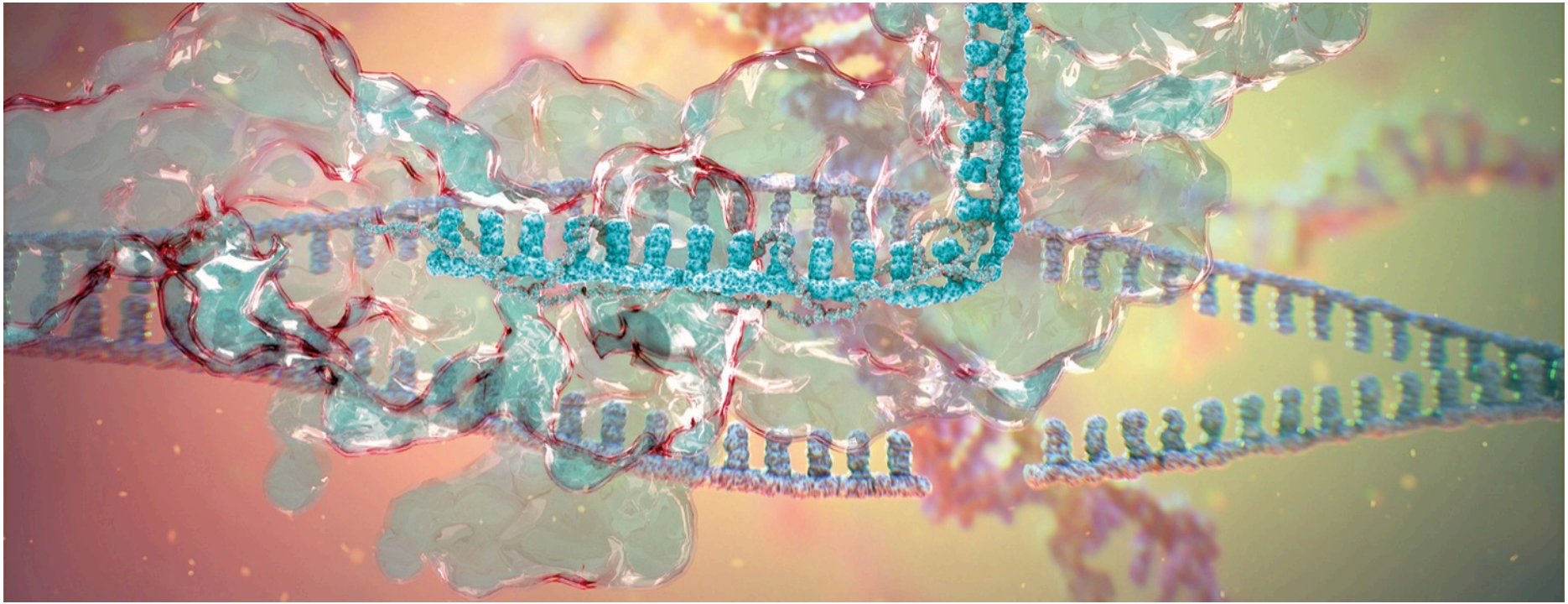
Clinical trials appendix
Q2 2016 update

AstraZeneca
What science can do



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from https://clinicaltrials.gov/ to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 30 June 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 (https://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	Life-Cycle 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 Q1 2016 update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
NMEs **AZD4635** A2aR inhibitor solid tumours **MEDI0562[#]+tremelimumab** hOX40 agonist+CTLA-4 solid tumours **MEDI0562[#]+durvalumab[#]** hOX40 agonist+PD-L1 solid tumours	**NMEs** **ATM AVI[#]** monobactam/beta lactamase inhibitor ***Tagrisso* combo[#] TATTON** EGFR+PD-L1/MEK/MET NSCLC		

Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from Registration
NMEs **MEDI0639[#]** DLL-4 mAb solid tumours **durvalumab[#]+MEDI6383** PD-L1 mAb+OX40 agonist solid tumours **MEDI6383[#]** OX40 agonist solid tumours **MEDI7836** IL-13 mAb YTE asthma		**Lifecycle Management** ***Epanova+Farxiga*[4]** omega-3 carboxylic acids/SGLT2 inhibitor NASH ***Lynparza* (olaparib) GOLD** PARP inhibitor 2nd line gastric	**NMEs** **MEDI-550[1]** pandemic influenza virus vaccine ***Zavicefta*[#] (CAZ AVI)[2]** BLI/cephalosporin SBI/cIAI/cUTI **Lifecycle Management** ***Zavicefta*[#] (CAZ AVI)[2]** BLI/cephalosporin HAP/VAP **saxagliptin/dapagliflozin FDC[3]** DPP-4/SGLT2 inhibitors type-2 diabetes

[#] Partnered and/or in collaboration
[1] MAA approval Q2 2016 (MEDI-550 does not count toward late-stage NME totals) [2] MAA approval Q2 2016 [3] MAA approval 19 July 2016 [4] Farxiga in the US; Forxiga in rest of world

Q2 2016 New Molecular Entity (NME)[1] Pipeline

Respiratory and autoimmunity | Cardiovascular and metabolic disease | Oncology | Infection, neuroscience, gastrointestinal

Phase I
32 New Molecular Entities

Small molecule	Large molecule
AZD1419# TLR9 asthma	MEDI0700# BAFF/B7RP1 SLE
AZD5634 inhaled ENaC cystic fibrosis	MEDI4920 CD40L-Tn3 pSS
AZD7986 DPP1 COPD	MEDI5872# B7RP1 SLE
AZD8871 MABA COPD	MEDI9314 IL4R atopic dermatitis
AZD9567 SGRM RA	MEDI0382 GLP-1/glucagon diabetes/obesity
AZD4076 miR103/107 NASH	MEDI8111 Rh-Factor II trauma/bleeding
AZD5718 FLAP CAD	MEDI0562# hOX40 solid tumours
AZD0156 ATM solid tumours	MEDI0680 PD-1 solid tumours
AZD1775# Wee1 solid tumours	MEDI1873 GITR solid tumours
AZD2811# Aurora solid tumours	MEDI3617# ANG-2 solid tumours
AZD4635 A2aR inhibitor solid tumours	MEDI4276 HER2 solid tumours
AZD6738 ATR solid tumours	MEDI-565# CEA BITE GI tumours
AZD8186 PI3Kβ solid tumours	MEDI9197# TLR 7/8 solid tumours
AZD9150# STAT3 haems & solids	MEDI9447 CD73 solid tumours
AZD9496 SERD ER+ breast	MEDI1814 amyloidβ Alzheimer's disease
AZD8108 NMDA suicidal ideation	MEDI7352 NGF/TNF osteoarthritis pain

Phase II
26 New Molecular Entities

Small molecule	Large molecule
abediterol LABA asthma/COPD	AZD9412# Inhaled βIFN asthma/COPD
AZD7594 Inhaled SGRM asthma	inebilizumab# CD19 neuromyelitis optica
AZD7624 Inhaled p38 inhibitor COPD	mavrilimumab# GM-CSFR rheumatoid arthritis
verinurad URAT-1 hyperuricemia/gout	MEDI2070# IL-23 Crohns
AZD3759 or *Tagrisso* BLOOM EGFR NSCLC brain mets	tezepelumab# TSLP asthma/atopic dermatitis
AZD4547 FGFR solid tumours	MEDI4166 PCSK9/GLP-1 diabetes/CV
AZD5363# AKT breast cancer	MEDI6012 LCAT ACS
savolitinib# MET pRCC	inebilizumab# CD19 DLBCL
vistusertib (AZD2014) mTOR 1/2 solid tumours	MEDI-573# IGF metastatic breast cancer
ATM AVI# BL/BLI SBI	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 early alzheimer's disease	moxetumomab pasudotox# PLAIT CD22 HCL

Applications Under Review
3 New Molecular Entities

Small molecule	Large molecule
ZS-9 potassium binder hyperkalaemia	brodalumab# IL-17R psoriasis
cediranib ICON 6 VEGF PSR ovarian	

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

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

Q2 2016 Lifecycle Management (LCM)[1] Pipeline

Respiratory and autoimmunity | Cardiovascular and metabolic disease | 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
7 Projects

Small molecule
- PT010 LABA/LAMA/ICS asthma
- *Brilinta/Brilique* HESTIA paeds w/ sickle cell
- Lynparza PARP prostate cancer

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

Phase III
23 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
- *Faslodex* FALCON oestrogen receptor 1L adv. breast
- *Lynparza* OlympiA PARP gBRCA adjuvant breast

Large molecule
- *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* ADAURA EGFR adj. EGFRm NSCLC
- *Tagrisso* AURA 3 EGFR T790M NSCLC >2L
- *Tagrisso* 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
1 Project

