FDC	Fixed-Dose Combination
FEV	Forced-Expiratory Volume
FPCD	First Patient Commenced Dosing
IM	Intra Muscular
IR	Immediate Release
IV	Intravenous
LCM	Lifecycle Management
LPCD	Last Patient Commenced Dosing
MAD	Multiple Ascending Dose
MDI	Metered-Dose Inhaler
MITT	Modified Intent To Treat
mMITT	Microbiological-Modified Intent To Treat
MTD	Maximum Tolerated Dose
NME	New Molecular Entity
OLE	Open Long-term Extension
ORR	Objective Response Rate
OS	Overall Survival
PFS	Progression-Free Survival
PK	Pharmacokinetics
PD	Pharmacodynamics
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)
SAD	Single Ascending Dose
SC	Subcutaneous
TID	Ter In Die (three times a day)
TOC	Test Of Cure
XR	Extended Release

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Movement since Q4 2017 update

New to Phase I

NMEs
AZD9977
MCR CV disease
***Calquence* + AZD6738**
BTK inhibitor + ATR inhibitor haematological malignancies
MEDI1314
alpha synuclein mAb parkinson's disease
MEDI7219
anti-diabetic type-2 diabetes

Additional indications
***Imfinzi* + danvatirsen (AZD9150) + chemotherapy**
PD-L1 mAb + STAT3 inhibitor + chemotherapy solid tumours

New to Phase II

NMEs
***Imfinzi* + *Lynparza* BAYOU**
PD-L1 mAb + PARP inhibitor 1st-line unresectable stage IV bladder cancer
AZD8601#
VEGF-A CV disease

New to Pivotal Study

Additional indications
roxadustat#
HIFPH anaemia in myelodysplastic syndrome

Life-cycle Management
***Fasenra*# OSTRO**
IL-5R mAb nasal polyposis

New to Registration

NMEs
moxetumomab# PLAIT [US] [1]
anti-CD22 recombinant immunotoxin 3rd-line hairy cell leukaemia

Life-cycle Management
***Forxiga* [EU] [1]**
SGLT2 inhibitor type-1 diabetes
***Bydureon* EXSCEL [EU] [1]**
GLP-1 receptor agonist type-2 diabetes outcomes trial

Removed from Phase I

NMEs
MEDI-565#
CEA BiTE mAb solid tumours
MEDI4920 [3]
anti-CD40L-Tn3 fusion protein primary Sjögren's syndrome
MEDI7734 [3]
IL-T7 mAb myositis
MEDI9314
IL-4R mAb atopic dermatitis

Removed from Phase II

NMEs
inebilizumab# [3]
CD19 mAb neuromyolitis optica
mavrilimumab# [3]
GM-CSFR mAb rheumatoid arthritis

Removed from Phase III

Additional indications
***Imfinzi*#+tremelimumab ARCTIC**
PD-L1 mAb+CTLA-4 mAb 3rd-line NSCLC

Removed from Registration

NMEs
***Lokelma* (ZS-9) [US] [2]**
potassium binder hyperkalameia

Life-cycle Management
***Imfinzi*# PACIFIC [US] [2]**
PD-L1 mAb locally-advanced (Stage III), NSCLC
***Tagrisso* FLAURA [US] [2]**
EGFR inhibitor 1st-line advanced EGFRm NSCLC

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

Q1 2018 New Molecular Entity (NME)[1] Pipeline

Phase I

31 New Molecular Entities

Small molecule

- AZD0156 ATM solid tumours
- AZD1390 ATM healthy volunteer study
- AZD2811# Aurora solid tumours
- AZD4573 CDK9 hematalogical malignancies
- AZD4635 A2aR inhibitor solid tumours
- AZD4785 KRAS solid tumours
- AZD5153 BRD4 solid tumours
- AZD5991 MCL1 hematalogical malignancies
- AZD6738 ATR solid tumours
- AZD8186 PI3Kβ solid tumours
- AZD9496 SERD ER+ breast
- MEDI9197# TLR 7/8 solid tumours
- AZD4831 MPO HFpEF
- AZD9977 MCR cardiovascular
- AZD1402# inhaled IL-4Ra asthma
- AZD5634 inhaled ENaC cystic fibrosis
- AZD7594+abediterol# Inhaled SGRM+LABA asthma/COPD
- AZD0284 RORg psoriasis/respiratory

Large molecule

- MEDI0562# hOX40 solid tumours
- MEDI1873 GITR solid tumours
- MEDI3726# PSMA prostate
- MEDI4276 HER2 solid tumours
- MEDI5083 CD40 ligand fusion protein solid tumours
- MEDI7247 antibody drug conjugate haems
- oleclumab CD73 solid tumours
- MEDI7219 anti-diabetic type-2 diabetes
- MEDI3506 IL-33 COPD
- MEDI0700# BAFF/B7RP1 SLE
- MEDI1341 alpha synuclein parkinson's disease
- MEDI1814# amyloidβ alzheimer's disease
- MEDI7352 NGF/TNF osteoarthritis pain

Phase II

21 New Molecular Entities

Small molecule

- adavosertib# (AZD1775)+chemotherapy Wee1+chemo ovarian cancer
- AZD4547 FGFR solid tumours
- capivasertib (AZD5363)# AKT breast cancer
- vistusertib mTOR 1/2 solid tumours
- AZD5718 FLAP coronary artery disease
- AZD8601# VEGF-A cardiovascular
- verinurad URAT-1 chronic kidney disease
- abediterol# LABA asthma/COPD
- AZD1419# inhaled TLR9 asthma
- AZD7594 Inhaled SGRM asthma/COPD
- AZD7986# DPP1 COPD
- AZD8871# MABA COPD
- AZD9567 SGRM RA/respiratory

Large molecule

- MEDI0382 GLP-1/glucagon type-2 diabetes
- MEDI5884# cholesterol modulation cardiovascular
- MEDI6012 LCAT cardiovascular
- MEDI3902 PsI/PcrV Pseudomonas pneumonia
- MEDI8852 influenza A treatment
- MEDI8897# passive RSV prophylaxis
- prezalumab# primary Sjögren's syndrome
- suvratoxumab α-Toxin Staphylococcus pneumonia

Phase III

8 New Molecular Entities

Small molecule

- *Lynparza*¶+cediranib CONCERTO PARP+VEGF recurrent Pt-R ovarian
- savolitinib# SAVOIR MET pRCC
- selumetinib ASTRA MEK differentiated thyroid cancer
- PT010 LABA/LAMA/ICS COPD
- lanabecestat# BACE early alzheimer's disease

Large molecule

- *Imfinzi*#+tremelimumab MYSTIC PD-L1+CTLA-4 1L NSCLC
- tezepelumab# NAVIGATOR SOURCE TSLP severe uncontrolled asthma
- anifrolumab# TULIP Type I IFN receptor SLE

Applications Under Review

2 New Molecular Entities

Small molecule

- roxadustat# HIFPH anaemia CKD/ESRD

Large molecule

- moxetumomab pasudotox# PLAIT CD22 3L HCL

[1] Includes significant fixed-dose combination projects, and parallel indications that are in a separate therapy area *(See LCM chart for other parallel indications and oncology combination projects)*

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

Oncology | Cardiovascular, Renal & Metabolism | Respiratory | Other

Q1 2018 Lifecycle Management (LCM)[1] Pipeline

Phase I

1 Projects

Small molecule

- adavosertib# (AZD1775) Wee1 solid tumours

Phase II

7 Projects

Small molecule

- *Tagrisso* BLOOM EGFR NSCLC CNS mets
- *Brilinta/Brilique* HESTIA P2Y12 paeds w/ sickle cell
- PT010 LABA/LAMA/ICS asthma

Large molecule

- *Imfinzi*# PD-L1 solid tumours
- tezepelumab# TSLP atopic dermatitis
- anifrolumab# Type I IFN receptor SLE SC
- anifrolumab# Type I IFN receptor lupus nephritis

Phase III

21 Projects

Small molecule

- *Calquence*# BTK inhibitor 1st line MCL
- *Calquence*# BTK inhibitor 1st line CLL
- *Calquence*# BTK inhibitor r/r CLL, high risk
- *Lynparza* OlympiA PARP gBRCA adjuvant breast
- *Lynparza* POLO PARP pancreatic cancer
- *Lynparza* PROfound PARP prostate cancer
- *Lynparza* SOLO-1 PARP 1L BRCAm ovarian
- *Lynparza* SOLO-3 PARP BRCAm PSR ovarian
- *Tagrisso* ADAURA EGFR adj. EGFRm NSCLC

- *Brilinta/Brilique* THALES P2Y12 stroke
- *Brilinta/Brilique* THEMIS P2Y12 diabetes & CAD outcomes
- *Epanova* STRENGTH outcomes
- *Farxiga/Forxiga* SGLT2 heart failure
- *Farxiga/Forxiga* SGLT2 CKD
- *Farxiga/Forxiga* DECLARE outcomes
- roxadustat# HIFPH anaemia MDS
- saxagliptin/dapagliflozin metformin DPP4 type-2 diabetes
- *Symbicort* SYGMA as needed in mild asthma

Large molecule

- *Imfinzi*# PEARL (China) PD-L1 1L NSCLC
- *Fasenra*# IL-5R COPD
- *Fasenra*# OSTRO IL-5R nasal polyposis

Applications Under Review

4 Projects

Small molecule

- *Bydureon* EXSCEL outcomes
- *Farxiga/Forxiga* type-1 diabetes
- linaclotide# (CN only) IBS-c
- *Nexium* (CN only) stress ulcer prophylaxis

Large molecule

[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

Q1 2018 Lifecycle Management (LCM)[1] Pipeline

Oncology Combinations

Phase I
18 Projects

- *Calquence*+AZD6738 BTK+ATR hematalogical tumours
- *Calquence*+vistusertib BTK+mTor hematalogical tumours
- *Imfinzi*# or Imfinzi#+(treme or danvatirsen#) PD-L1 or PD-L1+(CTLA-4 or STAT3) DLBCL
- *Imfinzi*#+adavosertib#(AZD1775) PD-L1+Wee1 solid tumours
- *Imfinzi*#+azacitidine# PD-L1+azacitidine MDS
- *Imfinzi*#+dabrafenib+trametinib PD-L1+BRAF+MEK melanoma
- *Imfinzi*#+*Iressa* PD-L1+EGFR NSCLC
- *Imfinzi*#+MEDI0562# PD-L1+hOX40 solid tumours
- *Imfinzi*#+MEDI9197# PD-L1+TLR 7/8 agonist
- *Imfinzi*#+monalizumab PD-L1+NKG2a solid tumours
- *Imfinzi*#+oleclumab PD-L1+CD73 solid tumours
- *Imfinzi*#+RT (platform) CLOVER PD-L1+RT HNSCC NSCLC SCLC
- *Imfinzi*#+selumetinib# PL-L1 solid tumours + MEK inhibitor
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 solid tumours
- *Imfinzi*#+tremelimumab+chemo PD-L1+CTLA-4 1L PDAC oesophageal
- *Imfinzi*+danvatirsen(AZD9150)+chemo PD-L1+STAT3+chemo solid tumours
- *Lynparza*+adavosertib# (AZD1775) PARP+Wee1 solid tumours
- tremelimumab+MEDI0562# CTLA-4+hOX40 solid tumours

Phase II
10 Projects

- *Imfinzi*#+AZD5069 PD-L1+CXCR2 PDAC
- *Imfinzi*#+AZD5069 or Imfinzi#+danvatirsen#(AZD9150)
- *Imfinzi*#+MEDI0457# PD-L1+DNA HPV vaccine HNSCC
- *Imfinzi*#+MEDI0680 PD-L1+PD-1 solid tumours
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 gastric cancer
- *Imfinzi*#+tremelimumab PD-L1+CTLA-4 biliary tract oesophageal
- *Imfinzi*+*Lynparza* BAYOU PD-L1+PARP bladder
- *Lynparza*#+*Imfinzi* MEDIOLA PARP+PD-L1 solid tumours
- *Lynparza*+AZD6738 PARP+ATR gastric
- *Tagrisso* combo# TATTON EGFR+PD-L1/MEK/MET NSCLC

Phase III
7 Projects

- *Imfinzi*#+tremelimumab DANUBE PD-L1+CTLA-4 1L bladder
- *Imfinzi*#+tremelimumab EAGLE PD-L1+CTLA-4 2L HNSCC
- *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+SoC CASPIAN PD-L1+CTLA-4+SoC 1L SCLC
- *Imfinzi*#+tremelimumab+SoC POSEIDON PD-L1+CTLA-4+SoC 1L NSCLC

