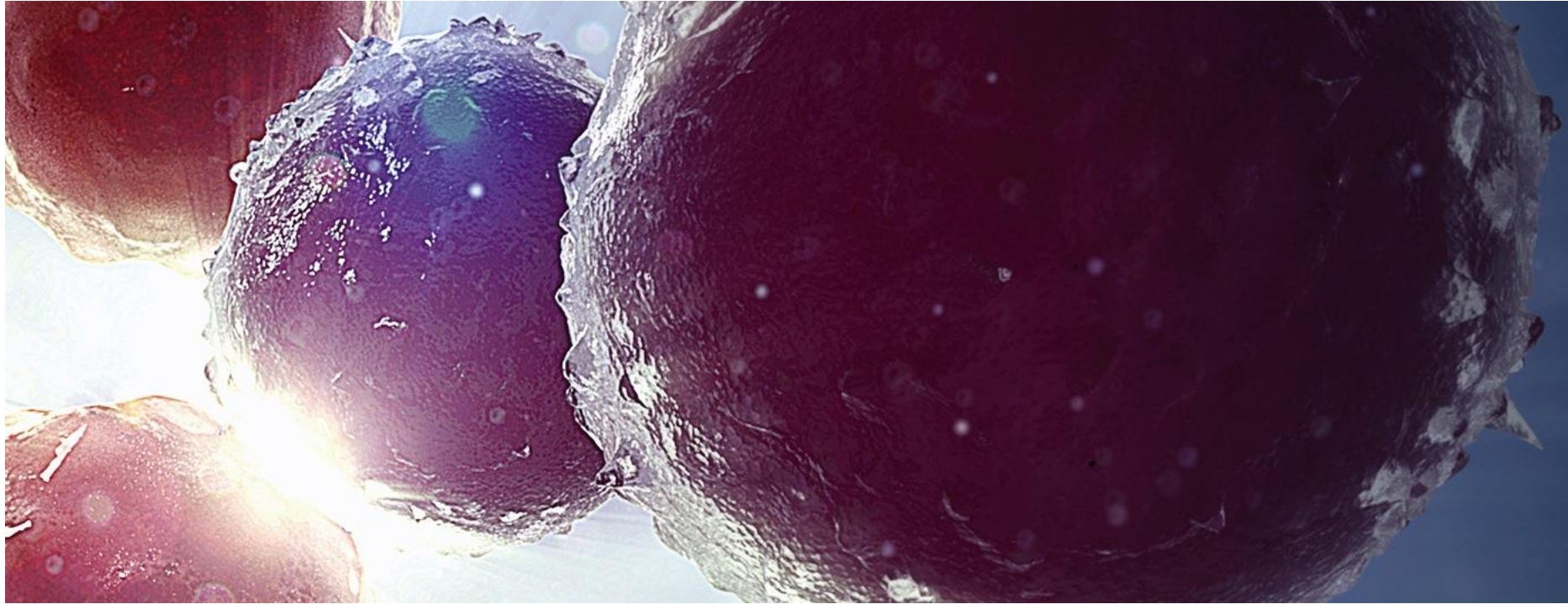


Clinical trials appendix

Q2 2017 Results update



The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from <https://clinicaltrials.gov/> to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company's knowledge as of 30 June 2017, 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	LCM	Life-Cycle Management	Q2W	Quaque (every) Two Weeks
AUC	Area Under Curve	LPCD	Last Patient Commenced Dosing	Q3W	Quaque (every) Three Weeks
BID	Bis In Die (two times a day)	MAD	Multiple Ascending Dose	Q4W	Quaque (every) Four Weeks
CE	Clinically Evaluable	MDI	Metered-Dose Inhaler	Q8W	Quaque (every) Eight Weeks
C_{MAX}	Maximum Concentration Absorbed	MITT	Modified Intent To Treat	QD	Quaque Die (one time a day)
cMITT	Clinical-Modified Intent To Treat	mMITT	Microbiological-Modified Intent To Treat	SAD	Single Ascending Dose
CNS	Central Nervous System	MTD	Maximum Tolerated Dose	SC	Sub Cutaneous
DLT	Dose-Limiting Toxicity	NME	New Molecular Entity	TID	Ter In Die (three times a day)
FDC	Fixed-Dose Combination	OLE	Open Long-term Extension	TOC	Test Of Cure
FEV	Forced-Expiratory Volume	ORR	Objective Response Rate	XR	Extended Release
FPCD	First Patient Commenced Dosing	OS	Overall Survival		
IM	Intra Muscular	PFS	Progression-Free Survival		
IR	Immediate Release	PK	Pharmacokinetics		
IV	Intravenous				



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Movement since Q1 2017 update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
<p>NME's AZD4785 KRAS inhibitor solid tumours MEDI7247 antibody drug conjugate haematological malignancies AZD9898 LTC4S asthma MEDI3506 IL-33 mAb chronic obstructive pulmonary disease</p> <p>Additional indications <i>Imfinz</i>[#] (durvalumab[#]) + MEDI9197[#] PD-L1 mAb + TLR 7/8 agonist solid tumours</p>	<p>NME's verinurad URAT1 inhibitor chronic kidney disease</p> <p>Additional indications <i>Imfinz</i>[#](durvalumab[#]) + AZD5069 PD-L1 mAb + CXCR2 antagonist pancreatic ductal adenocarcinoma</p>	<p>Additional indications acalabrutinib[#] BTK inhibitor 1st-line mantle cell lymphoma Imfinz[#](durvalumab[#]) + tremelimumab + chemotherapy POSEIDON PD-L1 mAb + CTLA-4 mAb 1st-line non-small cell lung cancer</p> <p>Life-cycle Management saxagliptin/dapagliflozin metformin DPP-4 inhibitor/ SGLT2 inhibitor type-2 diabetes</p>	<p>Life-cycle Management Lynparza SOLO-2 [EU & JP]¹ PARP >2L BRCAm PSR ovarian Nexium [CN]¹ proton pump inhibitor stress ulcer prophylaxis</p>
Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from Registration
	<p>NME's MEDI4076 anti-miR103/107 oligonucleotide non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH) MEDI4166 PCSK9/GLP-1 mAb + peptide fusion diabetes/cardiovascular verinurad selective uric acid reabsorption inhibitor (URAT-1) chronic treatment of hyperuricemia in patients with gout</p>		<p>NME's Imfinz[#] (durvalumab[#]) [US]² PD-L1 mAb ≥2nd-line advanced bladder cancer</p> <p>Life-cycle Management Faslodex FALCON [JP]² oestrogen receptor antagonist 1st-line hormone receptor +ve advanced breast cancer</p>

† Registrational Phase II/III study

Partnered and/or in collaboration

¹ Submission Accepted ² Submission Approved ⁴ Completed ⁵ Complete Response Letter



Q2 2017 New Molecular Entity (NME)¹ Pipeline

Phase I 36 New Molecular Entities				Phase II 22 New Molecular Entities				Phase III 9 New Molecular Entities	
Small molecule		Large molecule		Small molecule		Large molecule		Small molecule	Large molecule
AZD0156 ATM solid tumours	AZD0284 ROrg psoriasis/respiratory	MEDI0562# hOX40 solid tumours	MEDI584# cholesterol modulation	AZD1775# Wee1 solid tumours	MEDI-573# IGF metastatic breast cancer	acalabrutinib# BTK inhibitor B cell malignancy	Imfinzi#+tremelumab MYSTIC PD-L1+CTLA-4 1L NSCLC		
AZD2811# Aurora solid tumours	AZD5634 inhaled ENaC cystic fibrosis	MEDI0680 PD-1 solid tumours	MEDI8111 Rh-Factor II trauma/bleeding	AZD4547 FGFR solid tumours	MEDI0382 GLP-1/glcagon type-2	selumetinib ASTRA MEK 2L diff. thyroid	moxetumomab pasudotox# PLA1T CD22 HCL		
AZD4635 A2aR inhibitor solid tumours	AZD7594+abeditero# Inhaled SGRM+LABA	MEDI1873 G1TR solid tumours	MEDI3506 IL-33 COPD	AZD5363# AKT breast cancer	MEDI8012 LCAT cardiovascular	roxadustat# HIFPH anaemia CKD/ESRD	tralokinumab IL-13 severe asthma		
AZD4785 KRAS solid tumours	AZD7986# DPP1 COPD	MEDI3726# PSMA prostate	MEDI1814# amyloidβ alzheimer's disease	Lynparza#+cediranib CONCERTO PARP+VEGF recurrent Pt-R ovarian	tezepelumab# TSLP asthma/atopic dermatitis	PT010 LABA/LAMA/ICS COPD	anifrolumab# TULIP IFNoR SLE		
AZD6738 ATR solid tumours	AZD9567 SGRM RA/respiratory	MEDI4276 HER2 solid tumours	MEDI17352 NGF/TNF osteoarthritis pain	sevofitinib# MET pRCC	inebilizumab# CD19 neuromyelitis optica	lanabecestat# BACE early alzheimer's disease			
AZD8186 PI3Kβ solid tumours	AZD9898 LTC4S asthma	MEDI5083 immune activator solid tumours	MEDI0700# BAFF/B7RP1 SLE	vistusertib mTOR 1/2 solid tumours	mavritumab# GM-CSFR rheumatoid arthritis				
AZD9150# STAT3 haems & solids		MEDI-565# CEA BITE GI tumours	MEDI4920 CD40L-Tr3 pSS	verinurad URAT-1 chronic kidney disease	MEDI5872# primary Sjögren's syndrome				
AZD9496 SERD ER+ breast		MEDI7274 antibody drug conjugate haems	MEDI1734 ILT7 myositis	abeditero# LABA asthma/COPD	MEDI3602 Psl/Pcrv Pseudomonas pneumonia				
AZD4831 MPO HfPpEF		MEDI9197# TLR 7/8 solid tumours	MEDI9314 IL4R atopic dermatitis	AZD1419# inhaled TLR9 asthma	MEDI4893 α-Toxin Staphylococcus pneumonia				
AZD5718 FLAP coronary artery disease		MEDI9447 CD73 solid tumours		AZD7584 Inhaled SGRM asthma	MEDI9852 influenza A treatment				
AZD9601# VEGF-A cardiovascular				AZD8871# MABA COPD	MEDI8897# RSV passive prophylaxis				