Small molecule
- *linaclotide*# (CN only) IBS-c

Large molecule

Oncology Combinations

Phase I
11 Projects
- AZD1775#+durvalumab# Wee1+PD-L1 solid tumours
- AZD1775#+Lynparza Wee1+PARP solid tumours
- durvalumab#+dabrafenib+trametinib PD-L1+BRAF+MEK melanoma
- durvalumab#+hrssa PD-L1+EGFR NSCLC
- durvalumab#+MEDI0680 PD-L1+PD-1 solid tumours
- durvalumab#+MEDI9447 PD-L1+CD73 solid tumours
- durvalumab#+monalizumabɣ PD-L1+NKG2a solid tumours
- durvalumab#+tremelimumab PD-L1+CTLA-4 solid tumours
- MEDI0562# + durvalumab# hOX40+PD-L1 solid tumours
- MEDI0562# + tremelimumab hOX40+CTLA-4 solid tumours
- selumetinib# +durvalumab# MEK inhibitor+PL-L1 solid tumours

Phase II
4 Projects
- AZD1775#+chemotherapy Wee1+chemo ovarian cancer
- durva#+AZD5069 or durva+AZD9150 PD-L1+(CXCR2 or STAT3) SCCHN
- durvalumab#+tremelimumab PD-L1+CTLA-4 gastric cancer
- *Tagrisso* combo# TATTON EGFR+PD-L1/MEK/MET NSCLC

Phase 3
8 Projects
- durvalumab#+tremelimumab ALP5¶ 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

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

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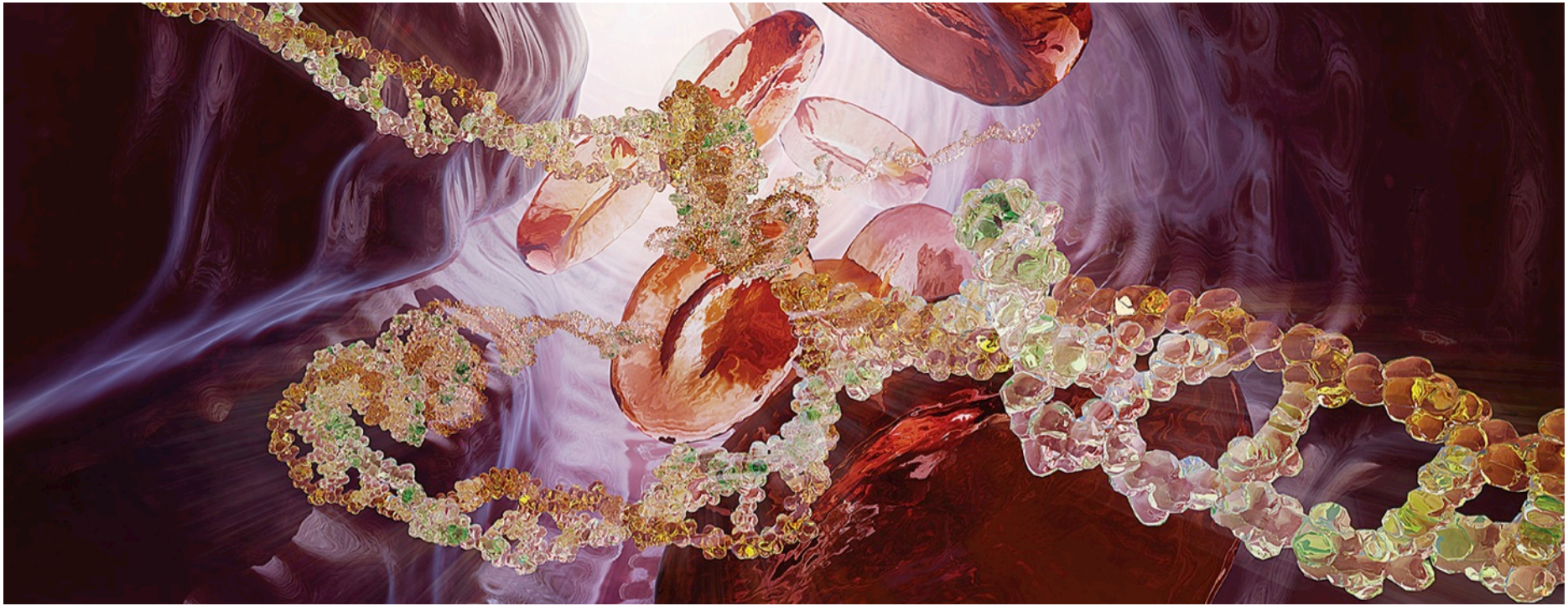
What science can do

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**µ**g bid • **Arm 2:** Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4mg Turbuhaler 'as needed' • **Arm 3:** terbutaline Turbuhaler 0.4mg 'as needed' + placebo Pulmicort 20**0µ**g 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**µ**g 'as needed' + Placebo Pulmicort Turbuhaler 200**µ**g bid • **Arm 2:** Pulmicort 200**µ**g Turbuhaler bid + terbutaline 0.4mg 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.

Ekliral/Tudorza (LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV NCT02375724 **CO-FUNDED:** Menarini	Patients with COPD	N = 224	• **Arm 1**: Aclidinium bromide 400µg • **Arm 2:** Placebo to aclidinium bromide 400µg Global Trial– 5 countries	• Change from baseline in Overall E-RS Total score (i.e. score over the whole 8 weeks study 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 FEV1	• FPD: Q1 2015 • LPCD: Q3 2015 • Clinically Completed • Topline results released: Q1 2016 • Estimated Completion: H2 2016
Phase IV **ASCENT** NCT01966107	Patients with moderate to very severe COPD	N = 4,000	• **Arm 1:** Aclidinium bromide 400µg • **Arm 2:** Placebo to aclidinium bromide 400µg Global Trial– 2 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 hospitalizations due to COPD exacerbation per patient per year during the first year of treatment • Time to first Major Adverse Cardiovascular Event (MACE) or other serious cardiovascular events of interest. Up to 36 months	• FPD: Q3 2013 • LPCD: H2 2016 • Estimated Topline Results: 2018 • Estimated Completion: 2018
Phase IV NCT02153489 **Partnered:** Almirall	Patients with stable moderate and severe COPD	N = 30	• **Arm 1:** aclidinium bromide 400µg • **Arm 2:** Placebo to Aclidinium bromide 400µg Local Trial– 1 country	• Change from baseline in normalized forced expiratory volume in one second (FEV1). Week 3. FEV1 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 study drug administration (for completed patients) or premature discontinuation visit (when applicable) to record adverse events	• FPD: Q2 2014 • LPCD: Q1 2015 • Clinically Completed • Topline results released: Q4 2015 • Estimated Completion: H2 2016

Duaklir (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIb **ACHIEVE** **NCT02796651**	Patients with moderate to COPD	N = 120	• **Arm 1:** Aclidinium/formoterol FDC 400/12µg • **Arm 2:** Placebo to aclidinium/formoterol FDC 400/12µg Global Trial– 1 Country	• Change from baseline in normalized FEV1 area under the curve (AUC) over the 12 h period immediately after morning study drug administration, AUC0-12/12h at Day 7 on treatment • Change from baseline in FEV1 AUC0-6/6h at Day 1 and Day 7 on treatment. • Change from baseline in morning pre-dose FEV1 at Day 7 on treatment	• FPD: H2 2016 • LPCD: H1 2017 • Estimated Topline Results: H2 2017 • Estimated Completion: H2 2017
Phase III **AMPLIFY** **NCT02796677**	Patients with stable COPD	N = 1,500	• **Arm 1:** Aclidinium bromide 400µg/Formoterol Fumarate 12µg • **Arm 2:** Aclidinium bromide 400µg • **Arm 3**: Formoterol fumarate 12µg • **Arm 4:** Tiotropium 18µg Global Trial– 13 Countries	• Change from baseline in 1-hour morning post-dose dose FEV1 of AB/FF 400/12µg compared to AB 400 µg at week 24 • Change from baseline in morning predose (trough) FEV1 of AB/FF 400/12 µg compared to FF 12µg at week 24 • Change from baseline in morning predose (trough) FEV1 at week 24 • comparing AB 400µg versus TIO 18 µg	• FPD: H2 2016 • LPCD: H1 2017 • Estimated Topline Results: H2 2017 • Estimated Completion: 2018
Phase IV **ACTIVATE** **NCT02424344** **CO-FUNDED:** Menarini	Patients with moderate to COPD	N = 268	• **Arm 1:** Aclidinium/formoterol FDC 400/12µg • **Arm 2:** Placebo to aclidinium/formoterol FDC 400/12µg Global Trial– 5 Countries	• Change from baseline in trough Functional Residual capacity (FRC) 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 Topline Results: H2 2016 Estimated Completion: 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* 500µg 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 500µg 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 400mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200mg 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: H2 2016 • Estimated results: H1 2017
Phase III **RDEA594-307 CRYSTAL Extension** **NCT01808144**	Gout previously enrolled in Phase III RDEA594-304 (CRYSTAL) trial	N = 196	• *Zurampic* 200 or 400mg QD All patients: febuxostat 80mg QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200mg 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: H22016 • Estimated results: H1 2017
Phase II **RDEA594-203 Open-label Extension** **NCT01001338**	Gout previously enrolled in Phase II RDEA594-203 trial	N = 87	• *Zurampic* 200, 400, or 600mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive *Zurampic* treatment dose of 200mg 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: H22016 • Estimated results: H2 2016