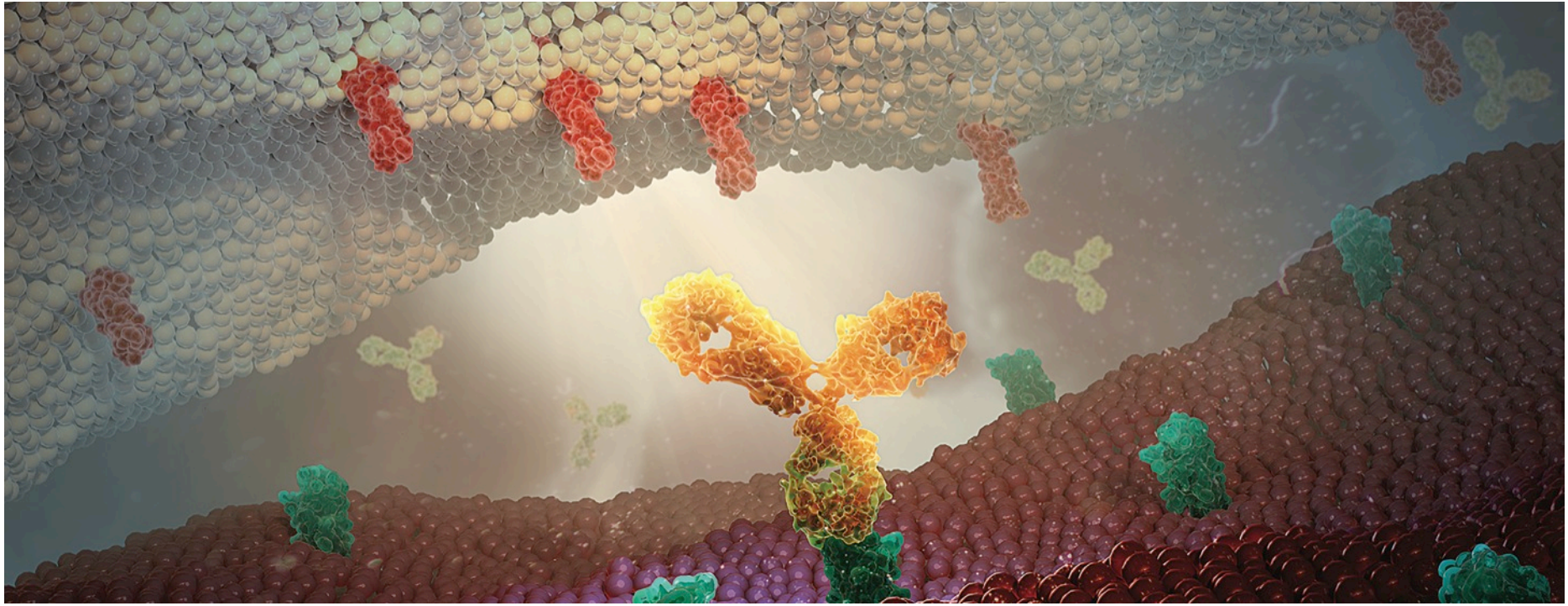
Applications Under Review
0 Projects

[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

Approved medicines



Lynparza (PARP inhibitor)

Ovarian cancer and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **SOLO-2** **NCT01874353**	Platinum-sensitive recurrent (PSR) BRCAm ovarian cancer	295	• Arm 1: *Lynparza* tablets 300mg BID as maintenance therapy until progression • Arm 2: placebo tablets BID Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q3 2013 • LPCD: Q4 2014 • Data readout: Q4 2016 • Primary endpoint met
Phase III **SOLO-1** **NCT01844986**	1L maintenance BRCAm ovarian cancer	391	• Arm 1: *Lynparza* tablets 300mg BID maintenance therapy for 2 years or until disease progression • Arm 2: placebo Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q3 2013 • LPCD: Q1 2015 • Data anticipated: H1 2018
Phase III **SOLO-3** **NCT02282020**	PSR gBRCAm ovarian cancer 3L+ Line	411	• Arm 1: *Lynparza* 300mg BID to progression • Arm 2: Physician's choice (single-agent chemotherapy) Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q1 2015
Phase I / II **MEDIOLA** **NCT02734004**	gBRCAm ovarian cancer 2L+ gBRCAm HER2-negative breast cancer 1-3L Small cell lung cancer (SCLC) 2L+ Gastric cancer 2L+	133	• Arm 1: *Lynparza* tablets 300mg BID starting on week 1 day 1 / *Imfinzi* IV 1.5g every 4 weeks starting on week 5 day 1 • Dose until progression Global trial	Primary endpoints • Disease control rate (DCR) at 12 weeks • Safety and tolerability Secondary endpoints • DCR at 28 weeks • ORR, duration of response (DoR), PFS, TDT, OS • PK	• FPCD: Q2 2016 • LPCD: Q2 2017

PARP = Poly ADP Ribose Polymerase

Lynparza (PARP inhibitor)

Breast cancer and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **OlympiAD** **NCT02000622**	BRCAm 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 **OlympiA** **NCT02032823** **Partnered**	BRCAm 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 **POLO** **NCT02184195**	gBRCAm pancreatic cancer	145	• 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 • Data readout: 2019
Phase II **NCT01972217**	Metastatic castration-resistant prostate cancer	142	• Arm 1: *Lynparza* 300mg BiD + abiraterone • Arm 2: Placebo + abiraterone Global trial	• Primary endpoint: Radiologic PFS	• FPCD: Q3 2014 • LPCD: Q3 2015 • Data readout: Q4 2017
Phase III **PROfound** **NCT02987543**	Metastatic castration-resistant prostate cancer HRRm, 2L+	340	• 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

PARP = Poly ADP Ribose Polymerase
HRRm = Homologous recombination repair mutation

Tagrisso (Highly-selective, irreversible EGFRi)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **AURA3** **NCT02151981**	Advanced EGFRm NSCLC tyrosine kinase inhibitor (TKI) failure and primary resistance mutation T790M	410	• Arm 1: *Tagrisso* 80mg QD • Arm 2: pemetrexed 500mg/m2 + carboplatin AUC5 or pemetrexed 500mg/m2 + cisplatin 75mg/m2 (2:1 randomisation) Global trial – 18 countries	• Primary endpoint: PFS • Secondary endpoints: OS and quality of life (QoL)	• FPCD: Q3 2014 • Data readout: Q3 2016 • Primary endpoint met
Phase III **FLAURA** **NCT02296125**	Advanced EGFRm NSCLC 1L	556	• Arm 1: *Tagrisso* 80mg • Arm 2: erlotinib 150mg or *Iressa* 250mg (physicians choice); 1:1 randomisation Global trial – 30 countries	• Primary endpoint: PFS • Secondary endpoints: OS and QoL	• FPCD: Q1 2015 • LPCD: Q4 2016 • Data readout: Q3 2017 • Primary endpoint met
Phase III **ADAURA** **NCT02511106**	Adjuvant EGFRm NSCLC	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: 2022
Phase II **AURA17** **NCT02442349**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	171	• *Tagrisso* 80mg QD Asia-Pacific regional trial – 3 countries	• Primary endpoint: ORR • Secondary endpoints: PFS and OS	• FPCD: Q3 2015 • Data readout: Q2 2016
Phase II **AURA2** **NCT02094261**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	210	• *Tagrisso* 80mg QD Global trial - 8 countries	• Primary endpoint: ORR • Secondary endpoints: PFS and DoR	• FPCD: Q2 2014 • LPCD: Q4 2014 • Data readout: Q2 2015
Phase I/II **AURA** **NCT01802632**	Advanced EGFRm NSCLC TKI failure + /- primary resistance mutation T790M	603	• Dose escalation trial • Ph II Extension cohort (T790M only) *Tagrisso* 80mg QD Global trial – 10 countries	• Primary endpoint: ORR • Secondary endpoints: PFS and OS	• FPCD: Q1 2013 • LPCD: Q4 2014 • Data readout: Q2 2015 (Phase II portion)

Tagrisso (Highly-selective, irreversible EGFRi)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
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
Phase II **ELIOS** **NCT03239340**	EGFR TKI treatment-naïve patients with locally-advanced or metastatic EGFRm+ NS	100	Single arm study – *Tagrisso* 80 mg Global trial – 5 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	
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 BICR) • Secondary endpoints: CNS PFS, OS, DoR, ORR, DCR	

Imfinzi (PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ADJUVANT** **NCT02273375** **Partnered**	Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK positive)	1,100	• 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 III **PACIFIC** **NCT02125461**	Unresectable NSCLC patients following platinum-based concurrent chemo-radiation therapy	702	• Arm 1: *Imfinzi* IV Q2W • Arm 2: Placebo Global trial	Primary endpoints: • PFS • OS	• FPCD: Q2 2014 • LPCD: Q2 2016 • Data readout: Q2 2017 • Primary endpoint met • OS Data anticipated: 2019
Phase II/III Lung Master Protocol **NCT02154490** **Partnered**	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	140 ; 100 *Imfinzi* treated	Umbrella trial with five arms based on biomarker expression • Substudy A: *Imfinzi* (non-match for other biomarker driven substudies) IVQ2W single arm *Imfinzi* PhII 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 (Substudy is closed)	Primary endpoints: • ORR • PFS • OS	• FPCD: Q2 2014 • Data anticipated: 2022
Phase I/II Sequencing Study **NCT02179671**	Stage IIIB-IV NSCLC patients	72	• Arm 1: *Iressa* initially then switch to *Imfinzi* IVQ2W • Arm 2: *Tagrisso* then switch to *Imfinzi* • Arm 3: selumetinib + docetaxel then switch to *Imfinzi* • Arm 4: tremelimumab then switch to *Imfinzi*	• Primary endpoint: Complete Response Rate • Secondary endpoints: ORR, Disease Control Rate	• FPCD: Q3 2014 • LPCD: Q2 2016 • Data readout: Q3 2016
Phase III **PEARL** **NCT03003962**	NSCLC 1L	440	• Arm 1 *Imfinzi* Q4W • Arm 2 Chemotherapy (SoC) Asia trial	Primary endpoints: • PFS • OS	• FPCD: Q1 2017 • Data anticipated: 2020
Phase III **PACIFIC-2**	*Imfinzi* + CRT in Unresected Locally Advanced NSCLC	300	• Arm 1: *Imfinzi* IV Q4W + Chemo/RT • Arm 2: Placebo + Chemo/RT ex US global trial	Primary endpoint: • PFS • ORR Secondary endpoint: • OS	• FPCD: Q2 2018 • Data readout: 2021

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, 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 anticipated: 2018
Phase I **NCT01938612**	Solid tumours (all-comers)	176	• Dose Escalation: 3 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 anticipated: 2018

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

Non-small cell lung cancer (NSCLC) and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III ARCTIC NCT02352948	Stage IIIB-IV 3L NSCLC patients who have not been tested positive for EGFR/ALK mutation	480	• Arm 1: *Imfinzi* + tremelimumab (PD-L1 –ve patients) • Arm 2: Standard of care • Arm 3: tremelimumab (PD-L1 –ve patients) • Arm 4: *Imfinzi* (PD-L1 –ve patients)	Primary endpoints: • PFS • OS	• FPCD: Q2 2015 • LPCD: Q3 2016 • Data readout: Q1 2018
Phase III MYSTIC NCT02453282	NSCLC 1L	1,118	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab • Arm 3: Standard of care	Primary endpoints: • PFS • OS	• FPCD: Q3 2015 • LPCD: Q3 2016 • Data anticipated: H2 2018 (OS) • PFS primary endpoint not met
Phase III NEPTUNE NCT02542293	NSCLC 1L	960	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: Standard of care	• Primary endpoint: OS • Secondary endpoint: PFS	• FPCD: Q4 2015 • LPCD: Q2 2017 • Data anticipated: 2019
Phase III POSEIDON NCT03164616	NSCLC 1L	1,000	• Arm 1: *Imfinzi* + CTx • Arm 2: *Imfinzi* + tremelimumab + chemotherapy • Arm 3: chemotherapy	Primary endpoints: • PFS	• FPCD: Q2 2017 • Data anticipated: 2019
Phase III EAGLE NCT02369874	HNSCC 2L	736	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: *Imfinzi* • Arm 3: Standard of care	• Primary endpoint: OS • Secondary endpoint: PFS	• FPCD: Q4 2015 • LPCD: Q3 2017 • Data anticipated: H2 2018
Phase III KESTREL NCT02551159	HNSCC 1L	823	• Arm 1: *Imfinzi* • Arm 2: *Imfinzi* + tremelimumab • Arm 3: Standard of care	Primary endpoints: • PFS • OS	• FPCD: Q4 2015 • LPCD Q1 2017 • Data anticipated: H2 2018
Phase III DANUBE NCT02516241	Bladder 1L cis-eligible and ineligible	1,005	• Arm 1: *Imfinzi* + tremelimumab • Arm 2: *Imfinzi* • Arm 3: Standard of care	Primary endpoints: • OS	• FPCD: Q4 2015 • LPCD: Q1 2017 • Data anticipated: 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: *Imfinzi* + EP (carboplatin or cisplatin + etoposide)	Primary endpoints: • PFS • OS	• FPCD: Q1 2017 • Data anticipated: 2019

