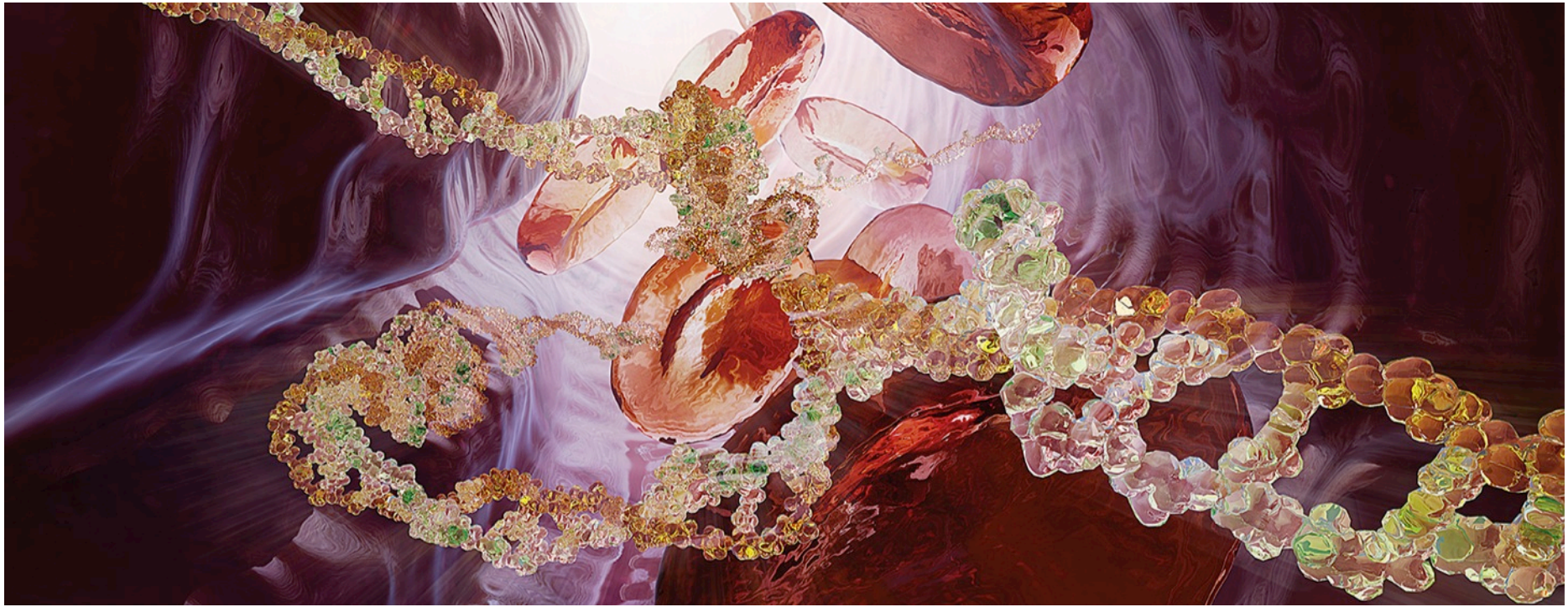
Clinical trials appendix
Year-To-Date and Q3 2016 Results update

AstraZeneca
What science can do



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from https://clinicaltrials.gov/ to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 30 September 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 and many times are event driven.

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

List of abbreviations

AE	Adverse Event
AUC	Area Under Curve
BID	Bis In Die (two times a day)
CE	Clinically Evaluable
CMAX	Maximum Concentration Absorbed
cMITT	Clinical-Modified Intent To Treat
CNS	Central Nervous System
DLT	Dose-Limiting Toxicity
FDC	Fixed-Dose Combination
FEV	Forced-Expiratory Volume
FPD	First Patient Dosed
IM	Intra Muscular
IR	Immediate Release
IV	Intravenous
LCM	Life-Cycle Management
LPCD	Last Patient Commenced Dosing
MAD	Multiple Ascending Dose
MDI	Metered-Dose Inhaler
MITT	Modified Intent To Treat
mMITT	Microbiological-Modified Intent To Treat
MTD	Maximum Tolerated Dose
NME	New Molecular Entity
OLE	Open Long-term Extension
ORR	Objective Response Rate
OS	Overall Survival
PFS	Progression-Free Survival
PK	Pharmacokinetics
Q2W	Quaque (every) Two Weeks
Q3W	Quaque (every) Three Weeks
Q4W	Quaque (every) Four Weeks
Q8W	Quaque (every) Eight Weeks
QD	Quaque Die (one time a day)
SAD	Single Ascending Dose
SC	Sub Cutaneous
TID	Ter In Die (three times a day)
TOC	Test Of Cure
XR	Extended Release

Movement since the last update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
NMEs **AZD4831** Myeloperoxidase Inhibitor **MEDI7734** ILT7 myositis	**NMEs** **MEDI0382** GLP-1/glucagon diabetes/obesity **MEDI5872#** B7RP-1 mAb primary Sjögren's syndrome **Additional indications** **durvalumab#+MEDI0680** PD-L1 + PD-1 mAb solid tumours ***Tagrisso*** EGFR tyrosine kinase inhibitor Leptomeningeal disease ***Lynparza* + AZD6738** ATR inhibitor gastric cancer		**NMEs** **ZS-9 [US] resubmission[5]** potassium binder hyperkalaemia **Additional indications** ***Tagrisso* AURA3 & AURA17 [CN][5]** EGFR tyrosine kinase inhibitor 2L advanced EGFRm T790M NSCLC ***Faslodex* FALCON [JP][5]** oestrogen receptor 1L adv. breast
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from Registration**
NMEs **MEDI3617#** ANG-2 mAb solid tumours **Additional indications** **lesinurad + allopurinol FDC[#2]** URAT-1+XO gout	**NMEs** **AZD7624** Inhaled P38 inhibitor COPD **inebilizumab#** CD19 mAb diffuse B-cell lymphoma **Additional indications** **tralokinumab[#2]** IL-13 mAb atopic dermatitis	**NMEs** **selumetinib# SELECT-1** MEK inhibitor 2nd line KRASm NSCLC **Additional indications** ***Brilinta* EUCLID** PAD outcomes	**NMEs** **cediranib ICON6[1]** VEGFR tyrosine kinase inhibitor PSR ovarian **MEDI-550[3]** pandemic influenza virus vaccine **brodalumab# AMAGINE 1,2,3[2]** IL-17R mAb psoriasis **Additional indications** ***Brilinta* [JP][4]** P2Y12 receptor antagonist arterial thrombosis ***Brilinta* PEGASUS-TIMI 54 [JP][4]** P2Y12 receptor antagonist outcomes trial in patients with prior myocardial infarction

Partnered and/or in collaboration
[1] Marketing Authorisation Application withdrawn [2] Divested [3] Completed (conditional approval received) [4] Submission Approved [5] Submission Accepted