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

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 Healthy Male & Female Subjects (Cohort 3 only)	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 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: H2 2016 • Estimated results: H2 2016

Bevespi Aerosphere (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*) 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder 18µg QD • Arm 5: Placebo MDI BiD Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active- controlled 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 = 1,615	Treatment (24-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere)* 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Placebo MDI BiD Multicentre, randomised, double-blind, parallel group, chronic dosing and placebo-controlled 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 = 893	Treatment (28-week Treatment Period) • Arm 1: GFF MDI (*Bevespi Aerosphere*) 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder QD Multi-centre, randomised, double-blind, parallel-group and active-controlled 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 14.4/9.6µg • 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 14.4/9.6µg BID • Placebo MDI BID Randomised, 2-period, 2-treatment Double-blind, Multi-centre and Cross-over 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 14.4/9.6µg BID • Placebo • Spiriva Respimat 5µg 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 = 80	Treatments (2 week treatment Period) • GFF MDI 14.4/9.6µg with a spacer • GFF MDI 14.4/9.6µg 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 14.4/9.6µg 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 • Top-line results: Q2 2016* * Clinically completed

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 14.4/9.6µg (N=514) • GP 14.4µg (N=440) • FF 9.6µg (N=440) • Placebo (N=220) • US/China: Trough FEV1 at week 24 of treatment • EU/Hybrid: Co-primary= Trough 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: H2 2016 • Estimated top-line results: H2 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: H2 2016 • LPCD: H1 2017 • Estimated top-line results: H1 2017

Brilinta (ADP receptor antagonist)

Cardiovascular

Trial phase	Patient population	Number of patients	Design	Endpoints (primary)	Status
Phase III **PEGASUS** **NCT01225562**	Patients with prior MI	N = 21,000	• Arm 1: *Brilinta* 90mg BiD • Arm 2: *Brilinta* 60mg 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: Q2 2013 • Completion date: Q4 2014
Phase III **EUCLID** **NCT01732822**	Patients with PAD	N = 13,500	• Arm 1: *Brilinta* 90mg BiD • Arm 2: Clopidogrel 75mg QD Global trial – 28 countries	• Composite of CV death, non-fatal MI and ischemic stroke	• FPD: Q4 2012 • LPCD: Q1 2014 • 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* 60mg 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: Q2 2016 • Estimated top-line results: 2018
Phase III (BE) **NCT02436577**	Japanese healthy volunteers	N = 36	Single dose, Cross-Over • Arm 1 *Brilinta* OD tablet 90mg + 150mL of water • Arm 2 *Brilinta* OD tablet 90mg without water • Arm 3 *Brilinta* IR tablet 90mg) + 200mL 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
Phase III (BE) **NCT02400333**	Caucasian healthy volunteers	N = 36	Single dose, Cross-Over • Arm 1 *Brilinta* OD tablet 90mg +200ml of water • Arm 2 *Brilinta* OD tablet 90mg without water • Arm 3 *Brilinta* OD tablet 90mg (suspended in water) via nasogastric tube • Arm 4 *Brilinta* IR tablet 90mg + 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 cell disease	N = 90	• Arm 1: *Brilinta* 10mg BiD • Arm 2: *Brilinta* 45mg 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: H2 2016

Farxiga (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: *Farxiga* 5mg • Arm 2: Placebo Japan trial	• Change from baseline in Haemoglobin A1C (HbA1c) at week 16 • 1 year LT data	• FPD: Q2 2014 • LPCD: Q4 2015 • Top-line Results: Q1 2016 • 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* 10mg 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: *Farxiga* 10mg 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 • Top-line results: Q2 2016 • Completion date: H2 2016
Phase III **DERIVE** **NCT02413398**	Patients with type-2 diabetes and moderate renal impairment	N = 302	• Arm 1: *Farxiga* 10mg QD for 24 weeks • Arm 2: Placebo 10mg QD for 24 weeks Global trial – five 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* 5mg QD 52 weeks + insulin • Arm 2: *Farxiga* 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 17 countries	Primary: • 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* 5mg QD 52 weeks + insulin • Arm 2: *Farxiga* 10mg QD 52 weeks + insulin • Arm 3: Placebo QD 52 weeks + insulin Global trial – 14 countries	Primary: • Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24	• FPD: Q3 2015 • LPCD: 2017 • Estimated top-line results: 2018

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* 5mg QD + insulin with or without metformin • Arm 2: Placebo QD + insulin with or without metformin 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: Q3 2015 • Completed: Q1 2016 • Top-line results: Q2 2016
Phase III **NCT02273050**	Type-2 diabetes mellitus	N = 639	• Arm 1: *Onglyza* 5mg + Met (500mg with titration) • Arm 2: *Onglyza* 5mg + Placebo • Arm 3: Met (500mg 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: Q1 2016 • Estimated completion date: H2 2016 • Estimated top-line results: H2 2016

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

Diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02284893**	Type-2 diabetes	N = 420	• Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: Sitagliptin 100mg + 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: Q3 2015 • Estimated top-line results: H2 2016
Phase III **NCT02419612**	Type-2 diabetes	N = 440	• Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: Glimeperide 1-6mg + 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: H2 2016 • Estimated top-line results: H2 2017
Phase III **NCT02551874**	Type-2 diabetes	N = 598	• Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR with or without SU • Arm 2: Insulin glargine + Met IR/XR with or without SU Global trial – 12 countries	Primary: • 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: H2 2016 • Estimated top-line results: H2 2017
Phase III **NCT02681094**	Type-2 diabetes	N = 900	• Arm 1: Saxagliptin 5mg + dapagliflozin 5mg + Met IR/XR • Arm 2: Dapagliflozin 5mg + placebo + Met IR/XR • Arm 3: Saxagliptin 5mg + placebo + Met IR/XR Global trial – six countries	Primary: • 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: H1 2017 • Estimated top-line results: H2 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 SoC 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 2mg 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
Phase III **DURATION 8** **NCT02229396**	Type-2 diabetes	N = 660	• Arm 1: *Bydureon* once weekly 2mg SC • Arm 2: Dapagliflozin 10mg • Arm 3: *Bydureon* once weekly 2mg SC + dapagliflozin 10mg Double-blind 1:1:1 randomisation. Background therapy with Metformin 1500mg/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* 2g and 4g 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* 4g vs. Placebo vs. Fenofibrate 200mg 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 10mg QD • Arm 4: Dapaglifozin 10mg Local trial – one country	• Reduction in liver fat content (%) at the end of 12 weeks	• FPD: Q1 2015 • LPCD: Q4 2015 • Completed: 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* 4g 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 • Completed: 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* 4g 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 →omega-3-acid ethyl esters capusles 4g QD • Arm 2: omega-3-acid ethyl esters capusles 4g →Epanova 4 g QD • Arm 3: *Epanova* 2g →omega-3-acid ethyl esters capusles 4g QD • Arm 4: omega-3-acid ethyl esters capusles 4g →Epanova 2g QD Global trial – two countries	• Plasma concentration vs. time curve (AUC0-τ) [Time Frame: 0 to 24 hours (AUC0-24)]	• FPD: Q3 2014 • LPCD: Q2 2015 • Completed: 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* 500mg monthly IM + an additional dose on d14 (+ oral placebo) • Arm 2: *Arimidex* 1mg (+ placebo injection) Global trial – 21 countries	• PFS • OS is a secondary endpoint	• FPD: Q4 2012 • LPCD: Q3 2014 • 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 300mg 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 300mg 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: H2 2017
Phase III **SOLO-3** **NCT02282020**	PSR gBRCAm ovarian cancer 3L+ Line	N = 411	• Arm 1: *Lynparza* 300mg BiD to progression • Arm 2: Physician's choice (single agent chemotherapy) Global trial	• PFS • OS secondary endpoint	• FPD: Q1 2015 • LPCD: H2 2017 • Estimated top-line results: 2018
Phase III **GOLD** **NCT01924533**	2L gastric cancer (all patients with a co-primary)	N = 525	• Arm 1: paclitaxel + *Lynparza* until progression • Arm 2: paclitaxel + placebo *Lynparza* dose 100mg BiD throughout paclitaxel dose cycle & 300mg BiD post cycle Asian trial	• OS	• FPD: Q3 2013 • LPCD: Q4 2015 • Top-line results reported: Q2 2016 • Primary endpoint not met • Full data to be presented at upcoming medical conference
Phase I / II **MEDIOLA** **NCT02734004**	gBRCAm ovarian cancer 3L gBRCAm HER2-negative breast cancer 1-3L Small cell lung cancer 2L+ ATM-negative gastric cancer 2L+	N = 139	• Arm 1: Lynparza tablets 300mg BID starting on week 1 day 1 / durvalumab IV 1.5g every 4 weeks starting on week 5 day 1. • Dose until progression. Global trial	Primary endpoints • DCR at 12 weeks • Safety and tolerability Secondary endpoints • DCR at 28 weeks • ORR, DoR, PFS, TDT, OS • PK	• FPD: Q2 2016 • LPCD: Q4 2016 • Estimated top-line results: 2018