Imfinzi (PD-L1 mAb) + tremelimumab (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: 2022
Phase II **NCT02527434**	Urothelial Bladder Cancer Triple-negative Breast Cancer Pancreatic Ductal-Adenocarcinoma	76	• Arm 1 tremelimumab in 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 anticipated: 2018
Phase II BALTIC **NCT02937818**	SCLC	80	• Arm 1: *Imfinzi* + tremelimumab Q4W • Arm 2: AZD1775 and carboplatin BID	• Primary endpoint: ORR	• FPCD: Q4 2016 • Data Anticipated: 2020
Phase I Combination in Advanced Solid Tumours **NCT02658214**	Solid tumours	80	• Arm 2 SCLC. *Imfinzi* + tremelimumab + carboplatin + etoposide • Arm 3 TNBC: *Imfinzi*+ tremelimumab + gemcitabine + carboplatin • Arm 4 TNBC: *Imfinzi* + tremelimumab + nab-paclitaxel (paclitaxel-albumin) + carboplatin • Arm 5 Gastric/gastro-Oesophageal junction (GEJ): *Imfinzi* + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid) • Arm 6 PDAC: *Imfinzi*+ tremelimumab + nab-paclitaxel (paclitaxel-albumin) + gemcitabine • Arm 7 ESSC: *Imfinzi*+ tremelimumab + cisplatin + 5-fluorouracil (5FU)	• Safety	• FPCD: Q1 2016 • LPCD: Q4 2016 • Data anticipated: 2019
Phase III HIMALAYA **NCT03298451**	Unresectable Hepatocellular Carcinoma	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	• Data anticipated: 2020

Calquence (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III **ACE-CL-006 (ELEVATE-RR)** **NCT02477696**	Relapsed/refractory chronic lymphocytic leukaemia (CLL), high risk	533	• Arm A: *Calquence* • Arm B: ibrutinib	• Primary endpoint: PFS • Secondary endpoints: comparison of incidence of infections, RTs and atrial fibrillation, OS	• FPCD: Q2 2015 • Data anticipated: 2019
Phase III **ACE-CL-007 (ELEVATE-TN)** **NCT02475681**	Previously untreated CLL	535	• Arm A: chlorambucil + obinutuzumab • Arm B: *Calquence*+ obinutuzumab • Arm C: *Calquence*	• Primary endpoint: PFS (Arm A vs Arm B) • Secondary endpoints: IRC assessed ORR, TTNT, OS (Arm A vs Arm B vs Arm C)	• FPCD: Q2 2015 • Data anticipated: 2019
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, TTNT, OS, DOR, PROs	• FPCD Q3 2016 • 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 NHL • Secondary endpoints: Investigator-assessed (IA) PFS, ORR; IRC-assessed ORR, DOR, time to response; OS	• FPCD: Q1 2017 • Data anticipated: 2022
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 • Secondary endpoints: Safety, TTP, PFS, OS	• FPCD: Q4 2014 • Data readout: Q4 2017
Phase II **ACE-LY-004** **NCT02213926**	Relapsed/refractory MCL	124	*Calquence* monotherapy	• ORR	• FPCD: Q1 2015 • Data readout: Q2 2017
Phase I/II **ACE-CL-001** **NCT02029443**	CLL/SLL/Richter's transformation (RT)	286	*Calquence* monotherapy Dose escalation and expansion	• Safety, PK, PD • Secondary endpoints: ORR, DOR, and PFS	• FPCD: Q1 2014 • Data anticipated: 2019

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: Q4 2014 • Data readout: Q4 2017
Phase I/II **ACE-LY-005** **NCT02362035**	Haematological Malignancies	159	*Calquence* + pembrolizumab	• Safety • Secondary endpoints: ORR, DOR, PFS, OS, TTNT	• FPCD: Q1 2015 • Data anticipated: 2021
Phase I/II **ACE-WM-001** **NCT02180724**	Waldenstrom Microglobulinaemia (WM)	106	*Calquence* monotherapy	• ORR	• FPCD: Q3 2014 • Data readout: 2020
Phase Ib **ACE-LY-002** **NCT02112526**	Relapsed/refractory de novo ABC Diffuse large B-cell lymphoma (DLBCL)	21	*Calquence* monotherapy	• Safety	• FPCD: Q3 2014 • Data readout: Q2 2017
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: 2021
Phase Ib **ACE-MY-001** **NCT02211014**	Relapsed/refractory Multiple Myeloma	28	• Arm A: *Calquence* • Arm B: *Calquence* + dexamethasone	• Safety	• FPCD: Q1 2015 • Data readout: Q2 2017
Phase I **ACE-LY-003** **NCT02180711**	Relapsed/refractory Follicular Lymphoma	80	• Arm A: *Calquence* • Arm B: *Calquence* + rituximab	• Safety	• FPCD: Q3 2014 • Data anticipated: 2022
Phase I **ACE-CL-002** **NCT02157324**	Relapsed/refractory CLL/SLL	12	*Calquence* in combination with ACP-319 Dose escalation	• Safety, PK, PD	• FPCD: Q3 2014 • Data anticipated: 2018
Phase I **ACE-CL-003** **NCT02296918**	CLL/SLL/Prolymphocytic leukaemia (PLL)	45	*Calquence* + obinutuzumab • Arm A: Relapsed/refractory • Arm B: Treatment naive	• Safety, ORR • Secondary endpoints: PD, PFS, TTN, OS	• FPCD: Q4 2014 • Data anticipated: 2022

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: 2021
Phase I/II **NCT03205046**	R/R B-cell Malignancies	59	• Arm A: *Calquence* daily + vistusertib daily • Arm B: *Calquence* daily + vistusertib 5 days on and 2 days off	• Identify dose and schedule for vistusertib • Safety of coadministration of *Calquence* + vistusertib	• FPCD: Q3 2017 • Data anticipated: 2019
Phase I/II **CL-110** **NCT03328273**	CLL R/R	62	Arm A: AZD 6738 monotherapy Arm B: *Calquence* + AZD 6738	Identify dose of AZD 6738 and safety of coadministration of *Calquence* + AZD 6738	FPCD: Q1 2018 Data anticipated: 2020

Calquence (BTK inhibitor)

Other cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II **ACE-ST-006** **NCT02454179**	≥ 2L advanced or metastatic HNSCC	74	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q2 2015 • Data readout: Q4 2017
Phase II **ACE-ST-007** **NCT02448303**	≥ 2L advanced or metastatic NSCLC	74	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q2 2015 • Data readout: Q2 2017
Phase II **ACE-ST-208** **NCT02537444**	Recurrent ovarian cancer	76	• Arm A: *Calquence* • Arm B: *Calquence* + pembrolizumab	• ORR	• FPCD: Q4 2015 • Data readout: Q4 2017
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: Q2 2017
Phase II **ACE-ST-005** **NCT02351739**	Platinum-resistant urothelial bladder cancer	75	• Arm A: pembrolizumab • Arm B: *Calquence* + pembrolizumab	• ORR	• Data readout: Q4 2017
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 • Secondary Endpoints: DOR, PFS, PFS-6, OS	• FPCD: Q1 2016 • Data anticipated: H1 2018

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: 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

Farxiga (SGLT2 inhibitor)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III/IV **DECLARE** **NCT01730534**	Type-2 diabetes with high risk for CV event	17,160	• Arm 1: *Farxiga* 10mg QD + SoC therapy QD • Arm 2: Placebo + SoC therapy for type-2 Diabetes Global trial – 33 countries	• Primary endpoint: Time to first event included in the composite endpoint of CV death, MI or ischaemic stroke	• FPCD: Q2 2013 • Data anticipated: H2 2018
Phase III **NCT02096705** **Partnered**	Asian patients with type-2 diabetes with inadequate glyceamic control on insulin	273	• Arm 1: *Farxiga* 10mg QD for 24 weeks + background insulin • Arm 2: Placebo QD for 24 weeks + background insulin Asia trial – three countries	• Primary endpoint: Change from baseline in Haemoglobin A1C (HbA1c) at week 24	• FPCD: Q1 2014 • LPCD: Q1 2016 • Data Readout: Q2 2016 • Primary endpoint met
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
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
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

Farxiga (SGLT2 inhibitor)

Diabetes / cardiovascular risk reduction

Trial	Population	Patients	Design	Endpoints	Status
Phase III **Dapa-HF** **NCT03036124**	Patients With Chronic Heart Failure (CHF)	4,500	• 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 • Data anticipated: 2019
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 eGFR or reaching end stage renal disease (ESRD) or CV death or renal death	• FPCD: Q1 2017 • Data anticipated: 2020

Qtern (saxagliptin/dapagliflozin) (DPP-4/SGLT2 inhibitor)

Type-2 diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III **NCT02284893**	Type-2 diabetes	420	• Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: sitagliptin 100mg + Met IR/XR Global trial – six countries	• Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: • The proportion of subjects achieving a therapeutic glycaemic response at week 24 defined as HbA1c<7% • Mean change in total body weight at week 24	• FPCD: Q1 2015 • LPCD: Q3 2015 • Data readout: Q3 2016 • Primary endpoint met
Phase III **NCT02419612**	Type-2 diabetes	440	• Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: glimeperide 1-6mg + Met IR/XR Global trial – 10 countries	• Primary endpoint: Mean change from baseline in HbA1c at week 52 Secondary endpoints: • Mean change from baseline in total body weight at week 52 • The proportion of subjects achieving a therapeutic glycaemic response at week 52 defined as HbA1c<7.0%	• FPCD: Q3 2015 • LPCD: Q3 2016 • Data readout: Q4 2017
Phase III **NCT02551874**	Type-2 diabetes	598	• Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR with or without SU • Arm 2: insulin glargine + Met IR/XR with or without SU Global trial – 12 countries	• Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: • Mean change in total body weight at week 24 • The proportion of subjects with confirmed hypoglycaemia at week 24	• FPCD: Q4 2015 • LPCD: Q4 2016 • Data readout: Q4 2017
Phase III **NCT02681094**	Type-2 diabetes	900	• Arm 1: saxagliptin 5mg + dapagliflozin 5mg + Met IR/XR • Arm 2: dapagliflozin 5mg + placebo + Met IR/XR • Arm 3: saxagliptin 5mg + placebo + Met IR/XR Global trial – six countries	• Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: • The proportion of subjects achieving a therapeutic glycaemic respons at week 24 defined as HbA1c<7% • Mean change in fasting plasma glucose at 24 weeks	• FPCD: Q1 2016 • LPCD: Q4 2016 • Data readout: Q4 2017

Bydureon (GLP-1 receptor agonist)

Type-2 diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase IV **EXSCEL** **NCT01144338** **Partnered**	Type-2 diabetes	14,742	• Arm 1: *Bydureon* once weekly 2mg SC • Arm 2: Placebo On a background of SoC medication, different degree of CV risk Global trial	• Primary endpoint: Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke)	• FPD: Q2 2010 • LPCD: Q4 2015 • Data readout: Q3 2017 • Primary safety endpoint met • Primary efficacy endpoint not met
Phase III **DURATION 7** **NCT02229383**	Type-2 diabetes	440	• Arm 1: *Bydureon* once weekly 2mg SC + titrated basal insulin • Arm 2: Placebo + titrated basal insulin Double-blind 1:1 randomisation. Background therapy with or without metformin Global trial	• Primary endpoint: Change in HbA1c from baseline at 28 weeks	• FPCD: Q3 2014 • LPCD: Q3 2016 • Data readout: Q4 2016 • Primary endpoint met
Phase III **DURATION 8** **NCT02229396**	Type-2 diabetes	660	• Arm 1: *Bydureon* once weekly 2mg SC • Arm 2: *Forxiga* 10mg • Arm 3: *Bydureon* once weekly 2mg SC + *Farxiga* 10mg Double-blind 1:1:1 randomisation. Background therapy with metformin 1500mg/day up to 2 months prior to screening Global trial	• Primary endpoint: Change in HbA1c from baseline at 28 weeks	• FPCD: Q3 2014 • LPCD: H2 2017 • Data readout: Q3 2016 – 28-week data Q1 2017 – 52-week data Q1 2018 – 104-week data • Primary endpoint met

