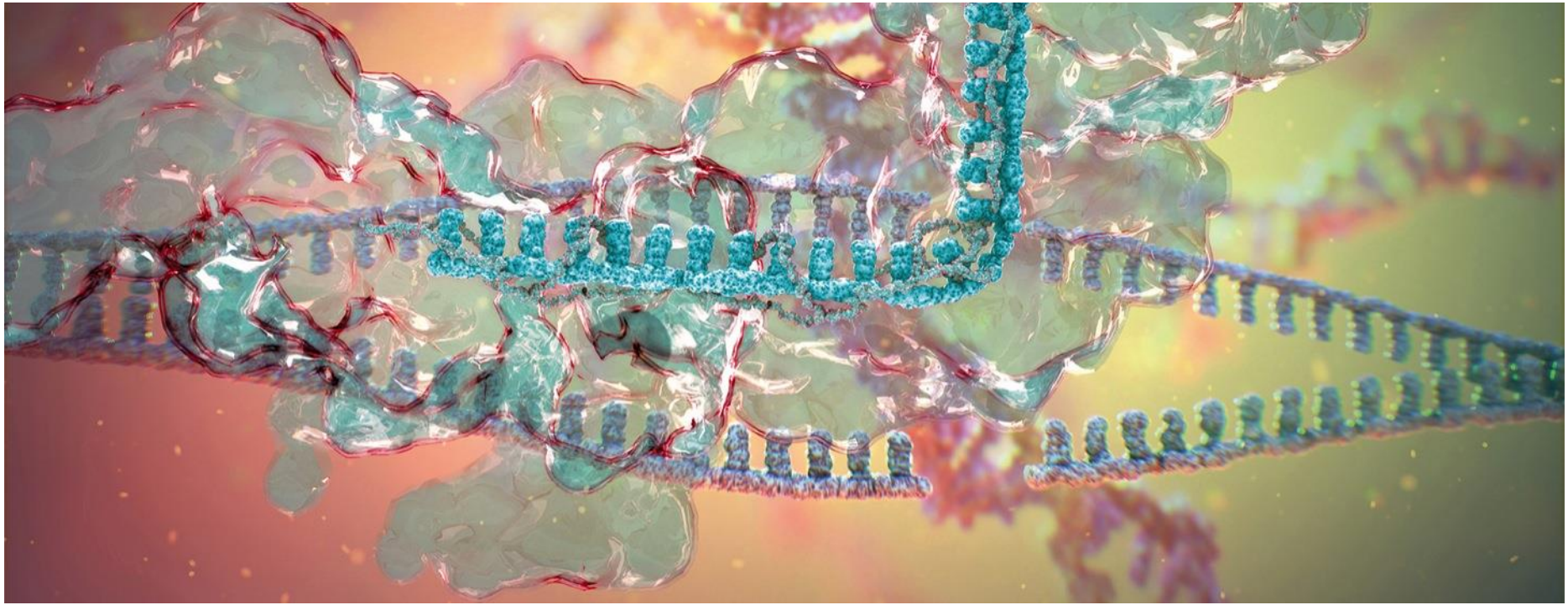
Clinical trials appendix
Q1 2016 update

AstraZeneca
What science can do



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from clinicaltrials.gov to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 31 March 2016, 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.

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

List of abbreviations

AEs	Adverse Events
ASA	Acetylsalicylic Acid
BiD	Twice Daily
CE	Clinically Evaluable
cMITT	Clinical Modified Intent-To-Treat population
DLT	Dose Limiting Toxicity
FEV	Forced Expiratory Volume
FPD	First Patient Dosed
HIF-PHI	Hypoxia-inducible factor prolyl hydroxylase inhibitor
ICS	Inhaled Corticosteroid
IM	Intra-muscular
IR	Immediate Release
IV	Intra-venous
LABA	Long Acting Beta Agonist
LAMA	Long Acting Muscarinic Agonist
LCM	Lifecycle Management
LPCD	Last Patient Commenced Dosing
MAD	Multiple Ascending Dose trial
MDI	Metered Dose Inhaler
MITT	Modified Intent-To-Treat population
mMITT	Microbiological Modified Intent-To-Treat population
MTD	Maximum Tolerated Dose
MTX	Methotrexate
NME	New Molecular Entity
OLE	Open Long Term Extension
ORR	Objective Response Rate
OS	Overall Survival
PARP	Poly ADP ribose polymerase
PFS	Progression Free Survival
Q2W	Every Other Week
Q3W	Every Three Weeks
Q4W	Every Four Weeks
Q8W	Every Eight Weeks
QD	Once Daily
SAD	Single Ascending Dose trial
SC	Sub-cutaneous
TiD	Three Times a Day
TOC	Test of Cure
XR	Extended Release

Movement since Q4 2015

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
NMEs **AZD5634** inhaled ENaC cystic fibrosis **MEDI9314** IL4R atopic dermatitis **MEDI0700**[#] BAFFI/B7RP1 systemic lupus erythematosus **AZD5718** FLAP CAD **MEDI7352** NGF/TNF bispecific mAb osteoarthritis pain **Additional indications** **durvalumab**[#] **+ monalizumab** PD-L1 + NKG2a mAb solid tumours **durvalumab**[#] **+ MEDI9447** PD-L1 + CD73 mAb solid tumours	**NMEs** **MEDI3902**[¶] Psl/PcrV pseudomonas **MEDI4166** PCSK9/GLP-1 diabetes/cardiovascular	**NMEs** **AZD3293**[#] **BACE Alz** Beta secretase inhibitor Alzheimer's disease	

Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from Registration
NMEs **AZD5312**[#] androgen receptor inhibitor solid tumours **AZD8835** PI3 kinase alpha inhibitor solid tumours **AZD8999** MABA COPD **Additional indications** **inebilizumab (MEDI-551**[#] **+ rituximab)** CD19 mAb + CD20 mAb haematological malignancies	**NMEs** **tremelimumab**[¶] **DETERMINE** CTLA-4 mAb mesothelioma **abrilumab**[#] alpha(4)beta(7) mAb Crohn's disease / ulcerative colitis	**Additional indications** ***Tagrisso* AZD9291 + durvalumab**[#] **CAURAL** ≥2nd-line advanced EGFRm T790M NSCLC ***Brilinta*/*Brilique* SOCRATES** P2Y12 receptor antagonist outcomes trial in patients with stroke or TIA	**NMEs** ***Bevespi Aerospace* (PT003 GFF) PINNACLE** LABA/LAMA COPD

[#] Collaboration
[¶] Registrational Phase II/III study

Q1 2016 New Molecular Entity (NME)[1] Pipeline

RIA CVMD Oncology Infection, Neuroscience, Gastrointestinal

Phase I
34 New Molecular Entities

Small molecule	Large molecule	
AZD1419# TLR9 asthma	MEDI0700# BAFF/B7RP1 SLE	MEDI9197# TLR 7/8 solid tumours
AZD5634 inhaled ENaC cystic fibrosis	MEDI4920 CD40L-Tn3 pSS	MEDI9447 CD73 solid tumours
AZD7986 DPP1 COPD	MEDI5872# B7RP1 SLE	MEDI1814 amyloidβ Alzheimer's disease
AZD8871 MABA COPD	MEDI7836 IL-13 asthma	MEDI7352 NGF/TNF osteoarthritis pain
AZD9567 SGRM RA	MEDI9314 IL4R atopic dermatitis	
AZD4076 miR103/107 NASH	MEDI0382 GLP-1/glucagon diabetes/obesity	
AZD5718 FLAP CAD	MEDI8111 Rh-Factor II trauma/bleeding	
AZD0156 ATM solid tumours	MEDI0562# hOX40 solid tumours	
AZD2811# Aurora solid tumours	MEDI0639# DLL-4 solid tumours	
AZD6738 ATR solid tumours	MEDI0680 PD-1 solid tumours	
AZD8186 PI3Kβ solid tumours	MEDI1873 GITR solid tumours	
AZD9150# STAT3 haems & solids	MEDI3617# ANG-2 solid tumours	
AZD9496 SERD ER+ breast	MEDI4276 HER2 solid tumours	
ATM AVI# BL/BLI SBI	MEDI-565# CEA BITE GI tumours	
AZD8108 NMDA suicidal ideation	MEDI6383# Ox40 agonist solid tumours	

Phase II
26 New Molecular Entities

Small molecule	Large molecule
abediterol (AZD0548) LABA asthma/COPD	AZD9412# Inhaled βIFN asthma/COPD
AZD7594 Inhaled SGRM asthma	inebilizumab (MEDI-551)# CD19 neuromyelitis optica
AZD7624 Inhaled p38 inhibitor COPD	mavrilimumab# GM-CSFR rheumatoid arthritis
verinurad (RDEA3170) URAT-1 hyperuricemia/gout	MEDI2070# IL-23 Crohns
AZD1775# Wee-1 ovarian	tezepelumab# (MEDI9929)# TSLP asthma/atopic dermatitis
AZD3759 or Tagrisso (AZD9291) BLOOM	MEDI4166 PCSK9/GLP-1 diabetes/CV
AZD4547 FGFR solid tumours	MEDI6012 LCAT ACS
AZD5363# AKT breast cancer	inebilizumab (MEDI-551)# CD19 DLBCL
savolitinib# MET pRCC	MEDI-573# IGF metastatic breast cancer
vistusertib (AZD2014) mTOR 1/2 solid tumours	MEDI3902¶ Psl/PcrV pseudomonas
CXL# BLI/cephalosporin MRSA	MEDI4893 staph alpha toxin SSI
AZD3241 MPO Multiple System Atrophy	MEDI7510 sF+GLA-SE RSV prevention
	MEDI8852 influenza A treatment
	MEDI8897# RSV passive prophylaxis

Phase III
10 New Molecular Entities

Small molecule	Large molecule
PT010 LABA/LAMA/ICS COPD	anifrolumab# TULIP IFNαR SLE
roxadustat# HIFPH anaemia CKD/ESRD	benralizumab# IL-5R severe asthma
acalabrutinib# BTK B-cell blood cancers	tralokinumab IL-13 severe asthma
selumetinib# SELECT-1 MEK 2L KRAS+ NSCLC	durvalumab# HAWK¶ PD-L1 2L SCCHN
AZD3293# AMARANTH BACE Alzheimer's disease	moxetumomab pasudotox# PLAIT CD22 HCL

Applications Under Review
4 New Molecular Entities

Small molecule	Large molecule
ZS-9 potassium binder hyperkalaemia	brodalumab# IL-17R psoriasis
cediranib ICON 6 VEGF PSR ovarian	
CAZ AVI# BLI/cephalosporin SBI/cIAI/cUTI	
	MEDI-550 pandemic influenza virus vaccine

[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)*

In collaboration; ¶ Registrational P2/3 study;

MEDI-550 does not count toward late-stage NME totals (submitted to EMEA December 2015)

Q1 2016 Lifecycle Management (LCM)[1] Pipeline

RIA CVMD Oncology Infection, Neuroscience, Gastrointestinal

Phase I
3 Projects

Small molecule
- lesinurad+allopurinol FDC — URAT-1+XO gout

Large molecule
- anifrolumab# — IFNαR SLE SC
- durvalumab# — PD-L1 solid tumours

Phase II
9 Projects

Small molecule
- PT010 — LABA/LAMA/ICS asthma
- Brilinta/Brilique HESTIA — paeds w/ sickle cell
- Epanova+Farxiga/Forxiga — NASH
- Lynparza — PARP prostate cancer
- selumetinib# — MEK 2L KRAS wt NSCLC

Large molecule
- anifrolumab# — IFNαR lupus nephritis
- tralokinumab — IL-13 atopic dermatitis
- durvalumab# — PD-L1 solid tumours
- durvalumab# — PD-L1 bladder

Phase III
24 Projects

Small molecule
- Symbicort BAI — asthma/COPD
- Symbicort SYGMA — as needed in mild asthma
- Brilinta/Brilique EUCLID — PAD outcomes
- Brilinta/Brilique THEMIS — diabetes & CAD outcomes
- Bydureon EXSCEL — outcomes
- Bydureon wkly suspension — Type-2 diabetes
- Epanova STRENGTH — outcomes
- Farxiga/Forxiga — Type-1 diabetes
- Farxiga/Forxiga DECLARE — outcomes
- Fasiodex FALCON — oestrogen receptor 1L adv. breast
- Lynparza GOLD — PARP 2L gastric cancer

Large molecule
- Lynparza OlympiA — PARP gBRCA adjuvant breast
- Lynparza OlympiAD — PARP gBRCA metastatic breast
- Lynparza POLO — PARP pancreatic cancer
- Lynparza SOLO-1 — PARP 1L BRCAm ovarian
- Lynparza SOLO-2 — PARP >2L BRCAm PSR ovarian
- Lynparza SOLO-3 — PARP BRCAm PSR ovarian
- selumetinib# ASTRA — MEK 2L diff. thyroid
- Tagrisso (AZD9291) ADAURA — EGFR adj. EGFRm NSCLC
- Tagrisso (AZD9291) AURA 3 — EGFR T790M NSCLC >2L
- Tagrisso (AZD9291) FLAURA — EGFR 1L adv. EGFRm NSCLC
- Nexium (CN only) — stress ulcer prophylaxis

Large molecule
- benralizumab# — IL-5R COPD
- durvalumab# PACIFIC — PD-L1 Stage 3 NSCLC

Applications Under Review
3 Projects

Small molecule
- saxa+dapa FDC — diabetes
- CAZ AVI# — BLI/cephalosporin HAP/VAP
- linaclotide# (CN only) — IBS-c

Large molecule

Oncology Combinations

Phase I
8 Projects

- durvalumab#+dabrafenib+trametinib — PD-L1+BRAF+MEK melanoma
- durvalumab#+Iressa — PD-L1+EGFR NSCLC
- durvalumab#+MEDI0680 — PD-L1+PD-1 solid tumours
- durvalumab#+MEDI6383# — PD-L1+Ox40 agonist solid tumours
- durvalumab#+MEDI9447 — PD-L1+CD73 solid tumours
- durvalumab#+monalizumabɣ — PD-L1+NKG2a solid tumours
- durvalumab#+tremelimumab — PD-L1+CTLA-4 solid tumours
- Tagrisso (AZD9291) combo# TATTON — EGFR+PD-L1/MEK/MET NSCLC

Phase II
2 Projects

Oncology Combinations
- AZD5069+durva# or AZD9150#+durva# — (CXCR2 or STAT3)+PD-L1 SCCHN
- durvalumab#+tremelimumab — PD-L1+CTLA-4 gastric cancer

Phase III
8 Projects

Oncology Combinations
- durvalumab# +tremelimumab ALPS¶ — PD-L1+CTLA-4 1L metastatic pancreatic
- durvalumab# +tremelimumab ARCTIC — PD-L1+CTLA-4 3L NSCLC
- durvalumab# +tremelimumab CONDOR¶ — PD-L1+CTLA-4 2L SCCHN
- durvalumab# +tremelimumab DANUBE — PD-L1+CTLA-4 1L bladder
- durvalumab# +tremelimumab EAGLE — PD-L1+CTLA-4 2L SCCHN
- durvalumab# +tremelimumab KESTREL — PD-L1+CTLA-4 1L SCCHN
- durvalumab# +tremelimumab MYSTIC — PD-L1+CTLA-4 1L NSCLC
- durvalumab# +tremelimumab NEPTUNE — PD-L1+CTLA-4 1L NSCLC

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

In collaboration; ¶ Registrational P2/3 study; ɣ MedImmune-sponsored study in collaboration with Innate Pharma

AstraZeneca

AstraZeneca
What science can do

Lifecycle management (new uses of existing medicines)

Symbicort (ICS/LABA)

Mild asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SYGMA1** **NCT02149199**	Patients in need of GINA step-2 treatment	N = 3,750	• **Arm 1**: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid • **Arm 2:** Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' • **Arm 3:** terbutaline Turbuhaler 0.4 mg 'as needed' + placebo Pulmicort 200 µg Turbuhaler bid Global trial – 19 countries	• Well-controlled asthma weeks • Time to first severe asthma exacerbation • Time to first moderate or severe asthma exacerbation • Average change from baseline in pre-dose FEV_1	• FPD: Q4 2014 • LPCD: 2017 • Estimated completion: 2017 • Estimated top-line results: 2017
Phase III **SYGMA2** **NCT02224157**	Patients in need of GINA step-2 treatment	N = 4,114*	• **Arm 1**: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid • **Arm 2:** Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' Global trial – 25 countries	• Annual severe asthma exacerbation rate • Time to first severe asthma exacerbation • Average change from baseline in pre-dose FEV_1 • Time to trial specific asthma related discontinuation	• FPD: Q1 2015 • LPCD: 2017 • Estimated completion: 2017 • Estimated top-line results: 2017

* There will be a blinded review for event rate which means that the final number of patients is uncertain until this review has taken place.