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* 300mg BiD, continuous to progression • Arm 2: Physician's choice: capecitabine 2500mg/m2 x 14 q 21 vinorelbine 30mg/m2 d 1, 8 q 21 eribulin 1.4mg/m2 d 1, 8 q 21 to progression Global trial	• 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* 30mg 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 300mg twice daily as maintenance therapy until progression. • Arm 2: **Pl**acebo tablets BiD Global trial	• Primary endpoint: PFS • Secondary endpoint: OS	• FPD: Q1 2015 • LPCD: H2 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 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* 250mg (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) + durvalumab (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* 80mg QD Asia Pacific Regional trial	• ORR • PFS and OS secondary endpoints	• FPD: Q3 2015 • Enrolment complete • Primary completion: Q2 2016
Phase II **AURA2** **NCT02094261**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 175	• *Tagrisso* 80mg 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* + durvalumab • Arm 2: *Tagrisso* + savolitinib • 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: H1 2017

Zavicefta (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: *Zavicefta* 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: *Zavicefta* 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 • Top-line results: Q3 2016

Zavicefta (BLI/cephalosporin SBI)

Serious infections

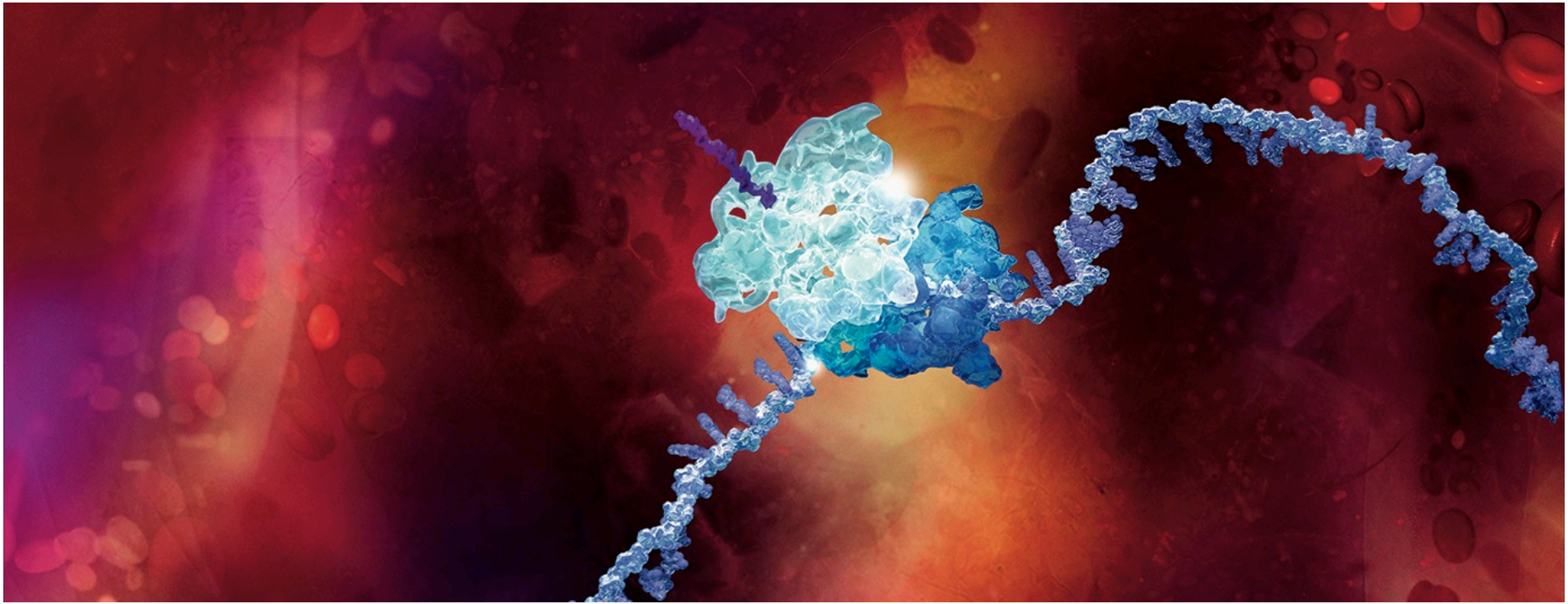
Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **RECLAIM-1** **NCT01499290**	Hospitalised patients with complicated intra-abdominal infections	N = 493	• Arm 1: *Zavicefta* 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global Trial– 20 countries	• Co primary 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: *Zavicefta* 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global Trial– 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: *Zavicefta* 2000/500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg 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: *Zavicefta* 2000/500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg 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: *Zavicefta* 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

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* 40mg bid intermittent iv infusions given for max.14 days • Arm 2: Cimetidine 300mg 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 • Completed: Q2 2016

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: 210mg brodalumab SC • Arm 2: 140mg brodalumab SC • Arm 3: Placebo SC	• PASI at week 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: 210mg brodalumab SC • Arm 2: 140mg brodalumab SC • Arm 3: 45 or 90mg ustekinumab SC • Arm 4: Placebo SC	• PASI at week 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: 210mg brodalumab SC • Arm 2: 140mg brodalumab SC • Arm 3: 45 or 90mg ustekinumab SC • Arm 4: Placebo SC	• PASI at week 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered

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 – 75 years	N = 1,026 HD + ~200 MD	• Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 56-week trial Global trial – 11 countries	• Annual asthma exacerbation rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM	• FPD: Q4 2013 • Completed: Q2 2016
Phase III **SIROCCO** **NCT01928771**	Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS Age 12 – 75 years	N = 1,134	• Arm 1: 30mg Q8w SC • Arm 2: 30mg 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 • Completed: 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 years	N = 210	• Arm 1: 30mg Q8w SC • Arm 2: 30mg 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
Phase III **Meltimi** **NCT02808819**	A multicenter, open-label, safety extension trial with Benralizumab (MEDI-563) for asthmatic adults on Inhaled Corticosteroid plus Long-acting β2 Agonist (MELTEMI) Age 18 – 75 years	N = 770	• Arm 1: 30mg Q4W SC • Arm 2: 30mg Q8W SC	• Safety and tolerability	• FPD: H2 2016 • Estimated completion: 2019
Phase III **ALIZE**	A multicenter, randomized, double-blind, parallel group, placebo-controlled, Phase 3b trial to evaluate the potential effect of Benralizumab on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years	N = 100	• Arm1 30mg Q4W SC with 1 dose of seasonal influenza virus vaccine Intramuscular (IM) at week 8. • Arm1 Placebo Q4W SC with 1 dose of seasonal influenza virus vaccine Intramuscular (IM) at week	• Post-dose strain-specific hemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs • Post-dose strain-specific serum HAI antibody geometric meant titers (GMTs) • Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer	• FPD: H2 2016 • Estimated completion: 2019

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 years	N = 200	• Arm 1: 30mg Q4W SC • Arm 3: Placebo SC 12-week trial Global trial – six countries	• Pulmonary function (FEV1)	• FPD: Q1 2015 • Completed: Q1 2016
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75 years	N = 2,550	• Arm 1: 30mg Q4W SC • Arm 2: 30mg Q8W SC* * Placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial	• 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 – 75 years	N = 120	• Arm 1: 30mg Q4W SC 28-week (adults) Global trial – two countries	• Functionality, **re**liability, and **p**erformance of **a** **p**re-filled **s**yringe With Benralizumab Administered at Home	• FPD: Q2 2015 • Completed: Q2 2016
Ph III **ARIA** **NCT02821416**	A Double-Blind, Randomized, Parallel Group, Placebo-Controlled Multi-Centre Trial to Evaluate the effect of Benralizumab on Allergen-Induced Inflammation in Mild, Atopic Asthmatic Age 18 – 65 years	N = 38	• Arm1 : 30mg Q4W SC • Arm2: Placebo SC	• Safety and tolerability	• H2 2016 • Estimated completion 2019

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: 10mg Q8W SC • Arm 2: 30mg Q4W SC • Arm 3: 100mg 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: 30mg Q4W SC • Arm 2: 100mg Q8W SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	• Rate of COPD exacerbation	• FPD: Q3 2014 • Estimated completion: 2018

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 320/9.6µg BiD • BFF MDI 160/9.6µg BiD • BFF MDI 80/9.6µg BiD • BD MDI 320µg BiD • FF MDI 9.6µg BiD Randomised, 4-period, 5-treatment incomplete-block and cross-over Estimated time from FSFV to DBL is approximately seven months. US	• Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV_1 AUC^{0-12})	• 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 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • *Symbicort* TBH 400/1 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: H1 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 320/14.4/9.6µg BID • BGF MDI 160/14.4/9.6µg BID • BFF MDI 320/9.6µg BID • GFF MDL 14.4/9.6µg BID Randomised, double-blind, multi-centre and parallel-group 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: H2 2017 • Estimated top-line results: H2 2018
Phase III (Lung function trial) KRONOS **NCT02497001**	Moderate to very severe COPD	N = 1,800	Treatments (24-week Treatment Period) • BGF MDI 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • *Symbicort* TBH 400/12µg 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: H2 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 320µg BiD • Arm 2: BD MDI 160µg BiD • Arm 3: BD MDI 80µg BiD • Arm 4: BD MDI 40µg BiD • Arm 5: Placebo MDI BiD Randomised, 4-period, 5-treatment incomplete-block and cross-over 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 (GP Dose-ranging in Asthma) **NCT02433834**	Intermittent asthma/mild to moderate persistent asthma	N = 200	Treatment (18-week Treatment Period) • GP MDI 28.8µg BiD • GP MDI 14.4µg BiD • GP MDI 7.2µ BID • GP MDI 3.6µ 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 • Top-line results: Q2 2016* *Clinically completed