New Molecular Entity (NME)[1] Pipeline

Oncology | Cardiovascular and metabolic disease | Respiratory | Other

Phase I

31 New Molecular Entities

Small molecule		Large molecule
AZD0156 ATM solid tumours	AZD4831 MPO HFpEF	MEDI0562# hOX40 solid tumours
AZD1775# Wee1 solid tumours	AZD5718 FLAP CAD	MEDI0680 PD-1 solid tumours
AZD2811# Aurora solid tumours	AZD1419# TLR9 asthma	MEDI1873 GITR solid tumours
AZD4635 A2aR inhibitor solid tumours	AZD5634 inhaled ENaC cystic fibrosis	MEDI4276 HER2 solid tumours
AZD6738 ATR solid tumours	AZD7986# DPP1 COPD	MEDI-565# CEA BITE GI tumours
AZD8186 PI3Kβ solid tumours	AZD8871# MABA COPD	MEDI9197# TLR 7/8 solid tumours
AZD9150# STAT3 haems & solids	AZD9567 SGRM RA	MEDI9447 CD73 solid tumours
AZD9496 SERD ER+ breast	AZD8108 NMDA suicidal ideation	MEDI8111 Rh-Factor II trauma/bleeding
AZD4076 miR103/107 NASH		MEDI9314 IL4R atopic dermatitis
		MEDI1814 amyloidβ Alzheimer's disease
		MEDI7352 NGF/TNF osteoarthritis pain
		MEDI0700# BAFF/B7RP1 SLE
		MEDI4920 CD40L-Tn3 pSS
		MEDI7734 ILT7 myositis

Phase II

25 New Molecular Entities

Small molecule	Large molecule
AZD3759 or *Tagrisso* BLOOM EGFR NSCLC CNS mets	MEDI-573# IGF metastatic breast cancer
AZD4547 FGFR solid tumours	MEDI0382 GLP-1/glucagon diabetes/obesity
AZD5363# AKT breast cancer	MEDI4166 PCSK9/GLP-1 diabetes/CV
savolitinib# MET pRCC	MEDI6012 LCAT ACS
vistusertib (AZD2014) mTOR 1/2 solid tumours	AZD9412# Inhaled βIFN asthma/COPD
abediterol# LABA asthma/COPD	tezepelumab# TSLP asthma/atopic dermatitis
AZD7594 Inhaled SGRM asthma	MEDI6872# primary Sjögren's syndrome
AZD3241 MPO Multiple System Atrophy	inebilizumab# CD19 neuromyelitis optica
verinurad URAT-1 hyperuricemia/gout	mavrilimumab# GM-CSFR rheumatoid arthritis
ATM AVI# BL/BLI SBI	MEDI2070# IL-23 Crohns
CXL# BLI/cephalosporin MRSA	MEDI3902¶ Psl/PcrV pseudomonas
	MEDI4893 staph alpha toxin SSI
	MEDI8852 influenza A treatment
	MEDI8897# RSV passive prophylaxis
	MEDI7510 sF+GLA-SE RSV prevention

Phase III

10 New Molecular Entities

Small molecule	Large molecule
acalabrutinib# BTK inhibitor B cell malignancy	durvalumab#¶ solid tumours
selumetinib# ASTRA MEK 2L diff. thyroid	moxetumomab pasudotox# PLAIT CD22 HCL
roxadustat# HIFPH anaemia CKD/ESRD	benralizumab# IL-5R severe asthma
PT010 LABA/LAMA/ICS COPD	tralokinumab IL-13 severe asthma
AZD3293# BACE Early Alzheimer's disease	anifrolumab# TULIP IFNαR SLE

Applications Under Review

1 New Molecular Entities

Small molecule	Large molecule
ZS-9 potassium binder hyperkalaemia	

[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

Lifecycle Management (LCM)[1] Pipeline

Oncology | Cardiovascular and metabolic disease | Respiratory | Other

Phase I

2 Projects

Small molecule

Large molecule

- durvalumab# PD-L1 solid tumours
- anifrolumab# IFNαR SLE SC

Phase II

7 Projects

Small molecule

- *Tagrisso* EGFRm LM
- *Lynparza* PARP prostate cancer
- *Brilinta/Brilique* HESTIA paeds w/ sickle cell
- PT010 LABA/LAMA/ICS asthma

Large molecule

- durvalumab# PD-L1 solid tumours
- durvalumab# PD-L1 bladder
- anifrolumab# IFNαR lupus nephritis

Phase III

23 Projects

Small molecule

- acalabrutinib# BTK inhibitor 1st line CLL
- acalabrutinib# BTK inhibitor r/r CLL, high risk
- *Faslodex* FALCON oestrogen receptor 1L adv. breast
- *Lynparza* OlympiA PARP gBRCA adjuvant breast
- *Lynparza* OlympiAD PARP gBRCA metastatic breast
- *Lynparza* POLO PARP pancreatic cancer
- *Lynparza* SOLO-1 PARP 1L BRCAm ovarian
- *Lynparza* SOLO-2 PARP >2L BRCAm PSR ovarian
- *Lynparza* SOLO-3 PARP BRCAm PSR ovarian
- *Tagrisso* ADAURA EGFR adj. EGFRm NSCLC
- *Tagrisso* AURA 3 EGFR T790M NSCLC >2L

- *Tagrisso* FLAURA EGFR 1L adv. EGFRm NSCLC
- *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
- *Symbicort* BAI asthma/COPD
- *Symbicort* SYGMA as needed in mild asthma
- *Nexium* (CN only) stress ulcer prophylaxis

Large molecule

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

Applications Under Review

1 Project

Small molecule

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

Large molecule

Oncology Combinations

Phase I

10 Projects

- AZD1775#+durvalumab# Wee1+PD-L1 solid tumours
- *AZD1775#*+Lynparza Wee1+PARP solid tumours
- durvalumab#+dabrafenib+trametinib PD-L1+BRAF+MEK melanoma
- durvalumab#+Iressa PD-L1+EGFR NSCLC
- 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

6 Projects

- *AZD6738*+Lynparza ATR inhibitor gastric
- durvalumab#+MEDI0680 PD-L1+PD-1 solid tumours
- 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 III