EkliralTudorza (LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **NCT02375724** **Partnered: Menarini**	Patients with COPD	N = 224	• **Arm 1**: Aclidinium bromide 400 µg • **Arm 2:** Placebo to aclidinium bromide 400 µg Global trial – five countries	• Change from baseline in Overall E-RS Total score (i.e. score over the whole 8 weeks trial period) • 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 FEV_1	• FPD: Q1 2015 • LPCD: Q3 2015 • Clinically completed • Top-line results released Q1 2016 • Estimated completion date: Q2 2016
Phase IV **ASCENT** **NCT01966107** **Partnered:** **Forest/Actavis**	Patients with moderate to very severe COPD	N = 4,000	• **Arm 1:** Aclidinium bromide 400 µg • **Arm 2:** Placebo to aclidinium bromide 400 µg Global trial – two countries	• 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. • 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	• FPD: Q4 2013 • LPCD: H2 2016 • Estimated completion date: 2018
Phase IV **NCT02153489** **Partnered:** **Almirall**	Patients with stable moderate and severe COPD	N = 30	• **Arm 1:** Aclidinium bromide 400 µg • **Arm 2:** Placebo to Aclidinium bromide 400 µg Local trial – one country	• Change from baseline in normalised FEV_1. Week 3. FEV_1 over the 24-hour period (AUC0-24) will be measured following morning administration • Adverse events. Week 5. A follow up telephone call will be made 14 days after the last trial drug administration (for completed patients) or premature discontinuation visit (when applicable) to record adverse events	• FPD: Q2 2014 • LPCD: Q1 2015 • Top-line results: Q4 2015 • Estimated completion date: H2 2016

Duaklir (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **ACTIVATE** **NCT02424344** **CO-FUNDED: Menarini**	Patients with moderate to COPD	N = 268	• **Arm 1:** Aclidinium/formoterol FDC 400/12 µg • **Arm 2:** Placebo to aclidinium/formoterol FDC 400/12 µg Global trial – five countries	• Change from baseline in trough Functional Residual capacity after 4 weeks of treatment • Change from baseline in Endurance Time (ET) during constant work rate cycle ergometry to symptom limitation at 75% of Wmax after 8 weeks of treatment • Percentage of inactive patients (<6000 steps per day) after 8 weeks on treatment	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion date: H2 2016

Daliresp (oral PDE4 inhibitor)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV RESPOND NCT01443845	COPD	N = 2,354	• 52W, randomised, DB with *Daliresp* 500µg OD vs placebo, in COPD on top of ICS/LABA	• Rate of moderate or severe COPD exacerbations per subject per year	• Completed: Q1 2016 • Estimated results: H2 2016
Phase IV OPTIMIZE NCT02165826	COPD	N = 1,323	• 12W, randomised, DB to evaluate tolerability and PK of *Daliresp* 500 µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg Roflumilast OD in subjects not tolerating 500 µg OD	• Percentage of participants prematurely discontinuing study treatment for any reason during the main period	• Completed: Q3 2015 • Estimated results: H2 2016
Phase IIIb ROBERT NCT01509677	COPD	N = 158	• 16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of Roflumilast in COPD	• Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period	• Completed: Q1 2016 • Estimated results: H2 2016

Zurampic (lesinurad) (SURI, URAT1 inhibitor)

Gout

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **RDEA594-306 CLEAR Extension** **NCT01808131**	Gout previously enrolled in studies Phase III RDEA594-301 & -302 (CLEAR 1 & 2) trials	N = 717	• *Zurampic* 200 or 400 mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200 mg QD in combination with their allopurinol	• Assess the long-term efficacy and safety of *Zurampic* in combination with allopurinol	• FPD: Q1 2013 • Trial ongoing • LPCD: 2017
Phase III **RDEA594-307 CRYSTAL Extension** **NCT01808144**	Gout previously enrolled in Phase III RDEA594-304 (CRYSTAL) trial	N = 196	• *Zurampic* 200 or 400 mg QD All patients: febuxostat 80 mg QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200 mg QD in combination with their febuxostat	• Assess the long-term efficacy and safety of *Zurampic* in combination with febuxostat	• FPD: Q1 2013 • Trial ongoing • LPCD: 2017
Phase II **RDEA594-203 Open-label Extension** **NCT01001338**	Gout previously enrolled in Phase II RDEA594-203 trial	N = 87	• *Zurampic* 200, 400, or 600 mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200 mg QD in combination with their allopurinol	• Assess the long-term efficacy and safety of *Zurampic* in combination with allopurinol	• FPD: Q1 2011 • Trial ongoing • LPCD: H2 2016

Lesinurad/allopurinol FDC (SURI, URAT1 inhibitor/XOI inhibitor)

Gout

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **RDEA594-501 Randomised, Open-label, cross-over, relative bioavailability** **NCT02581553**	Healthy Male Subjects	N = 124	Cohort 1: cross-over, rel. BA Tx. 1: lesinurad/allopurinol 200/300 FDC Tx. 2: coadministered lesinurad 200mg + allopurinol 300mg Cohort 2: cross-over, Food Effect, BA Tx. 1: lesinurad/allopurinol 200/300 FDC (fasted) Tx. 2: lesinurad/allopurinol 200/300 FDC (fed – high fat meal) Cohort 3: cross-over, rel. BA Tx. 1: lesinurad/allopurinol 200/200 FDC Tx. 2: coadministered lesinurad 200mg + allopurinol 200mg	• Assess the bioavailability of lesinurad/allopurinol 200/300 FDC and lesinurad/allopurinol 200/200 FDC tablets relative to coadministered lesinurad and allopurinol tablets in healthy adult male subjects • To assess the effect of a high fat/high calorie meal on the pharmacokinetics of lesinurad/allopurinol 200/300 FDC tablets in healthy adult male subjects	• FPD: Q4 2015 • LPCD: Q2 2016

Bevespi Aerosphere (PT003, LABA/LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PINNACLE 1** **NCT01854645**	Moderate to very severe COPD	N = 2,103	Treatment (24-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere*) 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder 18 µg QD • Arm 5: Placebo MDI BiD Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active- controlled Estimated time from FSFV to DBL is approximately 21 months. US, Australia, New Zealand	• Change from baseline in morning pre-dose trough FEV_1	• FPD: Q2 2013 • LPCD: Q3 2014 • Top-line results: Q1 2015* * Clinically completed
Phase III **PINNACLE 2** **NCT01854658**	Moderate to very severe COPD	N = 1,618	Treatment (24-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere)* 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Placebo MDI BiD Multicentre, randomised, double-blind, parallel group, chronic dosing and placebo-controlled Estimated time from FSFV to DBL is approximately 20 months. US	• Change from baseline in morning pre-dose trough FEV_1	• FPD: Q3 2013 • LPCD: Q3 2014 • Top-line results: Q2 2015* * Clinically completed
Phase III **PINNACLE 3** **NCT01970878**	Moderate to very severe COPD	N = 850	Treatment (28-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere*) 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder QD Multi-centre, randomised, double-blind, parallel-group and active-controlled Estimated time from FSFV to DBL is approximately 16 months. US, Australia, New Zealand	• Overall safety, tolerability and efficacy	• FPD: Q4 2013 • LPCD: Q3 2014 • Top-line results: Q2 2015* * Clinically completed

Bevespi Aerosphere (PT003, LABA/LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIIb (Dose Indicator trial) **NCT02268396**	Moderate to severe COPD	N = 150	Treatment (5- to 6- week Treatment Period) • GFF 14.4/9.6 µg • Placebo MDI BID Open-label and multiple-centre Estimated time from FSFV to DBL is approximately 11 weeks, US	• Percentage of devices where number of actuations as counted at the end of the trial using dose indicator reading is consistent (± 20 actuations) with number of actuations reported by subject	• FPD: Q4 2014 • LPCD: Q4 2014 • Top-line results: Q1 2015* * Clinically completed
Phase IIIb (24 Hr Lung Function Placebo) **NCT02347085**	Moderate to severe COPD	N = 40	Treatments (8-week Treatment Period) • GFF MDI 14.4/9.6 µg BID • Placebo MDI BID Randomised, 2-period, 2-treatment Double-blind, Multi-centre and Crossover Estimated time from FSFV to DBL is approximately four months, US	• FEV_1 AUC0-24 on Day 29	• FPD: Q1 2015 • LPCD: Q1 2015 • Top-line results: Q3 2015 * Clinically completed
Phase IIIb (24 Hr Lung Function Active) **NCT02347072**	Moderate to severe COPD	N = 80	Treatments (12-week Treatment Period) • GFF MDI 14.4/9.6 µg BID • Placebo • Spiriva Respimat 5 µg QD (open-label) Randomised and 3-way cross-over Estimated time from FSFV to DBL is approximately six months, US	• FEV_1 AUC0-24 on Day 29	• FPD: Q1 2015 • LPCD: Q2 2015 • Top-line results: Q3 2015 * Clinically completed
Phase III (Spacer trial) **NCT02454959**	Moderate to severe COPD	N = 60	Treatments (2 week treatment Period) • GFF MDI 14.4/9.6 µg with a spacer • GFF MDI 14.4/9.6 µg without a spacer Randomised, 7-day, cross-over in subjects with moderate to severe COPD Estimated time from FSFV to DBL is approximately nine months, US	• Change from morning pre-dose trough FEV_1 GFF 14.4/9.6 µg with Aerochamber Plus VHC relative to GFF14.4µg w/o Aerochamber Plus VHC on Day 8 • PK parameters at all doses will include Cmax, AUC0-12, AUC0-t, tmax, Other PD/PK parameters may be calculated, as appropriate	• FPD: Q2 2015 • LPCD: Q1 2016 • Estimated top-line results: Q2 2016

Bevespi Aerosphere (PT003, LABA/LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design (G = glycopyrronium, F = formoterol fumarate)	Endpoints	Status
Phase III **(Asia Pacific trial)** **NCT02343458**	Moderate to very severe COPD	N = 1,614	Treatments (24-week Treatment Period) • GFF 14.4/9.6 µg (N=514) • GP 14.4 µg (N=440) • FF 9.6 µg (N=440) • Placebo (N=220) • US/China: Trough FEV1 at Week 24 of treatment • EU/Hybrid: Co-primary= Trough FEV1 over Week 24 of treatment and TDI score over 24 weeks Randomised, Double-Blind, Chronic-Dosing , Placebo-Controlled, Parallel-Group and Multi-centre Estimated time from FSFV to DBL is approximately 20 months. US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan	• For the US/China approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV_1 at Week 24 of treatment • For the Japan approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV_1 over Weeks 12 to 24 of treatment • For the EU and Hybrid approaches, the primary endpoint will be the change from baseline in morning pre-dose trough FEV_1 over 24 weeks of treatment • TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 Weeks]	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated top-line results: 2017
Phase IIb **(CV trial)** **NCT02685293**	Moderate to severe COPD	N = 40	Treatments (5-week Treatment Period) • GFF MDI (PT003) 14.4/9.6 µg ex-actuator • Placebo MDI Randomised, 2-period, Double-blind, 2-treatment, Chronic-dosing (7 Days), Crossover trial Estimated time from FSFV to DB is approximately eight months, US	• Right Ventricular End Diastolic Volume Index (RVEDVi) measured at 2-hours post-dose on Day 8	• FPD: Q2 2016 • LPCD: H2 2016 • Estimated top-line results: 2017

BrilintalBrilique (ADP receptor antagonist)

Cardiovascular

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PEGASUS** **NCT01225562**	Patients with prior MI	N = 21,000	• Arm 1: *Brilinta*/*Brilique* 90 mg BiD • Arm 2: *Brilinta*/*Brilique* 60 mg BiD • Arm 3: Placebo BiD *on a background of ASA* Global trial – 31 countries	• Composite of CV death, non-fatal MI and non-fatal stroke	• FPD: Q4 2010 • LPCD: Q4 2014 • Completion date: Q4 2014
Phase III **EUCLID** **NCT01732822**	Patients with PAD	N = 13,500	• Arm 1: *Brilinta*/*Brilique* 90 mg BiD • Arm 2: Clopidogrel 75 mg QD *monotherapy trial* Global trial – 28 countries	• Composite of CV death, non-fatal MI and ischemic stroke	• FPD: Q4 2012 • LPCD: H2 2016 • Estimated top-line results: H2 2016
Phase III **THEMIS** **NCT01991795**	Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	N = 19,000	• Arm 1: *Brilinta*/*Brilique* 60 mg BiD • Arm 2: Placebo BiD *on a background of ASA if not contra indicated or not tolerated* Global trial – 42 countries	• Composite of CV death, non-fatal MI and non-fatal stroke	• FPD: Q1 2014 • LPCD: 2018 • Estimated top-line results: 2018
Phase III (BE) **NCT02436577**	Japanese healthy volunteers	N = 36	Single dose, Cross-Over • Arm 1 *Brilinta*/*Brilique* OD tablet 90 mg + 150 mL of water • Arm 2 *Brilinta*/*Brilique* OD tablet 90 mg without water • Arm 3 *Brilinta*/*Brilique* IR tablet 90 mg) + 200 mL of water Local trial – one country	• BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet	• FPD: Q2 2015 • LPCD: Q3 2015 • Completion date: Q3 2015 • Top-line results: Q4 2015

BrilintalBrilique (ADP receptor antagonist)

Cardiovascular

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III (BE) **NCT02400333**	Caucasian healthy volunteers	N = 36	Single dose, Cross-Over • Arm 1 *Brilinta*/*Brilique* OD tablet 90 mg +200 ml of water • Arm 2 *Brilinta*/*Brilique* OD tablet 90 mg without water • Arm 3 *Brilinta*/*Brilique* OD tablet 90 mg (suspended in water) via nasogastric tube • Arm 4 *Brilinta*/*Brilique* IR tablet 90 mg + 200mL of water Local trial – one country	• BA/BE of *Brilinta*/*Brilique* Dispersible Tablet vs *Brilinta*/*Brilique* IR tablet	• FPD: Q2 2015 • LPCD: Q3 2015 • Completion date: Q3 2015 • Top-line results: Q4 2015
Phase II **HESTIA2** **NCT02482298**	Patients with sickle disease	N = 90	• Arm 1: *Brilinta*/*Brilique* 10 mg BiD • Arm 2: *Brilinta*/*Brilique* 45 mg BiD • Arm 3: Placebo BiD Global trial – eight countries	• Number of days with pain due to Sickle Cell Disease	• FPD: Q3 2015 • LPCD: H2 2016 • Estimated completion date: H2 2016

Onglyza (DPP-4 inhibitor)

Type-2 Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02104804**	Type-2 diabetes mellitus	N = 444	• Arm 1: *Onglyza* 5 mg QD +insulin or *Onglyza* 5 mg QD+ insulin + Met: Placebo QD + insulin or Placebo • Arm 2: QD + insulin + Met Trial in China	Primary: • Change from baseline in HbA1C at 24 weeks Secondary: • Change from baseline at 24 weeks in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance	• FPD: Q3 2014 • LPCD: Q1 2016 • Estimated top-line results: Q2 2016
Phase III **NCT02273050**	Type-2 diabetes mellitus	N = 639	• Arm 1: *Onglyza* 5 mg + Met (500 mg with titration) • Arm 2: *Onglyza* 5 mg + Placebo • Arm 3: Met (500 mg with titration) + Placebo Trial in China	Primary: • The change in HbA1c from baseline to week 24 (prior to rescue) Secondary: • The proportion of subjects achieving a therapeutic glycaemic response at week 24 (prior to rescue) defined as HbA1c <7.0%	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated top-line results: 2017

Farxiga/*Forxiga* (SGLT2 inhibitor)

Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **NCT02157298**	Japanese patients with type-2 diabetes with inadequate glycemic control on insulin	N = 266	• Arm 1: *Forxiga* 5mg • Arm 2: Placebo Japan trial	• Change from baseline in HbA1c at week 16 • 1 year LT data	• FPD: Q2 2014 • LPCD: Q4 2015 • Top-line Results: Q1 2016 • Estimated completion date: Q2 2016
Phase III/IV **DECLARE** **NCT01730534**	Type-2 diabetes mellitus with high risk for CV event	N = 17,276	• Arm 1: Farxiga/*Forxiga* 10 mg QD + standard of care therapy QD • Arm 2: Placebo + standard of care therapy for type-2 Diabetes Global trial – 33 countries	• Time to first event included in the composite endpoint of CV death, MI or ischemic stroke	• FPD: Q2 2013 • LPCD: 2019 • Estimated top-line results: 2019 • Estimated completion date: 2019
Phase III **NCT02096705** Partnered: BMS	Asian subjects with type-2 diabetes who have inadequate glycemic control on insulin	N = 273	• Arm 1: *Forxiga* 10 mg QD for 24 weeks + background Insulin • Arm 2: Placebo QD for 24 weeks + background Insulin Asian trial – three countries	• Change from baseline in HbA1c at week 24	• FPD: Q1 2014 • LPCD: Q1 2016 • Estimated top-line results: Q2 2016 • Estimated completion date: Q2 2016
Phase III **DERIVE** **NCT02413398**	Patients with type-2 diabetes and moderate renal impairment	N = 302	• Arm 1: Farxiga/*Forxiga* 10 mg QD for 24 weeks • Arm 2: Placebo 10 mg QD for 24 weeks Global trial – 5 countries	• Change from baseline in HbA1c at Week 24	• FPD: Q2 2015 • LPCD: 2017 • Estimated top-line results: 2017 • Estimated completion date: 2017
Phase III **DEPICT 1** **NCT02268214** Partnered: BMS	Type-1 diabetes mellitus	N = 768	• Arm 1: Farxiga/*Forxiga* 5 mg QD 52 weeks + insulin • Arm 2: Farxiga/*Forxiga* 10 mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 17 countries	Primary: • Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24	• FPD: Q4 2014 • LPCD: 2017 • Estimated top-line results: 2017
Phase III **DEPICT 2** **NCT02460978** Partnered: BMS	Type-1 diabetes mellitus	N = 768	• Arm 1: Farxiga/*Forxiga* 5 mg QD 52 weeks + insulin • Arm 2: Farxiga/*Forxiga* 10 mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 14 countries	Primary: • Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24	• FPD: Q3 2015 • LPCD: 2017 • Estimated top-line results: 2018

Saxagliptin/dapagliflozin (DPP-4/SGLT2 inhibitors)

Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02284893**	Type-2 diabetes mellitus	N = 420	• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR • Arm 2: Sitagliptin 100 mg + Met IR/XR Global trial – six countries	Primary: • Mean change from baseline in HbA1C at week 24 Secondary: • The proportion of subjects achieving a therapeutic glycemic respons at week 24 defined as HbA1C<7% • Mean change in total body weight at week 24	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2016
Phase III **NCT02419612**	Type-2 diabetes mellitus	N = 440	• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR • Arm 2: Glimeperide 1-6 mg + Met IR/XR Global trial – 10 countries	Primary: • Mean change from baseline in HbA1c at week 52 Secondary: • Mean change from baseline in total body weight at week 52 • The proportion of subjects achieving a therapeutic glycemic response at week 52 defined as HbA1c<7.0%	• FPD: Q3 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase III **NCT02551874**	Type-2 diabetes mellitus	N = 598	• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR with or without SU • Arm 2: Insulin glargine + Met IR/XR with or without SU Global trial – 12 countries	Primary: • Mean change from baseline in HbA1C at week 24 Secondary: • Mean change in total body weight at week 24 • The proportion of subjects with confirmed hypoglycemia at week 24	• FPD: Q4 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase III **NCT02681094**	Type-2 diabetes mellitus	N = 900	• Arm 1: Saxagliptin 5 mg + dapagliflozin 5 mg + Met IR/XR • Arm 2: Dapagliflozin 5 mg + placebo + Met IR/XR • Arm 3: Saxagliptin 5 mg + placebo + Met IR/XR Global trial – six countries	Primary: • Mean change from baseline in HbA1C at week 24 Secondary: • The proportion of subjects achieving a therapeutic glycemic respons at week 24 defined as HbA1C<7% • Mean change in fasting plasma glucose at 24 weeks	• FPD: Q1 2016 • LPCD: 2017 • Estimated top-line results: 2017

Bydureon (GLP-1 receptor agonist)

Type-2 Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **EXSCEL** **NCT01144338** Partnered	Type-2 diabetes	N = 14,000	• Arm 1: *Bydureon* once weekly 2mg SC • Arm 2: Placebo On a background of standard of care medication, different degree of CV risk Global trial	• Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke)	• FPD: Q2 2010 • LPCD: 2017 • Estimated completion: 2018
Phase III **DURATION-NEO 1** **NCT01652716** Partnered	Type-2 diabetes	N = 375	• Arm 1: *Bydureon* BiD SC (autoinjector) • Arm 2: *Bydureon* weekly suspension SC (autoinjector) On a background of diet & exercise alone or with stable regimen of oral antidiabetics US only	• Change in HbA1c from baseline at 28 weeks	• FPD: Q1 2013 • Completed: Q3 2014
Phase III **DURATION-NEO 2** **NCT01652729** Partnered	Type-2 diabetes	N = 360	• Arm 1: Sitagliptin • Arm 2: *Bydureon* weekly suspension SC (autoinjector) • Arm 3: Placebo On a background of diet & exercise alone or with stable regimen of oral antidiabetics US only	• Change in HbA1c from baseline at 28 weeks	• FPD: Q1 2013 • Completed : Q3 2014
Phase III **DURATION 7** **NCT02229383**	Type-2 diabetes	N = 440	• Arm 1: *Bydureon* once weekly 2 mg SC + Titrated Basal Insulin • Arm 2: Placebo + Titrated Basal Insulin Double-blind 1:1 randomisation Background therapy with or without Metformin Global trial	• Change in HbA1c from baseline at 28 weeks	• FPD: Q3 2014 • LPCD: H2 2016 • Estimated completion: H2 2016

Bydureon (GLP-1 receptor agonist)

Type-2 Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **DURATION 8** **NCT02229396**	Type-2 diabetes	N = 660	• Arm 1: *Bydureon* once weekly 2 mg SC • Arm 2: Dapagliflozin 10 mg • Arm 3: *Bydureon* once weekly 2 mg SC + dapagliflozin 10 mg Double-blind 1:1:1 randomisation Background therapy with Metformin 1500 mg/day up to 2 months prior to screening Global trial	• Change in HbA1c from baseline at 28 weeks	• FPD: Q3 2014 • LPCD: 2017 • Estimated completion: H2 2016 - 28-week data 2017 - 52-week data 2018 - 104-week data

Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **Japanese Long-term Safety** **NCT02463071**	Japanese patients with hypertriglyceridemia	N = 375	• *Epanova* 2 g and 4 g vs. Placebo (after meal) daily for 52 weeks Global trial – one country	• Safety in Japanese patients • % change in triglycerides	• FPD: Q2 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase III **EVOLVE II** **NCT02009865**	Severe hyper-triglyceridaemia	N = 162	• Arm 1: *Epanova* 2g QD • Arm 2: Placebo (olive oil) Global trial – seven countries	• Change in serum triglycerides over 12 weeks	• FPD: Q4 2013 • LPCD: Q4 2014 • Completed: Q4 2015
Phase III **STRENGTH (CVOT)** **NCT02104817**	Patients with hypertri-glyceridaemia and high CVD risk	N = 13,000	• Arm 1: *Epanova* 4g QD + statin • Arm 2: Placebo (corn oil) + statin Global trial – 22 countries	• Composite of MACE	• FPD: Q4 2014 • Estimated top-line results: 2019
Phase II **EFFECT I** **NCT02354976**	Overweight patients with hypertriglyceridemia	N = 75	• *Epanova* 4 g vs. Placebo vs. Fenofibrate 200 mg daily for 12 weeks Global trial – one country	• 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	• FPD: Q3 2015 • LPCD: Q2 2016 • Estimated top-line results: H2 2016
Phase II **EFFECT II** **NCT02279407**	Type-2 DiM Liver fat >5.5%	N = 80	• Arm 1: *Epanova* 4g QD • Arm 2: Placebo (olive oil) • Arm 3: *Epanova* 4gm + dapaglifozin 10 mg QD • Arm 4: Dapaglifozin 10 mg Local trial – one country	• Reduction in liver fat content (%) at the end of 12 weeks	• FPD: Q1 2015 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016
Phase I **PRECISE** **NCT02370537**	Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes	N = 66	• Arm 1: *Epanova* 4g single dose • Arm 2: *Omacor* 4 g single dose Global trial – six countries in Europe	• Presence of Pancreatic Exocrine Insufficiency (PEI), Pharmacokinetics of Epanova and Omacor following a single oral dose in patients with different degrees of PEI	• FPD: Q1 2015 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016

Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **Microsphere bioavailability** **NCT02359045**	Healthy volunteers	N = 40 Part A N = 42 Part B	• Arm 1: D1400147 4g • Arm 2: D14000136 4g • Arm 3: D14000137 4g • Arm 4: *Epanova* 4g Local trial – one country	• Rate and extent of absorption of omega-3-carboxylic acids following single-dose oral administration of test formulations A, B and C and reference formulation (Epanova®) under fed and fasted condition, by assessment of AUC, AUC(0-72) and Cmax	• FPD: Q1 2015 • LPCD: Q3 2015 • Completed: Q4 2015
Phase I **Japanese food interaction** **NCT02372344**	Healthy male volunteers	N = 42	• *Epanova* 4 g X 3 separate occasions (fasting, before meal, and after meal) Local trial – one country	• Effect of food timing (fasting, before meal, and after meal) on pharmacokinetics (AUC, Cmax, AUC0-72)	• FPD: Q1 2015 • LPCD: Q2 2015 • Completed: Q4 2015
Phase I **SAD/MAD** **NCT02209766**	Healthy male Japanese and Caucasian subjects	N = 18	• Arm 1: (Japanese): *Epanova* 2g vs. Placebo QD • Arm 2: (Japanese): *Epanova* 4g vs Placebo QD • Arm 3: (Caucasian): *Epanova* 4g vs Placebo Local trial – one country	• PK of single and multiple doses in healthy male Japanese subjects • Safety/tolerability profile	• FPD: Q3 2014 • LPCD: Q4 2014 • Completed: Q3 2015
Phase I **NCT02189252**	Patients with a history of pancreatitis	N = 16	• Arm 1: *Epanova* 4g →Lovaza 4g QD • Arm 2: Lovaza 4g →Epanova 4 g QD • Arm 3: *Epanova* 2g →Lovaza 4g QD • Arm 4: Lovaza 4g →Epanova 2g QD Global trial – two countries	• Plasma concentration vs. time curve ($AUC_{0-\tau}$) [Time Frame: 0 to 24 hours (AUC0-24)]	• FPD: Q3 2014 • LPCD: Q2 2015 • Top-line results: Q4 2015

Faslodex (oestrogen receptor antagonist)

Breast cancer - metastatic

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **FALCON** **NCT01602380**	Postmenopausal women with HR+ locally advanced or metastatic breast cancer, who have not previously been treated with any hormonal therapy (1L)	N ~ 450	• Arm 1: *Faslodex* 500 mg monthly IM + an additional dose on d14 (+ oral placebo) • Arm 2: *Arimidex* 1 mg (+ placebo injection) Global trial – 21 countries	• PFS • OS is a secondary endpoint	• FPD: Q4 2012 • LPCD: Q3 2014 • Estimated top-line results: Q2 2016

Lynparza (PARP inhibitor)

Ovarian cancer and other solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SOLO-2** **Partnered** **NCT01874353**	PSR BRCAm ovarian cancer	N = 264	• Arm 1: *Lynparza* tablets 300 mg BiD as maintenance therapy until progression • Arm 2: placebo tablets BiD Global trial	• PFS • OS secondary endpoint	• FPD: Q3 2013 • LPCD: Q4 2014 • Estimated top-line results: H2 2016
Phase III **SOLO-1** **Partnered** **NCT01844986**	1L maintenance BRCAm ovarian cancer	N = 344	• Arm 1: *Lynparza* tablets 300 mg BiD maintenance therapy for 2 years or until disease progression • Arm 2: placebo Global trial	• PFS • OS secondary endpoint	• FPD: Q3 2013 • LPCD: Q1 2015 • Estimated top-line results: 2017
Phase III **SOLO-3** **NCT02282020**	PSR gBRCAm ovarian cancer 3L+ Line	N = 411	• Arm 1: *Lynparza* 300 mg BiD to progression • Arm 2: Physician's choice (single agent chemotherapy) Global trial	• PFS • OS secondary endpoint	• FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2018
Phase III **GOLD** **NCT01924533**	2L gastric cancer (all patients with a co-primary sub population)	N = 525	• Arm 1: paclitaxel + *Lynparza* until progression • Arm 2: paclitaxel + placebo *Lynparza* dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle Asian trial	• OS	• FPD: Q3 2013 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016

Lynparza (PARP inhibitor)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **OlympiAD** **NCT02000622**	BRCAm metastatic breast cancer	N = 310	• Arm 1: *Lynparza* 300 mg BiD, continuous to progression • Arm 2: Physician's choice: capecitabine 2500 mg/m2 x 14 q 21 vinorelbine 30 mg/m2 d 1, 8 q 21 eribulin 1.4 mg/m2 d 1, 8 q 21 to progression Global trial	• PFS • Secondary endpoint: OS	• FPD: Q2 2014 • LPCD: Q4 2015 • Estimated top-line results: H2 2016
Phase III **OlympiA** **Partnered** **NCT02032823**	BRCAm adjuvant breast cancer	N = 1,500	• Arm 1: *Lynparza* 300 mg BiD 12 month duration • Arm 2: Placebo 12 month duration Global trial partnership with BIG and NCI/NRG	• Invasive Disease Free Survival (IDFS) • Secondary endpoint: Distant Disease Free Survival and OS	• FPD: Q2 2014 • LPCD: 2018 • Estimated top-line results: 2020
Phase III **POLO** **NCT02184195**	Pancreas gBRCA	N = 145	• Arm 1: *Lynparza* tablets 300 mg twice daily as maintenance therapy until progression. • Arm 2: placebo tablets BiD Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2018
Phase II **NCT01972217**	Metastatic castration resistant prostate CA	N = 140	• Arm 1: *Lynparza* 300mg BiD + abiraterone • Arm 2: Placebo + abiraterone Global trial	• Radiologic PFS	• FPD: Q3 2014 • LPCD: Q3 2015 • Estimated top-line results: H2 2016

Tagrisso (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **AURA3** **NCT02151981**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 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	• PFS • OS is a secondary endpoint • PFS • OS and QoL as secondary endpoints	• FPD: Q3 2014 • Enrolment complete • Estimated primary completion: H2 2016
Phase III **FLAURA** **NCT02296125**	Advanced EGFRm NSCLC 1L	N = 530	• Arm 1: *Tagrisso* 80mg • Arm 2: erlotinib 150mg or *Iressa* 250 mg (dealers choice); 1:1 randomisation Global trial	• PFS • OS and QoL as secondary endpoints	• FPD: Q1 2015 • Estimated completion: 2017
Phase III **ADAURA** **NCT02511106**	Adjuvant EGFRm NSCLC	N = 700	• Arm 1: *Tagrisso* 80mg QD following complete tumour resection, with or without chemotherapy • Arm 2: Placebo Global trial	• DFS • DFS Rate, OS, OS Rate, QoL	• FPD: Q4 2015 • Estimated completion: 2022
Phase III **CAURAL** **NCT02454933**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 350	• Arm 1: *Tagrisso* (80mg QD) + MEDI4736 (10mg/kg q2w (IV) infusion) • Arm 2: *Tagrisso* (80mg QD) Global trial	• PFS • ORR, OS, QoL as secondary endpoints	• FPD: Q3 2015 • Enrolment hold implemented in Q4 2015 Will not restart
Phase II **AURA17** **NCT02442349**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 175	• *Tagrisso* 80 mg QD Asia Pacific Regional trial	• ORR • PFS and OS secondary endpoints	• FPD: Q3 2015 • Enrolment complete • Estimated primary completion: Q2 2016
Phase II **AURA2** **NCT02094261**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 175	• *Tagrisso* 80 mg QD Global trial	• ORR • PFS and OS secondary endpoints	• FPD: Q2 2014 • Enrolment complete (N = 210)
Phase I/II **AURA** **NCT01802632**	Advanced EGFRm NSCLC TKI failure + /- primary resistance mutation T790M	N ~ 500	• Dose escalation trial • Ph II Extension cohort (T790M only) *Tagrisso* 80mg QD Global trial	• Safety and tolerability • ORR • PFS and OS secondary endpoints	• FPD: Q1 2013 • Enrolment complete (N = 201 in extension portion)

Tagrisso (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib **TATTON** **NCT02143466**	Advanced EGFRm NSCLC TKI failure	N ~ 90	• Arm 1: *Tagrisso* + MEDI4736 • Arm 2: *Tagrisso* + AZD6094 • Arm 3: *Tagrisso* + selumetinib Global trial	• Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity	• FPD: Q3 2014 • Dose escalation completed • Dose expansions ongoing • Enrolment to durvalumab combo arms will not restart
Phase I **BLOOM** **NCT02228369**	EGFRm NSCLC, CNS disease	N = 47	• MAD • Expansion in LM patients at RP2D with AZD3759 • Expansion in LM patients at 160mg with *Tagrisso* including cohort with T790M NSCLC Global trial – four countries	• Safety and tolerability • Preliminary anti-tumour activity	• FPD: Q4 2014 • Estimated primary completion: H2 2016

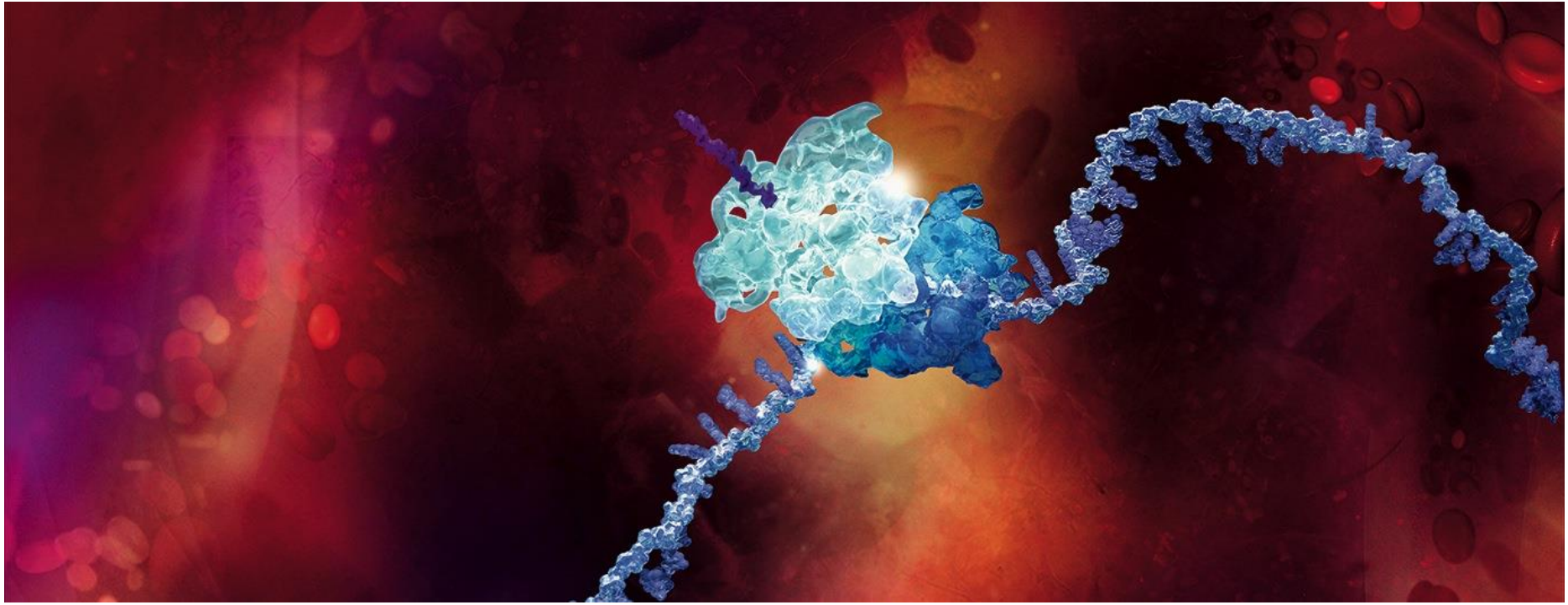
Nexium

Gastrointestinal

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02157376**	Seriously ill patients with at least one major risk factor for stress ulcer related bleeding (Stress Ulcer Prophylaxis)	N = 300	• Arm 1: *Nexium* 40 mg bid intermittent iv infusions given for max.14 days • Arm 2: Cimetidine 300 mg bolus iv infusion followed by continuous iv infusion 50mg/h for a maximum of 14 days China-only trial	• Clinically significant upper GI bleeding	• FPD: Q3 2014 • LPCD: Q1 2016 • Estimated completion: Q2 2016