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 = 60	• Arm 1: BGF MDI 320/14.4/9.6µg • Arm 2: BFF MDI (320/9.6µg) • Arm 3: *Symbicort Turbuhaler* 400/12µg Randomised, double-blind, single-dose, 3-period, 3-treatment and cross-over Estimated time from FSFV to DBL is approximately three months US	• Overall safety • PK parameters AUC^{0-12} 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 = 28	Treatment (2-week Treatment Period) • Arm 1: BGF MDI 320/14.4/9.6µg • Arm 2: BGF MDI 160/14.4/9.6µg • 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^{0-12} 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 14.4/9.6µg • Arm 2: GFF MDI 28.8/9.6µg • Arm 2: GP MDI 14.4µg • Arm 2: GP MDI 28.8µg Randomised, double-blind, single-dose, 4-period, 4-treatment and cross-over Estimated time from FSFV to DBL is approximately 13 weeks Japan	• Overall safety • PK parameters AUC^{0-12} and Cmax	• FPD: Q3 2014 • LPCD: Q3 2014 • Top-line results: Q4 2014* * Clinically completed

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 **s**econdary: • 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 **s**econdary: • 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 **s**econdary: • 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 • sub-mucosal 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: 2018 • Estimated top-line results: 2018

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: 300mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 150mg 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: 300mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 150mg 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	• Arm 1: 300mg IV MEDI-546 Q4W for 48 weeks • Arm 2: 1000mg 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 300mg 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 = 31	• Arm A: Acalabrutinib + methotrexate • Arm B: Methotrexate	Disease Activity Score 28-CRP at week 4	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated Completion: H1 2017

Roxadustat (HIF-PHI)

Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD)

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	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	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	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	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	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	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	Haemoglobin response	• FPD: Q4 2014 • Estimated completion: 2017 Sponsored by Astellas

Roxadustat (HIF-PHI)

Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III HIMALAYAS **NCT02052310**	Anaemia in newly initiated dialysis patients	N = 1,000	• Arm 1: Roxadustat • Arm 2: Epoetin alfa Global trial	Haemoglobin response	• FPD: Q4 2013 • Estimated completion: 2017 Sponsored by FibroGen
Phase III **NCT02652819**	Anemia in CKD patients not receiving dialysis	N = 150	Arm 1: FG-4592 (roxadustat) Arm 2: Placebo China trial	Haemoglobin response	• FPD: Q4 2015 • Estimated completion: 2017 Sponsored by FibroGen
Phase III **NCT02652806**	Anemia in CKD patients receiving dialysis	N = 300	Arm 1: FG-4592 (roxadustat) Arm 2: Epoetin alfa China trial	Haemoglobin response	• FPD: Q4 2015 • Estimated completion: 2017 Sponsored by FibroGen

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: durvalumab 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 + durvalumab) 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, durvalumab Q4W 20mg/kg + tremelimumab Q4W 1mg/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: Durvalumab + tremelimumab (PD-L1 –ve patients) • Arm 2: Standard of Care • Arm 3: tremelimumab (PD-L1 –ve patients) • Arm 4: Durvalumab (PD-L1 –ve patients)	• PFS • OS • Safety	Combination therapy • FPD: Q2 2015 • LPCD: Q3 2016 • Estimated completion: 2017 (PFS, OS)
Phase III **MYSTIC** **NCT02453282**	NSCLC 1L	N = 1,092	• Arm 1: Durvalumab • Arm 2: Durvalumab + tremelimumab • Arm 3: Standard of care	• PFS • OS • Safety	• FPD: Q3 2015 • LPCD: Q3 2016 • Estimated completion: 2017
Phase III **NEPTUNE**	NSCLC 1L	N = 800	• Arm 1: Durvalumab + 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: Durvalumab + tremelimumab • Arm 2: Durvalumab • 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: Durvalumab • Arm 2: Durvalumab + 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: Durvalumab + tremelimumab • Arm 2: Durvalumab • 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: Durvalumab • Arm 2: Tremelimumab • Arm 3: Tremelimumab + durvalumab	• ORR • Safety	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion: 2017
Phase II **ALPS** **NCT02558894**	Metastatic pancreatic ductal carcinoma 2L	N = 130	• Arm 1: Durvalumab + tremelimumab • Arm 2: Durvalumab	• 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 + durvalumab • Dose escalation trial • Tremelimumab Q4W/Q12W 3-10mg/kg • Tremelimumab Q4W/Q12W X mg/kg + durvalumab 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

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: Durvalumab 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: Durvalumab 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 (4,736 substudy only);	Umbrella trial with 5 arms based on biomarker expression • Substudy A: Durvalumab (non-match for other biomarker driven substudies) IVQ2W single arm durvalumab 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: Durvalumab IV Q2W (EFGR/ALK WT) • Arm 2: Durvalumab IV Q2W (EFGR/ALK M+) • Arm 3: Durvalumab 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 Trial **NCT02179671**	Stage IIIB-IV NSCLC patients	N = 72	• Arm 1: Iressa initially then switch to durvalumab IVQ2W • Arm 2: AZD9291 then switch to durvalumab • Arm 3: selumetinib + docetaxel then switch to durvalumab • Arm 4: tremelimumab then switch to durvalumab	• Complete Response Rate • ORR, Disease Control Rate	• FPD: Q3 2014 • LPCD: Q2 2016 • Estimated completion: H2 2016

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

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 75mg/m2 IV on day 1 of each 21 day cycle • Arm 2: Placebo BiD + docetaxel 75mg/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 months 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 75mg/m2 IV on day 1 of each 21 day cycle • Arm 2: Selumetinib 75mg BiD + docetaxel 60mg/m2 IV on day 1 of each 21 day cycle • Arm 3: Placebo BiD + docetaxel 75mg/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 • Top-line results: Q2 2016

Phase II
 	
NCT01362803– partnered (NCI)
	Pediatric Neurofibromatosis type 1	N = minimum of 50 symptomatic points	• 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 - durvalumab 20mg/kg Q4 – after 7 days of selumetinib dosing • Note: No escalation in durvalumab dose; Selumetinib escalation with 25mg bd increment / dose cohort	• Safety and tolerability • PK of Selumetinib and durvalumab and preliminary anti-tumour activity	• FPD: Q1 2016 • LPCD: 2017 • 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 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/SLL	N = 48	Acalabrutinib monoherapy • **Arm A:** Lymph node biopsy • **Arm B:** Bone marrow biopsy	Safety	• FPD: Q1 2015 • Estimated completion: H2 2017
Phase II **ACE-LY-004** **NCT02213926**	Relapsed/refractory Mantle Cell Lymphoma	N = 124	Acalabrutinib monotherapy	ORR	• FPD: Q1 2015 • LPCD: Q1 2016 • Estimated completion: H2 2016
Phase I/II **ACE-CL-001** **NCT02029443**	CLL/SLL/RT	N = 307	Acalabrutinib monotherapy Dose escalation and expansion	Safety, PK, PD Secondary endpoints: ORR, DOR, and PFS	• FPD: Q1 2014 • LPCD: Q2 2016 • 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: H2 2017
Phase I/II **ACE-LY-005** **NCT02362035**	Hematological Malignancies	N = 324	Acalabrutinib + pembrolizumab	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 • Estimated completion: H2 2016
Phase Ib **ACE-LY-002** **NCT02112526**	Relapsed/refractory de novo ABC DLBCL	N = 21	Acalabrutinib monotherapy	Safety	• FPD: Q3 2014 • LPCD: Q2 2016 • Estimated completion: H1 2017
Phase Ib **ACE-LY-106** **NCT02717624**	Mantle Cell Lymphoma	N = 48	Acalabrutinib in combination with bendamustine and rituximab • **Arm A:** Treatment naive • **Arm B:** Relapsed/refractory	Safety	• FPD: 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: H1 2017
Phase I **ACE-LY-003** **NCT02180711**	Relapsed/refractory Follicular Lymphoma	N = 38	• **Arm A:** Acalabrutinib • **Arm B:** Acalabrutinib + rituximab	Safety	• FPD: Q1 2015 • LPCD: Q2 2016 • Estimated completion: 2018
Phase I **ACE-CL-002** **NCT02157324**	Relapsed/refractory CLL	N = 12	Acalabrutinib in combination with ACP-319 Dose escalation	Safety, PK, PD	• FPD: Q3 2014 • LPCD: Q3 2015 • Estimated completion: 2018
Phase I **ACE-CL-003** **NCT02296918**	CLL/SLL/PLL	N = 45	Acalabrutinib + obinutuzumab • **Arm A:** Relapsed/refractory • **Arm B:** Treatment naive	Safety ORR	• FPD: Q1 2015 • LPCD: Q1 2016 • 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 head and neck squamous cell carcinoma	N = 78	• **Arm A:** Pembrolizumab • **Arm B:** Acalabrutinib+ pembrolizumab	ORR	• FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion: H2 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 • LPCD Q2 2016 • Estimated completion: H1 2017
Phase II **ACE-ST-208** **NCT02537444**	Recurrent ovarian cancer	N = 78	• **Arm A:** Acalabrutinib • **Arm B:** Acalabrutinib+ pembrolizumab	ORR	• FPD: Q4 2015 • LPCD Q2 2016 • Estimated completion: H2 2017
Phase II **ACE-ST-004** **NCT02570711**	1L metastatic pancreatic cancer	N = 3	• **Arm A:** Acalabrutinib+ Nab-Paclitaxel+ Gemcitabine • **Arm B:** Nab-Paclitaxel+ Gemcitabine	ORR	• FPD: Q4 2015 • LPCD: Q1 2016 • Trial terminated
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 • Estimated completion: H1 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 • Estimated completion: H1 2017
Phase Ib/II **ACE-ST-209** **NCT02586857**	≥ 2L glioblastoma multiforme	N = 72	• **Arm A:** Acalabrutinib 200mg BID • **Arm B:** Acalabrutinib 400mg QD	Safety ORR	• FPD: Q1 2016 • Estimated completion: 2018