Applications Under Review


2 New Molecular Entities

Small molecule	Large molecule
ZS-9 potassium binder hyperkalaemia	benralizumab# IL-5R severe asthma

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

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

 Oncology

 Cardiovascular and metabolic disease

 Respiratory

 Other



Q2 2017 Lifecycle Management (LCM)¹ Pipeline

Phase I 0 Projects		Phase II 6 Projects		Phase III 23 Projects		Applications Under Review 4 Projects	
Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule
		<i>Tagrisso</i> BLOOM EGFR NSCLC CNS mets	<i>Imfinz</i> # PD-L1 solid tumours	<i>acalabrutinib</i> # BTK inhibitor 1st line MCL	<i>Tagrisso</i> FLAURA EGFR 1L adv. EGFRm NSCLC	<i>Imfinz</i> # PACIFIC PD-L1 stage-3 NSCLC	<i>Lymparza</i> SOLO-2 PARP >2L BRCAm PSR ovarian
		<i>Brinta/Brintique</i> HESTIA paeds w/ sickle cell	<i>anifrolumab</i> # IFN α R SLE SC	<i>acalabrutinib</i> # BTK inhibitor 1st line CLL	<i>Brinta/Brintique</i> THEMIS diabetes & CAD outcomes	<i>Imfinz</i> # PEARL (China) PD-L1 1L NSCLC	<i>Bydureon</i> autoinjector type-2 diabetes
		PTD10 LABA/LAMA/ICS asthma	<i>anifrolumab</i> # IFN α R lupus nephritis	<i>acalabrutinib</i> # BTK inhibitor 1 st CLL, high risk	<i>Bydureon</i> EXSCEL outcomes	<i>benralizumab</i> # IL-5R COPD	<i>linaclotide</i> # (CN only) IBS-c
				<i>Lymparza</i> OlympiA PARP gBRCA adjuvant breast	<i>Epanova</i> STRENGTH outcomes		<i>Nexium</i> (CN only) stress ulcer prophylaxis
				<i>Lymparza</i> OlympiAD PARP gBRCA metastatic breast	<i>Faniga/Foniga</i> type-1 diabetes		
				<i>Lymparza</i> POLO PARP pancreatic cancer	<i>Faniga/Foniga</i> SGLT2 heart failure		
				<i>Lymparza</i> PROfound PARP prostate cancer	<i>Faniga/Foniga</i> SGLT2 CKD		
				<i>Lymparza</i> SOLO-1 PARP 1L BRCAm ovarian	<i>Faniga/Foniga</i> DECLARE outcomes		
				<i>Lymparza</i> SOLO-3 PARP BRCAm PSR ovarian	<i>saxagliptin/dapagliflozin metformin</i> DPP4 type-2 diabetes		
				<i>Tagrisso</i> ADAURA EGFR adj. EGFRm NSCLC	<i>Symbicort</i> SYGMA as needed in mild asthma		

Phase I 12 Projects	Phase II 8 Projects	Phase III 7 Projects
<i>AZD1775#</i> + <i>Imfinz</i> # Wee1+PD-L1 solid tumours	<i>AZD1775#</i> +chemotherapy Wee1+chemo ovarian cancer	<i>Imfinz</i> #+ <i>tremelimumab</i> ARCTIC PD-L1+CTLA-4 3L NSCLC
<i>Imfinz</i> # or <i>Imfinz</i> #+ <i>treme</i> or <i>AZD8150#</i> PD-L1 or PD-L1+CTLA-4 or STAT3 DLBCL	<i>Imfinz</i> #+ <i>AZD5363</i> PD-L1+CXCR2 PDAC	<i>Imfinz</i> #+ <i>tremelimumab</i> DANUBE PD-L1+CTLA-4 1L bladder
<i>Imfinz</i> #+ <i>dabrafenib</i> + <i>tremetinib</i> PD-L1+BRAF+MEK melanoma	<i>Imfinz</i> #+ <i>AZD5363</i> or <i>Imfinz</i> #+ <i>AZD8150</i> PD-L1+CXCR2 or STAT3 HNSCC	<i>Imfinz</i> #+ <i>tremelimumab</i> EAGLE PD-L1+CTLA-4 2L SCCIN
<i>Imfinz</i> #+ <i>trassa</i> PD-L1+EGFR NSCLC	<i>Imfinz</i> #+ <i>MEDI0680</i> PD-L1+PD-L1 solid tumours	<i>Imfinz</i> #+ <i>tremelimumab</i> KESTREL PD-L1+CTLA-4 1L SCCIN
<i>Imfinz</i> #+ <i>MEDI0562#</i> PD-L1+hOX40 solid tumours	<i>Imfinz</i> #+ <i>tremelimumab</i> PD-L1+CTLA-4 HCC	<i>Imfinz</i> #+ <i>tremelimumab</i> NEPTUNE PD-L1+CTLA-4 1L NSCLC
<i>Imfinz</i> #+ <i>MEDI0197#</i> PD-L1+TLR 7/9 agonist	<i>Imfinz</i> #+ <i>tremelimumab</i> PD-L1+CTLA-4 gastric cancer	<i>Imfinz</i> #+ <i>tremelimumab</i> +SoC CASPIAN PD-L1+CTLA-4+SoC 1L SCLC
<i>Imfinz</i> #+ <i>MEDI0447</i> PD-L1+CD73 solid tumours	<i>Lymparza</i> + <i>AZD8730</i> PARP+ATR gastric	<i>Imfinz</i> #+ <i>tremelimumab</i> +SoC POSEIDON PD-L1+CTLA-4+SoC 1L NSCLC
<i>Imfinz</i> #+ <i>monalizumab</i> Y PD-L1+NKG2a solid tumours	<i>Tagrisso</i> combor# TATTON EGFR+PD-L1/MEK/MET NSCLC	
<i>Imfinz</i> #+ <i>tremelimumab</i> PD-L1+CTLA-4 solid tumours		
<i>Lymparza</i> + <i>AZD1775#</i> PARP+Wee1 solid tumours		
<i>sotimatinib</i> #+ <i>Imfinz</i> # MEK inhibitor+PL-L1 solid tumours		
<i>tremelimumab</i> + <i>MEDI0562#</i> CTLA-4+hOX40 solid tumours		

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; ¹ Registrational P2/3 study