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 MACE	• FPCD: Q4 2014 • LPCD: Q2 2017 • Data anticipated: 2019
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 • % 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 II **EFFECT I** **NCT02354976**	Overweight patients with hypertriglyceridaemia	75	• *Epanova* 4g vs Placebo vs Fenofibrate 200mg daily for 12 weeks Global trial – one country	Primary endpoints: • Reduction in liver fat content (%) at the end of 12 weeks compared to placebo • Reduction in liver fat content (%) at the end of 12 weeks compared to fenofibrate	• FPCD: Q3 2015 • LPCD: Q2 2016 • Data readout: Q4 2016
Phase II **EFFECT II** **NCT02279407**	Type-2 diabetes Liver fat >5.5%	80	• Arm 1: *Epanova* 4g QD • Arm 2: Placebo (olive oil) • Arm 3: *Epanova* 4g + *Farxiga* 10mg QD • Arm 4: *Farxiga* 10mg Local trial – one country	• Primary endpoints: Reduction in liver fat content (%) at the end of 12 weeks	• FPCD: Q1 2015 • LPCD: Q4 2015 • Data readout: Q2 2016
Phase I **PRECISE** **NCT02370537**	Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes	66	• Arm 1: *Epanova* 4g single dose • Arm 2: *Omacor* 4g single dose Global trial – six countries in Europe	• Primary endpoint: PEI, PK of *Epanova* and *Omacor* following a single oral dose in patients with different degrees of PEI	• FPCD: Q1 2015 • LPCD: Q4 2015 • Data readout: Q2 2016

Lokelma (ZS-9, sodium zirconium cyclosilicate)

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT01493024**	Hyperkalaemia and moderate chronic kidney disease (CKD)	90	• Arm 1: Escalating TID doses (0.3g, 3g and 10g) of ZS • Arm 2: Placebo TID US	• Primary endpoint: Change in serum potassium levels from baseline	• FPCD: Q4 2011 • LPCD: Q2 2012 • Data readout: Q2 2012
Phase III **NCT01737697**	Hyperkalaemia	754	• Arm 1: ZS-9 1.25g TID for 48 hrs followed by QD for 12 days • Arm 2: ZS-9 2.5g TID for 48 hrs followed by QD for 12 days • Arm 3: ZS-9 5g TID for 48 hrs followed by QD for 12 days • Arm 4: ZS-9 10g TID for 48 hrs followed by QD for 12 days • Arm 5: Placebo TID for 48 hrs followed by QD for 12 days Global trial – three countries	• Primary endpoint: Change in serum potassium levels from baseline	• FPCD: Q4 2012 • LPCD: Q4 2013 • Data readout: Q4 2013 • Primary endpoint met
Phase III **NCT02088073**	Hyperkalaemia	258	Open-label ZS-9 10g TID for 48 hrs followed by: • Arm 1: ZS-9 5g QD for 28 days • Arm 2: ZS-9 10g QD for 28 days • Arm 3: ZS-9 15g QD for 28 days • Arm 4: Placebo QD for 28 days Global trial – three countries	• Primary endpoint: Maintenance of normokalaemia	• FPCD: Q1 2014 • LPCD: Q3 2014 • Data readout: Q4 2014 • Primary endpoint met
Phase III **Open-label Extension to Study NCT02088073** **NCT02107092**	Participation in trial NCT02088073	123	• Arm 1: ZS-9 10g QD for 11 months. Option to uptitrate to 15g QD or downtitrate to 5g QD and 5g QOD Global trial – three countries	• Primary endpoint: Maintenance of normokalaemia	• FPCD: Q2 2014 • LPCD: Q3 2015 • Data readout: Q3 2015
Phase III **NCT02163499**	Hyperkalaemia	751	• Arm 1: ZS-9 5g QD for 12 months. Option to uptitrate to 10 and15g QD or downtitrate to 5g QOD Global trial – seven countries	• Primary endpoint: Safety and tolerability	• FPCD: Q2 2014 • LPCD: Q4 2016 • Data readout: Q2 2017 • Primary endpoint met
Phase III **NCT02875834**	Hyperkalaemia	255	Open-label ZS-9 10g TID for 48 hrs followed by: • Arm 1: ZS-9 5g QD for 28 days • Arm 2: ZS-9 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
Phase II/III **NCT03127644**	Hyperkalaemia	102	Arm 1: ZS-9 5g TID for 48 hours Arm 2: ZS-9 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
Phase III **NCT03172702**	Hyperkalaemia	150	Arm 1: Open-label ZS 10g TID for up to 72 hrs followed by ZS-9 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

Lokelma (ZS-9, sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03283267**	Healthy Subjects	22	Arm 1: Open-label ZS 5g QD for 4 days Arm 2: Open-label ZS 10g QD for 4 days China	• Primary endpoint: Mean change from baseline to ZS treatment period in urine potassium excretion	• FPCD: Q4 2017 • LPCD: Q4 2017
Phase IIIb **NCT03303521**	Patients on haemodialysis with persistent pre-dialysis hyperkalaemia	180	Arm 1: ZS 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
Phase II **NCT03337477**	Hyperkalaemia	132	Arm 1: ZS 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

Eklira/*Tudorza* (LAMA)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IV **NCT02375724** **Partnered**	Patients with COPD	224	• Arm 1: *Eklira/Tudorza* 400µg • Arm 2: Placebo to aclidinium bromide 400µg Global trial – five countries	• Primary endpoint: Change from baseline in overall E-RS Total score (i.e. score over the whole eight weeks study period) Secondary endpoints: • Change from baseline in overall E-RS Cough and Sputum domain score • Change from baseline in the LCQ Total score at Week 8. Average change from baseline in pre-dose FEV1	• FPCD: Q1 2015 • LPCD: Q3 2015 • Data readout: Q1 2016
Phase IV **ASCENT** **NCT01966107**	Patients with moderate to very severe COPD	4,000	• Arm 1: *Eklira/Tudorza* 400µg • Arm 2: Placebo to aclidinium bromide 400µg Global trial – two countries	Primary endpoints: • Time to first Major Adverse Cardiovascular Event (MACE). Up to 36 Months • Rate of moderate or severe COPD exacerbations per patient per year during the first year of treatment Secondary endpoints: • Rate of hospitalisations due to COPD exacerbation per patient per year during the first year of treatment • Time to first MACE or other serious cardiovascular events of interest. Up to 36 Months	• FPCD: Q3 2013 • LPCD: Q3 2016 • Data readout: Q4 2017 • Primary endpoints met
Phase IV **NCT02153489** **Partnered**	Patients with stable moderate and severe COPD	30	• Arm 1: *Eklira/Tudorza* 400µg • Arm 2: Placebo to aclidinium bromide 400µg Local trial – one country	• Primary endpoint: Change from baseline in normalised forced expiratory volume in one second (FEV1). Week 3. FEV1 over the 24-hour period (AUC0-24) will be measured following morning administration • Secondary endpoint: Adverse events. Week 5	• FPCD: Q2 2014 • LPCD: Q1 2015 • Data readout: Q4 2015

LAMA = Long Acting Muscarinic Agonist

Ekliral/Tudorza (LAMA)

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 study • **Arm 1:** Aclidinium bromide 200 µg • **Arm 2:** Aclidinium bromide 400 µg • **Arm 3:** Aclidinium bromide 800 µg Global Study – 1 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: H1 2018 • Data readout: H2 2018

Duaklir Genuair (LAMA/LABA)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb **ACHIEVE** **NCT02796651**	Patients with moderate COPD	120	• Arm 1: *Duaklir Genuair* 400/12 µg • Arm 2: Placebo to aclidinium/formoterol FDC 400/12 µg Global trial – one country	• Primary endpoint: Change from baseline in normalised FEV1 AUC over the 12h period immediately after morning trial drug administration, AUC0-12/12h at Day 7 on treatment Secondary endpoint: • Change from baseline in FEV1 AUC0-6/6h at day one and day seven on treatment • Change from baseline in morning pre-dose FEV1 at day seven on treatment	• FPCD: Q3 2016 • LPCD: Q3 2016 • Data readout: Q1 2017
Phase III **AMPLIFY** **NCT02796677**	Patients with stable COPD	1,500	• Arm 1: *Duaklir Genuair* 400/12 µg • Arm 2: aclidinium bromide 400µg • Arm 3: formoterol fumarate 12µg • Arm 4: tiotropium 18µg Global trial – 13 countries	Primary endpoints: • Change from baseline in 1-hour morning post-dose dose FEV1 of *Duaklir Genuair* 400/12 µg compared to AB 400µg at week 24 • Change from baseline in morning predose (trough) FEV1 of *Duaklir Genuair* 400/12 µg compared to FF 12µg at week 24 • Change from baseline in morning predose (trough) FEV1 at week 24 comparing AB 400µg versus TIO 18µg	• FPCD: Q3 2016 • LPCD: Q4 2016 • Data readout Q3 2017 • Primary endpoint met
Phase III **AVANT** **NCT03022097**	Patients with stable COPD	1,060	• Arm 1: *Duaklir Genuair* 400/12 µg • Arm 2: aclidinium bromide 400 µg • Arm 3: formoterol fumarate 12 µg • Arm 4: tiotropium 18 µg Global Study – five countries	Primary endpoints: • Change from baseline in 1-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: 2019

LAMA = Long Acting Muscarinic Agonist
LABA = Long Acting Beta Agonist

Duaklir Genuair (LAMA/LABA)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT03276078**	Chinese patients with stable moderate to severe COPD	20	• Single and multiple twice daily doses of inhaled aclidinium bromide/formoterol fumarate 400/12 Global Study – One country	• To evaluate the pharmacokinetics (PK) of aclidinium bromide, its metabolites LAS34850 and LAS34823 and formoterol after administration of aclidinium bromide/formoterol 400/12 µg twice-daily (BID) for five days • To evaluate the safety and tolerability of aclidinium bromide/formoterol 400/12 µg twice-daily (BID) administered for 5 days	• FPCD: Q4 2017 • Data anticipated: H2 2018

LAMA = Long Acting Muscarinic Agonist
LABA = Long Acting Beta Agonist

Bevespi Aerosphere (LAMA/LABA)

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 MDI (*Bevespi Aerosphere*) 14.4/9.6µg BID • 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 • 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
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 • 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
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 • Arm 2: GP MDI (PT001) 14.4µg BID • Arm 3: FF MDI (PT005) 9.6µg BID • Arm 4: Open-label tiotropium bromide inhalation powder 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

LAMA = Long Acting Muscarinic Agonist
LABA = Long Acting Beta Agonist
GFF = Glycopyrronium and formoterol

Bevespi Aerosphere (LAMA/LABA)

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 MDI (*Bevespi Aerosphere*) 14.4/9.6µg (N=514) • GP 14.4µg (N=440) • FF 9.6µg (N=440) • Placebo (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 • Primary endpoint met
Phase IIIb **AERISTO** **NCT03162055**	Moderate to very severe COPD	1,000	Treatments (24-week Treatment Period) • GFF MDI (Bevespi Aerosphere) 14.4/9.6µg • Umeclidinium/vilanterol DPI 62.5/25µg Randomised, Double-Blind, Double-Dummy, Multicentre, 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 2 hours post-dosing over 24 weeks	• FPCD: Q2 2017 • LPCD: Q4 2017

LAMA = Long Acting Muscarinic Agonist
LABA = Long Acting Beta Agonist
GFF = Glycopyrronium and formoterol

Dalirespl/Daxas (oral PDE4 inhibitor)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IV RESPOND **NCT01443845**	COPD	2,354	• 52W, randomised, DB with *Dalirespl* 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 *Dalirespl* 500µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg *Dalirespl* OD in subjects 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 *Dalirespl* 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	124080	• This is a retrospective cohort study comparing COPD patients aged 40 years and older with new exposure to **roflumilast** with up to 5 unexposed (ie, not **roflumilast-**exposed) COPD controls matched by propensity score (PS), age, sex, and year of cohort entry. The study is using electronic healthcare databases in the US (Military Health System database), Germany (GER) (German Pharmacoepidemiological Research Database), and Sweden (SWE) (national databases including healthcare, death, and demographics data).	• Primary endpoint: All-cause mortality (up to 5 years)	• Data readout: 2020