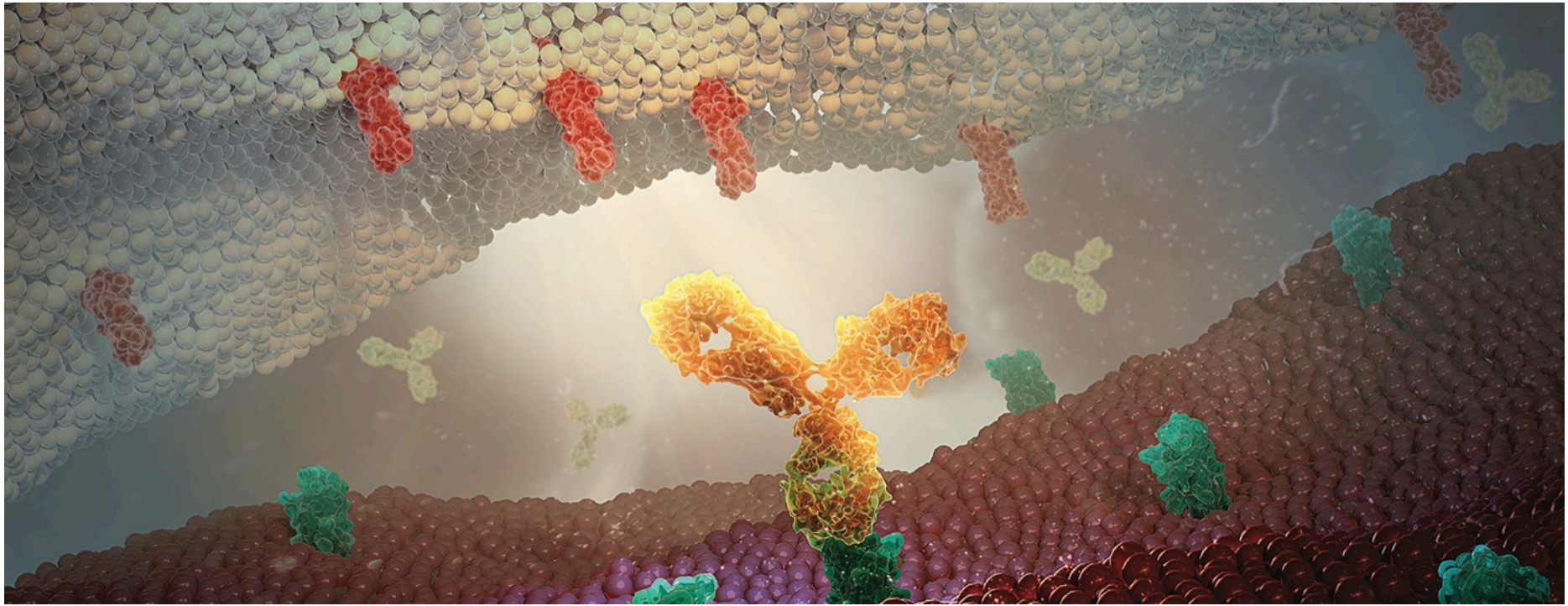
8 Projects

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

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

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

Approved medicines



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 • Top-line results reported: Q4 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 I / II **MEDIOLA** **NCT02734004**	gBRCAm ovarian cancer 2L+ gBRCAm HER2-negative breast cancer 1-3L Small cell lung cancer 2L+ Gastric cancer 2L+	N = 133	• 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: 2017 • Estimated top-line results: 2018

PARP= Poly ADP Ribose Polymerase

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: H1 2017
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	• PFS • Secondary endpoint: OS	• FPD: Q1 2015 • LPCD: H2 2017 • Estimated top-line results: 2018
Phase II **NCT01972217**	Metastatic castration resistant prostate cancer	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: H1 2017

PARP= Poly ADP Ribose Polymerase

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 • Primary completion: Q3 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: H2 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 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)

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 combination 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

Brilinta (ADP receptor antagonist)

Cardiovascular

Trial phase	Patient population	Number of patients	Design	Endpoints (primary)	Status
Phase III **THEMIS** **NCT01991795**	Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	N = 19,000	• Arm 1: *Brilinta* 60mg BiD • Arm 2: Placebo BiD *on a background of Acetylsalicylic Acid if not contra indicated or not tolerated* Global trial – 42 countries	• 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 subjects	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 *Brilinta* dispersible tablet vs *Brilinta* IR tablet	• FPD: Q2 2015 • LPCD: Q3 2015 • Completion date: Q3 2015 • Top-line results: Q4 2015
Phase III (BE) **NCT02400333**	Caucasian healthy subjects	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* dispersible tablet vs *Brilinta* immediate release 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)

Type-2 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 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 Asia trial – three countries	• Change from baseline in HbA1c at week 24	• FPD: Q1 2014 • LPCD: Q1 2016 • Top-line results: Q2 2016 • Completion date: Q3 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: H1 2017 • Estimated top-line results: H2 2017 • Estimated completion date: H2 2017
Phase III **DEPICT 1** **NCT02268214** Partnered: BMS	Type-1 diabetes	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 Q2 2016 • Estimated top-line results : H1 2017
Phase III **DEPICT 2** **NCT02460978** Partnered: BMS	Type-1 diabetes	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: H1 2017 • Estimated top-line results: 2018

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

Onglyza (DPP-4 inhibitor)

Type-2 diabetes

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02104804**	Type-2 diabetes	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 • Completion: Q1 2016 • Top-line results: Q2 2016
Phase III **NCT02273050**	Type-2 diabetes	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 • Completion: Q3 2016 • Top-line results: Q4 2016

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

Type-2 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 • Top-line results: Q3 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: Q3 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: 2H 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: Q3 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: 2H 2017 • Completed: Q3 2016 - 28-week data • Estimated completion: H1 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: 2016 • 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 cardiovascular disease 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 • LPCD: Q3 2017 • 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 • Completed: Q4 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* 4g + 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 subjects	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: Q2 2016
Phase I **Japanese food interaction** **NCT02372344**	Healthy male subjects	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

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 = 3,850	• Arm 1: *Symbicort Turbuhaler* 160/4.5 µg 'as needed' + Placebo *Pulmicort Turbuhaler* 200µg bid • Arm 2: *Pulmicort* 200 µg Turbuhaler bid + terbutaline 0.4mg Turbuhaler 'as needed' • Arm 3: terbutaline Turbuhaler 0.4mg 'as needed' + placebo *Pulmicort* 200µg 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 FEV1	• FPD: Q4 2014 • LPCD: Q3 2016 • Estimated completion: H2 2017 • Estimated top-line results: H2 2017
Phase III **SYGMA2** **NCT02224157**	Patients in need of GINA step-2 treatment	N = 4,214	• Arm 1: *Symbicort Turbuhaler* 160/4.5µg 'as needed' + Placebo *Pulmicort Turbuhaler* 200µg bid • Arm 2: *Pulmicort* 200µg 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 FEV1 • Time to trial specific asthma related discontinuation	• FPD: Q1 2015 • LPCD: Q3 2016 • Estimated completion: H2 2017 • Estimated top-line results: H2 2017

ICS= Inhaled corticosteroids
LABA= Long Acting Beta Agonist

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 – five 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 • Top-line 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 – two countries	• Time to first Major Adverse Cardiovascular Event (MACE). Up to 36 Months • Rate of moderate or severe COPD exacerbations per patient per year during the first year of treatment. • Rate of hospitalisations due to COPD exacerbation per patient per year during the first year of treatment • Time to first Major Adverse Cardiovascular Event (MACE) or other serious cardiovascular events of interest. Up to 36 Months	• FPD: Q3 2013 • LPCD: Q3 2016 • Estimated top-line 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 – one country	• Change from baseline in normalised forced expiratory volume in one second (FEV1). Week 3. FEV1 over the 24-hour period (AUC0-24) will be measured following morning administration • 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 • Top-line results released: Q4 2015 • Estimated completion: Q3 2016