■ Oncology

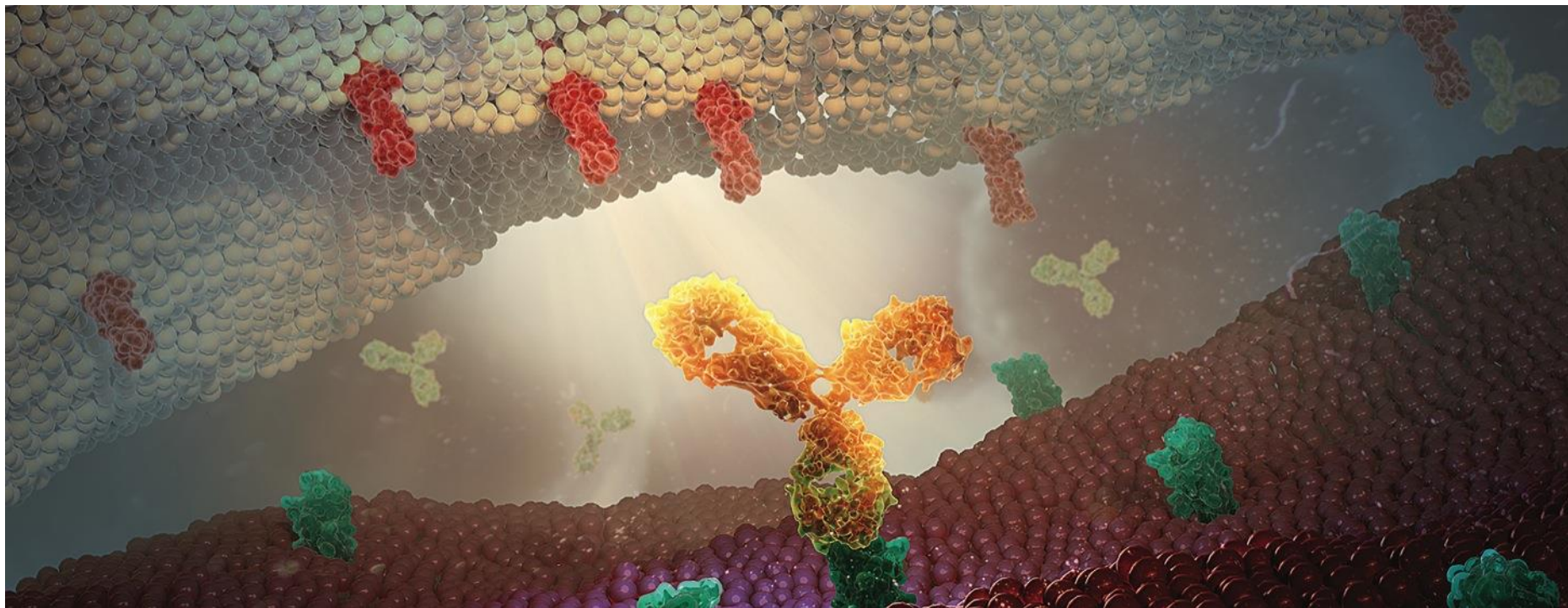
■ Cardiovascular and metabolic disease

■ Respiratory

■ Other



Approved medicines



Lynparza (PARP inhibitor)

Ovarian cancer and other solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III SOLO-2 Partnered NCT01874353	Platinum-sensitive recurrent (PSR) BRCAm ovarian cancer	295	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg BiD as maintenance therapy until progression Arm 2: placebo tablets BiD Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPCD: Q4 2014 Data readout: Q4 2016 Primary endpoint met
Phase III SOLO-1 Partnered NCT01844986	1L maintenance BRCAm ovarian cancer	391	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg BiD maintenance therapy for 2 years or until disease progression Arm 2: placebo Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPCD: Q1 2015 Data anticipated: H1 2018
Phase III SOLO-3 NCT02282020	PSR gBRCAm ovarian cancer 3L+ Line	411	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BiD to progression Arm 2: Physician's choice (single agent chemotherapy) Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q1 2015
Phase I / II MEDIOLA NCT02734004	gBRCAm ovarian cancer 2L+ gBRCAm HER2-negative breast cancer 1-3L Small cell lung cancer 2L+ Gastric cancer 2L+	133	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg BID starting on week 1 day 1 / <i>Iminzi</i> IV 1.5g every 4 weeks starting on week 5 day 1 Dose until progression Global trial	Primary endpoints <ul style="list-style-type: none"> DCR at 12 weeks Safety and tolerability Secondary endpoints <ul style="list-style-type: none"> DCR at 28 weeks ORR, DoR, PFS, TDT, OS PK 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q2 2017

PARP = Poly ADP Ribose Polymerase



Lynparza (PARP inhibitor)

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III OlympiAD NCT02000622	BRCAm metastatic breast cancer	302	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 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 <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q4 2015 Data readout: Q1 2017 Primary endpoint met
Phase III OlympiA NCT02032823 Partnered	BRCAm adjuvant breast cancer	1,500	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BiD 12 month duration Arm 2: Placebo 12 month duration <p>Global trial partnership with BIG and NCI/NRG</p>	<ul style="list-style-type: none"> Primary endpoint: Invasive Disease Free Survival (IDFS) Secondary endpoint: Distant Disease Free Survival and OS 	<ul style="list-style-type: none"> FPCD: Q2 2014
Phase III POLO NCT02184195	Pancreas gBRCA	145	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> tablets 300mg twice daily as maintenance therapy until progression Arm 2: Placebo tablets BiD <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q1 2015
Phase II NCT01972217	Metastatic castration resistant prostate cancer	142	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BiD + abiraterone Arm 2: Placebo + abiraterone <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: Radiologic PFS 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q3 2015
Phase III PROfound NCT02987543	Metastatic castration resistant prostate cancer HRRm, 2L+	340	<ul style="list-style-type: none"> Arm 1: <i>Lynparza</i> 300mg BiD Arm 2: Physician's choice: enzalutamide 160mg once daily abiraterone acetate 1000mg once daily <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: Radiologic PFS Secondary endpoints: ORR, Time to Pain Progression, OS 	<ul style="list-style-type: none"> FPCD: Q2 2017

PARP = Poly ADP Ribose Polymerase



Tagrisso

(Highly-selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III AURA3 NCT02151981	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	410	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> 80mg QD Arm 2: pemetrexed 500mg/m² + carboplatin AUC5 or pemetrexed 500mg/m² + cisplatin 75mg/m² (2:1 randomisation) Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: OS and QoL 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data readout: Q3 2016 Primary endpoint met
Phase III FLAURA NCT02296125	Advanced EGFRm NSCLC 1L	530	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> 80mg Arm 2: erlotinib 150mg or <i>Iressa</i> 250mg (dealers choice); 1:1 randomisation Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: OS and QoL 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q4 2016 Data anticipated: H2 2017 Primary endpoint met
Phase III ADAURA NCT02511106	Adjuvant EGFRm NSCLC	700	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> 80mg QD following complete tumour resection, with or without chemotherapy Arm 2: Placebo Global trial	<ul style="list-style-type: none"> Primary endpoint: Disease Free Survival DFS Secondary endpoints: DFS Rate, OS, OS Rate, QoL 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2022
Phase II AURA17 NCT02442349	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	171	<ul style="list-style-type: none"> <i>Tagrisso</i> 80mg QD Asia Pacific regional trial	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: PFS and OS 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data readout: Q2 2016
Phase II AURA2 NCT02094261	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	210	<ul style="list-style-type: none"> <i>Tagrisso</i> 80mg QD Global trial	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: PFS and DoR 	<ul style="list-style-type: none"> FPCD: Q2 2014
Phase I/II AURA NCT01802632	Advanced EGFRm NSCLC TKI failure +/- primary resistance mutation T790M	605	<ul style="list-style-type: none"> Dose escalation trial Ph II Extension cohort (T790M only) <i>Tagrisso</i> 80mg QD Global trial	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: PFS and OS 	<ul style="list-style-type: none"> FPCD: Q1 2013



Tagrisso

(Highly-selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib TATTON NCT02143466	Advanced EGFRm NSCLC TKI failure	~90	<ul style="list-style-type: none"> Arm 1: <i>Tagrisso</i> + <i>Imfinzi</i> Arm 2: <i>Tagrisso</i> + savolitinib Arm 3: <i>Tagrisso</i> + selumetinib Global trial	<ul style="list-style-type: none"> Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity 	<ul style="list-style-type: none"> FPCD: Q3 2014 Enrolment to <i>Imfinzi</i> combination arms will not restart
Phase I BLOOM NCT02228369	EGFRm NSCLC, CNS disease	41	<ul style="list-style-type: none"> MAD Expansion in leptomeningeal metastasis (LM) and brain metastasis (BM) patients at RP2D with AZD3759 Expansion in LM patients at 160mg with <i>Tagrisso</i> including cohort with T790M NSCLC Global trial – four countries	<ul style="list-style-type: none"> Safety and tolerability Preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data readout: Q2 2017