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist

Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **CALIMA** **NCT01914757**	Severe, uncontrolled asthma, despite background controller medication, medium dose (MD) & high dose (HD) ICS + LABA ± chronic OCS Age 12-75 years	1,026 HD + ~200 MD	• Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 56-week trial Global trial – 11 countries	• Primary endpoint: Annual asthma exacerbation rate • Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM	• FPCD: Q4 2013 • Data readout: Q2 2016 • Primary endpoint met
Phase III **SIROCCO** **NCT01928771**	Severe, uncontrolled asthma, despite background controller medication HD ICS + LABA ± chronic OCS Age 12-75 years	1,134	• Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	• Primary endpoint: Annual asthma exacerbation rate • Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM	• FPCD: Q4 2013 • Data readout: Q2 2016 • Primary endpoint met
Phase III **ZONDA** **NCT02075255**	Severe, uncontrolled asthma on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18-75 years	210	• Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 46-week trial Global trial – 12 countries	• Primary endpoint: Reduction of oral corticosteroid dose	• FPCD: Q3 2014 • Data readout: Q3 2016 • Primary endpoint met
Phase III **MELTEMI** **NCT02808819**	A multi-centre, open-label, safety extension trial with benralizumab for asthmatic adults on ICS plus LABA2 Agonist Age 18-75 years	770	• Arm 1: 30mg Q4W SC • Arm 2: 30mg Q8W SC	• Primary endpoint: Safety and tolerability	• FPCD: Q2 2016 • Data anticipated: 2019
Phase III **ALIZE** **NCT02814643**	A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of benralizumab 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 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 IM 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 meant 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

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist

Fasenra (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III **BISE** **NCT02322775**	Asthmatic with FEV1 (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18-75 years	200	• Arm 1: 30mg Q4W SC • Arm 3: Placebo SC 12-week trial Global trial – six countries	• Primary endpoint: Pulmonary function (FEV1)	• FPCD: Q1 2015 • Data readout: Q1 2016 • Primary endpoint met
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	2,550	• Arm 1: 30mg Q4W SC • Arm 2: 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 anticipated: H2 2018
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: 30mg Q4W SC 28-week (adults) Global trial – two countries	• Primary endpoint: Functionality, reliability, and performance of a pre-filled syringe with benralizumab 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 benralizumab on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years	38	• Arm 1 : 30mg Q4W SC • Arm 2: Placebo SC	• Primary endpoint: Safety and tolerability	• FPCD Q4 2016 • Data anticipated: 2019

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist

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: 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: H2 2018
Phase III **GRECO** **NCT02918071**	Severe asthma Age 18-75 years	120	Open label 30mg Q4w 28-week trial Global trial - two countries	• Primary endpoint: % of patients/ caregivers who successfully self administer at home	• FPCD: Q4 2016 • Data readout: Q4 2017 • Primary endpoint met
Phase IIIb **ANDHI** **NCT03170271**	A Multicenter, Randomised, Double-blind, Parallel Group, Placebo Controlled, Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients With Severe Asthma Uncontrolled on Standard of Care Treatment. Age 18-75	800	• Arm 1: 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 2019
Phase I **AMES** **NCT02968914**	Healthy Volunteer Age 18-55 years	162	Open label study to compare 30 mg benralizumab PK administered by APFS or AI device 8-week study Global trial – two countries	• Primary endpoint: PK Comparability	• FPCD: Q1 2017 • Data readout: Q3 2017

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist

Fasenra (IL-5R mAb)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase III **TERRANOVA** **NCT02155660**	Moderate to very severe COPD with exacerbation history	2,168	• Arm 1: 10mg Q8W SC • Arm 2: 30mg Q4W SC • Arm 3: 100mg Q8W SC • Arm 4: Placebo SC 48-week trial Global trial – 23 countries	• Primary endpoint: Rate of COPD exacerbation	• FPCD: Q3 2014 • Data anticipated: Q2 2018
Phase III **GALATHEA** **NCT02138916**	Moderate to very severe COPD with exacerbation history	1,626	• Arm 1: 30mg Q4W SC • Arm 2: 100mg Q8W SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	• Primary endpoint: Rate of COPD exacerbation	• FPCD: Q3 2014 • Data readout: Q2 2018 • Primary endpoint not met

Fasenra (IL-5R mAb)

Nasal Polyposis

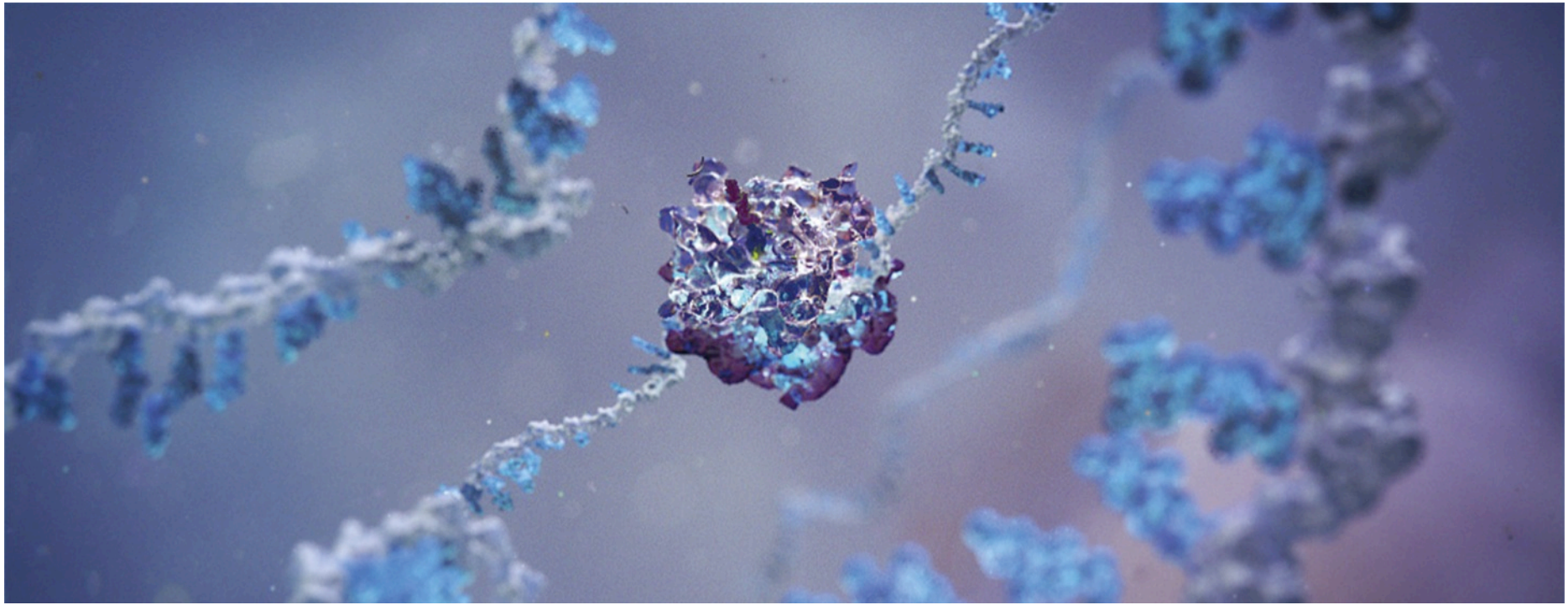
Trial	Population	Patients	Design	Endpoints	Status
Phase III **OSTRO** **NCT03401229**	Patients with severe bilateral nasal polyposis who are still symptomatic despite standard of care therapy	400	• Arm 1: 30mg Q8W SC • Arm 2: Placebo SC 56-week trial Global trial- 8 countries	• Primary endpoint: Effect of *Fasenra* on nasal polyp burden and on patient reported nasal blockage	• FPCD: Q1 2018 • Data anticipated: 2020

Calquence (BTK inhibitor)

Rheumatoid arthritis

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II **ACE-RA-001** **NCT02387762**	Rheumatoid Arthritis	31	• Arm A: *Calquence* + methotrexate • Arm B: methotrexate	Disease Activity Score 28-CRP at week 4	FPCD: Q2 2015 LPCD: Q2 2016 Data readout: Q2 2016

Late-stage pipeline



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 • Moxetumomab pasudotox IV at the recommended dose	• Primary endpoint: Rate of durable CR: 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 • Moxetumomab pasudotox IV	• Maximum tolerated dose (MTD) and efficacy	• FPCD: Q2 2007 • LPCD: Q1 2014 • Data readout: Q2 2015

Selumetinib (MEK inhibitor)

Thyroid cancer and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III **ASTRA** **NCT01843062**	Differentiated thyroid cancer	304	• Arm 1: selumetinib 75mg BiD 5 weeks duration + radioactive iodine (RAI) 100mCi[a] • Arm 2: Placebo BiD 5 weeks duration + RAI 100mCi[a] Global trial – eight countries [a] Single dose of 100mCi ^{131}I administered following 4 weeks of selumetinib (or placebo)	• Primary endpoint: Complete remission (CR) rate at 18 months post-radioactive iodine	• FPCD: Q3 2013 • LPCD: Q1 2016 • Data anticipated: H2 2018

Phase II
SPRINT
 	
NCT01362803
 	
Partnered
	Paediatric neurofibromatosis type 1 (NF-1)	50	• 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: 2021
Phase I **NCT01985555** **Partnered**	Advanced cancer (all comers)	~70	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPCD: Q2 2013 • Data anticipated: H2 2018
Phase I **NCT02374645**	NSCLC	64	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPCD: Q2 2015 • Data anticipated: H2 2018
Phase II **NCT02897479** **Partnered**	Lung Pulmonary Sarcomatoid Carcinoma (PSC)	45	• Single arm trial: savolitinib 600mg QD Conducted in China	• ORR	• FPCD: Q1 2017 • Data anticipated: 2019

Cediranib (VEGF receptor inhibitor)

Ovarian cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CONCERTO	Platinum resistant recurrent (PRR) ovarian cancer - heavily pre-treated BRCAwt	100	• Cediranib 30 mg + *Lynparza* 200 mg bd	• ORR DoR, DCR, QoL. OS; Safety	• FPCD: Q1 2017

VEGF - Vascular endothelial growth factor

Roxadustat (HIF-PHI inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III ANDES **NCT01750190** **Partnered**	Anaemia in CKD patients not receiving dialysis	900	• Arm 1: roxadustat • Arm 2: placebo Global trial	Primary endpoint: Haemoglobin response	• FPCD: Q4 2012 • Data anticipated: H2 2018 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 anticipated: H2 2018 Sponsored by Astellas
Phase III DOLOMITES **NCT02021318** **Partnered**		570	• Arm 1: roxadustat • Arm 2: darbepoetin alfa Global trial	Primary endpoint: Haemoglobin response	• FPCD: Q1 2014 • Data anticipated: H2 2018 Sponsored by Astellas
Phase III OLYMPUS **NCT02174627**		2,700	• Arm 1: roxadustat • Arm 2: Placebo Global trial	Primary endpoint: MACE	• FPCD: Q3 2014 • Data anticipated: H2 2018 Sponsored by AstraZeneca
Phase III ROCKIES **NCT02174731**	Anaemia in CKD in patients receiving dialysis	2,100	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	Primary endpoint: MACE	• FPCD: Q3 2014 • Data anticipated: H2 2018 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 anticipated: H2 2018 Sponsored by FibroGen
Phase III PYRENEES **NCT02278341** **Partneredee-1**		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 (HIF-PHI inhibitor)

Anaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III HIMALAYAS **NCT02052310** **Partnered**	Anaemia in newly initiated dialysis patients	750	• Arm 1: roxadustat • Arm 2: epoetin alfa Global trial	Primary endpoint: Haemoglobin response	• FPCD: Q4 2013 • Data anticipated: 2018 Sponsored by FibroGen
Phase III **NCT02652819** **Partnered**	Anaemia in CKD patients not receiving dialysis	150	• 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	300	• 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**	Anemia 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: Q1 2018 Sponsored by FibroGen
Phase II/III **NCT03303066** **Partnered**	Anemia in lower risk Myelodysplastic Syndrome (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

PT010 (LAMA/LABA/ICS)

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 MDI 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg 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 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 • BGF MDI 160/14.4/9.6µg BID • BFF MDI 320/9.6µg BID • GFF MDL 14.4/9.6µg BID 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
Phase III **KRONOS** **NCT02497001**	Moderate to very severe COPD	1,800	Treatments (24-week Treatment Period) • BGF MDI 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • *Symbicort Turbuhaler* 400/12µg 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 • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • *Symbicort Turbuhaler* 400/12µg 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

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 – 7 countries	• Primary endpoint: Reduction from baseline in daily OCS dose while not losing asthma control • Secondary endpoint: Annual asthma exacerbation rate	• FPCD: Q2 2018

TSLP = thymic stromal lymphopoietin

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 anticipated: H2 2018
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 2018
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 anticipated: H2 2018
Phase II **NCT01559090**	Japanese SLE patients	17	Open-label, dose escalation trial: • Arm 1: 100mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks • Arm 2: 300mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks • Arm 3: 1000mg IV Q4W for 48 weeks then1000mg IV Q4W for 104 weeks	• Safety, tolerability, PK/PD	• FPCD: Q1 2012 • Data readout: Q1 2015
Phase I **NCT02601625**	Healthy subjects	30	• Arm 1: 300mg SC single dose • Arm 2: 300mg IV single dose • Arm 3: 600 mg SC single dose	• Safety, tolerability, PK/PD	• FPCD: Q4 2015 • LPCD: H1 2016 • Data readout: Q3 2016
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: 2019