Moxetumomab pasudotox (CD22 mAb)

Haematological malignancies

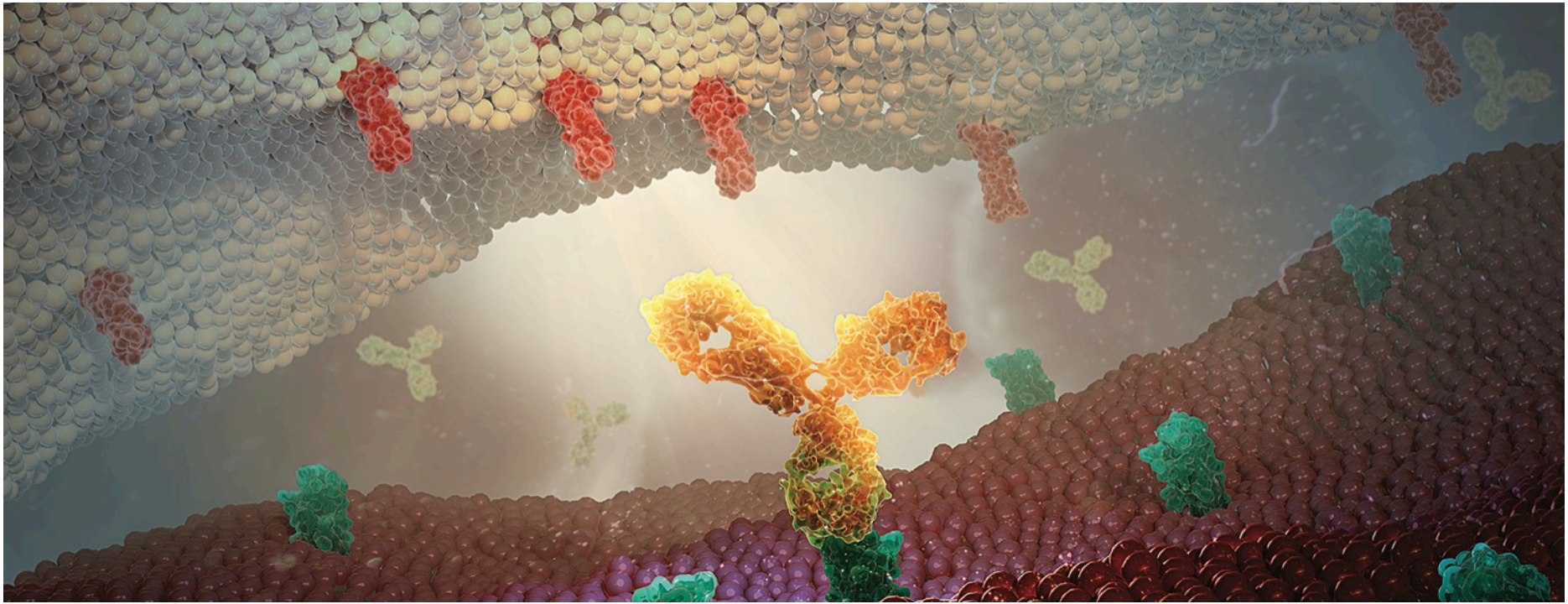
Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PLAIT** **NCT01829711**	Adults with relapsed or refractory hairy cell leukemia (HCL)	N = 77	• Multicentre, single-arm, open-label trial3	• Primary: Rate of durable CR: CR maintained for > 180 days • Efficacy: CR rate, 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)

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 20mg once daily • Arm 2: AZD3293 50mg 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 **NCT02246673**	Combination therapy trial with febuxostat in subjects with gout	N = 60	• Arm A: Verinurad 2.5mg QD • Arm B: Verinurad 5.0mg QD • Arm C: Verinurad 10mg QD • Arm D: Verinurad 15mg QD • Arm E: Sequential doses of verinurad 10, 15 and 20mg QD in combination with 40mg QD febuxostat *Arms A-D include combination with 40mg QD febuxostat for 7 days followed by combination with 80mg QD febuxostat for 7 days	• To assess the PK and PD profiles of verinurad administered with febuxostat	• FPD: Q4 2014 • LPCD: Q2 2015 • Complete
Phase II **NCT02317861**	Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients	N = 92	• Arm A: Verinurad 2.5mg QD + 10mg or 20mg QD febuxostat • Arm B: Verinurad 5.0mg QD + 10mg or 20mg QD febuxostat • Arm C: Verinurad 5.0mg QD + 20mg or 40mg QD febuxostat • Arm D: Verinurad 10mg QD + 20mg or 40mg QD febuxostat • Arm E: Benzbromarone 50mg QD	• To assess the PD, PK and safety profiles of verinurad administered with febuxostat	• FPD: Q4 2014 • LPCD: Q2 2015 • Complete
Phase II **NCT02498652**	Combination therapy trial with allopurinol in subjects with gout	N = 40	• Arm A: Placebo • Arm B: Verinurad 2.5mg QD • Arm C: Verinurad 5.0mg QD • Arm D: Verinurad 7.5mg QD • Arm E: Verinurad 10mg QD • Arm F: Verinurad 15mg QD • Arm G: Verinurad 20mg QD *All arms include combination with 300mg QD allopurinol. Placebo group also includes combination with 300mg BID allopurinol or 600mg 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 trial in healthy adult male subjects	N = 40	• Part 1: Single doses of verinurad at 4.5mg, 6.0mg, or 12mg • Part 2: Multiple doses of verinurad at 12mg QD for 7 days • Part 3: Food effect trial with single doses of verinurad at 6.0mg	• 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/Chronic Obstructive Pulmonary Disease (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 cross-over, multi-centre trial to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma	• 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 trial in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered intravenously, orally and inhaled via two different dry powder inhalers (DPI) and a pressurised metered-dose inhaler (pMDI)	• Bioavailability and pharmacokinetics	• FPD: Q1 2016 • Completed
Phase I **NCT02645253**	Healthy subjects	N = 36	A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of AZD7594 given once daily as inhaled formulation in healthy Japanese men	• Safety and tolerability	• FPD: Q1 2016 • Completed

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 • Completed
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 2016 • Completed
Phase I **NCT02653872**	Healthy subjects	N = 15	A phase 1, non-randomized, fixed sequence, 3-period, drug-drug interaction trial to assess the pharmacokinetics (PK) of AZD7986 in healthy subjects when administered alone and in combination with multiple doses of verapamil and itraconazole or diltiazem.	• Effect of verapamil and the effect of itraconazole/diltiazem on the pharmacokinetics (PK) of AZD7986 • Safety and tolerability of AZD7986	• FD: Q1 2016 • Completed

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

AZD8871 (MABA2)

Asthma/Chronic Obstructive Pulmonary Disease (COPD)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I NCT02573155	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 - 50µg, 200µg, 400µg, 900µg, 1800µg, and 2100µg **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 400µg once daily (double-blind) • AZD8871 1800µg once daily (double-blind) • Indacaterol 150µg once daily (open-label) • Tiotropium 18µg 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: Q4 2015 Part 2 • FPD: Q2 2016 • LPCD: H2 2016 Estimated Topline Results: H2 2016 Estimated Completion: H1 2017
Phase I NCT02814656	Healthy Volunteers	N = 24	MAD study with 3 planned dose levels - 300µg, 600/900µg, up to 1800µg and placebo Global Trial – one country	**Primary Endpoint:** • The primary objective is to investigate the safety and tolerability of AZD8871 at steady state **Secondary Endpoint:** • To characterize the PK of AZD8871 and its metabolites LAS191861 and LAS34850 after multiple doses of AZD8871 and assess the time required to reach steady state, the degree of accumulation and the time dependency	• FPD: H2 2016 • LPCD: H2 2016 Estimated Topline Results: H2 2016 Estimated Completion: H1 2017