Imfinzi (durvalumab, PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase III ADJUVANT NCT02273375 Partnered	Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK positive)	1,100	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> mg/kg IV Q4W x 12m Arm 2: Placebo Global trial	<ul style="list-style-type: none"> Primary endpoint: DFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2020
Phase III PACIFIC NCT02125461	Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	702	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> IV Q2W Arm 2: Placebo Global trial	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q2 2016 Data readout: Q2 2017 Primary endpoint met
Phase II/III Lung Master Protocol NCT02154490 Partnered	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	140 ; 100 <i>Imfinzi</i> treated	Umbrella trial with 5 arms based on biomarker expression <ul style="list-style-type: none"> Substudy A: <i>Imfinzi</i> (non-match for other biomarker driven substudies) IVQ2W single arm <i>Imfinzi</i> PhII only Substudy B: PI3K inhibitor vs docetaxel Substudy C: CDK4/6 inhibitor vs docetaxel Substudy D: AZD4547 (FGFR inhibitor) vs docetaxel Substudy E: C-MET/HGFR Inhibitor + erlotinib vs erlotinib (Substudy is closed) 	Primary endpoints: <ul style="list-style-type: none"> ORR PFS OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 Data anticipated: 2022
Phase II ATLANTIC NCT02087423	Stage IIIB-IV NSCLC patients PD-L1+ve patients 3L	293	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> IV Q2W (EGFR/ALK WT) Arm 2: <i>Imfinzi</i> IV Q2W (EGFR/ALK M+) Arm 3: <i>Imfinzi</i> IV Q2W (EGFR/ALK WT) (90% PD-L1 - expression) Global trial – 18 countries	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: Duration of response, PFS and OS 	<ul style="list-style-type: none"> FPCD: Q1 2014 LPCD: Q2 2015 Data readout: Q4 2015
Phase I/II Sequencing Study NCT02179671	Stage IIIB-IV NSCLC patients	72	<ul style="list-style-type: none"> Arm 1: Iressa initially then switch to <i>Imfinzi</i> IVQ2W Arm 2: AZD9291 then switch to <i>Imfinzi</i> Arm 3: selumetinib + docetaxel then switch to <i>Imfinzi</i> Arm 4: tremelimumab then switch to <i>Imfinzi</i> 	<ul style="list-style-type: none"> Primary endpoint: Complete Response Rate Secondary endpoints: ORR, Disease Control Rate 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q2 2016 Data readout: Q3 2016
Phase III PEARL NCT03003962	NSCLC 1L	440	<ul style="list-style-type: none"> Arm 1 <i>Imfinzi</i> Q4W Arm 2 Chemotherapy (SoC) Asia study	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020



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

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III ARCTIC NCT02352948	Stage IIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/ALK mutation	480	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab (PD-L1 –ve patients) Arm 2: Standard of care Arm 3: tremelimumab (PD-L1 –ve patients) Arm 4: <i>Imfinzi</i> (PD-L1 –ve patients) 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q3 2016 Data anticipated: H2 2017
Phase III MYSTIC NCT02453282	NSCLC 1L	1,118	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Arm 2: <i>Imfinzi</i> + tremelimumab Arm 3: Standard of care 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q3 2016 Data anticipated: H1 2018 (final OS) PFS Primary endpoint not met
Phase III NEPTUNE NCT02542293	NSCLC 1L	960	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: Standard of care 	<ul style="list-style-type: none"> Primary endpoint: OS Secondary endpoint: PFS 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q2 2017 Data anticipated: H2 2018
Phase III POSEIDON NCT03164616	NSCLC 1L	801	<ul style="list-style-type: none"> Arm 1: durvalumab + CTx Arm 2: durvalumab + tremelimumab + CTx Arm 3: CTx 	Primary endpoints: <ul style="list-style-type: none"> PFS 	<ul style="list-style-type: none"> FPCD: Q2 2017 Data anticipated: 2019
Phase III EAGLE NCT02369874	HNSCC 2L	720	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: <i>Imfinzi</i> Arm 3: Standard of care 	<ul style="list-style-type: none"> Primary endpoint: OS Secondary endpoint: PFS 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: H1 2018
Phase III KESTREL NCT02551159	HNSCC 1L	823	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Arm 2: <i>Imfinzi</i> + tremelimumab Arm 3: Standard of care 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD Q1 2017 Data anticipated: H1 2018
Phase III DANUBE NCT02516241	Bladder 1L cis eligible and ineligible	1,005	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Arm 2: <i>Imfinzi</i> Arm 3: Standard of care 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q1 2017 Data anticipated: H2 2018
Phase III CASPIAN NCT03043872	SCLC 1L	795	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab+EP (carboplatin or cisplatin + etoposide) Arm 2: <i>Imfinzi</i>+EP (carboplatin or cisplatin + etoposide) Arm 3: <i>Imfinzi</i>+EP (carboplatin or cisplatin + etoposide) 	Primary endpoints: <ul style="list-style-type: none"> PFS OS 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2020

Imfinzi (durvalumab, PD-L1 mAb)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02301130 Partnered	Solid tumours	108	<ul style="list-style-type: none"> Dose Escalation: N=36, 3 cohorts receiving Treatment A (mogamulizumab + <i>Imfinzi</i>) 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) 	<ul style="list-style-type: none"> Safety and Tolerability MTD ORR, DoR, DCR, PFS, OS 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPD: Q3 2017 Data anticipated: 2018
Phase I NCT01938612	Solid tumours (all-comers)	176	<ul style="list-style-type: none"> 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, <i>Imfinzi</i> Q4W 20mg/kg + tremelimumab Q4W 1mg/kg <p>Trial conducted in Japan</p>	<ul style="list-style-type: none"> Safety Optimal biologic dose 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPD: Q1 2017 Data anticipated: 2018



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

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III STRONG NCT03084471	Advanced Solid Malignancies	1200	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Arm 2: <i>Imfinzi</i> + tremelimumab 	<ul style="list-style-type: none"> Primary endpoint: Safety 	<ul style="list-style-type: none"> FPCD: Q2 2017 Data anticipated: 2022
Phase II NCT02527434	Urothelial Bladder Cancer Triple-negative Breast Cancer Pancreatic Ductal-Adenocarcinoma	76	<ul style="list-style-type: none"> Arm 1 tremelimumab in urothelial bladder cancer Arm 2 tremelimumab triple-negative breast cancer Arm 3 tremelimumab pancreatic ductal-adenocarcinoma 	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: <ul style="list-style-type: none"> Safety Duration of Response 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2018
Phase II BALTIC NCT02937818	SCLC	80	<ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> + tremelimumab Q4W Arm 2: AZD1775 and carboplatin BID 	<ul style="list-style-type: none"> Primary endpoint: ORR 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data Anticipated: 2020
Phase I Combination in advanced solid tumours in Japanese patients NCT02141347	Solid tumours (treme Phase I)	22	<ul style="list-style-type: none"> tremelimumab + <i>Imfinzi</i> Dose Escalation trial tremelimumab Q4W/Q12W 3-10mg/kg tremelimumab + <i>Imfinzi</i>: 3 cohorts; tremelimumab Q4W 10 mg/kg + <i>Imfinzi</i> Q4W 15 mg/kg, tremelimumab Q4W 20 mg/kg + <i>Imfinzi</i> Q4W 1 mg/kg, tremelimumab Q4W 1500 mg + <i>Imfinzi</i> Q4W 75 mg 	<ul style="list-style-type: none"> Safety Optimal biologic dose 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q2 2015 Data readout: Q2 2017
Phase 1 Combination in Advanced Solid Tumours NCT02658214	Solid tumours	80	<ul style="list-style-type: none"> Arm 2 SCLC: <i>Imfinzi</i> + tremelimumab + carboplatin + etoposide Arm 3 TNBC: <i>Imfinzi</i>+ tremelimumab + gemcitabine + carboplatin Arm 4 TNBC: <i>Imfinzi</i> + tremelimumab + nab-paclitaxel (paclitaxel-albumin) + carboplatin Arm 5 Gastric/gastro-Oesophageal junction (GEJ): <i>Imfinzi</i> + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid) 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q4 2016 Data anticipated: 2019



Brilinta (ADP receptor antagonist)

Cardiovascular

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints (primary)	Status
Phase III THEMIS NCT01991795	Patients with type-2 diabetes and coronary artery disease without a previous history of myocardial infarction (MI) or stroke	19,000	<ul style="list-style-type: none">• Arm 1: <i>Brilinta</i> 60mg BiD• Arm 2: Placebo BiD <i>on a background of acetylsalicylic acid if not contra-indicated or not tolerated</i> Global trial – 42 countries	<ul style="list-style-type: none">• Primary endpoint: Composite of cardiovascular (CV) death, non-fatal MI and non-fatal stroke Secondary endpoints: <ul style="list-style-type: none">• Prevention of CV death• Prevention of MI• Prevention of ischaemic stroke• Prevention of all-cause death	<ul style="list-style-type: none">• FPCC: Q1 2014• LPCD: Q2 2016• Data anticipated: 2019