AstraZeneca
What science can do

Late-stage development



Brodalumab (IL-17R mAb)

Psoriasis

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III AMAGINE-1 NCT01708590	Moderate to severe plaque psoriasis	N = 661	• Arm 1: 210 mg brodalumab SC • Arm 2: 140 mg brodalumab SC • Arm 3: Placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered
Phase III AMAGINE-2 NCT01708603	Moderate to severe plaque psoriasis	N = 1,800	• Arm 1: 210 mg brodalumab SC • Arm 2: 140 mg brodalumab SC • Arm 3: 45 or 90 mg ustekinumab SC • Arm 4: Placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered
Phase III AMAGINE-3 NCT01708629	Moderate to severe plaque psoriasis	N = 1,881	• Arm 1: 210 mg brodalumab SC • Arm 2: 140 mg brodalumab SC • Arm 3: 45 or 90 mg ustekinumab SC • Arm 4: Placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered

PT009 (ICS/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design (G = Glycopyrronium, F = Formoterol fumarate)	Endpoints	Status
Phase II **(BFF Dose-ranging)** **NCT02196077**	Moderate to severe COPD	N = 180	• BFF MDI 320/9.6 µg BiD • BFF MDI 160/9.6 µg BiD • BFF MDI 80/9.6 µg BiD • BD MDI 320 µg BiD • FF MDI 9.6 µg BiD Randomised, 4-period, 5-treatment incomplete-block and crossover Estimated time from FSFV to DBL is approximately 7 months. US	• Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV_1 $AUC_{0\text{-}12}$)	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q2 2015* * Clinically completed

PT010 (LABA/LAMA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **(Long-term BMD and Ocular Safety)** **NCT02536508**	Moderate to very severe COPD	N = 500	Treatments (52-week Treatment Period) • BGF MDI 320/14.4/9.6 µg • GFF MDI 14.4/9.6 µg • BFF MDI 320/9.6 µg • *Symbicort* TBH 400/12 µg Randomised, double-blind, chronic-dosing, multi-centre Estimated time from FSFV to DBL is approximately 21 months, Country – US	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	• FSD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: 2017
Phase III **(Exacerbation trial)** **ETHOS** **NCT02465567**	Moderate to very severe COPD	N = 8,000 (possible increase by 4,000 after blinded sample size re-assessment)	Treatments (1-year Treatment Period) • BGF MDI 320/14.4/9.6 µg BID • BGF MDI 160/14.4/9.6 µg BID • BFF MDI 320/9.6 µg BID • GFF MDL 14.4/9.6 µg BID Randomised, double-blind, multi-centre and parallel-group Estimated time from FSFV to DBL is approximately three years. Multi-country	• Rate of moderate or severe COPD exacerbations • Time to first moderate or severe COPD exacerbation	• FPD: Q3 2015 • LPCD: 2017 • Estimated top-line results: 2018
Phase III **(Lung function trial)** **KRONOS** **NCT02497001**	Moderate to very severe COPD	N = 1,800	Treatments (24-week Treatment Period) • BGF MDI 320/14.4/9.6 µg • GFF MDI 14.4/9.6 µg • BFF MDI 320/9.6 µg • *Symbicort* TBH 400/12 µg Randomised, double-blind, parallel-group, and chronic dosing and multi-centre Estimated time from FSFV to DBL is approximately two years. Multi-country	Co-Primary Endpoints (EU): • FEV1 area under curve from 0 to 4 hours (AUC0-4) over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs *Symbicort* TBH) • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs GFF MDI) • Transition dyspnea index (TDI) focal score over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs GFF MDI) Primary Endpoint (Japan): • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs BFF MDI, BGF MDI vs GFF MDI) Primary Endpoint (US): • FEV1 area under curve from 0 to 4 hours (AUC0-4) at Week 24 (BGF MDI vs BFF MDI • Change from baseline in morning pre-dose trough FEV1 at Week 24 (MDI vs GFF MDI)	• FPD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: 2017

PT010 (LABA/LAMA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II (BD Dose-ranging in Asthma) **NCT02105012**	Adult mild to moderate persistent asthma	N = 150	• Arm 1: BD MDI 320 µg BiD • Arm 2: BD MDI 160 µg BiD • Arm 3: BD MDI 80 µg BiD • Arm 4: BD MDI 40 µg BiD • Arm 5: Placebo MDI BiD Randomised, 4-period, 5-treatment incomplete-block and crossover Four week estimated time from FSFV to DBL is approximately 18 months. US	• Change from baseline in morning pre-dose trough forced expiratory volume in one second (FEV_1) • Mean evening pre-dose peak flow rate (PEFR) • Mean number of puffs of rescue Ventolin hydrofluoroalkane (HFA) • Asthma Control Questionnaire score	• FPD: Q2 2014 • LPCD: Q1 2015 • Top-line results: Q3 2015 ***** Clinically completed
Phase II **NCT02433834**	Intermittent asthma/mild to moderate persistent asthma	N = 200	Treatment (18-week Treatment Period) • GP MDI 28.8 µg BiD • GP MDI 14.4 µg BiD • GP MDI 7.2 µ BID • GP MDI 3.6 µ BID • Severent® Diskus® 50µ BID • Placebo MDI Randomised, double-blind, chronic-dosing, placebo controlled, incomplete block, cross over, multi-centre, dose-ranging trial Estimated time from FSFV to DBL is approximately 11 months. US	• Peak change from baseline in FEV_1 within 3 hours post-dosing on Day 15	• FPD: Q2 2015 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016

PT010 (LABA/LAMA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **(BGF PK trial)** **NCT02189304**	Healthy volunteers	N = 72	• Arm 1: BGF MDI 320/14.4/9.6 µg • Arm 2: BFF MDI (320/9.6 µg) • Arm 3: *Symbicort Turbuhaler* 400/12 µg Randomised, double-blind, single-dose, 3-period, 3-treatment and crossover Estimated time from FSFV to DBL is approximately three months. US	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q4 2014* * Clinically completed
Phase I **(BGF PK in Japanese Subjects)** **NCT02197975**	Japanese healthy volunteers	N = 20	Treatment (2-week Treatment Period) • Arm 1: BGF MDI 320/14.4/9.6 µg • Arm 2: BGF MDI 160/14.4/9.6 µg • Arm 3: Placebo MDI Randomised, double-blind, placebo-controlled, 2-period, ascending-dose and crossover Estimated time from FSFV to DBL is approximately eight weeks. Japan	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q4 2014* ***** Clinically completed
Phase I **(GFF PK in Japanese Subjects)** **NCT02196714**	Japanese healthy volunteers	N = 24	Treatment (4-day Treatment Period) • Arm 1: GFF MDI 14.4/9.6 µg • Arm 2: GFF MDI 28.8/9.6 µg • Arm 2: GP MDI 14.4 µg • Arm 2: GP MDI 28.8 µg Randomised, double-blind, single-dose, 4-Period, 4-treatment and crossover Estimated time from FSFV to DBL is approximately 13 weeks. Japan	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q4 2014* ***** Clinically completed

Benralizumab (IL-5R mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **CALIMA** **NCT01914757**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75yrs	N = 1,026 HD + ~200 MD	• Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 56-week trial Global trial – 11 countries	• Annual asthma exacerbation rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM	• FPD: Q4 2013 • Estimated completion: Q2 2016
Phase III **SIROCCO** **NCT01928771**	Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS Age 12 – 75 yrs	N = 1,134	• Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	• Annual asthma exacerbation rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM	• FPD: Q4 2013 • Estimated completion: Q2 2016
Phase III **ZONDA** **NCT02075255**	Severe asthma, inadequately controlled on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18 – 75 yrs	N = 210	• Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 46-week trial Global trial – 12 countries	• Reduction of oral corticosteroid dose	• FPD: Q3 2014 • Estimated completion: H2 2016

Benralizumab (IL-5R mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **BISE** **NCT02322775**	Asthmatic with FEV1 (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18 – 75 yrs	N = 200	• Arm 1: 30 mg Q4W SC • Arm 3: Placebo SC 12-week trial Global trial – six countries	• Pulmonary function (FEV1)	• FPD: Q1 2015 • Completion: Q1 2016
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75yrs	N = 2,550	• Arm 1: 30 mg Q4W SC • Arm 2: 30 mg Q8W SC* * Placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial	• Safety and tolerability	• FPD: Q4 2014 • Estimated completion: 2018
Phase III **GREGALE** **NCT02417961**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 18 – 75yrs	N = 120	• Arm 1: 30 mg Q4W SC 28-week (adults) Global trial – two countries	• Functionality, Reliability, and Performance of a Pre-filled Syringe With Benralizumab Administered at Home	• FPD: Q2 2015 • Estimated completion: H2 2016

Benralizumab (IL-5R mAb)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **TERRANOVA** **NCT02155660**	Moderate to very severe COPD with exacerbation history	N = 2,168	• Arm 1: 10 mg Q8W SC • Arm 2: 30 mg Q4W SC • Arm 3: 100 mg Q8W SC • Arm 4: Placebo SC 48-week trial Global trial – 23 countries	• Rate of COPD exacerbation	• FPD: Q3 2014 • Estimated completion: 2018
Phase III **GALATHEA** **NCT02138916**	Moderate to very severe COPD with exacerbation history	N = 1,626	• Arm 1: 30 mg Q4W SC • Arm 2: 100 mg Q8W SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	• Rate of COPD exacerbation	• FPD: Q3 2014 • Estimated completion: 2018

Tralokinumab (IL-13 mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **STRATOS 1** **NCT02161757**	Adults with uncontrolled severe asthma	N = 1,140	Cohort 1: • Arm 1: Tralokinumab dose regimen 1, SC • Arm 2: Placebo SC Cohort 2 : • Arm 1: Tralokinumab dose regimen 2, SC • Arm 2: Placebo SC 2:1 randomisation in both cohorts Global trial – 15 countries	Primary: • Asthma exacerbation rate reduction Key Secondary: • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12)	• FPD: Q3 2014 • LPCD: Q1 2016 • Estimated completion date: 2017 • Estimated top-line results: 2017
Phase III **STRATOS 2** **NCT02194699**	Adults with uncontrolled severe asthma	N = 770	• Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – 13 countries including Japan	Primary: • Asthma exacerbation rate reduction Key Secondary: • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12)	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated completion date: 2017 • Estimated top-line results: 2017
Phase III **TROPOS** **NCT02281357**	Adults with oral corticosteroid dependent asthma	N = 120	• Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – six countries	Primary: • % Change in OCS dose Key Secondary: • Proportion of subjects achieving final daily OCS dose ≤5 mg • Proportion of subjects achieving ≥50% reduction in OCS dose	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated completion date: 2017 • Estimated top-line results: 2017
Phase II **MESOS** **NCT02449473**	Adults with uncontrolled asthma	N = 80	• Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – three countries	Primary: • Change in number of airway submucosal eosinophils Secondary: • Change in blood eosinophils levels • Change in eosinophil cationic protein as a measure of activated eosinophils in blood and sputum	• FPD: Q3 2015 • LPCD: 2017 • Estimated completion date: 2017 • Estimated top-line results: 2017

Tralokinumab (IL-13 mAb)

Atopic dermatitis

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02347176**	Adults with atopic dermatitis	N = 306	• Arm 1: Tralokinumab dose 45mg SC • Arm 2: Tralokinumab dose 150mg SC • Arm 3: Tralokinumab dose 300mg SC • Arm 4: Placebo SC Global trial – six countries	• Change from baseline in SCORAD at week 12 Key Secondary Endpoints: • Percentage of subjects achieving IGA of 0 or 1 • Change from baseline in EASI • Percentage of subjects achieving EASI50 and SCORAD50 • Change from baseline in pruritis • Safety and tolerability • Tralokinumab serum concentration	• FPD: Q1 2015 • LPCD: Q4 2015 • Completion date: Q1 2016 • Top-line results: Q1 2016

Anifrolumab (type I IFN receptor mAb)

Systemic Lupus Erythematosus (SLE)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02446912**	Moderate to severe SLE TULIP SLE 1	N = 450	• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 150 mg IV MEDI-546 Q4W for 48 weeks • Arm 3: Placebo IV Q4W for 48 weeks	Response in SLE responder index at week 52	• FPD: Q3 2015 • LPCD: 2018 • Estimated top-line results: 2018
Phase III **NCT02446899**	Moderate to severe SLE TULIP SLE 2	N = 360	• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 150 mg IV MEDI-546 Q4W for 48 weeks	Response in SLE responder index at week 52	• FPD: Q3 2015 • LPCD: 2018 • Estimated top-line results: 2018
Phase II **NCT01438489**	Moderate to severe SLE patients	N = 307 (final)	• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 1000 mg IV MEDI-546 Q4W for 48 weeks • Arm 3: Placebo IV Q4W for 48 weeks	Response in SLE responder index at 6 months	• FPD: Q1 2012 • Top-line results: Q3 2014
Phase II **NCT01753193**	Moderate to severe SLE patients	N = 218	• Arm 1: MEDI-546, IV Q4W for 104 weeks	Open-label extension to evaluate long-term safety and tolerability	• FPD: Q1 2013 • Estimated top-line results: 2017
Phase II **NCT01559090**	Japanese SLE patients	N = 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	• Top-line results: Q1 2015
Phase I **NCT02601625**	Healthy volunteers	N= 30	• Arm 1: 300mg SC single dose • Arm 2: 300mg IV single dose • Arm 3: 600 mg SC single dose	Safety, tolerability, PK/PD	• FPD: Q4 2015 • LPCD: H1 2016 • Estimated top-line results: H2 2016

Anifrolumab (type I IFN receptor mAb)

Lupus Nephritis (LN)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02547922**	Active Proliferative LN (TULIP-LN1)	N = 150	• Arm 1: 900 mg IV Q4W for 12 weeks then 300 mg IV MEDI-546 Q4W for 36 weeks • Arm 2: 300 mg IV MEDI-546 Q4W for 48 weeks • Arm 3: Placebo IV Q4W for 48 weeks	Response in proteinuria at week 52	• FPD: Q4 2015 • LPCD: 2018 • Estimated top-line results: 2018

Acalabrutinib (ACP-196)

Rheumatoid Arthritis

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase II **ACE-RA-001** **NCT02387762**	Rheumatoid Arthritis	N=70	• Arm A: Acalabrutinib + methotrexate • Arm B: Methotrexate	Disease Activity Score 28-CRP at week 4	FPD: Q2 2015 Estimated Completion: 2017

Roxadustat (HIF-PHI)

Chronic Kidney Disease (CKD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III ANDES **NCT01750190**	Anaemia in CKD patients not receiving dialysis	N = 600	• Arm 1: Roxadustat • Arm 2: Placebo Global trial – 15 countries	Haemoglobin response	• FPD: Q4 2012 • Estimated completion: 2017 Sponsored by FibroGen
Phase III ALPS **NCT01887600**		N = 600	• Arm 1: Roxadustat • Arm 2: Placebo Global trial – 16 countries	Haemoglobin response	• FPD: Q2 2013 • Estimated completion: Q2 2016 Sponsored by Astellas
Phase III DOLOMITES **NCT02021318**		N = 570	• Arm 1: Roxadustat • Arm 2: Darbepoetin alfa Global trial –17 countries	Haemoglobin response	• FPD: Q1 2014 • Estimated completion: 2017 Sponsored by Astellas
Phase III OLYMPUS **NCT02174627**		N = 2,600	• Arm 1: Roxadustat • Arm 2: Placebo Global trial – 24 countries	MACE	• FPD: Q3 2014 • Estimated completion: 2017 Sponsored by AstraZeneca
Phase III ROCKIES **NCT02174731**	Anaemia in CKD in patients receiving dialysis	N = 1,425	• Arm 1: Roxadustat • Arm 2: Epoetin alfa Global trial – 18 countries	MACE	• FPD: Q3 2014 • Estimated completion: 2017 Sponsored by AstraZeneca
Phase III SIERRAS **NCT02273726**		N = 600	• Arm 1: Roxadustat • Arm 2: Epoetin alfa Global trial – one country	Haemoglobin response	• FPD: Q4 2014 • Estimated completion: 2017 Sponsored by FibroGen
Phase III PYRENEES **NCT02278341**		N = 750	• Arm 1: Roxadustat • Arm 2: Erythropoiesis Stimulating Agent • Arm 3: Darbepoetin alfa Global trial – 19 countries	Haemoglobin response	• FPD: Q4 2014 • Estimated completion: 2017 Sponsored by Astellas
Phase III HIMALAYAS **NCT02052310**	Anaemia in newly initiated dialysis patients	N = 1000	• Arm 1: Roxadustat • Arm 2: Epoetin alfa Global trial – 18 countries	Haemoglobin response	• FPD: Q4 2013 • Estimated completion: 2017 Sponsored by FibroGen