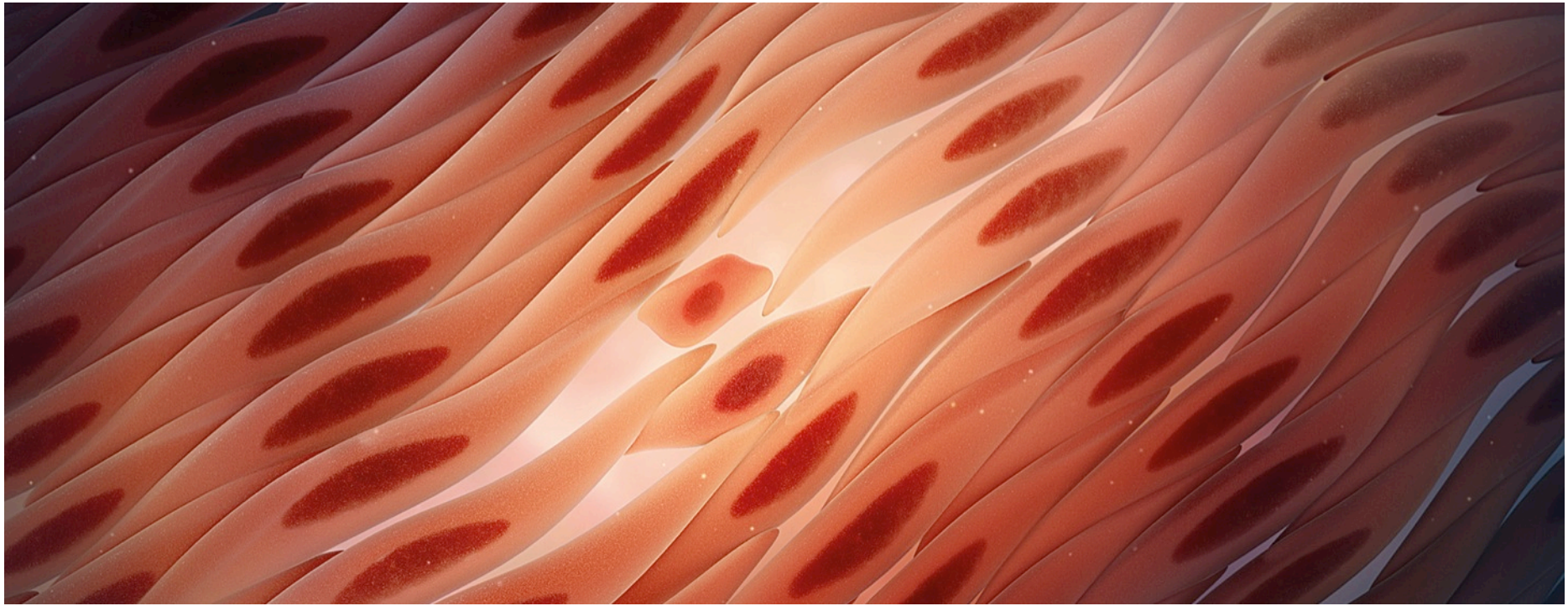
Lanabecestat (BACE inhibitor)

Alzheimer's disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III **AMARANTH** **NCT02245737**	Early Alzheimer's disease patients	2,218	• Arm 1: lanabecestat 20mg once daily • Arm 2: lanabecestat 50mg once daily • Arm 3: Placebo once daily 24-month treatment duration Global trial – 14 countries	• Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale Secondary endpoints: • Changes in other cognitive and functional (ADCS-ADL) scales • Changes in composite scales (CDR-SB) • Changes in biomarkers and imaging assays • Safety and tolerability	• FPCD: Q4 2014 • LPCD: Q3 2017 • Data anticipated: 2019
Phase III **AMARANTH - EXTENSION** **NCT02972658** **Partnered**	Early Alzheimer's disease patients	1,400	• lanabecestat 20mg or 50mg once daily 24-month delayed start treatment extension Global trial – 14 countries	• Primary endpoint: Delayed start analysis	• FPCD: Q1 2017 • Data anticipated: 2021
Phase III **DAYBREAK-ALZ** **NCT02783573**	Mild Alzheimer's disease patients	1,899	• Arm 1: lanabecestat 20 mg once daily • Arm 2: lanabecestat 50 mg once daily • Arm 3: placebo once daily 18-month treatment duration + 18-month delayed start extension Global trial – 18 countries	• Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale Secondary endpoints: • Changes in cognitive and functional (ADCS-ADL) scales • Changes in composite scales (CDR-SB) • Changes in biomarkers and imaging assays • Safety and tolerability	• FPCD: Q3 2016 • Data anticipated: 2020

AstraZeneca
What science can do

Early development - IMED (AstraZeneca Research and Early Development)



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: 2019

Vistusertib (mTORC1/2 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase II **MANTA** **NCT02216786** **Partnered**	2L oestrogen-receptor positive (ER+) metastatic breast cancer	316	• Arm 1: *Faslodex* • Arm 2: *Faslodex* + vistusertib 50mg BD continuous dosing • Arm 3: *Faslodex* + vistusertib 125mg BD two days on, 5 off • Arm 4: *Faslodex* + everolimus Multicentre: European sites	• Primary endpoint: PFS • Secondary endpoint: OS	• FPCD: Q2 2014 • LPCD: H2 2016 • Data readout: Q4 2017
Phase I **NCT02398747**	Japanese Patients with Advanced Solid Malignancies	18	Open label Monotherapy and combination with paclitaxel cohorts	• Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel • PK	• FPCD: Q2 2015 • Data readout: Q4 2017
Phase I/II **PASTOR** **NCT02599714**	Postmenopausal women with locally advanced/metastatic oestrogen receptor positive (ER+) breast cancer	225	Part A – Phase I triplet dose finding to determine the maximum tolerated dose (MTD) of the triplet (vistusertib + palbociclib + fulvestrant) Part B – Phase I single arm expansions (vistusertib + palbociclib + *Faslodex*) Part C – randomised, double-blind, placebo-controlled, stratified, parallel group extension at RP2D for triplet combination (vistusertib + palbociclib + *Faslodex* vs matching vistusertib placebo + palbociclib + *Faslodex*)	Primary endpoints: • Part A:Safety and tolerability of the triplet. MTD and recommended dose for Parts B and C • Part B: Safety and tolerability • Part C: PFS Secondary endpoints: Best Objective Response Rate (BOR) and Objective Response Rate (ORR)	• FPCD: Q1 2016 • Data anticipated: 2019
Phase I/II **NCT03205046** **Partnered**	Relapsed/Refractory B-cell Malignancies	59	Part 1 - Identify a dose and schedule for vistusertib in combination with acalabrutinib Part 2: Evaluation of the safety of acalabrutinib and vistusertib when coadministered	• Number of participants experiencing dose-limiting toxicities • Incidence of adverse events from the combination of acalabrutinib and vistusertib	• FPCD: Q3 2016 • Data anticipated: 2019
Phase I/II **NCT03205046**	Relapsed/Refractory B-cell Malignancies	59	Part 1 - Identify dose and schedule for vistusertib + acalabrutinib Part 2: Single arm expansions to further explore tolerability, PK and clinical activity of vistusertib + acalabrutinib Conducted in US, EU	Primary endpoints: • Safety and tolerability Secondary endpoints: • Overall response rate, Duration of response, Durable response rate, PFS • PK	• FPCD: Q3 2017 • Data anticipated: 2019

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: 2018

AZD1390 (ATM inhibitor, blood brain barrier)

Cancer

Trial	Population	Subjects	Design	Endpoints	Status
Phase I **NCT03215381**	Healthy Volunteers	8	• Positron-Emission Tomography (PET) Study • [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: 2018

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 + AZD1775 • Arm C: carboplatin + AZD1775 Global trial	• Primary endpoint: ORR • Secondary endpoints: Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability	• FPCD: Q1 2015
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 (BRCAm PARP failures and BRCAwt 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 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 (AZD1775 + *Lynparza*) followed by expansions into specific tumour types, inc ovarian cancer, triple negative breast cancer (TNBC) and small cell lung cancer (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 (AZD1775 + *Imfinzi*) Conducted in US	• Safety and tolerability	• FPCD: Q4 2015
Phase I **NCT02341456**	Advanced solid tumours	19	• Dose escalation trial to determine MTD (AZD1775 + carboplatin + paclitaxel: AZD1775 + Carbo) Conducted in Australia, Japan and Republic of Korea	• Safety and tolerability	• FPCD: Q1 2015 • LPCD: Q2 2016 • Data readout Q1 2018

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 AZD1775 • Fed (Treatment B): Single dose 300 mg AZD1775 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
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 AZD1775 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, AZD1775 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 intervals (QTcF) for absolute values and time-matched change from baseline • Secondary endpoints: • Plasma tmax, t½, λz, CL/F and Vz/F for cocktail parent compounds (midazolam, omeprazole, and caffeine). Plasma AUC, AUC0-t, tmax, Cmax, t½, and λz for cocktail metabolites (1'-hydroxy-midazolam, 5-hydroxy-omeprazole, and paraxanthine) and the AUC and Cmax ratios in relation to parent compound. • Plasma AZD1775 Day 1: Part B only: AUC0-12, tmax, and Cmax Plasma AZD1775 Day 3: Parts A & B: AUC0-12, tmax, Cmax, Cmin, Cavg, CLss/F and FI; Part B only: RAUC0-12 and Rcmax • dECG intervals (heart rate, RR, PR, QRS, QTcB, QTcF and QT) for absolute values and time-matched change from baseline; changes in dECG morphology • Safety and tolerability	• FPCD: Q4 2017
Phase I **D6014C00007** **NCT03313557**	Advanced solid tumours	54	AZD1775 monotherapy once daily. Conducted in US and Europe	• Safety and tolerability	• FPCD: Q4 2017

AZD2811 (aurora kinase B inhibitor)

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: 2019
Phase I **NCT03217838**	Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome	36	• Part A: AZD2811 single agent dose escalation cohorts • Part B: AZD2811 dose expansion to further explore the tolerability, PK and clinical activity.	• Safety and tolerability • Pharmacokinetics and efficacy	• FPCD: Q3 2017 • Data anticipated: 2019
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: 2019
Phase I **NCT03217838**	Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome	36	• Part A: AZD2811 single agent dose escalation cohorts • Part B: AZD2811 dose expansion to further explore the tolerability, PK and clinical activity.	• Safety and tolerability • Pharmacokinetics and efficacy	• FPCD: Q3 2017 • Data anticipated: 2019

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 od (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 maximum tolerated dose (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: AZD1775 + *Imfinzi* • Arm 5: *Imfinzi* • Arm 6: vistusertib + *Imfinzi* • Arm 7: AZD9150 + *Imfinzi* Planned in North America and Europe	• Safety and tolerability of the combinations • PK and preliminary anti-tumour activity	• FPCD: Q4 2016 • Data anticipated: 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 trial	• FPCD: Q4 2017 • Data anticipated: 2019

* clinicaltrials.gov being updated

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02740985**	Phase Ia: patients with advanced solid tumours	36 (estimated)	• Phase 1a: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4635 given as monotherapy and in combination with *Imfinzi*. When the combination MTD is determined, additional patients with advanced solid malignancies will be enrolled to a dose expansion cohort to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity	Primary Outcome Measure: Safety and tolerability Secondary Outcome Measures: • PK of AZD4635 as monotherapy and combination with *Imfinzi* • Preliminary assessment of anti-tumour activity	• FPCD: Q2 2016 • Data anticipated: 2018
	Phase Ib: patients with advanced NSCLC who have previously received anti-PD-1 therapy, but either failed to respond or stopped responding after an initial response	15	• Phase 1b will consist of an additional expansion phase in NSCLC at the combination MTD or maximum feasible dose Both parts conducted at sites in the US		

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 Maximum Tolerated Dose (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 USA 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: 2019

AZD5069 (CXCR2 antagonist)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Squamous Cell Carcinoma of the Head & Neck (HNSCC)	465	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)	• Safety/Efficacy trial	• FPCD: Q3 2015 • Data anticipated: 2019
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: 2018

* clinicaltrials.gov being updated

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 6 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 trial	• FPCD: Q2 2017 • Data anticipated: 2019