LAMA= Long Acting Muscarinic Agonist

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 400/12 µg • Arm 2: Placebo to aclidinium/formoterol FDC 400/12 µg Global trial – one Country	• Change from baseline in normalised FEV1 AUC over the 12h 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 one and day seven on treatment. • Change from baseline in morning pre-dose FEV1 at day seven on treatment.	• FPD: Q3 2016 • LPCD: H1 2017 • Estimated top-line 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 12 µg • 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 400µg at week 24. • Change from baseline in morning predose (trough) FEV1 of AB/FF 400/12µg compared to FF 12µg at week 24. • Change from baseline in morning predose (trough) FEV1 at week 24 • comparing AB 400µg versus TIO 18µg.	• FPD: Q3 2016 • LPCD: Q3 2016 • Estimated top-line results: H1 2017 • Estimated completion: H2 2017
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 – five Countries	• Change from baseline in trough Functional Residual capacity (FRC) after four weeks of treatment • Change from baseline in Endurance Time (ET) during constant work rate cycle ergometry to symptom limitation at 75% of Wmax after eight weeks of treatment • Percentage of inactive patients (<6000 steps per day) after eight weeks on treatment	• FPD: Q2 2015 • LPCD: Q2 2016 Estimated top-line results: Q3 2016 Estimated completion: H1 2017

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

Bevespi Aerosphere (LAMA/LABA)

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 first subject first visit to database lock is approximately 21 months. US, Australia, New Zealand	• Change from baseline in morning pre-dose trough FEV1	• 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 FEV1	• 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

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

Bevespi Aerosphere (LAMA/LABA)

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	• FEV1 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	• FEV1 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 FEV1 GFF 14.4/9.6µg with Aerochamber Plus VHC relative to GFF14.4µg w/o Aerochamber Plus VHC on day eight • 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

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

Bevespi Aerosphere (LAMA/LABA)

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 FEV1 at week 24 of treatment • For the Japan approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV1 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 FEV1 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 eight	• FPD: Q4 2016 • LPCD: H2 2017 • Estimated top-line results: 2018

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

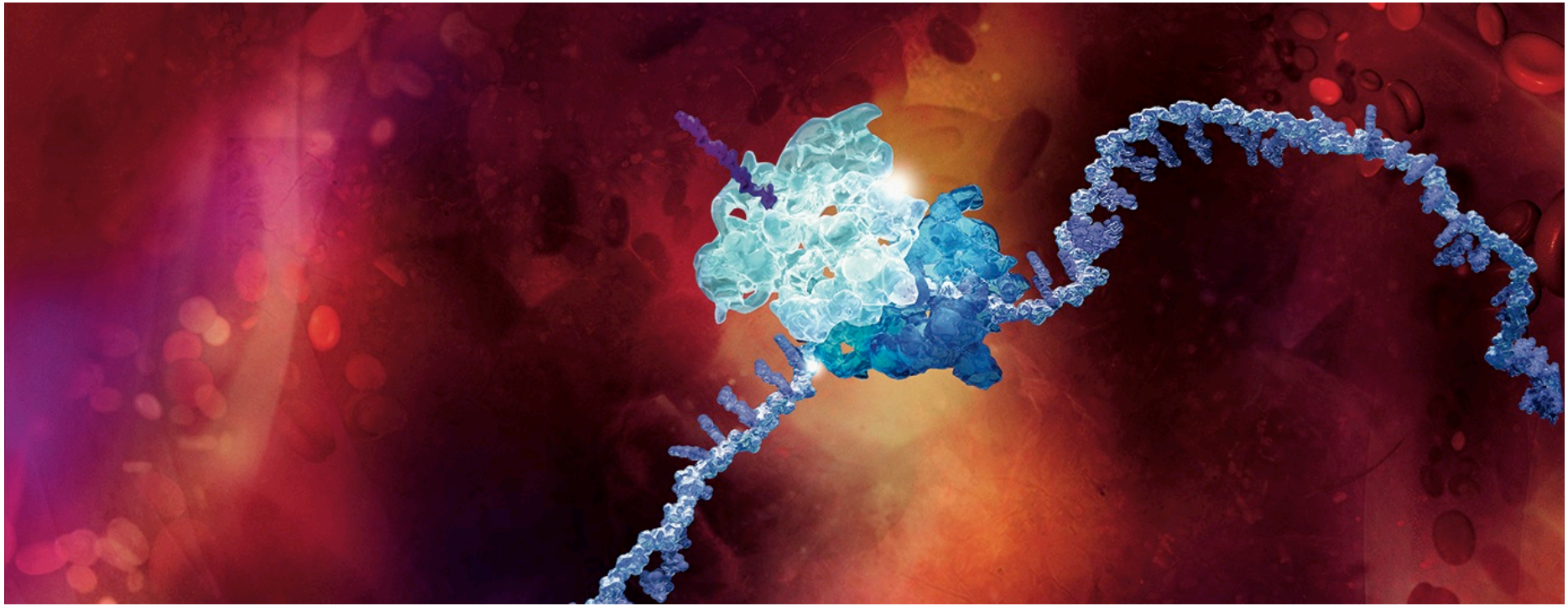
Daliresp/Daxas (oral PDE4 inhibitor)

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: Q4 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 trial treatment for any reason during the main period	• Completed: Q3 2015 • Estimated results: Q4 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: Q4 2016

ICS= Inhaled corticosteroids
LABA= Long Acting Beta Agonist

Late-stage pipeline



Durvalumab (MEDI4736; PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III ADJUVANT **NCT02273375** **Partnered with NCIC CTG**	Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK pos)	N = 1,100	• Arm 1: MEDI4736 mg/kg IV Q4W x 12 mos • Arm 2: Placebo Global trial	• DFS • OS	• FPD: Q1 2015 • Estimated completion: 2020
Phase III PACIFIC **NCT02125461**	Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	N = 702	• Arm 1: MEDI4736 IV Q2W • Arm 2: placebo Global trial	• PFS • OS	• FPD: Q2 2014 • LPCD: Q2 2016 • Estimated completion: H2 2017
Phase II/III Lung Master Protocol **NCT02154490** **Partnered with NCI, FNIH, and SWOG**	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	N = 140 ; 100 Durvalumab treated (4736 substudy only);	Umbrella trial with 5 arms based on biomarker expression • Substudy A: MEDI4736 (non-match for other biomarker driven substudies) IVQ2W single arm MEDI4736 PhII only • Substudy B: PI3K Inhibitor vs. docetaxel • Substudy C: CDK4/6 inhibitor vs. docetaxel • Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel • Substudy E: C-MET/HGFR Inhibitor + erlotinib vs. Erlotinib (Substudy is closed)	Arm 1 • ORR, PDL1 +	• FPD: Q2 2014 • Estimated completion: 2022
Phase II ATLANTIC **NCT02087423**	Stage IIIB-IV NSCLC patients PD-L1+ve patients 3L	N = 293	• Arm 1: MEDI4736 IV Q2W (EFGR/ALK WT) • Arm 2: MEDI4736 IV Q2W (EFGR/ALK M+) • Arm 3: MEDI4736 IV Q2W (EFGR/ALK WT) (90% PD-L1 - expression) Global trial – 18 countries	• Objective Response Rate • Secondary endpoints include duration of response, PFS and OS	• FPD: Q1 2014 • LPCD: Q2 2015 • First data: Q4 2015 • Completed: Q3 2016
Phase I/II Sequencing Study **NCT02179671**	Stage IIIB-IV NSCLC patients	N = 72	• Arm 1: Iressa initially then switch to MEDI4736 IVQ2W • Arm 2: AZD9291 then switch to MEDI4736 • Arm 3: selumetinib + docetaxel then switch to MEDI4736 • Arm 4: tremelimumab then switch to MEDI4736	• Complete Response Rate • ORR, Disease Control Rate	• FPD: Q3 2014 • LPCD: Q2 2016 • Completed: Q3 2016