AZD9412 (Inhaled IFN-beta)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **INEXAS** **NCT02491684**	Asthma	N = 220	• Arm 1: 24µg (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 patients	Design	Endpoints	Status
Phase I NCT02512575	Healthy Volunteers	N = 72	SAD trial with 6 dose levels - 2µg, 10µg, 40µg, 100µg, 200µg, and up to 400µg 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 (all capitals!)	• FPD: Q4 2015 • LPCD: Q2 2016 Estimated Topline Results: H2 2016 Estimated Completion: H2 2016
Phase I NCT02760316	Healthy Volunteers	N = 36	MAD trial with 4 dose levels – 10mg, 20mg, 40mg, 80mg and Prednisolone 20 mg Global trial – two countries	Primary Endpoint: • To assess the safety and tolerability of AZD9567 following multiple oral ascending doses in subjects with BMI between 28 and 38 kg/m2 and with a positive glucose tolerance test (7,8 to 11,0 mmol/L) Secondary Endpoints: • To characterize the pharmacokinetics of AZD9567 following multiple oral administration of ascending doses. • To characterize the pharmacodynamics of AZD9567 assessed as effect on glucose homeostasis through OGTT (oral glucose tolerance test) in comparison with prednisolone 20mg	• FPD: Q2 2016 • LPCD: H2 2016 Estimated Topline results: H1 2017 Estimated Completion: H1 2017

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 (one study site in US) • 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
Phase I/IIa **NCT02826525**	Type-2 Diabetic patients with non-alcoholic fatty liver disease	N = up to 51	MAD trial (one study site in US) • Up to 3 different dose levels investigated vs. placebo • Sub-cutaneous injection	• Safety and tolerability • Glucose infusion rate at hyperinsulinemic clamp • Reduction in liver fat content (%) per MRI • 24 hour glucose area under the curve • PK parameters	• FPD: H2 2016 • LPCD: H1 2017 • Estimated completion: 2017

AZD4831

Cardiovascular disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02712372**	Healthy subjects	N = 96	SMAD trial (one study site in Germany) SAD • Planned to investigate 6 different dose levels vs. placebo but up to 10 cohort may be used MAD • The planned number of cohorts is three but up to five cohorts may be included	• Safety and tolerability • PK parameters	• FPD: H2 2016 • LPCD: H1 2017 • Estimated completion: H2 2017

AZD5718

Cardiovascular disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02632526**	Healthy subjects	N = 96	SMAD trial (one study site in UK) SAD • Planned to investigate 8 different dose levels vs. placebo but up to 11 cohort may be used • Amorphous and crystalline form of AZD5718 will be investigated • Oral administration MAD • The planned number of cohorts is four but up to six cohorts may be included • Once or twice daily oral administration of AZD5718	• Safety and tolerability • PK parameters • Pharmacodynamic analysis by ex-vivo stimulation of LTB4 production using calcium ionophore • Pharmacodynamics of AZD5718 after single single ascending doses and multiple ascending doses • To evaluate the relative bioavailability between the amorphous and crystalline form of AZD5718	• FPD: Q1 2016 • LPCD: H2 2016 • Estimated completion: H2 2016

AZD0156 (ATM)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02588105**	Solid tumours	N = 130	• Arm 1: AZD0156 + *Lynparza* • 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 Global trial	• Overall Response Rate (ORR) • Secondary endpoints: 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: 2019 • Estimated completion: 2019
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: H1 2017 • Estimated completion: H1 2017
Phase I **NCT02511795**	Advanced solid tumours	N = 36	• Dose escalation trial (AZD1775 + *Lynparza*) Conducted in US	• Safety and tolerability	• FPD: Q3 2015 • LPCD: H2 2016 • Estimated completion: H1 2017
Phase I **NCT02617277**	Advanced solid tumours	N = 18	• Dose escalation trial (AZD1775 + durvalumab) Conducted in US	• Safety and tolerability	• FPD: Q4 2015 • LPCD: H1 2017 • Estimated completion: 2018
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

Vistusertib (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: Q4 2015 • 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 Multicentre: European sites	• PFS • Secondary endpoint: OS	• FPD: Q2 2014 • LPCD: H2 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: H1 2017

AZD4547 (FGFR)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status

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)
			
			Conducted in eight countries in Europe
				• **Part A:** MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547
				• **Part B Interim analysis:** Tumour size analysis on 30 FGFR amplified patients
				• **Part B Final analysis:** PFS
					• FPD: Q4 2010
					• LPCD: Q1 2014
					• Completed: Q3 2014

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) Conducted in 16 countries across Europe and Asia	• PFS • Key Secondary: OS/Tumour size	• FPD: Q4 2011 • LPCD: Q2 2013 • 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. eight patients) Conducted in Japan	• **Part A:** MTD and Recommended dose for Parts B and C • **Part B:** Safety and tolerability and preliminary anti-tumour activity	• FPD: Q4 2010 • LPCD: Q4 2012 • Completed: Q2 2013
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 Conducted in seven countries across North America and Europe	• **Part A:** MTD and Recommended dose for Parts B and C • **Part B and C:** Safety and tolerability, PK and preliminary anti-tumour activity	• FPD: Q4 2009 • LPCD: Q4 2013 • Completed: Q1 2015
Phase I **BISCAY** **NCT02546661**	2L Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy	N = 110	• Multi-drug biomarker-directed trial • Arm 1: AZD454 • Arm 2: AZD4547 + durvalumab • Arm 3: *Lynparza* + durvalumab • Arm 4: AZD1775 + durvalumab • Arm 5: durvalumab Planned in North America and Europe	• Safety and tolerability of the combinations • PK and preliminary anti-tumour activity	• FPD Estimated: Q3 2016 • Estimated completion: 2018

AZD4635 ($A_{2A}R$)

Solid tumours and Non Small Cell Lung Cancer (NSCLC)

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

AZD5069 (CXCR2)

Solid Tumors

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/durvalumab • Arm A2 : AZD5069/durvalumab Dose Expansion 2L SCCHN: • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/durvalumab • Arm B4: AZD5069/durvalumab	• Safety/Efficacy trial	• FPD: Q3 2015 • LPCD: 2017 • Estimated completion: 2019
Phase Ib/II **NCT02583477**	Metastatic Pancreatic Ductal Carcinoma	N = 26	Dose escalation and expansion Arms: Durvalumab in combination with nab-paclitaxel and gemcitabine Durvalumab in combination with AZD5069	• Safety/Efficacy trial	• FPD: Q1 2016 • LPCD: 2017 • Estimated completion: 2017

* clinicaltrials.gov being updated

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 points 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 weeks (CBR24) [Parts E & F only]	• FPD: Q3 2013 • Estimated primary completion: H2 2017 • Part C Arms 1 & 2 completed • Part D Arms 1 & 3 completed • Part D Arm 2 paused pending interim analysis • Part E Arms 1 & 2 ongoing [CBR24 data for 12 patients per arm estimated 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: H1 2017 • 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: H2 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 • Terminated
Phase I **NCT02374645**	Non-Small Cell Lung Cancer	N ~ 53	• 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 + *Lynparza* • 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 anti-tumour activity (POM) • Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of anti-tumour activity of AZD8186 in combination with abiraterone. • Part D: PK, safety, tolerability and recommended dose and schedule of AZD8186 in combination with AZD2014. Preliminary assessment of anti-tumour activity of AZD8186 in combination with AZD2014.	• 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/durvalumab • Arm A2 : AZD5069/durvalumab Dose Expansion 2L SCCHN: • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/durvalumab • Arm B4: AZD5069/durvalumab	• Safety/Efficacy trial	• FPD: Q3 2015 • LPCD: 2017 • Estimated completion: 2019
Phase 1b/II **NCT02549651**	Diffuse Large B-cell Lymphoma	N = 186	Dose escalation and expansion Arms: Experimental Arm: durvalumab monotherapy Experimental Arm: durvalumab and tremelimumab Experimental Arm: durvalumab and AZD9150	• Safety/Efficacy trial	• FPD: Q2 2016 • LPCD: 2021 • Estimated completion: 2021

* 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
Phase I **NCT02780713**	Healthy subjects	N ~ 14	• This is a Phase I open label single centre trial to assess the pharmacokinetics and safety of different forms and formulations of AZD9496 in healthy subjects	• Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites • Secondary Outcome Measures: Safety and tolerability	• FPD: Q2 2016 • Estimated completion: H2 2016

ATM AVI

Infections

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02655419**	Complicated Intra-Abdominal Infections (cIAIs)	N = 40	• Prospective open-label, multicentre trial to determine the pharmacokinetics (PK) and safety and tolerability of aztreonam-avibactam (ATM-AVI) for the treatment of complicated Intra-Abdominal Infections (cIAIs) in hospitalized adults Multi-centre trial in Germany, France, Spain	• Pharmacokinetics • Safety/tolerability • Treatment Outcomes (secondary)	• FPD: Q2 2016 • LPCD: H1 2017 • Completion: H2 2017