Cediranib (VEGF receptor inhibitor)

Ovarian cancer

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **ICON 6** **NCT00532194**	Patients with platinum-sensitive relapsed ovarian cancer	N = 486	• Arm 1: Placebo • Arm 2: concurrent cediranib • Arm 3: concurrent and maintenance cediranib	• PFS	• FPD: Q2 2007 • Completed

Durvalumab (MEDI4736; PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III ADJUVANT **NCT02273375** **Partnered with NCIC CTG**	Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK pos)	N = 1,100	• Arm 1: MEDI4736 mg/kg IV Q4W x 12 mos • Arm 2: Placebo Global trial	• DFS • OS	• FPD: Q1 2015 • Estimated completion: 2020
Phase III PACIFIC **NCT02125461**	Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	N = 702	• Arm 1: MEDI4736 IV Q2W • Arm 2: placebo Global trial	• PFS • OS	• FPD: Q2 2014 • LPCD: Q2 2016 • Estimated completion: 2017
Phase II/III Lung Master Protocol **NCT02154490** **Partnered with NCI, FNIH, and SWOG**	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	N = 140 ; 100 Durvalumab treated (4736 substudy only);	Umbrella trial with 5 arms based on biomarker expression • Substudy A: MEDI4736 (non-match for other biomarker driven substudies) IVQ2W single arm MEDI4736 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)	Arm 1 • ORR, PDL1 +	• FPD: Q2 2014 • Estimated completion: 2022
Phase II ATLANTIC **NCT02087423**	Stage IIIB-IV NSCLC patients PD-L1+ve patients 3L	N = 293	• Arm 1: MEDI4736 IV Q2W (EFGR/ALK WT) • Arm 2: MEDI4736 IV Q2W (EFGR/ALK M+) • Arm 3: MEDI4736 IV Q2W (EFGR/ALK WT) (90% PD-L1 - expression) Global trial – 18 countries	• Objective Response Rate • Secondary endpoints include duration of response, PFS and OS	• FPD: Q1 2014 • LPCD: Q2 2015 • First data: Q4 2015 • Estimated completion: H2 2016
Phase I/II Sequencing Study **NCT02179671**	Stage IIIB-IV NSCLC patients	N = 72	• Arm 1: Iressa initially then switch to MEDI4736 IVQ2W • Arm 2: AZD9291 then switch to MEDI4736 • Arm 3: selumetinib + docetaxel then switch to MEDI4736 • Arm 4: tremelimumab then switch to MEDI4736	• Complete Response Rate • ORR, Disease Control Rate	• FPD: Q3 2014 • LPCD: Q2 2016 • Estimated completion: H2 2016

Durvalumab (MEDI4736; PD-L1 mAb)

Squamous Cell Carcinoma of the Head & Neck (SCCHN) and other solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **HAWK** **NCT02207530**	SCCHN 2L PD-L1 positive	N = 112	• Single-arm: MEDI4736 IV Q2W	• ORR	• FPD: Q1 2015 • LPCD: Q2 2016 • Estimated completion: H2 2016
Phase I **NCT02301130** **Partnered with KHK**	Solid tumours	N = 108	• Dose Escalation: N=36, 3 cohorts receiving Treatment A (mogamulizumab + MEDI4736) and 3 cohorts receiving Treatment B (mogamulizumab + treme), in parallel • Dose Expansion: N=72, Multiple solid tumour types (NSCLC, Head and Neck, Pancreatic), Treatment A or B (12 subjects per treatment per disease type, in parallel)	• Safety and Tolerability • MTD • ORR, DoR, DCR, PFS, OS	• FPD: Q4 2014 • LPCD: Q4 2015 • Estimated completion: H2 2016
Phase I **NCT01938612**	Solid tumours (all-comers)	N = 176	• Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W • Dose Expansion: Biliary Tract Cancer, Esophageal Cancer and SCCNH, Q2, and Q4 schedule • Dose Expansion of combination: Biliary Tract Cancer and Esophageal Cancer, MEDI4736 Q4W 20 mg/kg + tremelimumab Q4W 1 mg/kg Trial conducted in Japan	• Safety • Optimal biologic dose	• FPD: Q3 2013 • LPCD: Q4 2014 • Estimated completion: 2017

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **ARCTIC** **NCT02352948**	Stage IIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/ALK mutation	N = 480	• Arm 1: MEDI4736 + tremelimumab (PD-L1 –ve patients) • Arm 2: Standard of Care • Arm 3: tremelimumab (PD-L1 –ve patients) • Arm 4: MEDI4736 (PD-L1 –ve patients)	• PFS • OS • Safety	Combination therapy • FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion: 2017 (PFS, OS)
Phase III **MYSTIC** **NCT02453282**	NSCLC 1L	N = 780	• Arm 1: MEDI4736 • Arm 2: MEDI4736 + tremelimumab • Arm 3: Standard of care	• PFS • OS • Safety	• FPD: Q3 2015 • LPCD: Q2 2016 • Estimated completion: 2017
Phase III **NEPTUNE**	NSCLC 1L	N = 800	• Arm 1: MEDI4736 + tremelimumab • Arm 2: Standard of care	• OS • Safety	• FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018
Phase III **EAGLE**	SCCHN 2L	N = 720	• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736 • Arm 3: Standard of care	• OS • PFS • Safety	• FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018
Phase III **KESTREL** **NCT02551159**	SCCHN 1L	N = 628	• Arm 1: MEDI4736 • Arm 2: MEDI4736 + tremelimumab • Arm 3: Standard of care	• PFS • OS • Safety	• FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018
Phase III **DANUBE** **NCT02516241**	Bladder 1L cis eligible and ineligible	N = 525	• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736 • Arm 3: Standard of care	• PFS • OS • Safety	• FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **CONDOR** **NCT02319044**	SCCHN 2L PD-L1 negative	N = 240	• Arm 1: MEDI4736 • Arm 2: Tremelimumab • Arm 3: Tremelimumab + MEDI4736	• ORR • Safety	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion: 2017
Phase II **ALPS** **NCT02558894**	Metastatic Pancreatic Ductal Carcinoma 2L	N = 130	• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736	• Safety • Objective Response rate • Pharmacokinetics	• FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018
Phase II **NCT02527434**	Urothelial Bladder Cancer Triple-negative Breast Cancer Pancreatic Ductal-Adneocarcinoma	N=76	• Arm 1 Tremelimumab in Urothelial Bladder Cancer • Arm 2 TremelimumabTriple-negative Breast Cancer • Arm 3 Tremelimumab Pancreatic Ductal-Adneocarcinoma	Safety Objective Response rate Duration of Response	• FPD: Q1 2016 • Estimated completion: 2018
Phase I combination in advanced solid tumours in Japanese patients **NCT02141347**	Solid tumours (treme Phase I)	N = 22	• Tremelimumab + MEDI4736 • Dose Escalation trial • Tremelimumab Q4W/Q12W 3-10mg/kg • Tremelimumab Q4W/Q12W X mg/kg + MEDI4736 Q4W X mg/kg	• Safety • Optimal biologic dose	• FPD: Q2 2014 • LPCD: Q2 2015 • Estimated completion: H2 2016
Phase 1 Combination in Advanced Solid Tumours **NCT02658214**	Solid tumours	N = 80	• Arm 1 Ovarian cancer and SCCHN: Durvalumab + tremelimumab + paclitaxel + carboplatin IV infusion • Arm 2 SCLC. Durvalumab + tremelimumab + carboplatin + etoposide • Arm 3 TNBC: Durvalumab + tremelimumab + gemcitabine + carboplatin • Arm 4 TNBC: Durvalumab + tremelimumab + nab-paclitaxel (paclitaxel-albumin) + carboplatin • Arm 5 Gastric/gastro-esophageal junction (GEJ): Durvalumab + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid)	• Safety	• FPD: Q1 2016 • LPCD: 2018 • Estimated Completion: 2018

Selumetinib (AZD6244) (MEK-inhibitor)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SELECT-1** **NCT01933932**	2L KRASm positive NSCLC	N = 500	• Arm 1: Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • Arm 2: Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global trial – 26 countries	• PFS • OS is a secondary endpoint	• FPD: Q4 2013 • LPCD: Q1 2016 • Estimated top-line results: H2 2016
Phase III **ASTRA** **NCT01843062**	Differentiated thyroid cancer	N = 304	• Arm 1: Selumetinib 75mg BiD 5 weeks duration + 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).	• Complete remission (CR) rate at 18 months post-RAI • Clinical remission rate at 18 m post RAI (per SoC)	• FPD: Q3 2013 • LPCD: Q1 2016 • Estimated top-line results: 2017
Phase II **SELECT-2** **NCT01750281**	2L KRASm negative NSCLC	N = 225	• Arm 1: Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • Arm 2: Selumetinib 75mg BiD + docetaxel 60 mg/m2 IV on day 1 of each 21 day cycle • Arm 3: Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global trial – seven countries	• PFS • OS is a secondary endpoint	• FPD: Q1 2013 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016

Phase II
 	
NCT01362803 (current Ph I) – partnered (NCI)
	Pediatric Neurofibromatosis type 1	N = minimum of 50 symptomatic pts	• 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
					• FPD: Q3 2015
					• LPCD: H2 2016
					• Estimated top-line results: 2017

Phase I **NCT02586987**	Advanced solid tumours	N = 40	• Dose escalation trial: Starting dose Selumetinib 50mg bd 1 week on/1 week off - MEDI4736 20mg/kg Q4 – after 7 days of selumetinib dosing. • Note: No escalation in MEDI4736 dose; Selumetinib escalation with 25 mg bd increment / dose cohort	• Safety and tolerability • PK of Selumetinib and MEDI4736 and preliminary anti-tumour activity	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated top-line results: 2017

Acalabrutinib (ACP-196)

Haematological malignancies

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase III **ACE-CL-006** **ELEVATE-RR** NCT02477696	Relapsed/refractory chronic lymphocytic leukaemia (CLL), high risk	N = 500	• Arm A: Acalabrutinib • Arm B: Ibrutinib	PFS Secondary endpoints: comparison of incidence of infections, RTs and atrial fibrillation, OS	• FPD: Q4 2015 • Estimated Completion: 2018
Phase III **ACE-CL-007** **ELEVATE-TN** NCT02475681	Previously untreated CLL	N = 510	• Arm A: Chlorambucil + obinutuzumab • Arm B: Acalabrutinib + obinutuzumab • Arm C: Acalabrutinib	PFS (Arm A vs Arm B) Secondary endpoints: IRC assessed ORR, TTNT, OS (arm A vs Arm B vs. Arm C)	• FPD: Q3 2015 • Estimated Completion: 2019
Phase II **ACE-CL-208** NCT02717611	Relapsed/refractory CLL, intolerant to ibrutinib	N = 80	Acalabrutinib monotherapy	ORR at 36 cycles	• FPD: Q1 2016 • Estimated Completion: 2020
Phase II **15-H-0016** NCT02337829	Relapsed/refractory and treatment naive/del17p CLL/small lymphocytic lymphoma(SLL)	N = 48	Acalabrutinib monoherapy • Arm A: Lymph node biopsy • Arm B: Bone marrow biopsy	Safety	• FPD: Q1 2015 • Estimated Completion: 2017
Phase II **ACE-LY-004** NCT02213926	Relapsed/refractory Mantle Cell Lymphoma	N = 124	Acalabrutinib monotherapy	ORR	• FPD: Q1 2015 • LPCD: Q1 2016 • Enrolment complete • Estimated Completion: H2 2016
Phase I/II **ACE-CL-001** NCT02029443	CLL/SLL/Richter's transformation	N = 286	Acalabrutinib monotherapy Dose escalation and expansion	Safety, PK, PD Secondary endpoints: ORR, DOR, and PFS	• FPD: Q1 2014 • Estimated completion: 2019
Phase I/II **ACE-LY-001** NCT02328014	B-Cell Malignancies	N = 126	• Dose escalation and expansion study of the combination of acalabrutinib and ACP-319 (Pi3K inhibitor)	Safety ORR	• FPD: Q1 2015 • Estimated completion: 2017
Phase I/II **ACE-LY-005** NCT02362035	Hematological Malignancies	N = 324	• Acalabrutinib + pemrolizumab	Safety	• FPD: Q1 2015 • Estimated completion: 2018

Acalabrutinib (ACP-196)

Haematological malignancies

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase I/II **ACE-WM-001** NCT02180724	Waldenstrom Microglobulinemia	N = 106	Acalabrutinib monotherapy	ORR	• FPD: Q3 2014 • LPCD: Q4 2015 • Enrolment Complete • Estimated completion: H2 2016
Phase Ib **ACE-LY-002** NCT02112526	Relapsed/refractory de novo ABC Diffuse large B-cell lymphoma	N = 21	Acalabrutinib monotherapy	Safety	• FPD: Q3 2014 • LPCD: Q2 2016 • Enrolment Complete • Estimated completion: 2017
Phase Ib **ACE-LY-106** NCT02717624	Mantle Cell Lymphoma	N = 48	Acalabrutinib in combination with bendamustin and rituximab • Arm A: Treatment naive • Arm B: Relapsed/refractory	Safety	• FPD estimated: Q2 2016 • Estimated completion: 2021
Phase Ib **ACE-MY-001** NCT02211014	Relapsed/refractory Multiple Myeloma	N = 40	• Arm A: Acalabrutinib • Arm B: Acalabrutinib + dexamethasone	Safety	• FPD: Q1 2015 • Estimated completion: 2017
Phase I **ACE-LY-003** NCT02180711	Relapsed/refractory Follicular Lymphoma	N = 36	• Arm A: Acalabrutinib • Arm B: Acalabrutinib + rituximab	Safety	• FPD: Q1 2015 • Estimated completion: 2018
Phase I **ACE-CL-002** NCT02157324	Relapsed/refractory chronic lymphocytic leukaemia (CLL)	N = 12	Acalabrutinib in combination with ACP-319 Dose escalation	Safety, PK, PD	• FPD: Q3 2014 • LPCD: Q3 2015 • Enrolment complete • Estimated completion: 2018
Phase I **ACE-CL-003** NCT02296918	CLL/small lymphocytic lymphoma/prolymphocytic leukaemia	N = 45	Acalabrutinib + obinutuzumab • Arm A: Relapsed/refractory • Arm B: Treatment naive	Safety ORR	• FPD: Q1 2015 • LPCD: Q1 2016 • Enrolment complete • Estimated completion: 2018

Acalabrutinib (ACP-196)

Solid Tumours

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase II **ACE-ST-006** NCT02454179	≥ 2L advanced or metastatic squamous cell carcinoma of the head and neck	N = 74	• Arm A: Pembrolizumab • Arm B: Acalabrutinib + pembrolizumab	ORR	• FPD: Q2 2015 • Estimated completion: 2017
Phase II **ACE-ST-007** NCT02448303	≥ 2L advanced or metastatic NSCLC	N = 74	• Arm A: Pembrolizumab • Arm B: Acalabrutinib + pembrolizumab	ORR	• FPD: Q2 2015 • Estimated completion: 2017
Phase II **ACE-ST-208** NCT02537444	Recurrent ovarian cancer	N = 76	• Arm A: Acalabrutinib • Arm B: Acalabrutinib+ pembrolizumab	ORR	• FPD: Q4 2015 • Estimated completion: 2017
Phase II **ACE-ST-004** NCT02570711	1L metastatic pancreatic cancer	N = 120	• Arm A: Acalabrutinib + Nab-Paclitaxel+ Gemcitabine • Arm B: Nab-Paclitaxel + Gemcitabine	ORR	• FPD: Q4 2015 • Estimated completion: 2017
Phase II **ACE-ST-003** NCT02362048	≥ 2L advanced or metastatic pancreatic cancer	N = 77	• Arm A: Acalabrutinib • Arm B: Acalabrutinib + pembrolizumab	Safety	• FPD: Q2 2015 • LPCD: Q1 2016 • Enrolment complete • Estimated completion: 2017
Phase II **ACE-ST-005** NCT02351739	Platinum-resistant urothelial bladder cancer	N = 78	• Arm A: Pembrolizumab • Arm B: Acalabrutinib + pembrolizumab	ORR	• FPD: Q2 2015 • LPCD: Q1 2016 • Enrolment complete • Estimated Completion 2017
Phase Ib/II **ACE-ST-209** NCT02586857	≥ 2L glioblastoma multiforme	N = 72	Acalabrutinib monotherapy • Arm A: 200 mg BID • Arm B: 400 mg QD	Safety ORR	• FPD: Q1 2016 • Estimated completion: 2018

Moxetumomab pasudotox (CD22 mAb)

Haematological malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PLAIT** **NCT01829711**	Adults with relapsed or refractory hairy cell leukemia (HCL)	N = 77	• Multicentre, single-arm, open-label trial3	• Primary: 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	• FPD: Q2 2013 • LPCD: H2 2016 • Estimated top-line results: 2017
Phase I **NCT00586924**	Adults with relapsed refractory HCL	N = 49	• Open Label dose escalation trial	• MTD and efficacy	• FPD: Q2 2007 • LPCD: Q1 2014 • Top-line results : Q2 2015 (completed)

CAZ AVI (BLI/cephalosporin SBI)