* clinicaltrials.gov being updated

AZD5991 (MCL1 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03218683**	Relapsed/refractory haematologic malignancies	30	Dose Escalation in relapsed/refractory haematological malignancies 5 dose escalation cohorts of AZD5991	• Primary-Safety/ secondary-Efficacy trial	• FPCD: Q3 2017 • Data anticipated: 2019

* clinicaltrials.gov being updated

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: Q1 2018

AZD8186 (PI3Kb/d inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT01884285**	Advanced Castrate Resistant Prostate Cancer /sqNSCLC /TNBC 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 & 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: 2019

AZD9150 (STAT3 inhibitor)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Squamous Cell Carcinoma of the Head & Neck (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)	• Safety/Efficacy trial	• FPCD: Q3 2015 • Data anticipated: 2019
Phase Ib/II **NCT02549651**	Diffuse Large B-cell Lymphoma	190	Dose escalation and expansion Arms: • Experimental Arm: *Imfinzi* monotherapy • Experimental Arm: *Imfinzi* and tremelimumab • Experimental Arm: *Imfinzi* and AZD9150	• Safety/Efficacy trial	• FPCD: Q3 2016 • Data anticipated: 2021
Phase Ib/II **NCT03421353**	Non Small Cell Lung Cancer (NSCLC)	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 B1: AZD9150 alternate week/Imfinzi • Arm B2: AZD9150 weekly/Imfinzi • Arm C1: AZD9150/*Imfinzi+SOC chemo*	• Safety/Efficacy trial	• FPCD: Q1 2018 • Data anticipated: 2020

* clinicaltrials.gov being updated

AZD9496 (selective estrogen receptor degrader)

Breast cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03236974**	ER+ Breast Cancer	~50	• This is an open label randomised multicentre pre-surgical pharmacodynamics study 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: 2019
Phase I **NCT02248090**	ER+ Breast Cancer	~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

Verinurad (RDEA3170, URAT1 inhibitor)

Chronic kidney disease

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT03118739**	CKD patients with hyperuricaemia, albuminuria, and Type 2 diabetes	60	• Arm A: verinurad 9 mg and febuxostat 80 mg • Arm B: Placebo The trial is a multi-centre trial conducted in the US	To assess the effects of intensive uric acid lowering therapy with RDEA3170 and febuxostat on UACR (urine albumin creatinine ratio)	• FPCD: Q2 2017
Phase II **NCT03316131**	Asymptomatic hyperuricemic subjects (sUA > 6.0 mg/dL)	24	• 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 UA 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: Q1 2018

AZD4831 & AZD5718

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
AZD4831 (MPO) **Phase I** **NCT02712372**	Healthy subjects	~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	~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
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 study (one trial site in UK) A Randomised, 5-Period, 5-Treatment, Single-Dose, open-label, cross-over study to	• 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)	100	Phase 2A 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 study in Japanese subjects (one trial site in USA)	• Safety and tolerability • PK and PD parameters	• FPCD: Q1 2018
AZD5718 (FLAP) **Phase I** **NCT03420092**	Healthy subjects	14	BA study (one trial site in UK) A randomised, 6-period, 6-treatment, single-dose, open-label, crossover, study to assess the relative bioavailability of different formulations of AZD5718 and the food effect	• PK and bioavailability • Safety and tolerability	• FPCD: Q1 2018

AZD8601 (VEGF-A)

Cardiovascular disease

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02935712**	Type 2 diabetic patients	~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 2A 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
Phase I **NCT03450759**	Healthy subjects	12	Bioavailability study 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

Abediterol (AZD0548, LABA)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03273127**	Patients With Asthma on Inhaled Corticosteroids	12	A randomised, single-blind, placebo-controlled study to assess PK and safety of abediterol 5 µg DPI given QD for 9 days, compared to placebo, in patients with asthma on ICSs	• To assess Cmax after single inhaled dose of abediterol 5 µg. Cmax will be taken directly from the individual concentration-time curve • To assess tmax after single inhaled dose of abediterol 5 µg. tmax will be taken directly from the individual concentration-time curve	• FPCD: Q3 2017 • LPCD: Q4 2017 • Data readout: Q2 2018

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 anticipated: H2 2018

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist

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 Study 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 Study 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

AZD7594 (inhaled SGRM)

Asthma/chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase II **NCT02479412**	Patients with mild to moderate asthma	48	A randomised, double blind, multiple dosing (14 days), placebo-controlled, incomplete block cross-over, multi-centre trial to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma	• Primary: morning trough forced expiratory volume in one second (FEV1)	• FPCD: Q3 2015 • LPCD: Q4 2015 • Data readout: Q3 2016
Phase I **NCT02967159**	Healthy subjects	32	A randomised open label cross-over study to evaluate pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination (FDC) and in free combination using dry powder inhaler (DPI), in male healthy volunteers	• PK, safety and tolerability	• FPCD: Q4 2016 • LPCD:Q1 2017 • Data readout: Q2 2017
Phase I **NCT02928354**	Healthy subjects	12	This study is an open label, randomised, three-way cross-over study to assess the effect of particle size on the PK and safety of single inhaled doses of AZD7594 in healthy subjects (males aged 18 to 55 years [inclusive]). The study will be performed at a single study centre	• PK and safety	• FPCD: Q4 2016 • LPCD:Q1 2017 • Data readout: Q2 2017
Phase I **NCT01636024**	Healthy subjects	73	SAD/MAD A Phase I, single centre, double-blind, randomised, placebo controlled, parallel-group trial to assess the safety, tolerability, Pharmacokinetics and Pharmacodynamics after single and multiple ascending inhaled doses of AZD7594 in healthy male Subjects – suspension inhaled via Spira nebuliser Trial conducted in the UK	• Safety and tolerability	• FPCD: Q4 2012 • LPCD: Q2 2013 • Data readout: Q4 2013
Phase I **NCT02648438**	Healthy subjects	30	An open label, partially randomised, four-period trial in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered intravenously, orally and inhaled via two different dry powder inhalers (DPI) and a pressurised metered-dose inhaler (pMDI)	• Bioavailability and pharmacokinetics	• FPCD: Q1 2016 • LPCD: Q2 2016 • Data readout: Q3 2016
Phase I **NCT02645253**	Healthy subjects	27	A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of AZD7594 given once daily as inhaled formulation in healthy Japanese men	• Safety and tolerability	• FPCD: Q1 2016 • LPCD: Q2 2016 • Data readout: Q4 2016

AZD7594 (inhaled SGRM)

Asthma/chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02928354**	Healthy subjects	18	A randomised open label three-way cross-over study in healthy male volunteers to Investigate the effect of particle size on PK following a single inhaled dose of AZD7594 via a dry powder inhaler (DPI)	• PK • Safety and tolerability	• FPCD: Q4 2016 • LPCD: Q1 2017
Phase I **NCT02967159**	Healthy subjects	32	A randomised open label cross-over study to evaluate the pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination and in free combination, using DPI, in male healthy volunteers	• PK • Safety and tolerability	• FPCD: Q4 2016 • LPCD: Q1 2017

AZD8871 (MABA2)

Chronic obstructive pulmonary disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT02971293**	Moderate to severe COPD	42	Comprises 3 treatment periods of 14 days each separated by a washout period of 28 to 35 days • AZD8871 600 µg once daily (double-blind) • AZD8871 100 µg once daily (double-blind) • Placebo (double-blind) Global study – 2 countries (UK & Germany)	**Primary Endpoint:** • To evaluate the efficacy of inhaled AZD8871 in patients with moderate to severe COPD **Secondary Endpoint:** • To investigate the PK of AZD8871 and its metabolites after multiple dose administration of AZD8871 in patients with moderate to severe COPD	• FPCD: Q1 2017 • LPCD: Q1 2017 • Data readout: Q3 2017
Phase I **NCT03159442**	Healthy Japanese Volunteers	24	MAD study with 3 dose levels - 300 µg, 600µg, and 900 µg (plus placebo control group in each dose level). Global Study – 1 country (UK)	Primary Endpoint: • The primary objective is to investigate the safety and tolerability of AZD8871 at steady state Secondary Endpoint: • To characterize the PK of AZD8871 and its metabolites LAS191861 and LAS34850 after multiple doses of AZD8871 and assess the time required to reach steady state, the degree of accumulation and the time dependency	• FPCD: Q3 2017 • LPCD: Q3 2017 • Data readout: Q4 2017

AZD9567 (oSGRM)

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 anticipated: Q2 2018
Phase IIa **NCT03368235**	Patients with active RA	40	A Phase II, Randomised, Double-blind, Parallel Study 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 rheumatoid arthritis in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs Secondary Endpoints: • To further assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active rheumatoid arthritis in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs • (e g SJC 66/TJC68, ACR response criteria) • To evaluate the pharmacokinetic profile of AZD9567	• FPCD: Q1 2018

AZD0284 (RORγ inverse agonist)

Plaque psoriasis vulgaris

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02976831**	Healthy subjects	80	Part 1 (SAD) • Seven different dose levels investigated vs placebo • oral administration	• Safety and tolerability and PK following oral administration with single ascending dose • Preliminary assessment of the effect of food on the single dose PK parameters of AZD0284	• FPCD: Q3 2016 • LPCD: Q2 2017
			Part 2 (MAD) • Three different dose levels investigated vs placebo in healthy subjects • oral administration	• Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses • 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 study performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The study 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 study	• Determination of absolute bioavailability of AZD0284 • Safety and tolerability of AZD0284	• FPCD: Q1 2017 • LPCD: Q1 2017

MedImmune

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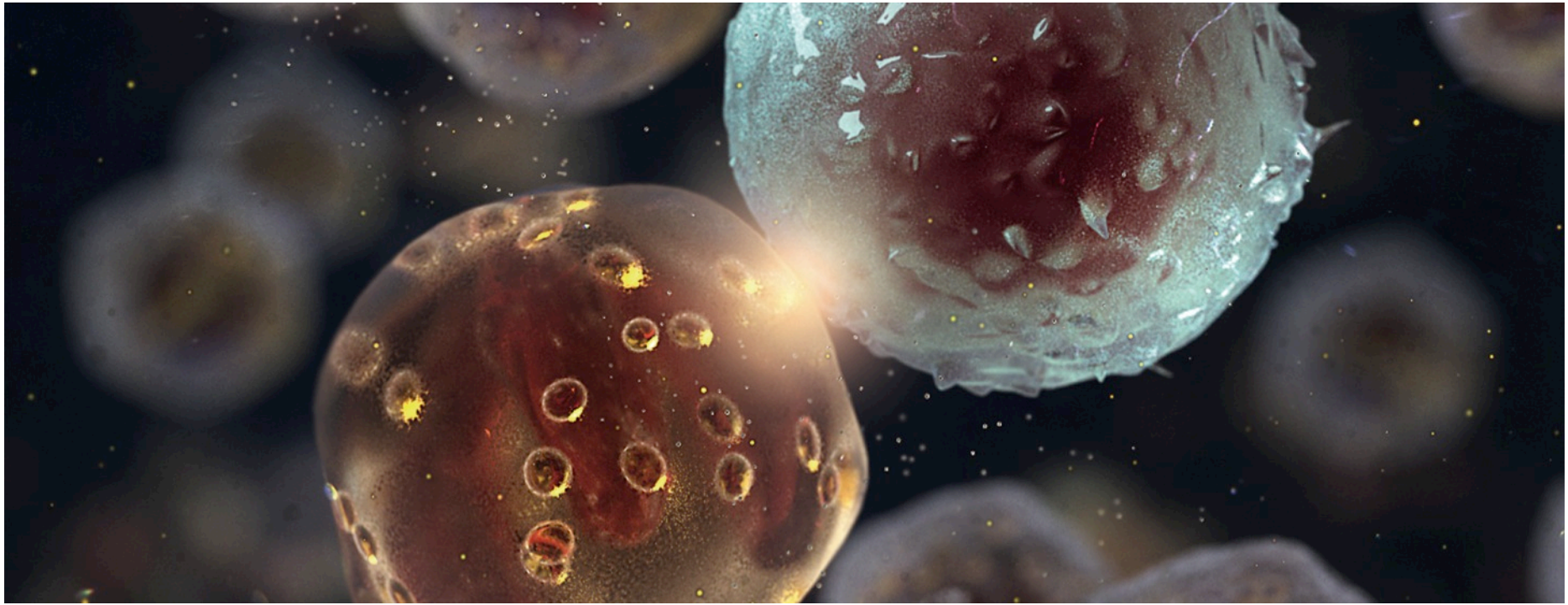

Imfinzi (PD-L1 mAb)