Durvalumab (MEDI4736; PD-L1 mAb)

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

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **HAWK** **NCT02207530**	HNSCC 2L PD-L1 positive	N = 112	• Single-arm: durvalumab IV Q2W	• ORR	• FPD: Q1 2015 • LPCD: Q2 2016 • Estimated completion: Q4 2016 (internal availability)
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: Q3 2017 • Estimated completion: 2018
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, Oesophageal Cancer and SCCNH, Q2, and Q4 schedule • Dose Expansion of combination: Biliary Tract Cancer and Oesophageal Cancer, durvalumab Q4W 20mg/kg + tremelimumab Q4W 1mg/kg Trial conducted in Japan	• Safety • Optimal biologic dose	• FPD: Q3 2013 • LPCD: H2 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 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: H1 2017
Phase III **MYSTIC** **NCT02453282**	NSCLC 1L	N=1,118	• Arm 1: durvalumab • Arm 2: durvalumab + tremelimumab • Arm 3: Standard of care	• PFS • OS • Safety	• FPD: Q3 2015 • LPCD: Q3 2016 • Estimated completion: H1 2017
Phase III **NEPTUNE** **NCT02542293**	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** **NCT02369874**	HNSCC 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**	HNSCC 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: H2 2017
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**	HNSCC 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: H1 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-Adenocarcinoma	N =76	• Arm 1 Tremelimumab in Urothelial Bladder Cancer • Arm 2 TremelimumabTriple-negative Breast Cancer • Arm 3 Tremelimumab Pancreatic Ductal-Adenocarcinoma	• 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: H1 2017
Phase 1 Combination in Advanced Solid Tumours **NCT02658214**	Solid tumours	N = 80	• Arm 1 Ovarian cancer and HNSCC: 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-oOesophageal junction (GEJ): Durvalumab + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid)	• Safety	• FPD: Q1 2016 • LPCD: 2018 • Estimated completion: 2018

Acalabrutinib (ACP-196)

Blood cancers

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: 2019
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	• Efficacy • Secondary endpoints: Safety, TTP, PFS, OS	FPD: Q1 2015 Estimated completion: 2017
Phase II **ACE-LY-004** **NCT02213926**	Relapsed/refractory Mantle Cell Lymphoma	N = 124	Acalabrutinib monotherapy	• ORR	FPD: Q1 2015 LPCD: Q1 2018 Enrolment complete Estimated completion: 2017
Phase I/II **ACE-CL-001** **NCT02029443**	CLL/SLL/RT	N=286	Acalabrutinib monotherapy Dose escalation and expansion	• Safety, PK, PD • Secondary endpoints: ORR, DOR, and PFS	FPD: Q1 2014 LPCD: Q2 2016 Enrolment complete Estimated completion: 2019
Phase I/II **ACE-LY-001** **NCT02328014**	B-Cell Malignancies	N=126	Dose escalation and expansion trial of the combination of acalabrutinib and ACP-319 (Pi3K inhibitor)	• Safety • ORR	FPD: Q1 2015 Estimated completion: 2017
Phase I/II **ACE-WM-001** **NCT02180724**	Waldenstrom Microglobulinemia	N=88	Acalabrutinib monotherapy	• ORR	FPD: Q3 14 LPCD: Q4 15 Enrolment Complete Estimated completion: 2017

Acalabrutinib (ACP-196)

Blood cancers

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase I/II **ACE-LY-005** NCT02362035	Hematological Malignancies	N=187	Acalabrutinib + pembrolizumab	• Safety • Secondary endpoints: ORR, DOR, PFS, OS, TTNT	FPD: Q1 2015 Estimated completion: 2021
Phase Ib **ACE-LY-002** NCT02112526	Relapsed/refractory de novo ABC DLBCL	N=21	Acalabrutinib monotherapy	• Safety	FPD: Q3 2014 LPCD: Q2 2016 Enrolment complete Estimated completion: 2017
Phase Ib **ACE-LY-106** NCT02717624	Mantle Cell Lymphoma	N=48	Acalabrutinib in combination with 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 LPCD: Q1 2016 Enrolment Complete Estimated completion: 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: Q3 2016 Enrolment complete Estimated completion: 2018
Phase I **ACE-CL-002** NCT02157324	Relapsed/refractory CLL/SLL	N=12	Acalabrutinib in combination with ACP-319 Dose escalation	• Safety, PK, PD	FPD: Q3 14 LPCD: Q3 15 Enrolment complete 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 • Secondary endpoints: PD, PFS, TTN, OS	FPD: Q1 2015 LPCD: Q1 2018 Enrolment complete Estimated completion: 2018

Acalabrutinib (ACP-196)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase II **ACE-ST-006** **NCT02454179**	≥ 2L advanced or metastatic head and neck squamous cell carcinoma	N = 78	• **Arm A:** pembrolizumab • **Arm B:** acalabrutinib+ pembrolizumab	• ORR	FPD: Q2 2015 LPCD: Q2 2016 Enrolment complete Est. 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 Enrolment complete Est. 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 Enrolment complete Est completion: H2 2017
Phase II **ACE-ST-003** **NCT02362048**	≥ 2L advanced or metastatic pancreatic cancer	N = 77	• **Arm A:** acalabrutinib • **Arm B:** acalabrutinib+ pembrolizumab	• Safety	FPD: Q2 15 LPCD: Q1 16 Enrolment complete Est. completion: H2 2017
Phase II **ACE-ST-005** **NCT02351739**	Platinum-resistant urothelial bladder cancer	N = 78	• **Arm A:** pembrolizumab • **Arm B:** acalabrutinib+ pembrolizumab	• ORR	FPD: Q2 2015 LPCD: Q1 2016 Enrolment complete Est. Completion 2018
Phase Ib/II **ACE-ST-209** **NCT02586857**	≥ 2L glioblastoma multiforme	N = 72	• **Arm A:** acalabrutinib 200 mg BID • **Arm B:** acalabrutinib 400 mg QD	• Safety, ORR • Secondary Endpoints: DOR, PFS, PFS-6, OS	FPD: Q1 2016 Est. completion: 2018

Moxetumomab pasudotox (CD22 mAb)

Blood cancers

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)

Selumetinib (AZD6244) (MEK-inhibitor)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
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
 	
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

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: 2018 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: 2018 Sponsored by Astellas

HIF-PHI= Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor

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

HIF-PHI= Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

Benralizumab (IL-5R mAb)