Serious infections

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **RECLAIM-1** **NCT01499290**	Hospitalised patients with complicated intra-abdominal infections	N = 493	• Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global study – 20 countries	• Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable)	• FPD: Q1 2012 • LPCD: Q2 2014 • Top-line results: Q3 2014
Phase III **RECLAIM-2** **NCT01500239**	Hospitalised patients with complicated intra-abdominal infections	N = 577	• Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global study – 21 countries	• Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable)	• FPD: Q2 2012 • LPCD: Q2 2014 • Top-line results: Q3 2014
Phase III **RECAPTURE-1** **NCT01595438**	Hospitalised adults with complicated urinary tract Infections	N = 563	• Arm 1: CAZ AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global trial – 26 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FPD: Q4 2012 • LPCD: Q3 2014 • Top-line results: Q3 2015
Phase III **RECAPTURE-2** **NCT01599806**	Hospitalised patients with complicated urinary tract infections	N = 583	• Arm 1: CAZ AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global trial – 25 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FPD: Q4 2012 • LPCD: Q3 2014 • Top-line results: Q3 2015
Phase III **REPRISE** **NCT01644643**	Patients with complicated urinary tract infections and complicated intra-abdominal infections	N = 345	• Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV • Arm 2: Best available therapy Global trial – 30 countries	• Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set	• FPD: Q1 2013 • LPCD: Q3 2014 • Top-line results: Q2 2015

CAZ AVI (BLI/cephalosporin SBI)

Serious infections

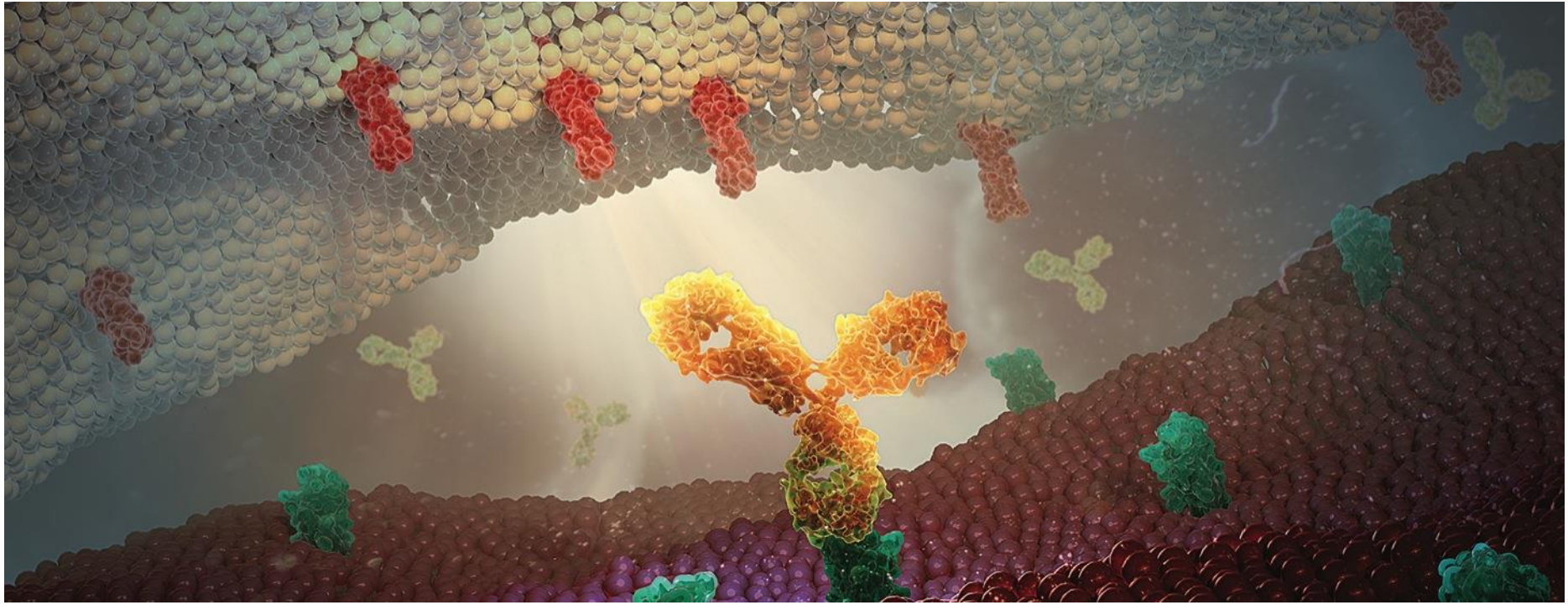
Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **RECLAIM-3** **NCT01726023**	Hospitalised patients with complicated intra-abdominal infections	N = 486	• Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Asia-focused trial – three countries (China, Vietnam & Korea)	• Clinical Cure at the TOC visit in the MITT analysis set	• FPD: Q1 2013 • LPCD: Q1 2015 • Top-line results: Q3 2015
Phase III **REPROVE** **NCT01808092**	Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP)	N = 1,000	• Arm 1: CAZ AVI 2000/500mg IV • Arm 2: Meropenem IV Global trial – 24 countries	• Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses)	• FPD: Q2 2013 • LPCD: Q4 2015 • Estimated top-line results: H2 2016

AZD3293 (BACE inhibitor)

Alzheimer's disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **AMARANTH** **NCT02245737**	Early Alzheimer's disease patients	N = 2,202	• Arm 1: AZD3293 20 mg once daily • Arm 2: AZD3293 50 mg once daily • Arm 3: placebo once daily 24-month treatment duration Global trial – 14 countries	• Changes in cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales • Changes in composite scales (CDR-SB) • Changes in biomarkers and imaging assays • Safety and tolerability	• FPD: Q4 2014 • LPCD: 2017 • Estimated top-line results: 2019

Early development - IMED



Verinurad (RDEA3170 - SURI, URAT1 inhibitor)

Gout and hyperuricemia development programme

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01927198**	Monotherapy study in subjects with gout	N = 160	• Arm A: Placebo • Arm B: Verinurad 5 mg QD • Arm C: Verinurad10 mg QD • Arm D: Verinurad12.5 mg QD	• Efficacy and Safety at Week 24	• FPD: Q3 2013 • LPCD: Q4 2013 • Study complete
Phase II **NCT02078219**	Monotherapy study in Japanese patients with gout or asymptomatic hyperuricemia	N = 200	• Arm A: Placebo • Arm B: Verinurad 5 mg QD • Arm C: Verinurad 10 mg QD • Arm D: Verinurad 12.5 mg QD • Arm E: Open-label Allopurinol 100mg BID	• To compare the efficacy of verinurad monotherapy at Week 16 with placebo and allopurinol	• FPD: Q1 2014 • LPCD: Q3 2014 • Study complete
Phase II **NCT02246673**	Combination therapy study with febuxostat in subjects with gout	N = 60	• Arm A: Verinurad 2.5 mg QD • Arm B: Verinurad 5.0 mg QD • Arm C: Verinurad 10 mg QD • Arm D: Verinurad 15 mg QD • Arm E: Sequential doses of verinurad 10, 15 and 20 mg QD in combination with 40 mg QD febuxostat *Arms A-D include combination with 40 mg QD febuxostat for 7 days followed by combination with 80 mg QD febuxostat for 7 days	• To assess the PK and PD profiles of verinurad administered with febuxostat	• FPD: Q4 2014 • LPCD: Q2 2015 • Estimated completion: Q2 2016
Phase II **NCT02317861**	Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients	N = 92	• Arm A: Verinurad 2.5 mg QD + 10mg or 20mg QD febuxostat • Arm B: Verinurad 5.0 mg QD + 10mg or 20mg QD febuxostat • Arm C: Verinurad 5.0 mg QD + 20mg or 40mg QD febuxostat • Arm D: Verinurad 10 mg QD + 20mg or 40mg QD febuxostat • Arm E: Benzbromarone 50 mg QD	• To assess the PD, PK and safety profiles of verinurad administered with febuxostat	• FPD: Q4 2014 • LPCD: Q2 2015 • Estimated completion: Q2 2016

Verinurad (RDEA3170 - SURI, URAT1 inhibitor)

Gout and hyperuricemia

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02498652**	Combination therapy study with allopurinol in subjects with gout	N = 40	• Arm A: Placebo • Arm B: Verinurad 2.5 mg QD • Arm C: Verinurad 5.0 mg QD • Arm D: Verinurad 7.5 mg QD • Arm E: Verinurad 10 mg QD • Arm F: Verinurad 15 mg QD • Arm G: Verinurad 20 mg QD *All arms include combination with 300 mg QD allopurinol. Placebo group also includes combination with 300 mg BID allopurinol or 600 mg QD allopurinol	• To assess the PK and PD profiles of verinurad administered with allopurinol	• FPD: Q3 2015 • LPCD: Q4 2015 • Estimated completion: H2 2016
Phase I **NCT02608710**	Pharmacokinetic and Pharmacodynamic study in healthy adult male subjects	N = 40	Part 1: Single doses of verinurad at 4.5 mg, 6.0 mg, or 12 mg Part 2: Multiple doses of verinurad at 12 mg QD for 7 days Part 3: Food effect study with single doses of verinurad at 6.0 mg	• To assess the PK, PD and food effect profiles of verinurad	• FPD: Q4 2015 • LPCD: Q4 2015 • Estimated completion: H2 2016

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD7594 (inhaled SGRM)

Asthma/COPD

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02479412**	Patients with mild to moderate asthma	N = 48	A randomised, double blind, multiple dosing (14 days), placebo-controlled, incomplete block crossover, multi centre study to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma	• Forced expiratory volume in one second (FEV1)	• FPD: Q3 2015 • Completed
Phase I **NCT01636024**	Healthy subjects	N = 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 Volunteers - Suspension inhaled via Spira nebuliser Trial conducted in the UK	• Safety and tolerability	• FPD: Q4 2012 • Completed
Phase I **NCT02648438**	Healthy subjects	N = 24	An open label, partially randomised, four-period study 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	• FPD: Q1 2016 • Estimated completion: Q2 2016
Phase I **NCT02645253**	Healthy subjects	N = 36	A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre study 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	• FPD: Q1 2016 • Estimated completion: Q2 2016

AZD7624 (p38 inhibitor)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT02238483**	COPD	N = 212	• Arm 1: AZD7624, 1.0mg • Arm 2: placebo • Inhaled (nebulised) administration Trial conducted in US, EU, South Africa & South America	• Effect on rate of exacerbations and lung function compared to placebo	• FPD: Q4 2014 • LPCD: Q1 2016 • Estimated top-line results: Q2 2016
Phase Ib **LPS** **NCT01937338**	Healthy subjects	N = 30	• 2-way cross-over RCT • Single administration of 1200µg of AZD7624 or placebo at 0.5 hours prior to lipopolysaccharide (LPS) challenge. • Inhaled (nebulised) administration Trial conducted in the UK	• Effect on neutrophils in induced sputum after oral inhalation of LPS, compared to placebo	• FSD: Q4 2013 • Completed
Phase I **NCT01754844**	Healthy subjects	N = 48	SAD • Five different dose levels investigated vs placebo • Inhaled (nebulised) administration Trial conducted in the UK	• Safety and tolerability following inhaled administration with single ascending dose	• FSD: Q1 2013 • Completed
Phase I **NCT01817855**	Healthy subjects and COPD	N = 47	MAD • Different dose levels investigated vs placebo in healthy volunteers and patients with COPD • Inhaled (nebulised) administration Trial conducted in the UK	• Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses	• FSD: Q3 2013 • Completed

AZD7986 (DPP1 inhibitor)

Chronic Obstructive Pulmonary Disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02303574**	Healthy subjects	N = 152	Part 1 (SAD) • Five 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 AZD7986	• FPD: Q4 2014 • Completed
			Part 2 (MAD) • Three different dose levels investigated vs placebo in healthy volunteers • oral administration Trial conducted in the UK	• Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses • NE activity	• FPD: Q1 2015 • LPCD: Q1 2016 • Estimated completion: Q2 2016

AZD8871 (MABA2)

Asthma/Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **CTs.gov Identifier:** **In progress**	Part 1: Mild Asthmatic Part 2: Moderate to severe COPD	N (Part 1) = 16 N (Part 2) = 40	Part 1 SAD trial with 6 planned dose levels - 50 µg, 100 µg, 300 µg, 600 µg, 1200 µg, and up to 1800 µg Part 2 Comprises 5 treatment periods of 36 hours each separated by a washout period of at least 7 to 14 days (one exception per patient of up to 28 days would be acceptable). • AZD8871 dose A once daily (double-blind) • AZD8871 dose B once daily (double-blind) • Indacaterol 150 µg once daily (open-label) • Tiotropium 18 µg once daily (open-label) • Placebo (double-blind) Global trial – one country	Part 1 Endpoints: • To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to mild persistent asthmatic male subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in mild persistent asthmatic male subjects Part 2 Endpoints: • To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to moderate to severe COPD subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in moderate to severe COPD subjects	Part 1 • FPD: Q4 2015 • LPCD: Q1 2016 Part 2 • FPD: Q2 2016 • LPCD: H2 2016 • Estimated completion date: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9412 (Inhaled IFN-beta)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **INEXAS** **NCT02491684**	Asthma	N = 220	• Arm 1: 24 µg (metered dose) AZD9412 once daily for 14 days • Arm 2: Placebo once daily for 14 days • Inhaled nebulised administration Conducted in Argentina, Australia, Colombia, France, Spain, South Korea and UK.	• Proportion of patients with a severe asthma exacerbation during 14 days of treatment	• FPD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: 2017

AZD9567 (oSGRM)

Rheumatoid Arthritis

Trial phase	Patient population	Number of subjects	Design	Endpoints	Status
Phase I **NCT02512575**	Healthy Volunteers	N = 72	SAD trial with 6 dose levels - 2 µg, 10 µg, 40 µg, 100 µg, 200 µg, and up to 400 µg Global trial – one country	• A Phase I, Randomised, Single-Blind, Placebo-Controlled trial To Assess The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of Single Ascending Oral Doses Of AZD9567 In Healthy subjects	Part • FPD: Q4 2015 • LPCD: Q2 2016 • Estimated top-line results: H2 2016

AZD4076 (anti-miR 103/107)

Non-alcoholic Steatohepatitis (NASH)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02612662**	Healthy subjects	N = up to 48	SAD trial • Up to 6 different dose levels investigated vs placebo • Sub cutaneous injection	• Safety and tolerability • PK parameters	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated completion: 2017

AZD0156 (ATM)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02588105**	Solid tumours	N = 130	• Arm 1: AZD0156 + olaparib • Arm 2: AZD0156 + irinotecan Trial conducted in North America, Europe and South Korea	• Safety, tolerability, pharmacokinetics and efficacy	• FPD: Q4 2015 • Estimated completion: 2018

AZD1775 (WEE-1)

Solid tumours, ovarian cancer and Non-Small Cell Lung Cancer

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01357161** Partnered	p53 mutant PSR ovarian cancer	N = 120	• Arm 1: Carbo/paclitaxel + AZD1775 225mg • Arm 2: Carbo/paclitaxel + placebo Global trial 10 countries	• PFS • Secondary endpoint: OS	• FPD: Q4 2012 • LPCD: H2 2016 • Estimated completion: H2 2016 (OS Follow up) • Note: Data collection for primary outcome measure completed Q4 2014
Phase II **NCT02272790**	PR ovarian cancer	N = 70	• Arm C: Carboplatin + AZD1775 • Arm D**:** Pegylated liposomal doxorubicin (PLD) + AZD1775 Global trial	• **Overall Response Rate (ORR)** • Secondaries : Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated completion: H2 2016
Phase I/II **NCT02482311**	Advanced solid tumours	N = 152	• 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 small cell lung cancer (SCLC) Conducted in US, Canada	• Safety and tolerability • Secondary endpoints: Overall response rate, Disease Control Rate, Duration or Response, PFS	• FPD: Q3 2015 • LPCD: 2017 • Estimated completion: 2017
Phase I **NCT02610075**	Advanced solid tumours	N = 18	• Monotherapy Dose escalation trial to determine MTD Conducted in US	• Safety and tolerability	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated completion: 2017
Phase I **NCT02511795**	Advanced solid tumours	N = 36	• Dose escalation trial (AZD1775 + olaparib) Conducted in US	• Safety and tolerability	• FPD: Q3 2015 • LPCD: Q1 2016 • Estimated completion: Q2 2016
Phase I **NCT02617277**	Advanced solid tumours	N = 18	• Dose escalation trial (AZD1775 + MEDI4736) Conducted in US	• Safety and tolerability	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated completion: 2017
Phase I **NCT02341456**	Advanced solid tumours	N = 36	• Dose escalation trial (AZD1775 + carboplatin + paclitaxel: AZD1775 + Carbo: AZD1775 + PLD) Conducted in Australia, Japan and Republic of Korea	• Safety and tolerability	• FPD: Q1 2015 • LPCD: H2 2016 • Estimated completion: 2017

AZD2014 (TORC 1/2)