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; one cohort at 20mg Q4W Global trial – eight countries	• Safety • Optimal biologic dose • Secondary endpoints include PK, immunogenicity and anti-tumour activity	• FPCD: Q3 2012 • LPCD: Q4 2015 • Data readout: Ongoing
Phase I **NCT02117219**	*Imfinzi*, azacitidine (Vidaza)	Myelodysplastic syndrome	73	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: 2019
Phase 1 **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: 2019
Phase II **HUDSON** **NCT03334617**	*Imfinzi* *Lynparza* Vistusertib AZD6738 AZD9150	NSCLC	200	4 modules encompassing 10 cohorts Module 1; *Imfinzi* and *Lynparza* Module 2; *Imfinzi* and AZD9150 Module 3; *Imfinzi* and AZD6738 Module 4; *Imfinzi* and vistusertib Open-Label, Biomarker-Directed, Multi-Centre Phase II Umbrella Study in Patients with Non-Small Cell Lung Cancer, who Progressed on an anti-PD-1/PD-L1 Containing Therapy (HUDSON)	• Primary outcome; Objective response rate (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 or GEJ adenocarcinoma	236	• Arm A: *Imfinzi* + tremelimumab 2L • Arm B: *Imfinzi* 2L • Arm C: tremelimumab 2L • Arm D: *Imfinzi* + tremelimumab 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: 2019
Phase Ib/II **STUDY 22** **NCT02519348**	Hepatocellular Carcinoma	144	• Arm A: *Imfinzi* + tremelimumab • Arm B: *Imfinzi* 2L • Arm C: tremelimumab 2L	• Primary endpoints: Safety & tolerability, ORR, PFS • Secondary endpoints: DCR, OS, DoR, PD-L1 Expression	• FPCD: Q4 2015 • Data anticipated: 2018
Phase Ib **STUDY 006** **NCT02000947**	NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	459	• Dose Escalation: minimum 5 cohorts exploring various treme Q4W and *Imfinzi* 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 trial centres, exploration of ex-US countries for expansion into EU and ROW	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK and immunogenicity	• FPCD: Q4 2013 • LPCD: H1 2017 • Data anticipated: 2019
Phase I **STUDY 10** **NCT02261220**	Solid tumours (Basket trial)	380	• Dose Exploration: 2 cohorts exploring various Q4W treme and *Imfinzi* dose combinations and 2 cohorts exploring various Q2W treme and *Imfinzi* dose combinations • Dose Expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 7 tumour types North American 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: H1 2017 • Data anticipated: H2 2018
Phase I **STUDY 11** **NCT02262741**	HNSCC	71	• Arm A: treatment-naïve, PD-L1+, combo • Arm B: treatment-naïve, PD-L1-, combo • Arm C: PD-1/PD-L1 refractory, combo North American trial centres	• Primary endpoint: Safety & tolerability • Secondary endpoints: OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers	• FPCD: Q4 2014 • LPCD: Q3 2016 • Data readout: Q4 2017
Phase Ib **STUDY 23** **NCT02549651**	Diffuse Large B cell Lymphoma	207	• Arm A: *Imfinzi* • Arm B: *Imfinzi* + tremelimumab • Arm C: tremelimumab + 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: 2023

Imfinzi (PD-L1 mAb) + *Iressa* (gefitinib)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02088112**	NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)	56	Escalation phase Standard 3+3 design with 28 days DLT period • *Iressa* (QD) + *Imfinzi* IV Expansion phase • *Iressa* (QD) + *Imfinzi* IV recommended dose Global trial – three countries	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints: tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2014 • LPCD: Q2 2015 • Data anticipated: 2019

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02118337**	Advanced malignancies (escalation phase) Renal cell carcinoma (RCC) (expansion phase)	96	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: 2021
Phase I **NCT02013804**	Advanced malignancies (escalation phase)	58	Dose-escalation phase • MEDI0680 IV	• Primary endpoint: Safety & Tolerability • Secondary endpoints include tumour response such as objective response rate, immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q4 2013 • Data anticipated: Q2 2017

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 enroll a total of 20 subjects per cohort Global trial – two 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 anticipated: Q2 2018

Imfinzi (PD-L1 mAb) + oleclumab (MEDI9447, CD73 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02503774**	Advanced malignancies	188	Dose-escalation phase • oleclumab IV • oleclumab IV + *Imfinzi* IV Dose expansion phase • oleclumab IV recommended dose • oleclumab IV recommended dose + *Imfinzi* IV US 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: 2022

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

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02671435**	Advanced solid tumours	280	Escalation phase • monalizumab + *Imfinzi* IV Expansion phase • monalizumab + *Imfinzi* IV recommended dose 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: 2022

MEDI0457
+ *Imfinzi* (PD-L1 mAb)

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 study 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: 2019

MEDI0562 (OX40 mAb)
MEDI0562 (OX40 mAb) + *Imfinzi* (PD-L1 mAb) or tremelimumab (CTLA-4 mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02318394**	Advanced malignancies	106	Dose-escalation phase • MEDI0562 IV Dose-expansion phase • MEDI0562 IV recommended dose	Primary endpoints: • Safety • Determination of MTD • Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, biomarker activity, and immunogenicity	• FPCD: Q1 2015 • Data readout : Q1 2018
Phase I **NCT02705482**	Advanced malignancies	404	• Arm A: MEDI0562 IV + *Imfinzi* IV • Arm B: MEDI0562 IV + tremelimumab IV	• Primary endpoint: Safety • Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, and immunogenicity and pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2020

MEDI1873 (GITR agonist)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02583165**	Adult subjects with select advanced solid tumours	51	Dose-escalation phase • MEDI1873 IV US trial centres	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	• FPCD: Q4 2015 • Data anticipated: 2021

MEDI2228

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03489525**	Relapsed/Refractory Multiple Myeloma	129	First-time-in-human Phase 1, 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: Planning Q2 2018

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 study
			  • Post-chemo
			  • Pre-chemo
			  • MEDI3726+Enzalutamide
				Primary endpoint:
				• Safety
				Secondary endpoints
				• RECIST response
				• PSA50 response
				• CTC response
				• Pharmacokinetics, and immunogenicity
					• FPCD: Q1 2017

MEDI4276 (HER2 ADC mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02576548**	Advanced HER2+ metastatic breast and gastric cancer	Dose escalation Up to 66 Dose expansion Up to 150	• First-time-in-human Phase 1, 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: 2019

MEDI5083 + *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: 2022

MEDI7247 (PBD ADC mAb)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03106428**	Relapsed/Refractory Haematological Malignancies	228	First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	• Primary endpoint: safety • Secondary endpoints: Pharmacokinetics, immunogenicity and anti-tumour activity	• FPCD: Q2 2017 • Data anticipated: 2020

MEDI9197 (TLR7/8 agonist)

Cancer

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02556463**	Advanced solid tumour malignancies readily accessible for injection	135	Dose-escalation phase • MEDI9197 IT • MEDI9197 IT + *Imfinzi* • MEDI9197 IT + *Imfinzi* + palliative radiation Global trial – three countries	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints include: – Objective response, disease control and duration of response – Intratumoural and systemic PK and PD profiles/relationships	• FPCD: Q4 2015 • Data anticipated: 2021

MEDI0382 (GLP-1-glucagon agonist)

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02394314** **Completed**	Healthy adult subjects	64	• SAD SC administration • Germany	• 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
Phase I **NCT03235375**	Adults with renal impairment	37	• ARM1: Subjects with CrCl <20ml/min MEDI082 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

MEDI0382 (GLP-1-glucagon agonist)

Diabetes

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
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: planned Q3 2018

MEDI7219

Diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT03362593**	Healthy Volunteers	106	• 4 part study • Part A : SAD • Part B & C : open label, single dose studies • Part D : MAD	• Safety and tolerability • Pharmacokinetics	• FPCD: Q1 2018 • Data anticipated: H2 2018

Biologics

Cardiovascular & metabolic diseases

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT02601560**	rhLCAT MEDI6012	Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL)	56	• SAD in stable CAD patients	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination • Changes in baseline adjusted post dose HDL-C	• FPCD: Q4 2015 • LPCD: Q2 2016 • Data readout: Q4 2016
Phase IIa **NCT03004638**		Adults with Stable Atherosclerotic Cardiovascular Disease (ACD)	32	• MAD in stable ACD patients	• Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables • Changes in baseline adjusted post dose HDL-C, HDL-CE, and CE AUC • PK, immunogenicity, Apolipoprotein A,LDL, and Apolipoprotein B	• FPCD: Q1 2017 • Data readout: Q4 2017
Phase I **NCT03001297**	MEDI5884 Cholesterol modulation	Healthy Volunteers	64	• SAD SC administration	• Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables • Changes in HDL-C over time	• FPCD Q1 2017 • LPCD Q3 2017 • Data anticipated: H2 2018
Phase IIa **NCT03351738**		Adults With Stable Coronary Heart Disease (CHD)	120	• 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 anticipated: H2 2018

MEDI3506 (IL-33 mAb)

COPD

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SAD / MAD) **NCT03096795**	SAD: Healthy subjects with mild atopy MAD: COPD	SAD: 56 MAD: 24	SAD: • 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 MAD: • 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	• Safety and tolerability	• FPCD: Q2 2017 • LPCD: Q3 2018 • Data anticipated: 2019

MEDI7836 (IL-13 mAb)

Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I **NCT02388347**	Healthy subjects	32	• Arm 1: 30mg MEDI7836 (6) or placebo (2) as a single SC dose • Arm 2: 105mg MEDI7836 (6) or placebo (2) as a single SC dose • Arm 3: 300mg MEDI7836 (6) or placebo (2) as a single SC dose • Arm 4: 600mg MEDI7836 (6) or placebo (2) as a single SC dose	• Safety and tolerability	• FPCD: Q1 2015 • LPCD: Q3 2015 • Data readout: Q1 2016

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

Systemic lupus erythematosus (SLE)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ia **NCT02618967** **Partnered**	Healthy subjects	48	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 anticipated: H2 2018

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

MEDI5872 - AMG 557 (B7RP-1 mAb)

Systemic lupus erythematosus (SLE)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa **NCT02334306** **Partnered**	Primary Sjögren's syndrome	42	• 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 score from baseline to Day 99	• FPCD: Q3 2015 • Data anticipated: H2 2018
Phase I **NCT01683695** **Partnered** **Completed**	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)

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: Q2 2018

Other biologics

Infections

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II **EudraCT 2014-001097-34**	Anti-Staph AT (MEDI4893)	Intubated ICU	285	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and safety	• FPCD: Q4 2014 • Data anticipated: 2019
Phase IIb **NCT02878330**	Anti-Respiratory Syncytial Virus mAb-YTE (MEDI8897)	29-35 WK GA infants	1,453	• Randomised, double-blind, placebo-controlled trial • Route of administration: IM	• Safety and efficacy	• FPCD: Q4 2016 • Data anticipated: 2019
Phase Ib/IIa **NCT02290340** **Completed**		32-35 WK GA infants	89	• Randomised, double-blind, placebo-controlled, Dose-escalation trial • Route of administration: IM	• Evaluate Safety, tolerability, PK and ADA	• FPCD: Q1 2015 • LPCD: Q3 2015 • Data readout: Q3 2016
Phase Ia **NCT02114268** **Competed**		Healthy adults	136	• Randomised, double-blind, placebo-controlled, Dose-escalation trial • Route of administration: IV and IM	• Evaluate Safety, tolerability, PK and ADA	• FPCD: Q2 2014 • LPCD: Q2 2014 • Data readout: Q2 2015
Phase Ib/IIa **NCT02603952** **Completed**	Anti-influenza A mAb (MEDI8852)	Adults	126	• Randomised, partial double-blind, single dose, active-controlled, dose ranging trial • Route of administration: intravenous	• Evaluate safety in adults with acute, uncomplicated Influenza	• FPCD: Q4 2015 • LPCD: Q4 2016 • Data readout: Q4 2016
Phase I **NCT02350751** **Completed**		Healthy adults	40	• Double-blind, single-dose, placebo-controlled, dose-escalation trial • Route of administration: intravenous	• Evaluate the safety and pharmacokinetics	• FPCD: Q1 2015 • LPCD: Q1 2015 • Data readout: Q2 2015
Phase I **NCT02255760** **Completed**	Anti-Pseudomonas A mAb (MEDI3902)	Healthy adults	56	• Randomised, double-blind, placebo-controlled, dose-escalation trial • Route of administration: intravenous	• Evaluate the safety, tolerability, and pharmacokinetics	• FPCD: Q3 2014 • LPCD: Q1 2015 • Data readout: Q2 2015
Phase II **NCT02696902**		Intubated ICU	429	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and safety	• FPCD: Q2 2016 • Data anticipated: 2021

Clinical trials appendix
Q1 2018 Results update

AstraZeneca
What science can do