Oncology

CVMD

Respiratory

Other



Farxiga (SGLT2 inhibitor)

Type-2 diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III/IV DECLARE NCT01730534	Type-2 diabetes with high risk for CV event	17,276	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD + standard of care therapy QD Arm 2: Placebo + standard of care therapy for type-2 Diabetes Global trial – 33 countries	<ul style="list-style-type: none"> Primary endpoint: Time to first event included in the composite endpoint of CV death, MI or ischaemic stroke 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: H2 2018
Phase III NCT02096705 Partnered	Asian patients with type-2 diabetes with inadequate glycemic control on insulin	273	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD for 24 weeks + background insulin Arm 2: Placebo QD for 24 weeks + background insulin Asia trial – three countries	<ul style="list-style-type: none"> Primary endpoint: Change from baseline in HbA1c at week 24 	<ul style="list-style-type: none"> FPCD: Q1 2014 LPCD: Q1 2016 Data Readout: Q2 2016 Primary endpoint met
Phase III DERIVE NCT02413398	Patients with type-2 diabetes and moderate renal impairment	302	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 10mg QD for 24 weeks Arm 2: Placebo 10mg QD for 24 weeks Global trial – eight countries	<ul style="list-style-type: none"> Primary endpoint: Change from baseline in HbA1c at week 24 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q2 2017
Phase III DEPICT 1 NCT02268214 Partnered	Type-1 diabetes	768	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 5mg QD 52 weeks + insulin Arm 2: <i>Farxiga</i> 10mg QD 52 weeks + insulin Arm 3: Placebo QD 52 weeks + insulin Global trial – 17 countries	<ul style="list-style-type: none"> Primary endpoint: Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD Q2 2016 Data readout: Q1 2017
Phase III DEPICT 2 NCT02460978 Partnered	Type-1 diabetes	768	<ul style="list-style-type: none"> Arm 1: <i>Farxiga</i> 5mg QD 52 weeks + insulin Arm 2: <i>Farxiga</i> 10mg QD 52 weeks + insulin Arm 3: Placebo QD 52 weeks + insulin Global trial – 14 countries	<ul style="list-style-type: none"> Primary endpoint: Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q1 2017



Farxiga (SGLT2 inhibitor)

Type-2 diabetes

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase III Dapa-HF NCT03036124	Patients With Chronic Heart Failure	4,500	<ul style="list-style-type: none">• Arm 1: <i>Farxiga</i> 10mg or 5 mg QD + standard of care therapy• Arm 2: Placebo + standard of care therapy <ul style="list-style-type: none">• Global trial - 20 countries	<ul style="list-style-type: none">• Primary endpoint: Time to the first occurrence of any of the components of the composite: CV death or hospitalization for HF or an urgent HF visit	<ul style="list-style-type: none">• FPCD: Q1 2017
Phase III Dapa-CKD NCT03036150	Patients With Chronic Kidney Disease	4,000	<ul style="list-style-type: none">• Arm 1: <i>Farxiga</i> 10mg or 5 mg QD• Arm 2: Placebo Global trial - 20 countries	<ul style="list-style-type: none">• Primary endpoint: Time to the first occurrence of any of the components of the composite: $\geq 50\%$ sustained decline in eGFR or reaching ESRD or CV death or renal death	<ul style="list-style-type: none">• FPCD: Q1 2017

Oncology

CVMD

Respiratory

Other



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

Type-2 diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02284893	Type-2 diabetes	420	<ul style="list-style-type: none"> Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR Arm 2: sitagliptin 100mg + Met IR/XR Global trial – six countries	<ul style="list-style-type: none"> Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: <ul style="list-style-type: none"> The proportion of subjects achieving a therapeutic glycaemic response at week 24 defined as HbA1c<7% Mean change in total body weight at week 24 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q3 2015 Data readout: Q3 2016
Phase III NCT02419612	Type-2 diabetes	440	<ul style="list-style-type: none"> Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR Arm 2: glimeperide 1-6mg + Met IR/XR Global trial – 10 countries	<ul style="list-style-type: none"> Primary endpoint: Mean change from baseline in HbA1c at week 52 Secondary endpoints: <ul style="list-style-type: none"> Mean change from baseline in total body weight at week 52 The proportion of subjects achieving a therapeutic glycaemic response at week 52 defined as HbA1c<7.0% 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPD: Q3 2016 Data anticipated: H2 2017
Phase III NCT02551874	Type-2 diabetes	598	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: <ul style="list-style-type: none"> Mean change in total body weight at week 24 The proportion of subjects with confirmed hypoglycaemia at week 24 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPD: Q4 2016 Data anticipated: H2 2017
Phase III NCT02681094	Type-2 diabetes	900	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Primary endpoint: Mean change from baseline in HbA1c at week 24 Secondary endpoints: <ul style="list-style-type: none"> The proportion of subjects achieving a therapeutic glycaemic response at week 24 defined as HbA1c<7% Mean change in fasting plasma glucose at 24 weeks 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPD: Q4 2016 Data anticipated: H2 2017



Bydureon (GLP-1 receptor agonist)

Type-2 diabetes

Trial	Population	Patients	Design	Endpoints	Status
Phase IV EXSCEL NCT01144338 Partnered	Type-2 diabetes	14,742	<ul style="list-style-type: none"> Arm 1: <i>Bydureon</i> once weekly 2mg SC Arm 2: Placebo <p>On a background of SoC medication, different degree of CV risk</p> <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke) 	<ul style="list-style-type: none"> FPD: Q2 2010 LPCD: Q4 2015 Data anticipated: H2 2017 Primary safety endpoint met Primary efficacy endpoint not met
Phase III DURATION-NEO 1 NCT01652716 Partnered	Type-2 diabetes	375	<ul style="list-style-type: none"> Arm 1: <i>Bydureon</i> BiD SC (autoinjector) Arm 2: <i>Bydureon</i> weekly suspension SC (autoinjector) <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetics</p> <p>US only</p>	<ul style="list-style-type: none"> Primary endpoint: Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> FPCD: Q1 2013 Data readout: Q3 2014 Primary endpoint met
Phase III DURATION-NEO 2 NCT01652729 Partnered	Type-2 diabetes	360	<ul style="list-style-type: none"> Arm 1: sitagliptin Arm 2: <i>Bydureon</i> weekly suspension SC (autoinjector) Arm 3: Placebo <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetics</p> <p>US only</p>	<ul style="list-style-type: none"> Primary endpoint: Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> FPCD: Q1 2013 Data readout : Q3 2014 Primary endpoint met
Phase III DURATION 7 NCT02229383	Type-2 diabetes	440	<ul style="list-style-type: none"> Arm 1: <i>Bydureon</i> once weekly 2mg SC + titrated basal insulin Arm 2: Placebo + titrated basal insulin <p>Double-blind 1:1 randomisation. Background therapy with or without metformin</p> <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q3 2016 Data readout: Q4 2016 Primary endpoint met
Phase III DURATION 8 NCT02229396	Type-2 diabetes	660	<ul style="list-style-type: none"> Arm 1: <i>Bydureon</i> once weekly 2mg SC Arm 2: dapagliflozin 10mg Arm 3: <i>Bydureon</i> once weekly 2mg SC + dapagliflozin 10mg <p>Double-blind 1:1:1 randomisation. Background therapy with metformin 1500mg/day up to 2 months prior to screening</p> <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: H2 2017 Data readout: Q3 2016 – 28-week data Q1 2017 – 52-week data Primary endpoint met Data anticipated: 2018 – 104-week data



Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02463071	Japanese patients with hypertriglyceridemia	375	<ul style="list-style-type: none"> <i>Epanova</i> 2g and 4g vs Placebo (after meal) daily for 52 weeks Global trial – one country	Primary endpoints: <ul style="list-style-type: none"> Safety in Japanese patients % change in triglycerides 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPD: Q1 2016 Data readout: Q2 2017
Phase III EVOLVE II NCT02009865	Severe hyper-triglyceridaemia	162	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 2g QD Arm 2: Placebo (olive oil) Global trial – seven countries	<ul style="list-style-type: none"> Primary endpoint: Change in serum triglycerides over 12 weeks 	<ul style="list-style-type: none"> FPCD: Q4 2013 LPD: Q4 2014 Data readout: Q4 2015 Primary endpoint met
Phase III STRENGTH (CVOT) NCT02104817	Patients with hypertriglyceridaemia and high cardiovascular disease risk	13,000	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 4g QD + statin Arm 2: Placebo (corn oil) + statin Global trial – 22 countries	<ul style="list-style-type: none"> Primary endpoint: Composite of MACE 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPD: Q2 2017 Data anticipated: 2019
Phase II EFFECT I NCT02354976	Overweight patients with hypertriglyceridemia	75	<ul style="list-style-type: none"> <i>Epanova</i> 4g vs Placebo vs Fenofibrate 200mg daily for 12 weeks Global trial – one country	Primary endpoints: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPD: Q2 2016 Data readout: Q4 2016
Phase II EFFECT II NCT02279407	Type-2 diabetes Liver fat >5.5%	80	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 4g QD Arm 2: Placebo (olive oil) Arm 3: <i>Epanova</i> 4g + dapagliflozin 10mg QD Arm 4: Dapagliflozin 10mg Local trial – one country	<ul style="list-style-type: none"> Primary endpoints: Reduction in liver fat content (%) at the end of 12 weeks 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q4 2015 Data readout: Q2 2016
Phase I PRECISE NCT02370537	Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes	66	<ul style="list-style-type: none"> Arm 1: <i>Epanova</i> 4g single dose Arm 2: <i>Omacor</i> 4g single dose Global trial – six countries in Europe	<ul style="list-style-type: none"> Primary endpoint: Presence of Pancreatic Exocrine Insufficiency (PEI), Pharmacokinetics of <i>Epanova</i> and <i>Omacor</i> following a single oral dose in patients with different degrees of PEI 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q4 2015 Data readout: Q2 2016



Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02359045	Healthy subjects	40 Part A 42 Part B	<ul style="list-style-type: none"> Arm 1: D1400147 4g Arm 2: D14000136 4g Arm 3: D14000137 4g Arm 4: Epanova 4g <p>Local trial – one country</p>	<ul style="list-style-type: none"> 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 C_{max} 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q3 2015 Data readout: Q2 2016
Phase I NCT02372344	Healthy male subjects	42	<ul style="list-style-type: none"> Epanova 4g X 3 separate occasions (fasting, before meal, and after meal) <p>Local trial – one country</p>	<ul style="list-style-type: none"> Effect of food timing (fasting, before meal, and after meal) on pharmacokinetics (AUC, C_{max}, AUC(0-72)) 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q2 2015 Data readout: Q4 2015
Phase I NCT02209766	Healthy male Japanese and Caucasian subjects	18	<ul style="list-style-type: none"> Arm 1: (Japanese): Epanova 2g vs Placebo QD Arm 2: (Japanese): Epanova 4g vs Placebo QD Arm 3: (Caucasian): Epanova 4g vs Placebo <p>Local trial – one country</p>	<ul style="list-style-type: none"> PK of single and multiple doses in healthy male Japanese subjects Safety/tolerability profile 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q4 2014 Data readout: Q3 2015
Phase I NCT02189252	Patients with a history of pancreatitis	16	<ul style="list-style-type: none"> Arm 1: Epanova 4g →omega-3-acid ethyl esters capsules 4g QD Arm 2: omega-3-acid ethyl esters capsules 4g →Epanova 4 g QD Arm 3: Epanova 2g →omega-3-acid ethyl esters capsules 4g QD Arm 4: omega-3-acid ethyl esters capsules 4g →Epanova 2g QD <p>Global trial – two countries</p>	<ul style="list-style-type: none"> Plasma concentration vs time curve (AUC(0-t)) [Time Frame: 0 to 24 hours (AUC(0-24))] 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q2 2015 Data readout: Q4 2015



Symbicort (ICS/LABA)

Mild asthma

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase III SYGMA1 NCT02149199	Patients in need of GINA step-2 treatment	3,850	<ul style="list-style-type: none"> Arm 1: <i>Symbicort Turbuhaler</i> 160/4.5 µg 'as needed' + Placebo <i>Pulmicort Turbuhaler</i> 200µg bid Arm 2: <i>Pulmicort Turbuhaler</i> 200 µg bid + terbutaline 0.4mg Turbuhaler 'as needed' Arm 3: terbutaline Turbuhaler 0.4mg 'as needed' + placebo <i>Pulmicort Turbuhaler</i> 200µg bid Global trial – 19 countries	<ul style="list-style-type: none"> Primary endpoint: Well-controlled asthma weeks (primary) Secondary endpoints: <ul style="list-style-type: none"> Time to first severe asthma exacerbation Time to first moderate or severe asthma exacerbation Average change from baseline in pre-dose FEV₁ 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPD: Q3 2016 Data anticipated: H2 2017
Phase III SYGMA2 NCT02224157	Patients in need of GINA step-2 treatment	4,214	<ul style="list-style-type: none"> Arm 1: <i>Symbicort Turbuhaler</i> 160/4.5µg 'as needed' + Placebo <i>Pulmicort Turbuhaler</i> 200µg bid Arm 2: <i>Pulmicort Turbuhaler</i> 200µg bid + terbutaline 0.4mg Turbuhaler 'as needed' Global trial – 25 countries	<ul style="list-style-type: none"> Primary endpoint: Annual severe asthma exacerbation rate (primary) Secondary endpoints: <ul style="list-style-type: none"> Time to first severe asthma exacerbation Average change from baseline in pre-dose FEV₁ Time to trial specific asthma related discontinuation 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q3 2016 Data anticipated: H2 2017

ICS = Inhaled corticosteroids

LABA = Long Acting Beta Agonist

GINA = Global Initiative for Asthma guidelines



Eklira/Tudorza (LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IV NCT02375724 Partnered	Patients with COPD	224	<ul style="list-style-type: none"> Arm 1: <i>Eklira/Tudorza</i> 400µg Arm 2: Placebo to acclidinium bromide 400µg Global trial – five countries	<ul style="list-style-type: none"> Primary endpoint: Change from baseline in overall E-RS Total score (i.e. score over the whole 8 weeks study period) Secondary endpoints: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q3 2015 Data readout: Q1 2016
Phase IV ASCENT NCT01966107	Patients with moderate to very severe COPD	4,000	<ul style="list-style-type: none"> Arm 1: <i>Eklira/Tudorza</i> 400µg Arm 2: Placebo to acclidinium bromide 400µg Global trial – two countries	Primary endpoints: <ul style="list-style-type: none"> Time to first Major Adverse Cardiovascular Event (MACE). Up to 36 Months Rate of moderate or severe COPD exacerbations per patient per year during the first year of treatment Secondary endpoints: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPD: Q3 2016
Phase IV NCT02153489 Partnered	Patients with stable moderate and severe COPD	30	<ul style="list-style-type: none"> Arm 1: <i>Eklira/Tudorza</i> 400µg Arm 2: Placebo to acclidinium bromide 400µg Local trial – one country	<ul style="list-style-type: none"> Primary endpoint: Change from baseline in normalised forced expiratory volume in one second (FEV1). Week 3. FEV1 over the 24-hour period (AUC0-24) will be measured following morning administration Secondary endpoint: Adverse events. Week 5 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPD: Q1 2015 Data readout: Q4 2015

LAMA = Long Acting Muscarinic Agonist



Duaklir Genuair (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb ACHIEVE NCT02796651	Patients with moderate COPD	120	<ul style="list-style-type: none"> Arm 1: <i>Duaklir Genuair</i> 400/12 µg Arm 2: Placebo to acclidinium/formoterol FDC 400/12 µg Global trial – one Country	<ul style="list-style-type: none"> Primary endpoint: 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 Secondary endpoint: <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q3 2016
Phase III AMPLIFY NCT02796677	Patients with stable COPD	1,500	<ul style="list-style-type: none"> Arm 1: <i>Duaklir Genuair</i> 400/12 µg Arm 2: acclidinium bromide 400µg Arm 3: formoterol fumarate 12µg Arm 4: tiotropium 18µg Global trial – 13 Countries	Primary endpoints: <ul style="list-style-type: none"> Change from baseline in 1-hour morning post-dose dose FEV1 of <i>Duaklir Genuair</i> 400/12 µg compared to AB 400µg at week 24 Change from baseline in morning predose (trough) FEV1 of <i>Duaklir Genuair</i> 400/12 µg compared to FF 12µg at week 24 Change from baseline in morning predose (trough) FEV1 at week 24 comparing AB 400µg versus TIO 18µg 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q4 2016
Phase III AVANT NCT03022097	Patients with stable COPD	1,060	<ul style="list-style-type: none"> Arm 1: <i>Duaklir Genuair</i> 400/12 µg Arm 2: acclidinium bromide 400 µg Arm 3: formoterol fumarate 12 µg Arm 4: tiotropium 18 µg Global Study – five Countries	Primary endpoints: <ul style="list-style-type: none"> Change from baseline in 1-hour morning post-dose dose FEV1 <i>Duaklir Genuair</i> 400/12 µg compared to Acclidinium bromide at Week 24 Change from baseline in morning pre-dose (trough) FEV1 of <i>Duaklir Genuair</i> 400/12 µg compared to Formoterol fumarate at Week 24 Change from baseline in trough FEV1 of Acclidinium bromide 400 µg compared to placebo at Week 24 	<ul style="list-style-type: none"> FPCD: Q1 2017