Breast and squamous Non-Small Cell Lung Cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **STORK** **NCT02403895**	Relapsed or refractory squamous NSCLC (at least one prior therapy)	N = 40	Open label Single arm – patient are divided in two groups Group A - intensive PK Group B – sparse PK Dose: intermittent AZD2014 50mg BID (3 days on + 4 days off) + weekly paclitaxel 80 mg/m^2 Multicentre: EU and US trial sites	• Primary: ORR according to RECIST 1.1 by Investigator assessment • Secondary: Number of patients experiencing adverse events (AE) and Serious Adverse Events (SAEs) including chemistry, haematology, vital signs and ECG variables	• FPD: Q2 2015 • LPCD: H2 2016 • Estimated completion: H2 2016
Phase II **MANTA** **NCT02216786** Partnered	2L ER+ metastatic breast cancer	N = 316	• Arm 1: *Faslodex* • Arm 2: *Faslodex* + AZD2014 50mg BD continuous dosing • Arm 3: *Faslodex* + AZD2014 125mg BD two days on, 5 off • Arm 4: *Faslodex* + everolimus The trial will be conducted in Europe	• PFS • Secondary endpoint: OS	• FPD: Q2 2014 • LPCD: Q2 2016 • Estimated completion: 2017
Phase I **NCT02398747**	Japanese Patients with Advanced Solid Malignancies	N = 18	Open label Monotherapy and combination with paclitaxel cohorts	• Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel • PK	• FPD: Q2 2015 • LPCD: 2017 • Estimated completion: 2017
Phase I/II **PASTOR** **NCT02599714**	Postmenopausal women with locally advanced/metastatic estrogen receptor positive (ER+) breast cancer.	N = 225	**Part A** - Phase I triplet dose finding to determine the maximum tolerated dose (MTD) of the triplet (AZD2014 + palbociclib + fulvestrant) **Part B** - Phase I single arm expansions (AZD2014 + palbociclib + *Faslodex*) **Part C** - randomised, double-blind, placebo-controlled, stratified, parallel group extension at RP2D for triplet combination (AZD2014 + palbociclib + *Faslodex* vs matching AZD2014 placebo + palbociclib + *Faslodex*)	**Primary** • **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**: Best Objective Response Rate (BOR) and Objective Response Rate (ORR)	• FPD: Q1 2016 • LPCD: 2018 • Estimated completion: 2019

AZD2811 (AURN)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02579226**	Solid tumours	N = 72	• Arm 1: AZD2811 dose escalation • Arm 2: AZD2811 dose expansion AZD2811 + irinotecan Trial conducted in North America	• Safety and tolerability • Pharmacokinetics and efficacy	• FPD: Q4 2015 • Estimated completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD3759 (EGFRm BBB)

Non-Small Cell Lung Cancer (NSCLC) with lung and/or brain metastases

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **BLOOM** **NCT02228369**	EGFRm+ NSCLC	N = 47	• MAD • Expansion in LM patients at RP2D with AZD3759 • Expansion in 12 LM patients at 160mg with AZD9291 including cohort with T790M NSCLC Trial conducted four countries	• Safety and tolerability • Preliminary anti-tumour activity	• FPD: Q4 2014 • Estimated completion: LM expansion at RP2D H2 2016 • AZD9291 LM expansion • Estimated primary completion: H2 2016

AZD4547 (FGFR)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II/III Lung Master Protocol **NCT02154490** Partnered with NCI and SWOG	Stage IIIB-IV NSCLC patients Biomarker-targeted 2L therapy	N = 318 (AZD4547 arm only)	6-Arm trial based on biomarker expression • Arm 1: MEDI4736 Unmatched biomarker • Arm 2: AZD4547 (FGFR inhibitor) • Arm 3: CDK4/6 inhibitor • Arm 4: PI3K Inhibitor • Arm 5: HGFR Inhibitor • Arm 6: CTLA-4 + PD-1 inhibitor	• PFS • OS	• FPD: Q4 2014 • Estimated completion: 2022 (final data collection for primary outcome measure Ph III)

Phase II
GLOW
 	
NCT01202591
	Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy	N = 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)
				• **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
					• LPCD: Q2 2014
					• Completed: Q1 2015

Phase II **SHINE** **NCT01457846**	Advanced gastro-oesophageal cancer	N = 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)	• PFS • Key Secondary: OS/Tumour size	• Recruitment closed after interim analysis: Q2 2013 • Completed: Q1 2015
Phase I **NCT01213160**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	N = 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. 8 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	• Completed: Q2 2013

AZD4547 (FGFR)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT00979134**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	N = 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 patiens with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A	• **Part A:** MTD and Recommended dose for Parts B and C • **Part B and C:** Safety and tolerability, PK and preliminary anti-tumour activity	• Completed: Q1 2014
Phase I **BISCAY** **NCT02546661**	2nd+ line Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy	N = 140	• Multi-drug biomarker-directed trial • Monotherapy: AZD4547, durvalumab • Combination therapy: AZD4547 + durvalumab, *Lynparza* + durvalumab, AZD1775 + durvalumab	• Safety and tolerability of the combinations • PK and preliminary anti-tumour activity	• FPD: Q2 2016 • Estimated completion: 2018

AZD5363 (AKT)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIb **NCT01625286**	ER+ breast cancer receiving 1st treatment with paclitaxel in the advanced setting	N = 100	• Arm 1: AZD5363 + paclitaxel • Arm 2: AZD5363 placebo + paclitaxel Two strata (50 pts per stratum): PIK3CA mutation positive vs Mutation not detected	• PFS • Response rate (ORR) & OS are secondary endpoints	• FPD: Q1 2014 • Estimated primary completion: H2 2016 • Estimated completion: 2017
Phase I **NCT01226316**	Breast and gynaecological cancers with PIK pathway mutation	N = 20 per arm (Parts C & D) N = 12-24 per arm (Parts E & F)	Monotherapy AZD5363 480mg BD 4 days on 3 days off • Part C arm 1: Breast with PIK3CA mutation • Part C arm 2: Gynaecological with PIK3CA mutation • Part D arm 1: Breast with AKT-1 mutation • Part D arm 2: Gynaecological with AKT-1 mutation • Part D arm 3: Other tumours with AKT-1 mutation 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 • Response Rate (ORR) • Clinical Benefit Rate at 24 wks (CBR24) [Parts E & F only]	• FPD: Q3 2013 • Estimated primary completion: H2 17 • Part C Arms 1 & 2 completed • Part D Arms 1 & 3 completed • Part D Arm 2 ongoing • Part E Arms 1 & 2 ongoing [CBR24 data for 12 patients per arm estimated Q2/Q3 2017] • Part F Arms 1 & 2 ongoing

Savolitinib (AZD6094) (MET)

Papillary renal cell and other cancers

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02127710**	Papillary renal cell cancer	N = 90	• Single arm trial: AZD6094 600mg QD Conducted in UK, Spain, US, Canada	• Overall Response Rate	• FPD: Q2 2014 • LPCD: H2 2016 • Estimated completion: 2017
Phase I **NCT01773018** Partnered	Advanced cancer (all-comers)	N = 50	• Dose escalation trial Conducted in Australia	• Safety and tolerability	• FPD: Q1 2012 • LPCD: Q3 2015 • Estimated completion: Q2 2016
Phase I **NCT01985555** Partnered	Advanced cancer (all comers)	N = 70	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPD: Q2 2013 • LPCD: H2 2016 • Estimated completion: 2017
Phase I **NCT02252913** Partnered	Advanced gastric cancer (all-comers)	N = 25	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPD: Q4 2014 • LPCD: Q4 2015 • Estimated completion: Q2 2016
Phase I **NCT02374645**	Non-Small Cell Lung Cancer	N ~ 32	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPD: Q2 2015 • LPCD: H2 2016 • Estimated completion: 2017

AZD6738 (ATR)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02264678**	Solid tumours	N = 160	• Arm 1: AZD6738 + carboplatin • Arm 2: AZD6738 dose escalation AZD6738 + olaparib • Arm 3: AZD6738 + durvalumab Trial conducted in North America, Europe and South Korea	• Safety and tolerability • Pharmacokinetics and efficacy	• FPD: Q4 2014 • Estimated completion: 2017

AZD8186 (PI3Kb/d)

Solid tumours

Trial phase	Patient population	Number of 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.	N = 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 actetate (with prednisone) in PTEN deficient mCRPC patients. Initial dose/ schedule confirmation phase using AZD8186 mononotherapy 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 1/2 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 antitumour activity (POM) • Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of antitumour 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 antitumour activity of AZD8186 in combination with AZD2014.	• FPD: Q2 2013 • Estimated completion: 2018

AZD9150 (STAT3)

Solid and Haematological Cancers

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Squamous Cell Carcinoma of the Head & Neck (SCCHN)	N = 147	Dose Escalation advanced solid and haematological cancers • Arm A1: AZD9150/MEDI4736 • Arm A2 : AZD5069/MEDI4736 Dose Expansion 2L SCCHN: • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/MEDI4736 • Arm B4: AZD5069/MEDI4736	• Safety/Efficacy trial	• FPD: Q3 2015 • LPCD: 2017 • Estimated completion: 2019

* clinicaltrials.gov being updated

AZD9496 (SERD)

Breast cancer

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02248090**	ER+ Breast Cancer	N ~ 150	• 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	• FPD: Q4 2014 • Estimated completion: 2017

ATM AVI

Infections

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT01689207**	Healthy volunteers		• Randomised, double-blind, 3-part trial in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination	• Safety/tolerability • Pharmacokinetics (secondary)	• FPD Q4 2012 • LPCD: Q4 2014 • Completion: Q4 2015
		N = 12	• Part A: single 1 hour IV infusions		
		N = 56	• Part B: single IV infusion on Days 1 and 11 and multiple (every 6 hr) IV infusions on Days 2-10. Various dose regimens of Aztreonam-Avibactam are being tested.		
		N = 24	• Part C: multiple (every 6 hr) IV infusions Days 1-10 in healthy young and elderly volunteers		
		(Total dosed = 94) *(Total enrolled = 124)*	Single centre in UK		

AZD3241 (MPO)

Multiple System Atrophy (MSA)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01527695**	Parkinson's disease patients	N = 24	• Arm 1: AZD3241 600 mg BID for 8 weeks • Arm 2: Placeb0 Randomisation 3:1 active to placebo. Three sites in Sweden and Finland	• Microglia activation represented by [11C]PBR28 binding Secondary endpoints: • PD symptoms measured by UPDRS • Plasma MPO activity	• Trial completed
Phase II **NCT01603069**	Parkinson's disease patients	N = 51	• Arm 1: AZD3241 300 mg BID for 12 weeks • Arm 2: AZD3241 600 mg BID for 12 weeks • Arm 3: Placebo Randomisation 1:1:1 across arms 13 sites in US	• AEs, labs, vital signs, ECGs Secondary endpoints: • PD symptoms measured by UPDRS • Plasma MPO activity	• Trial completed
Phase II **NCT02388295**	MSA	N = 54	• Arm 1: AZD3241 300 mg BID for 12 weeks • Arm 2: AZD3241 600 mg BID for 12 weeks • Arm 3: Placebo Randomisation 1:1:1 across arms Eight sites in US Nine sites in Europe	• Microglia activation represented by [11C]PBR28 binding • AEs, labs, vital signs, ECGs Secondary endpoints: • MSA symptoms measured by UMSARS and MSA QoL • Plasma MPO activity	• FPD: Q2 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2016
Phase I **NCT00729443**	Healthy subjects	N = 46	• Active ArmS: SAD • Comparator Arm: placebo One site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Trial completed
Phase I **NCT01457807**	Healthy subjects	N = 18	• Active ArmS: MAD • Comparator Arm: placebo One site in UK	• AEs, labs, vital signs, ECGs • PK	• Trial completed
Phase I **NCT00914303**	Healthy subjects	N = 59	• Active ArmS: MAD • Comparator Arm: placebo One site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Trial completed

AZD8108 (NMDA)

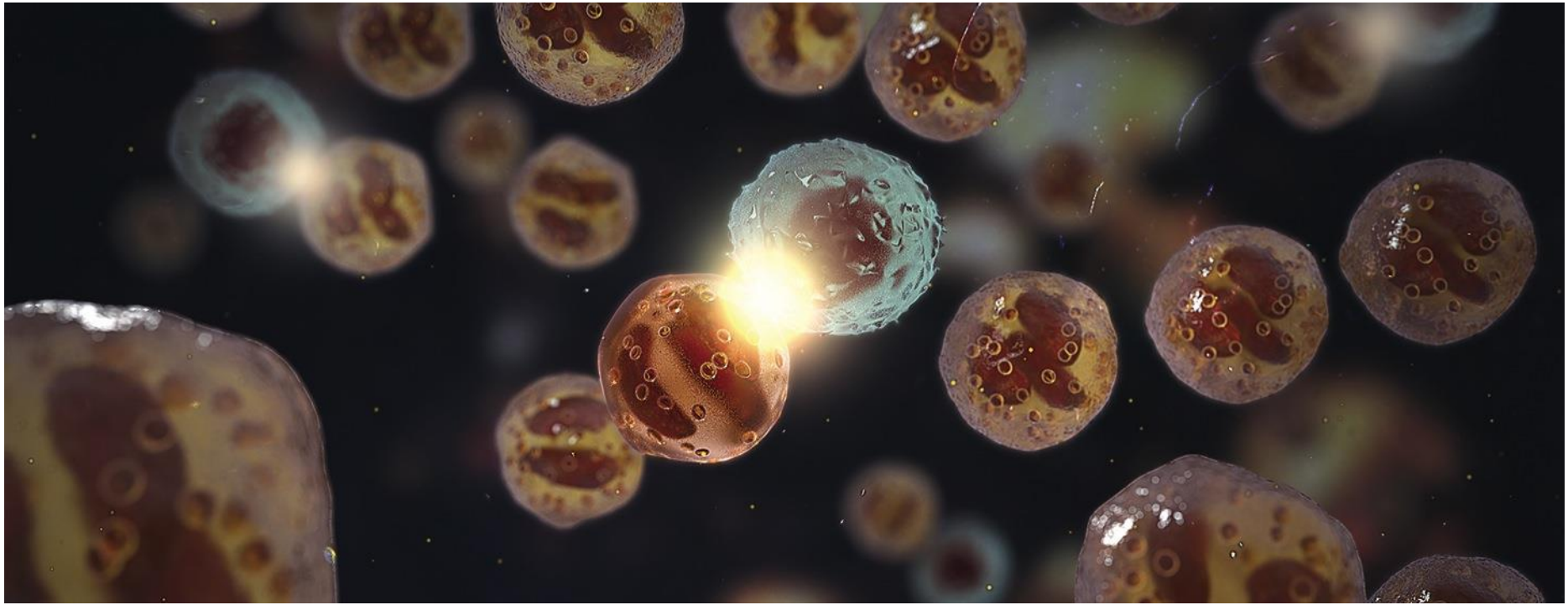
Phase I clinical development programme

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02248818**	Healthy volunteers	N = 40	• Randomised, double-blind, placebo-controlled • Part 1 SAD 3 dosage-level cohorts • Part 2 MAD 2 dosage-level cohorts US only trial – one site	• Safety and tolerability Additional endpoints: • Pharmacokinetics • Pharmacodynamics	• FPD: Q4 2014 • LPCD: Q3 2015 • Estimated top-line results: Q2 2016

MedImmune

MedImmune
A member of the AstraZeneca Group

Early development - MedImmune



Mavrilimumab (GMCSF mAb)

Rheumatoid arthritis (RA)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **EARTH Explorer 2** **NCT01715896**	RA patients who have failed 1 or 2 anti-TNF for efficacy, intolerance or safety, OR Inadequate response to DMARDs	N = 138	• Arm 1: Mavrilimumab SC • Arm 2: Golimumab Global trial (ex-US) on MTX background; 17 countries	• ACR 20/50/70 at wk 24 • DAS28 remission • Function (HAQ-DI)	• FPD: Q1 2013 • LPCD: Q3 2014 • Top-line results: Q4 2014 • Completed
Phase I **NCT02213315**	Healthy Japanese subjects	N = 24	• Arm 1: Mavrilimumab medium dose SC • Arm 2: Mavrilimumab high dose SC • Arm 3: Placebo SC UK trial; Japanese subjects	• Pharmacokinetic profile • Safety and tolerability	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q4 2014 • Completed

MEDI5872 (B7RP-1 mAb)

Systemic Lupus Erythematosus (SLE)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT02334306** Partnered	Primary Sjögren's syndrome	N = 42	• Arm 1: MEDI5872 210 mg 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	• FPD: Q3 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase I **NCT01683695** Partnered	SLE and lupus related inflammatory arthritis	N = 40	Dose escalation trial: • Arm 1: MEDI5872 SC • Arm 2: placebo SC Global trial – eight countries	• Safety and tolerability • Lupus Arthritis Response Rate	• FPD: Q2 2012 • LPCD: Q4 2015 • Estimated top-line results: Q2 2016

MEDI7836 (IL-13 mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02388347**	Healthy volunteers	N = 32	• Arm 1: 30 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 2: 105 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 3: 300 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 4: 600 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose	• Safety and tolerability	• FPD: Q1 2015 • LPCD: Q3 2015 • Top-line results: Q1 2016

MEDI9929 (TSLP mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **PATHWAY** **NCT02054130** Partnered	Adult subjects with inadequately controlled, severe asthma	N = 552	• Arm 1: Placebo • Arm 2: Low dose MEDI9929 70mg SC • Arm 3: Medium dose MEDI9929 210mg SC • Arm 4: High dose MEDI9929 280mg SC	• Reduction in the annualised asthma exacerbation rate (AER) measured at Week 52	• FPD: Q2 2014 • LPCD: Q4 2015 • Estimated top-line results: H2 2016
Phase II **NCT02525094** Partnered	Adult subjects with moderate-to-severe atopic dermatitis	N = 100	• Arm 1: Placebo • Arm 2: Dose of MEDI9929 SC	• 50% reduction from baseline in the Eczema Area and Severity Index measured at Week 12	• FPD: Q2 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2016

MEDI9314 (IL-4Ra mAb)

Atopic Dermatitis

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT 02669667**	Healthy volunteers	N = 44	• Arm 1: 45mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose • Arm 2: 150 mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose • Arm 3: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose • Arm 4: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose • Arm 5: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose (Japanese subjects) • Arm 6: 450 mg MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose	• Safety and tolerability • Pharmacokinetic profile • Incident of ADA antibodies to MEDI9314 • Change relative to baseline of IL-4-induced STAT6 phosphorylation	• FPD: Q1 2016 • LPCD: H2 2016 • Estimated top-line results: H2 2016