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 600mg BID for 8 weeks • Arm 2: Placebo 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 300mg BID for 12 weeks • Arm 2: AZD3241 600mg 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 = 30	• Arm 1: AZD3241 300mg BID for 12 weeks • Arm 2: AZD3241 600mg 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

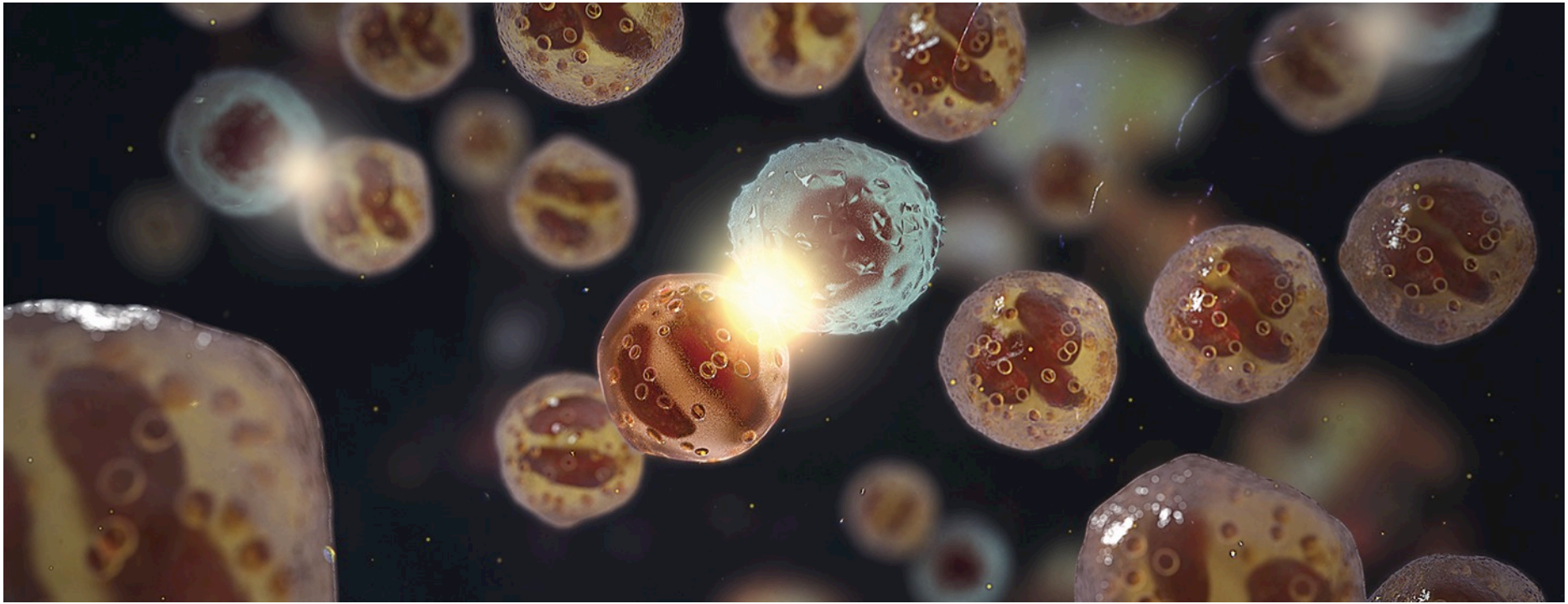
Trial phase	Patient population	Number of patients	Design	Endpoints	Status

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
					• Top-line results: Q2 2016

MedImmune

MedImmune
A member of the AstraZeneca Group

Early development - MedImmune



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 210mg SC QW for 3 weeks and then Q2W for 9 weeks • Arm 2: placebo SC QW for 3 weeks and then Q2W for 9 weeks Global trial – five countries	• Safety and tolerability • Change in the ESSDAI score from baseline to Day 99	• 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: 30mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 2: 105mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 3: 300mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • Arm 4: 600mg 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

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: 150mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose • Arm 3: 300mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose • Arm 4: MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose • Arm 5: 300300mg mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose (Japanese subjects) • Arm 6: 450mg 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

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

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: 3mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • Arm 2: 10mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • Arm 3: 3mg MEDI4920 (n = 3) or placebo (n = 2) as a single IV dose • Arm 4: 100mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 5: 300mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 6: 1000mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • Arm 7: 2000mg 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
Phase I **NCT02780674**	Anti-ILT7 (MEDI7734)	Patients with Type I Interferon-Mediated Autoimmune Diseases: Dermatomyositis, Polymyositis, Sjogren's Syndrome, Systemic Lupus Erythematosus, Systemic Sclerosis	N = 36	• Arm 1: 1mg MEDI7734 (n = 3) or placebo (n = 1) as a single SC dose • Arm 2: 5mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose • Arm 3: 15mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose • Arm 4: 50mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose • Arm 5: 150mg MEDII7734 (n = 6) or placebo (n = 2) as a single SC dose	• Safety, tolerability • Pharmacokinetics and pharmacodynamics	• FPD H2 2016 • LPCD: H2 2017 • Estimated top-line results: 2017

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: Q2 2016 • Top-line results: H2 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 **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 **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 **NCT02548585**	GLP-1-Glu MEDI0382	Male Adults with type-2 diabetes	N = 75	• MAD SC administration • Germany	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination • Efficacy: MMT glucose AUC, HbA1c, fructosamine and body weight loss	• FPD: Q1 2016 • LPCD: H2 2016 • Top-line results: 2017
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 level	• 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)	Solid tumours	N = 1,014	• 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 (durvalumab, Vidaza)	Myelodysplastic syndrome	N = 41	Dose-escalation and dose-expansion trial • Arm 1: durvalumab 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 and hematologic tumours

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

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02340975**	Gastric or GEJ adenocarcinoma	N = 236	• 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 = 144	• 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 = 446	• Dose Escalation: minimum 5 cohorts exploring various treme Q4W and durvalumab 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 = 380	• Dose Exploration: 2 cohorts exploring various Q4W treme and durvalumab dose combinations and 2 cohorts exploring various Q2W treme and durvalumab 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 anti-tumour 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
Phase Ib **NCT02549651**	Diffuse Large B-cell Lymphoma	N = 186	• Arm A: durvalumab • Arm B: durvalumab + tremelimumab • Arm C: tremelimumab + AZD9150 US and European trial centres	• Safety & tolerability • Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers	• FPD: Q3 2016 • LPCD: H2 2018 • Estimated top-line results: 2021

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) + durvalumab IV Expansion phase • *Iressa* (QD) + durvalumab 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: 2019

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/ durvalumab IV • Cohort B trametinib 2mg QD/ durvalumab IV • Cohort C trametinib 2mg QD/ durvalumab 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 (escalation phase) RCC (expansion phase)	N = 150	Dose-escalation phase • Durvalumab IV + MEDI0680 IV Dose-expansion phase at selected dose from dose-escalation phase • Durvalumab 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	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02318394**	Advanced malignancies	N = 196	Dose-escalation phase • MEDI0562 IV Dose-expansion phase • MEDI0562 IV recommended dose	• Safety • Determination of MTD • Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, biomarker activity, and immunogenicity	• FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2017
Phase I **NCT02705482**	Advanced malignancies	N = 364	• ARM A: MEDI0562 IV + durvalumab IV • ARM B: MEDI0562 IV + tremelimumab IV	• Safety • Secondary endpoints include preliminary anti-tumour 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 = 39	Dose-escalation phase • MEDI6383 IV • MEDI6383 IV + durvalumab IV Dose-expansion phase • MEDI6383 IV recommended dose • MEDI6383 IV + durvalumab IV recommended dose US-only trial	• Safety • Determination of MTD • Secondary endpoints include preliminary anti-tumour 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: Q2 2016 • Estimated top-line results: H2 2016
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 2011 • LPCD: Q3 2015 • Top-line results: Q3 2015 • completed

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 preliminary anti-tumour 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: 2019

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 = 43	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 = 188	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 preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	• FPD: Q3 2015 • LPCD: 2018 • Estimated top-line results: 2019

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: Q4 2015 • Completed

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: Q2 2016 • Estimated top-line results: H2 2016

MEDI7352 (NGF TNF Bispecific)

Alzheimer's disease

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02508155**	Painful osteoarthritis of the knee	N = 160	• SAD & MAD • Up to 10 iv cohorts are planned vs. placebo • 2 SC cohorts are planned vs. placebo Europe only	• Safety, tolerability, PK, PD	• FPD: Q1 2016 • LPCD: H1 2017 • Estimated top-line results: H2 2017

Vaccine biologics

Influenza vaccines

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02269488**	MEDI3250 *FluMist Quadrivalent*	Healthy Japanese 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*	Healthy Japanese 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: Q2 2016 • Estimated top-line results: H2 2016
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: Q2 2015 • Complete
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: H2 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

Clinical trials appendix
Q2 2016 update

AstraZeneca
What science can do