LAMA = Long Acting Muscarinic Agonist

LABA = Long Acting Beta Agonist



Duaklir Genuair (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase IV ACTIVATE NCT02424344 Partnered	Patients with moderate COPD	268	<ul style="list-style-type: none">• Arm 1: <i>Duaklir Genuair</i> 400/12 µg• Arm 2: Placebo to acclidinium/formoterol FDC 400/12 µg Global Study – five Countries	<ul style="list-style-type: none">• Primary endpoint: Change from baseline in trough Functional Residual capacity (FRC) after 4 weeks of treatment Secondary endpoints: <ul style="list-style-type: none">• Change from baseline in Endurance Time (ET) during constant work rate cycle ergometry to symptom limitation at 75% of Wmax after 8 weeks of treatment• Percentage of inactive patients (<6000 steps per day) after 8 weeks on treatment	<ul style="list-style-type: none">• FPCD: Q2 2015• LPD: Q2 2016• Data readout: Q3 2016

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



Bevespi Aerosphere (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase III PINNACLE 1 NCT01854645	Moderate to very severe COPD	2,103	Treatment (24-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder 18µg QD • Arm 5: Placebo MDI BiD Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active- controlled US, Australia, New Zealand	<ul style="list-style-type: none"> • Primary endpoint: Change from baseline in morning pre-dose trough FEV₁ 	<ul style="list-style-type: none"> • FPCC: Q2 2013 • LPCD: Q3 2014 • Data readout: Q1 2015
Phase III PINNACLE 2 NCT01854658	Moderate to very severe COPD	1,615	Treatment (24-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Placebo MDI BiD Multicentre, randomised, double-blind, parallel group, chronic dosing and placebo-controlled US	<ul style="list-style-type: none"> • Primary endpoint: Change from baseline in morning pre-dose trough FEV₁ 	<ul style="list-style-type: none"> • FPCC: Q3 2013 • LPCD: Q3 2014 • Data readout: Q2 2015
Phase III PINNACLE 3 NCT01970878	Moderate to very severe COPD	893	Treatment (28-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD • Arm 2: GP MDI (PT001) 14.4µg BiD • Arm 3: FF MDI (PT005) 9.6µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder QD Multi-centre, randomised, double-blind, parallel-group and active-controlled US, Australia, New Zealand	<ul style="list-style-type: none"> • Primary endpoint: Change from baseline in morning pre-dose trough FEV₁ 	<ul style="list-style-type: none"> • FPCC: Q4 2013 • LPCD: Q3 2014 • Data readout: Q2 2015

LAMA = Long Acting Muscarinic Agonist

LABA = Long Acting Beta Agonist

GFF = Glycopyrronium and formoterol



Bevespi Aerosphere (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase IIIb NCT02268396	Moderate to severe COPD	150	Treatment (5- to 6- week Treatment Period) <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD Placebo MDI BiD Open-label and multi-centre US	<ul style="list-style-type: none"> Primary endpoint: 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 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q4 2014 Data readout: Q1 2015
Phase IIIb NCT02347085	Moderate to severe COPD	40	Treatments (8-week Treatment Period) <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD Placebo MDI BiD Randomised, 2-period, 2-treatment Double-blind, Multi-centre and cross-over US	<ul style="list-style-type: none"> Primary endpoint: FEV₁ AUC₀₋₂₄ on Day 29 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q1 2015 Data readout: Q3 2015
Phase IIIb NCT02347072	Moderate to severe COPD	80	Treatments (12-week Treatment Period) <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg BiD Placebo Spiriva Respimat 5µg QD (open-label) Randomised and 3-way cross-over US	<ul style="list-style-type: none"> Primary endpoint: FEV₁ AUC₀₋₂₄ on Day 29 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q2 2015 Data readout: Q3 2015
Phase III NCT02454959	Moderate to severe COPD	80	Treatments (2 week treatment Period) <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg with a spacer GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg without a spacer Randomised, 7-day, cross-over in subjects with moderate to severe COPD US	<ul style="list-style-type: none"> Primary endpoint: 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 Secondary endpoint: PK parameters at all doses will include C_{max}, AUC₀₋₁₂, AUC_{0-t}, t_{max}. Other PD/PK parameters may be calculated, as appropriate 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q1 2016 Data readout: Q2 2016

LAMA = Long Acting Muscarinic Agonist

LABA = Long Acting Beta Agonist

GFF = Glycopyrronium and formoterol



Bevespi Aerosphere (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design (G = glycopyrronium, F = formoterol fumarate)	Endpoints	Status
Phase III NCT02343458	Moderate to very severe COPD	1,614	<p>Treatments (24-week Treatment Period)</p> <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg (N=514) GP 14.4µg (N=440) FF 9.6µg (N=440) Placebo (N=220) <p>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</p> <p>Randomised, Double-Blind, Chronic-Dosing, Placebo-Controlled, Parallel-Group and Multi-Centre</p> <p>US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan</p>	<ul style="list-style-type: none"> Primary endpoint: change from baseline in morning pre-dose trough FEV1 of treatment [Time Frame: At Week 24] Assessed at week 24 for US/China and over weeks 12-24 for Japan, and over 24 weeks for EU/South Korea/Taiwan Secondary endpoint: TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 weeks] 	<ul style="list-style-type: none"> FPCD: Q2 2015 LPD: H2 2016 Data anticipated: H2 2017
Phase IIb NCT02685293	Moderate to severe COPD	40	<p>Treatments (5-week Treatment Period)</p> <ul style="list-style-type: none"> GFF MDI (<i>Bevespi Aerosphere</i>) 14.4/9.6µg ex-actuator Placebo MDI <p>Randomised, 2-period, Double-Blind, 2-treatment, Chronic-Dosing (7 Days), cross-over trial</p> <p>US</p>	<ul style="list-style-type: none"> Primary endpoint: Right Ventricular End Diastolic Volume Index (RVEDVI) measured at 2-hours post-dose on day eight 	<ul style="list-style-type: none"> FPCD: Q4 2016 LPD: H2 2017 Data anticipated: 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)