Other biologics

Inflammation

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01714726** Partnered	Anti-IL-23 mAb MEDI2070	Patients with moderate to severe Crohn's disease	N = 121	• Arm 1: MEDI2070, 700mg IV (210mg SC for OLE) • Arm 2: Placebo, IV Global trial – nine countries	• CDAI response at Week 8 defined by either a CDAI score of < 150 or a CDAI reduction from baseline of at least 100 points	• FPD: Q1 2013 • LPCD: Q1 2014 • Top-line results: Q2 2014
Phase II **NCT02574637** Partnered		Patients with moderate to severe Crohn's disease	N = 342	• Arm 1: MEDI2070 High dose • Arm 2: MEDI2070 High-Med dose • Arm 3: MEDI2070 Low-Med dose • Arm 4: MEDI2070 Low dose • Arm 5: Placebo	• The primary endpoint is Crohn's Disease Activity Index (CDAI) clinical remission at Week 8, defined by a CDAI score of <150.	• FPD: Q1 2016 • LPCD: 2019 • Estimated top-line results: 2018

Other biologics

Autoimmunity

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase II/III **NCT02200770**	Inebilizumab Anti-CD19 mAb (MEDI-551)	Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders (NMO/NMOSD)	N = 212 (estimated)	• Arm 1: MEDI-551 500mg IV • Arm 2: placebo IV • Open-label extension 300mg Global trial 26 Countries	• **Primary:** Time to attack • **Secondary:** Attack rate, safety and tolerability	• FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2018
Phase I **NCT02151110**	Anti-CD40L (MEDI4920)	Healthy adults	N = 56	• Arm 1: 3 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • Arm 2: 10 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • Arm 3: 30 mg MEDI4920 (n = 3) or placebo (n = 2) as a single IV dose • Arm 4: 100 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 5: 300 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 6: 1000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 7: 2000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose	• Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response	• FPD: Q2 2014 • LPCD: Q4 2015 • Top-line results: Q1 2016

Biologics

Cardiovascular & metabolic disease

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT02601560**	rhLCAT MEDI6012	Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL)	N = 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	• FPD: Q4 2015 • LPCD: Q1 2016 • Top-line results: Q1 2016
Phase I **NCT01554800**	rhLCAT MEDI6012	Adults with stable coronary artery disease and low HDL	N = 16	SAD IV	• Safety • Changes in total HDL • Change in Cholestryl Ester	• Completed by Alphacore
Phase I **NCT01958645**	rh-Factor II MEDI8111	Healthy male subjects	N = 12	SAD IV administration UK trial site	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination	• FPD: Q4 2013 • LPCD: Q4 2014 • Completed: Q4 2014
Phase I **NCT02394314**	GLP-1-Glu MEDI0382	Healthy male subjects	N = 64	SAD SC administration Germany	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination	• FPD: Q1 2015 • LPCD: Q4 2015 • Top-line results: Q4 2015 • Complete
Phase I/IIa **NCT02524782**	MEDI4166	Adults with type-2 diabetes	N =124	SAD/MAD SC administration	Part A (Ph1) • Safety/tolerability following SC dosing of 4166 Part B (Ph2a) • Characterise the effect of multiple-ascending SC doses on glucose metabolism following an MMTT as measured by glucose AUC • Characterise the effect of multiple-ascending SC doses on LDL-c levels	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2016

Durvalumab (MEDI4736; PD-L1 mAb)

Immuno-oncology

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I/II **NCT01693562**	PD-L1 (durvalumab, MEDI4736)	Solid tumours	N = 1,038	• 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 antitumour activity	• FPD: Q3 2012 • LPCD: Q4 2015 • Estimated top-line results: 2017
Phase I **NCT02117219**	PD-L1, azacitidine (MEDI4736, Vidaza)	Myelodysplastic syndrome	N = 41	Dose-escalation and dose-expansion trial • Arm 1: MEDI4736 IV Global trial – four countries	• Safety and tolerability of monotherapy and combination • Secondary endpoints include duration of response, PFS and OS	• FPD: Q2 2014 • LPCD: Q2 2015 • Estimated top-line results: 2017

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02340975**	Gastric or GEJ adenocarcinoma	N = 174	• Arm A: durvalumab + tremelimumab 2L • Arm B: durvalumab 2L • Arm C: tremelimumab 2L • Arm D: durvalumab + tremelimumab 3L US and ROW trial centres	• Safety & tolerability, ORR, PFS • Secondary endpoints include DCR, OS, DoR, PD-L1 Expression	• FPD: Q2 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase Ib/II **NCT02519348**	Hepatocellular Carcinoma	N = 129	• Arm A: durvalumab + tremelimumab • Arm B: durvalumab 2L • Arm C: tremelimumab 2L	• Safety & tolerability, ORR, PFS • Secondary endpoints include DCR, OS, DoR, PD-L1 Expression	• FPD: Q4 2015 • LPCD: 2018 • Estimated top-line results: 2018
Phase Ib **NCT02000947**	Non-small cell lung cancer (Immunotx naïve and Immunotx pretreated patient cohorts)	N = 388	• Dose Escalation: minimum 5 cohorts exploring various treme Q4W and MEDI4736 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	• Safety • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK and immunogenicity	• FPD: Q4 2013 • LPCD: H2 2016 • Estimated top-line results: 2018
Phase I **NCT02261220**	Solid tumours (Basket trial)	N = 393	• Dose Exploration: *2* cohorts exploring various Q4W treme and MEDI4736 dose combinations and 2 cohorts exploring various Q2W treme and MEDI4736 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	• Safety & tolerability • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK/PD and immunogenicity	• FPD: Q4 2014 • LPCD: H2 2016 • Estimated top-line results: 2018
Phase I **NCT02262741**	Squamous Cell Carcinoma of the Head & Neck	N = 69	• 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	• Safety & tolerability • Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers	• FPD: Q4 2014 • LPCD: Q1 2016 • Estimated top-line results: 2017

Durvalumab (MEDI4736; PD-L1 mAb) + *Iressa* (gefitinib)

Non-small cell lung cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02088112**	NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)	N = 36	Escalation phase Standard 3+3 design with 28 days DLT period • *Iressa* (QD) + MEDI4736 IV Expansion phase • *Iressa* (QD) + MEDI4736 IV recommended dose Global trial – three countries	• 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	• FPD: Q2 2014 • LPCD: Q2 2015 • Estimated top-line results: 2017

Durvalumab (MEDI4736; PD-L1 mAb) + Tafinlar (dabrafenib)/ Mekinist (trametinib)

Melanoma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I/II **NCT02027961**	Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&C)	N = 69	Dose Escalation: • Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ MEDI4736 IV • Cohort B trametinib 2mg QD/ MEDI4736 IV • Cohort C trametinib 2mg QD/ MEDI4736 IV Dose Expansion: • Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global trial – two countries	• 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	• FPD: Q1 2014 • LPCD: Q2 2015 • Estimated top-line results: 2017

MEDI0680 (PD-1 mAb) + durvalumab (MEDI4736)

Advanced malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02118337**	Advanced malignancies	N = 150	Dose-escalation phase • MEDI4736 IV + MEDI0680 IV Dose-expansion phase at selected dose from dose-escalation phase • MEDI4736 IV + MEDI0680 IV recommended dose	• 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	• FPD: Q2 2014 • LPCD: Q3 2015 • Estimated top-line results: 2018

MEDI0562 (OX40 mAb)
MEDI0562 (OX40 mAb) + durvalumab (MEDI4736; PD-L1) or tremelimumab (CTLA-4 mAb)

Advanced malignancies

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02318394**	OX40 (MEDI0562)	Advanced malignancies	N = 196	Dose-escalation phase • MEDI0562 IV Dose-expansion phase • MEDI0562 IV recommended dose	• Safety • Determination of MTD • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, biomarker activity, and immunogenicity	• FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase I **NCT02705482**	OX40 (MEDI0562) + durvalumab (MEDI4736; PD-L1)	Advanced malignancies	N = 324	• ARM A: MEDI0562 IV + durvalumab IV • ARM B: MEDI0562 IV + tremelimumab IV	• Safety • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, and immunogenicity	• FPD: Q2 2016 • LPCD: 2018

MEDI6383 (OX40 agonist) + durvalumab (MEDI4736; PD-L1 mAb)

Advanced malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02221960**	Advanced malignancies	N = 212	Dose-escalation phase • MEDI6383 IV • MEDI6383 IV + MEDI4736 IV Dose-expansion phase • MEDI6383 IV recommended dose • MEDI6383 IV + MEDI4736 IV recommended dose US-only trial	• Safety • Determination of MTD • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, Biomarker activity, and immunogenicity	• FPD: Q2 2015 • LPCD: H2 2016 • Estimated top-line results: 2018

Inebilizumab (MEDI-551, CD19 mAb)

Haematological malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01453205**	Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma	N = 170	• Arm 1: MEDI-551 dose level 1 and ICE/DHAP • Arm 2: MEDI-551 dose level 2 and ICE/DHAP • Arm 2: Rituxan + ICE/DHAP Open-label trial	• ORR, including Complete Response (CR) or Partial Response (PR)	• FPD: Q1 2012 • LPCD: Q1 2016 • Estimated top-line results: 2018
Phase I **NCT01957579**	Adults with relapsed or refractory B-cell malignancies	N = 18	• Dose-escalation trial IV Conducted in Japan	• MTD and efficacy	• FPD: Q2 11 • LPCD: Q3 2015 • Top-line results: Q3 2015

MEDI1873 (GITR agonist)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02583165**	Adult subjects with select advanced solid tumours	N = 42	Dose-escalation phase • MEDI1873 IV US trial centres	• Safety • Determination of MTD • Secondary endpoints include PK/PD, preliminary antitumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated top-line results: 2019

MEDI4276 (HER2 ADC mAb)

Advanced malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02576548**	Advanced HER2+ metastatic breast and gastric cancer	Dose escalation N = 21-36 Dose expansion N = 80	• First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	• Primary: Safety • Secondary endpoints include anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size	• FPD: Q4 2015 • LPCD: 2017 • Estimated top-line results: 2018

MEDI9197 (TLR7/8 agonist)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02556463**	Advanced solid tumour malignancies readily accessible for injection	N = 45	Dose-escalation phase • MEDI9197 IT US trial centres- Ex US under evaluation	• Safety • Determination of MTD • Secondary endpoints include: – Objective response, disease control and duration of response . – Intra-tumoural and systemic PK and PD profiles/relationships	• FPD: Q4 2015 • LPCD: 2017 • Estimated top-line results: 2018

MEDI9447 (CD73 mAb) + durvalumab (MEDI4736; PD-L1 mAb)

Advanced malignancies

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02503774**	Advanced malignancies	N = 132	Dose-escalation phase • MEDI9447 IV • MEDI9447 IV + durvalumab IV Dose—expansion phase • MEDI9447 IV recommended dose • MEDI9447 IV recommended dose + Durvalumab IV US and Australian trial centres	• Safety • Determination of MTD • Secondary endpoints include PK/PD, preliminary anti-tumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity	• FPD: Q3 2015 • LPCD: 2018 • Estimated top-line results: 2018

Other biologics

Solid tumours

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I/II **NCT01446159**	Anti-IGF ligand mAb (MEDI-573)	Patients with HR+ HER2-, 1L, metastatic breast cancer taking aromatase inhibitors	N = 176	• Arm 1: MEDI-573 IV and Aromatase Inhibitor • Arm 2: Aromatase Inhibitor alone Open label trial	• PFS • Retrospective evaluation of predictive biomarker +ve subgroups	• FPD: Q2 2012 • LPCD: Q2 2013 • Estimated top-line results: 2017
Phase I **NCT01248949**	Anti-Ang2 mAb (MEDI3617)	Solid tumours and ovarian cancer	N = 25	• MEDI3617 Dose Escalation	• Safety and tolerability	• FPD: Q4 10 • LPCD: Q2 2015 • Top-line results: Q3 2015 (completed)
			N = 16	• MEDI3617 + bevacizumab dose escalation, administered Q3W, IV (US only)		
			N = 13	• MEDI3617 + paclitaxel dose escalation, IV (US only)		
			N = 7	• MEDI3617 + carboplatin + paclitaxel dose escalation, IV (US only)		
			N = 27	• MEDI3617 + bevacizumab dose escalation, administered Q2W , IV (US only)		
			N = 17	• MEDI3617 single-agent expansion in ovarian cancer patients, IV (US only)		
			N = 15	• MEDI3617 + bevacizumab dose expansion in recurrent malignant glioma • US-only trial centres		

Other biologics

Solid tumours

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT01284231** **Partnered**	Anti-CEA BiTE mAb (MEDI-565)	Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments. Refractory pancreatic, colorectal and gastro-esophageal cancers	N = 51 max N = 60 max, 20 in each cohort	• Dose-escalation (3+3), IV • Dose expansion trial, IV	• MTD and safety profile	• FPD: Q1 11 • LPCD Q3 2014 • Top-line results: Q1 2015 completed
Phase I **NCT01577745**	Anti-DLL4 mAb (MEDI0639)	Adults with advanced solid tumours including SCLC	N = up to 28	• Dose-escalation trial (3+3); IV	• MTD and safety profile	• FPD: Q2 2012 • LPCD: Q2 2015 • Estimated top-line results: H2 2016

Vaccine biologics

Influenza vaccines

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02269488**	MEDI3250 *FluMist*	Children 2 to 6 years of age	N = 100	• Open-label • Route of administration: intranasal	• Safety and tolerability	• FPD: Q4 2014 • LPCD: Q1 2015 • Top-line results: Q1 2015 (completed)
Phase III **NCT02269475**	MEDI3250 *FluMist Quadrivalent*	Children 7 through 18 years of age	N = 1,008	• Randomised, double-blind placebo-controlled • Route of administration: intranasal	• Efficacy assessed by incidence of laboratory-confirmed influenza-like illness in the two treatment arms • Safety and tolerability	• FPD: Q4 2014 • LPCD: Q4 2014 • Top-line results: Q2 2015 (completed)

Other biologics

Infections

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase II **EudraCT 2014-001097-34**	Anti-Staph AT (MEDI4893)	Intubated ICU	N = 462	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and Safety	• FPD: Q4 2014 • LPCD: 2017 • Estimated top-line results: 2017
Phase IIb **NCT02508194**	RSV sF+GLA-SE (MEDI7510)	Adults ≥ 60 yrs	N = 1,901	• Randomised, Double-blind trial • Route of administration: intramuscular	• Efficacy	• FPD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: 2017
Phase Ib **NCT02289820**			N = 264	• Double blind, randomised, placebo and active controlled cohort escalation trial • Route of administration: intramuscular	• Safety and tolerability • Humoral and cell-mediated immune responses	• FPD: Q1 2015 • LPCD: Q1 2015 • Top-line results: Q1 2016
Phase Ia **NCT02115815**			N = 144	• Double blind, randomised, placebo and active controlled cohort escalation trial • Route of administration: intramuscular	• Safety and tolerability • Humoral and cell-mediated immune responses	• FPD: Q2 2014 • LPCD: Q2 2014 • Top-line results: Q2 2015 • Complete
Phase Ib/IIa **NCT02290340**	Anti-RSV mAb-YTE (MEDI8897)	32-35 WK GA infants	N = 89	• Randomised, Double-blind, Placebo-controlled, Dose-escalation trial • Route of administration: IM	• Evaluate Safety, Tolerability, PK and ADA	• FPD: Q1 2015 • LPCD: Q3 2015 • Estimated top-line results: H2 2016
Phase Ia **NCT02114268**		Healthy adults	N = 136	• Randomised, Double-blind, Placebo-controlled, Dose-escalation trial • Route of administration: IV and IM	• Evaluate Safety, Tolerability, PK and ADA	• FPD: Q2 2014 • LPCD: Q2 2014 • Top-line results: Q2 2015 (completed)
Phase Ib/IIa **NCT02603952**	Anti-influenza A mAb (MEDI8852)	Adults	N = 160	• Randomised, Partial Double-blind, Single Dose, Active-controlled, Dose Ranging trial • Route of administration: intravenous	• Evaluate Safety in Adults with Acute, Uncomplicated Influenza	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated top-line results: Q2 2016
Phase I **NCT02350751**		Healthy adults	N = 40	• Double-blind, Single-dose, Placebo-controlled, Dose-escalation trial • Route of administration: intravenous	• Evaluate the Safety and Pharmacokinetics	• FPD: Q1 2015 • LPCD: Q1 2015 • Top-line results: Q2 2015 • Complete
Phase I **NCT02255760**	Anti-Pseudomonas A mAb (MEDI3902)	Healthy adults	N = 56	• Randomised, Double-blind, Placebo-Controlled, Dose-Escalation trial • Route of administration: intravenous	• Evaluate the Safety, Tolerability, and Pharmacokinetics	• FPD: Q3 2014 • LPCD: Q1 2015 • Top-line results: Q2 2015 • Complete
Phase II **NCT02696902**		Intubated ICU	N = 429	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous/	• Efficacy and Safety	• FPD: H1 2016 • LPCD: 2018 • Estimated top-line results: 2018

MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02036645**	Alzheimer's disease & healthy elderly	N = 121	• SAD & MAD • Up to 10 iv cohorts are planned vs placebo • 2 SC cohorts are planned vs placebo US only	• Safety, tolerability	• FPD: Q2 2014 • LPCD: H2 2016 • Estimated top-line results: H2 2016

Clinical trials appendix
Q1 2016 update

AstraZeneca
What science can do