Severe, uncontrolled asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **CALIMA** **NCT01914757**	Severe, uncontrolled asthma, 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, uncontrolled asthma, 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, uncontrolled asthma 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 • Completed: Q3 2016
Phase III **MELTEMI** **NCT02808819**	A multicenter, open-label, safety extension trial with benralizumab (MEDI-563) for asthmatic adults on Inhaled Corticosteroid plus Long-acting Beta2 Agonist Age 18-75 years	N = 770	• Arm 1: 30mg Q4W SC • Arm 2: 30mg Q8W SC	• Safety and tolerability	• FPD: Q2 2016 • Estimated completion: 2019
Phase III **ALIZE**	A multicenter, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of benralizumab on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years	N = 100	• Arm1 30mg Q4W SC with one dose of seasonal influenza virus vaccine Intramuscular (IM) at week eight. • Arm1 Placebo Q4W SC with one dose of seasonal influenza virus vaccine 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: Q2 2016 • Estimated completion: 2017

Benralizumab (IL-5R mAb)

Severe, uncontrolled 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, reliability, and performance of a pre-filled syringe With Benralizumab Administered at Home	• FPD: Q2 2015 • Completed: Q2 2016
Ph III **ARIA** **NCT02821416**	A Double-Blind, randomised, parallel group, placebo-controlled multi-centre trial to evaluate the effect of Benralizumab on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years	N = 38	• Arm1 : 30mg Q4W SC • Arm2: Placebo SC	• Safety and tolerability	• FPD Q3 2016 • Estimated completion 2019

ICS= Inhaled corticosteroids
LABA= Long Acting Beta Agonist

Benralizumab (IL-5R mAb)

Severe, uncontrolled asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SOLANA** **NCT02869438**	Severe asthma Age 18-75 years	N = 230	• Arm1: 30mg Q4W SC • Arm2: Placebo SC 16-week trial Global trial – six countries	• Onset and maintenance of effect on lung function	• Estimated FPD: Q4 2016 • Estimated completion: 2018
Phase III **GRECO** **NCT02918071**	Severe asthma Age 18-75 years	N = 120	Open label 30mg Q4w 28-week trial Global trial - two countries	• % of patients/ caregivers who successfully self administer at home	• Estimated FPD: Q4 2016 • Estimated completion: 2018

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

Tralokinumab (IL-13 mAb)

Severe, uncontrolled asthma

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

PT010 (LAMA/LABA/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* Turbuhaler 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: 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* Turbuhaler 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* Turbuhaler) • 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 (LAMA/LABA/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, four-period, five-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 (FEV1) • 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 FEV1 within three hours post-dosing on Day 15	• FPD: Q2 2015 • LPCD: Q4 2015 • Top-line results: Q2 2016* • Clinically completed

PT010 (LAMA/LABA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I (BGF PK trial) **NCT02189304**	Healthy subjects	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, three-period, three-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 subjects	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 subjects	N = 24	Treatment (four-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, four-period, four-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

LAMA= Long Acting Muscarinic Agonist
LABA= Long Acting Beta Agonist
ICS= Inhaled corticosteroids

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: 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 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 subjects	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 • Top-line results: Q3 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

AZD3293 (BACE inhibitor)

Alzheimer's disease

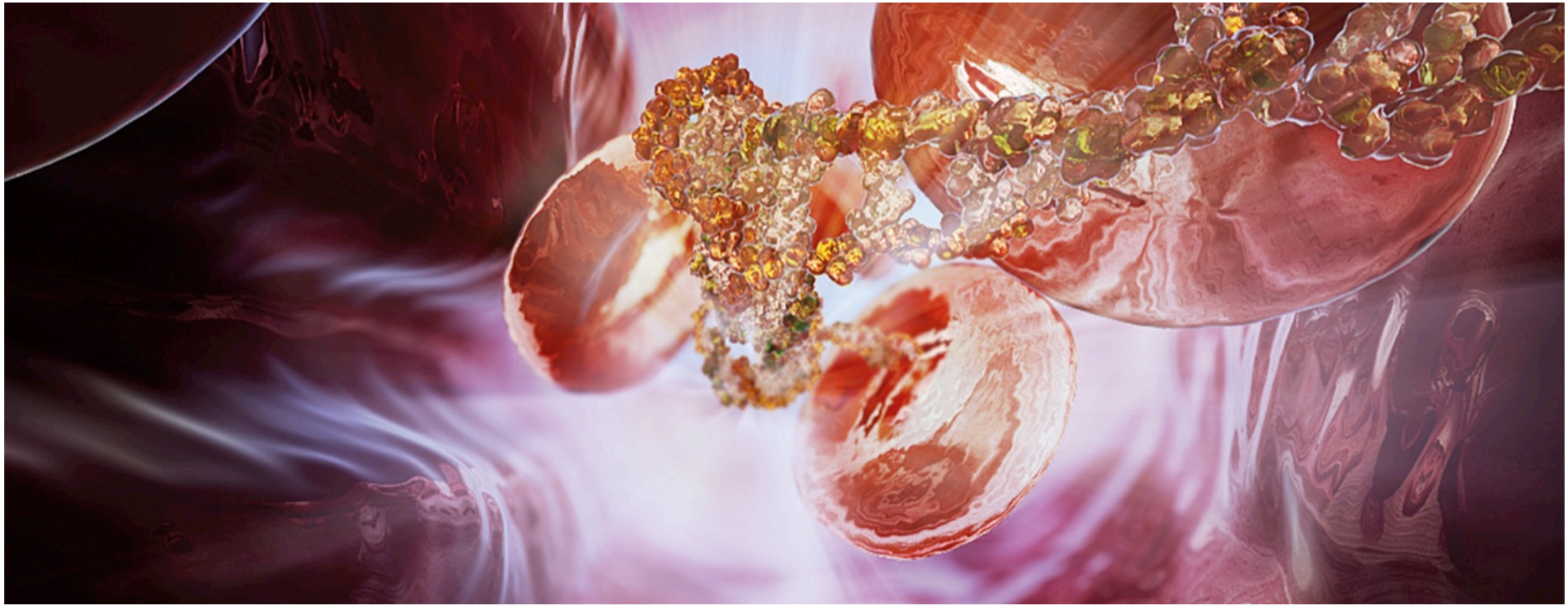
Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **AMARANTH** **NCT02245737**	Early Alzheimer's disease patients	N = 2,202	• Arm 1: AZD3293 20mg once daily • Arm 2: AZD3293 50mg once daily • Arm 3: Placebo once daily 24-month treatment duration Global trial – 14 countries	• 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: H2 2017 • Estimated top-line results: 2019
Phase III **DAYBREAK-ALZ** **NCT02783573**	Mild Alzheimer's disease patients	N = 1,899	• Arm 1: AZD3293 20 mg once daily • Arm 2: AZD3293 50 mg once daily • Arm 3: placebo once daily 18-month treatment duration + 18-month delayed start extension Global trial – 18 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: Q3 2016 • LPCD: 2018 • Estimated top-line results: 2019

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 Enrolment complete. Estimated completion: Q2 2016

Early development - IMED



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)

Ovarian cancer, triple-negative breast cancer, Non-Small Cell Lung Cancer (NSCLC)

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: Q3 2014 • Estimated completion: H2 2016 (OS Follow-up) • Note: Data collection for primary outcome measure completed Q4 2014
Phase II **NCT02272790**	PR ovarian cancer	N = 70	• Arm C: Carboplatin + AZD1775 • Arm D: PLD + 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 of Response, PFS	• FPD: Q3 2015 • LPCD: 2018 • Estimated completion: 2018
Phase I **NCT02610075**	Advanced solid tumours	N = 18	• Monotherapy Dose escalation trial to determine MTD Conducted in US	• Safety and tolerability	• FPD: Q4 2015 • LPCD: H2 2017 • Estimated completion: 2018
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: H2 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

Approved medicines
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** **Partnered**	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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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-oOesophageal 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: Q4 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 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 = 36 (estimated) N = 15	• 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. • 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	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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

AZD5069 (CXCR2)

Solid tumours

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Squamous Cell Carcinoma of the Head & Neck (HNSCC)	N = 147	Dose Escalation advanced solid and blood cancers • Arm A1: AZD9150/durvalumab • Arm A2 : AZD5069/durvalumab Dose Expansion 2L HNSCC: • 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 = 19	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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 • ORR & OS are secondary endpoints	• FPD: Q1 2014 • Estimated primary completion: Q1 2016 • Estimated completion: 2017
Phase I **NCT01226316**	Breast and gynaecological cancers with PIK pathway mutation	N = 12-24 per arm (Parts E & F)	AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant [initially 12 patients per arm with option to expand to 24 patients in one or more arms] • Part E arm 1: ER+ Breast with AKT-1 mutation (prior *Faslodex* resistance) • Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to *Faslodex*) • Part F arm 1: ER+ Breast with PTEN mutation (prior *Faslodex* resistance) • Part F arm 2: ER+ Breast with PTEN mutation (first exposure to *Faslodex*)	• Safety and tolerability • ORR • Clinical Benefit Rate at 24 weeks (CBR24) [Parts E & F only]	• Estimated completion: 2017 • Part E Arms 1 & 2 ongoing 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	• ORR	• FPD: Q2 2014 • LPCD: Q4 2015 • 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: Q4 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 **NCT02374645**	Non-Small Cell Lung Cancer	N ~ 53	• Dose escalation trial Conducted in China	• Safety and tolerability	• FPD: Q2 2015 • LPCD: Q1 2017 • 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 tumours and blood cancers

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	Squamous Cell Carcinoma of the Head & Neck (HNSCC)	N = 147	Dose Escalation advanced solid and blood cancers • Arm A1: AZD9150/durvalumab • Arm A2 : AZD5069/durvalumab Dose Expansion 2L HNSCC: • 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: Q3 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 • Completed

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 = 40	SAD trial (one trial site in US) • 5 different dose levels investigated vs. placebo • Sub-cutaneous injection	• Safety and tolerability • PK parameters	• FPD: Q4 2015 • LPCD: Q3 2016 • Estimated completion: 2016
Phase I/IIa **NCT02826525**	Type-2 Diabetic patients with non-alcoholic fatty liver disease	N = up to 51	MAD trial (one trial 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: Q3 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 trial 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: Q3 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 trial 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: Q3 2016 • Estimated completion: H2 2016

Abediterol (AZD0548) (LABA)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02777827**	**Patients With Asthma on Inhaled Corticosteroids**	N = 36	Single-dose 6-way crossover to investigate ultra-low doses of abediterol and to compare 2 different devices (pMDI and 3 DPI). • Abediterol 0.156 µg • Drug: Abediterol 2.5 µg • Drug: Abediterol 0.05 µg • Other: Placebo Global trial. - 1 country	Primary Endpoint. • To assess the PD response (bronchodilation) of ultra-low doses of abediterol. • To compare the PD response at the same doses between the 2 devices • To compare PK (2.5 µg dose only) between the 2 devices	• FPD: Q3 2016 • LPCD: Q4 2016 Topline Results: H1 2017 Estimated Completion: H1 2017

AZD1419 (TLR9 agonist)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **INCONTRO** **NCT02898662**	Adults with eosinophilic, moderate to severe asthma on ICS + LABA background treatment	N = 70	• Arm 1: AZD1419, once-weekly adaptive dosing (4mg, 1mg, 8mg) • Arm 2: placebo Inhaled (nebulised) administration Trial conducted in EU.	• Time to loss of asthma control	• FPD: Q4 2016

ICS= Inhaled corticosteroids
LABA= Long Acting Beta Agonist

Approved medicines
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 subjects - 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

AZD7986 (DPP1 inhibitor)

Chronic Obstructive Pulmonary Disease (COPD)

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 subjects • 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-randomised, 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

AZD8871 (MABA2)

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 dose levels - 50 µg, 200 µg, 400 µg, 900 µg, 1800 µg, and 2100 µg **Part 2** Comprises 5 treatment periods of 36 hours each separated by a washout period of at least 7 to 14 days (one exception per patient of up to 28 days would be acceptable). • AZD8871 400 µg once daily (double-blind) • AZD8871 1800 µg once daily (double-blind) • Indacaterol 150 µg once daily (open-label) • Tiotropium 18 µg once daily (open-label) • Placebo (double-blind) Global trial – 1 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: Q3 2016 Estimated Topline Results: Q4 2016 Estimated Completion: H1 2017
Phase I **NCT02814656**	Healthy subjects	N = 24	MAD trial with 3 dose levels - 300 µg, 600µg, and 900 µg (TBC) and placebo Global trial – 1 country	**Primary Endpoint:** • The primary objective is to investigate the safety and tolerability of AZD8871 at steady state **Secondary Endpoint:** • To characterise 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: Q3 2016 • LPCD: Q4 2016 Estimated Topline Results: H1 2017 Estimated Completion: H1 2017

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9567 (oSGRM)

Respiratory

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02512575**	**Healthy subjects**	N = 72	SAD trial with 6 dose levels - 2 µg, 10 µg, 40 µg, 100 µg, 200 µg, and up to 400 µg Global trial – one country	• A Phase I, Randomised, Single-Blind, Placebo-Controlled trial To Assess The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of Single Ascending Oral Doses Of AZD9567 In Healthy subjects	• FPD: Q4 2015 • LPCD: Q2 2016 Estimated Topline Results: H2 2016 Estimated Completion: H2 2016
Phase I **NCT02760316**	**Healthy subjects**	N = 64	MAD trial with 4 dose levels – 10 mg, 20mg, 40mg, 80mg and Prednisolone 20 mg Global trial – one country	Primary Endpoint: • To assess the safety and tolerability of AZD9567 following multiple oral ascending doses in subjects with BMI between 28 and 38 kg/m2 and with a positive glucose tolerance test (7,8 to 11,0 mmol/L). Secondary Endpoints: • To characterise the pharmacokinetics of AZD9567 following multiple oral administration of ascending doses. • To characterise the pharmacodynamics of AZD9567 assessed as effect on glucose homeostasis through OGTT (oral glucose tolerance test) in comparison with prednisolone 20 mg.	• FPD: Q2 2016 • LPCD: Q4 2016 Estimated Topline results: H1 2017 Estimated Completion: H1 2017

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 trial 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 • Complete
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 • Complete

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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8108 (NMDA)

Phase I clinical development programme

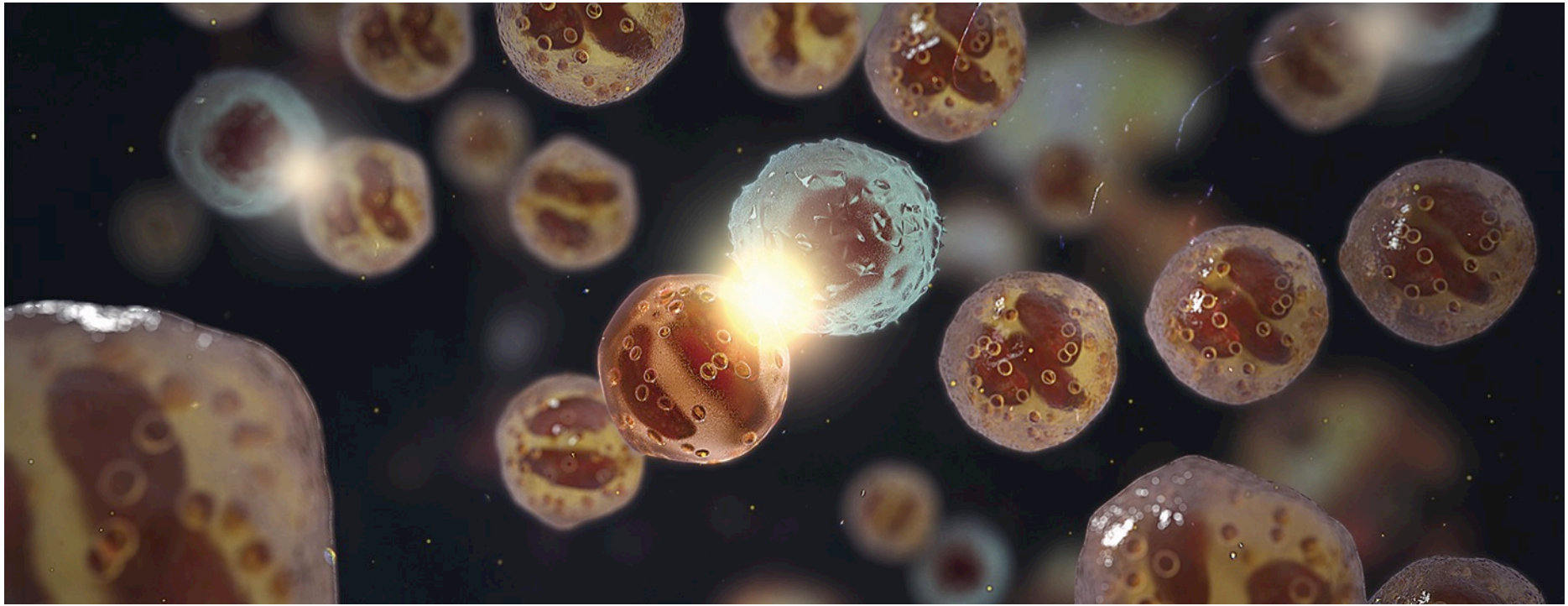
Trial phase	Patient population	Number of patients	Design	Endpoints	Status

Phase I
 	
NCT02248818
	Healthy subjects	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



Durvalumab (MEDI4736; PD-L1 mAb)

Immuno-oncology

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I/II **STUDY 1108** **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 anti-tumour activity	• FPD: Q3 2012 • LPCD: Q4 2015 • Estimated top-line results: H2 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: 2018
Phase 1 **NCT02900157**	PD-L1 (durvalumab)	Solid tumours	N = 30	Multi-centre, open-label, single-arm trial for adult subjects	• Safety, PK, number of subjects reporting infusion related reaction	• FPD: Q3 2016 • LPCD: Q1 2018 • Estimated top-line results: 2018

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

Solid and hematologic tumours

Approved medicines
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: H2 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 **STUDY 006** **NCT02000947**	NSCLC (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**	HNSCC	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: H1 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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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

Advanced cancers

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: 2019
Phase I **NCT02013804**	Advanced malignancies (escalation phase)	N = 58	Dose-escalation phase • MEDI0680 IV	• Safety & Tolerability • Secondary endpoints include tumour response such as objective response rate, immunogenicity, pharmacokinetics, pharmacodynamics	• FPD: Q4 2013 • LPCD: Q2 2017 • Estimated top-line results: Q4 2016

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

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

Advanced cancers

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

Inebilizumab (MEDI-551, CD19 mAb)

Blood cancers

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 cancers

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 . – Intratumoural 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 cancers

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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 **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-Oesophageal 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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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 Pharma, part of MedImmune
Phase II **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 • Completed
Phase II **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 • Completed
Phase II **NCT02548585v**	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

MEDI7836 (IL-13 mAb)

Asthma

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02388347**	Healthy subjects	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

MEDI9929 tezepelumab (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

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

Systemic Lupus Erythematosus (SLE)

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ia **NCT02618967** **Partnered**	Healthy Subjects	N = 40	Single Ascending Dose • Arm 1: MEDI0700 administered as single SC dose • Arm 2: Dose levels of Placebo administered as single SC dose	• Safety and tolerability • PK/PD	• FPD: Q1 2016 • LPCD: Q3 2017 • Estimated top-line results: H2 2017

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

MEDI5872 - AMG 557 (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: H1 2017
Phase I **NCT01683695** **Partnered** **Completed**	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 • Top-line results: Q2 2016

MEDI7352 (NGF TNF Bispecific)

Osteoarthritis pain

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02508155**	MEDI7352 (NGF TNF Bispecific)	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

MEDI9314 (IL-4Ra mAb)

Atopic Dermatitis

Trial phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02669667**	Healthy subjects	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

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, Sjögren'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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

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: Q3 2016
Phase Ib **NCT02289820** **Completed**			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 • Completed
Phase Ia **NCT02115815** **Completed**			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 • Completed
Phase IIb **NCT02878330**	Anti-Respiratory Syncytial Virus mAb-YTE (MEDI8897)	32-35 WK GA infants	N = 1,500	• Randomised, double-blind, placebo-controlled trial • Route of administration: IM	• Safety and efficacy	• FPD: Q4 2016 • LPCD: Q2 2018 • Estimated top-line results: 2018
Phase Ib/IIa **NCT02290340**		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: Q3 2016
Phase Ia **NCT02114268** **Competed**		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

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Infections

Trial phase	Compound	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/IIa **NCT02603952** **Phase I** **NCT02350751** **Completed**	Anti-influenza A mAb (MEDI8852)	Adults Healthy adults	N = 160 N = 40	• Randomised, partial double-blind, single dose, active-controlled, dose ranging trial • Route of administration: intravenous • Double-blind, single-dose, placebo-controlled, dose-escalation trial • Route of administration: intravenous	• Evaluate safety in adults with acute, uncomplicated Influenza • Evaluate the safety and pharmacokinetics	• FPD: Q4 2015 • LPCD: H2 2016 • Estimated top-line results: Q4 2016 • FPD: Q1 2015 • LPCD: Q1 2015 • Top-line results: Q2 2015 • Completed
Phase I **NCT02255760** **Completed**	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 • Completed
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
Year-To-Date and Q3 2016 Results update

AstraZeneca
What science can do