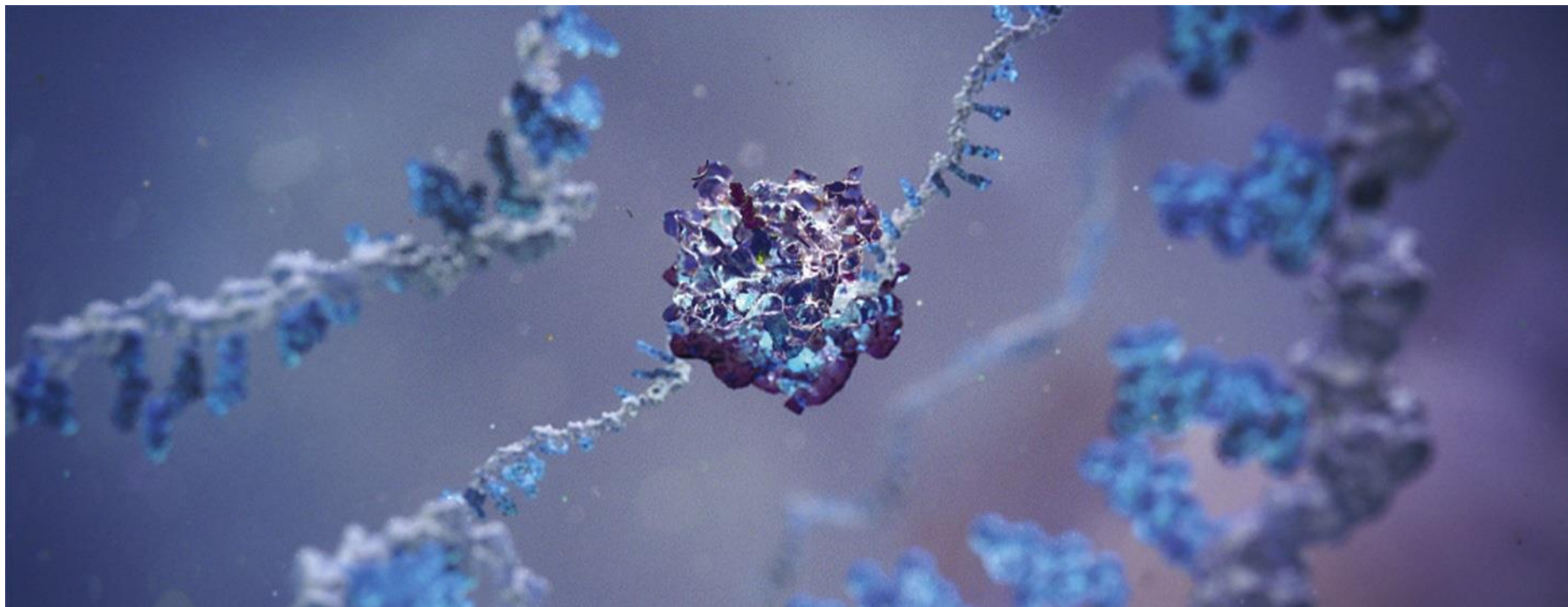
Trial	Population	Patients	Design	Endpoints	Status
Phase IV RESPOND NCT01443845	COPD	2,354	<ul style="list-style-type: none"> 52W, randomised, DB with <i>Daliresp</i> 500µg OD vs placebo, in COPD on top of ICS/LABA 	<ul style="list-style-type: none"> Primary endpoint: Rate of moderate or severe COPD exacerbations per subject per year 	<ul style="list-style-type: none"> FPCD: Q4 2011 LPCD: Q1 2016 Data readout: Q4 2016
Phase IV OPTIMIZE NCT02165826	COPD	1,323	<ul style="list-style-type: none"> 12W, randomised, DB to evaluate tolerability and PK of <i>Daliresp</i> 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 	<ul style="list-style-type: none"> Primary endpoint: Percentage of participants prematurely discontinuing trial treatment for any reason during the main period 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q3 2015 Data readout: Q4 2016
Phase IIIb ROBERT NCT01509677	COPD	158	<ul style="list-style-type: none"> 16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of Roflumilast in COPD 	<ul style="list-style-type: none"> Primary endpoint: Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period 	<ul style="list-style-type: none"> FPCD: Q1 2012 LPCD: Q1 2016 Data readout: Q4 2016

ICS = Inhaled corticosteroids

LABA = Long Acting Beta Agonist



Late-stage pipeline



Acalabrutinib (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase III ACE-CL-006 (ELEVATE-RR) NCT02477696	Relapsed/refractory chronic lymphocytic leukaemia (CLL), high risk	500	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: ibrutinib 	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoints: comparison of incidence of infections, RTs and atrial fibrillation, OS 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2019
Phase III ACE-CL-007 (ELEVATE-TN) NCT02475681	Previously untreated CLL	535	<ul style="list-style-type: none"> Arm A: chlorambucil + obinutuzumab Arm B: acalabrutinib + obinutuzumab Arm C: acalabrutinib 	<ul style="list-style-type: none"> Primary endpoint: PFS (Arm A vs Arm B) Secondary endpoints: IRC assessed ORR, TTNT, OS (Arm A vs Arm B vs Arm C) 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: 2019
Phase III ACE-CL-309 NCT02970318	Relapsed/refractory CLL	306	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: rituximab + idelalisib or bendamustine (investigator's choice) 	<ul style="list-style-type: none"> Primary endpoint: IRC assessed PFS (arm A vs Arm B) Secondary endpoints: INV assessed ORR, TTNT, OS, DOR, PROs 	<ul style="list-style-type: none"> FPCD Q3 2016 Data anticipated: 2020
Phase III ACE-LY-308 NCT02972840	Previously untreated Mantle cell lymphoma (MCL)	546	<ul style="list-style-type: none"> Arm A: acalabrutinib + bendamustine + rituximab Arm B: bendamustine + rituximab 	<ul style="list-style-type: none"> Primary endpoint: PFS by Lugano Classification for NHL Secondary endpoints: Investigator-assessed (IA) PFS, ORR; IRC assessed ORR, DOR, time to response; OS 	<ul style="list-style-type: none"> Data anticipated: 2022
Phase II ACE-CL-208 NCT02717611	Relapsed/ refractory CLL, intolerant to ibrutinib	60	Acalabrutinib monotherapy	<ul style="list-style-type: none"> ORR at 36 cycles 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2020
Phase II 15-H-0016 NCT02337829	Relapsed/refractory and treatment naive/del17p CLL/small lymphocytic lymphoma (SLL)	48	Acalabrutinib monotherapy <ul style="list-style-type: none"> Arm A: Lymph node biopsy Arm B: Bone marrow biopsy 	<ul style="list-style-type: none"> ORR Secondary endpoints: Safety, TTP, PFS, OS 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: H2 2017
Phase II ACE-LY-004 NCT02213926	Relapsed/refractory MCL	124	Acalabrutinib monotherapy	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q3 2014 Data readout: Q2 2017
Phase I/II ACE-CL-001 NCT02029443	CLL/SLL/Richter's transformation (RT)	286	Acalabrutinib monotherapy Dose escalation and expansion	<ul style="list-style-type: none"> Safety, PK, PD Secondary endpoints: ORR, DOR, and PFS 	<ul style="list-style-type: none"> FPCD: Q1 2014 LPCD: Q2 2016 Data anticipated: 2019



Acalabrutinib (BTK inhibitor)

Blood cancers

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I/II ACE-LY-001 NCT02328014	B-Cell Malignancies	126	Dose escalation and expansion trial of the combination of acalabrutinib and ACP-319 (Pi3K inhibitor)	<ul style="list-style-type: none"> Safety ORR 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: H2 2017
Phase I/II ACE-LY-005 NCT02362035	Hematological Malignancies	159	Acalabrutinib + pembrolizumab	<ul style="list-style-type: none"> Safety Secondary endpoints: ORR, DOR, PFS, OS, TTNT 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2021
Phase I/II ACE-WM-001 NCT02180724	Waldenstrom Microglobulinemia (WM)	106	Acalabrutinib monotherapy	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q4 2015 Data readout: Q2 2017
Phase Ib ACE-LY-002 NCT02112526	Relapsed/refractory de novo ABC DLBCL	21	Acalabrutinib monotherapy	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q2 2016 Data readout: Q2 2017
Phase Ib ACE-LY-106 NCT02717624	Mantle Cell Lymphoma (MCL)	48	Acalabrutinib in combination with bendamustine and rituximab <ul style="list-style-type: none"> Arm A: Treatment naive Arm B: Relapsed/refractory 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2021
Phase Ib ACE-MY-001 NCT02211014	Relapsed/refractory Multiple Myeloma	28	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: acalabrutinib + dexamethasone 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q1 2016 Data readout: Q2 2017
Phase I ACE-LY-003 NCT02180711	Relapsed/refractory Follicular Lymphoma	40	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: acalabrutinib + rituximab 	<ul style="list-style-type: none"> Safety 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q3 2016 Data anticipated: 2018
Phase I ACE-CL-002 NCT02157324	Relapsed/refractory CLL/SLL	12	Acalabrutinib in combination with ACP-319 Dose escalation	<ul style="list-style-type: none"> Safety, PK, PD 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q3 2015 Data anticipated: 2018
Phase I ACE-CL-003 NCT02296918	CLL/SLL/Prolymphocytic leukemia (PLL)	45	Acalabrutinib + obinutuzumab <ul style="list-style-type: none"> Arm A: Relapsed/refractory Arm B: Treatment naive 	<ul style="list-style-type: none"> Safety, ORR Secondary endpoints: PD, PFS, TTN, OS 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q1 2018 Data anticipated: H2 2018

Acalabrutinib (BTK inhibitor)

Blood cancers

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase I NCT03198650	Japanese Adults with Advanced B-cell Malignancies	28	<ul style="list-style-type: none">Acalabrutinib monotherapyDose confirmation and expansion	<ul style="list-style-type: none">Safety	<ul style="list-style-type: none">FPCD: Q2 2017Data anticipated: 2021
Phase I/II NCT03205046	R/R B-cell Malignancies	59	<ul style="list-style-type: none">Arm A: acalabrutinib daily + vistusertib dailyArm B: acalabrutinib daily + vistusertib 5 days on and 2 days off	<ul style="list-style-type: none">Identify dose and schedule for vistusertibSafety of coadministration of acalabrutinib + vistusertib	<ul style="list-style-type: none">FPCD: Q1 2017Data anticipated: 2019



Acalabrutinib (BTK inhibitor)

Solid tumours

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II ACE-ST-006 NCT02454179	≥ 2L advanced or metastatic head and neck squamous cell carcinoma	74	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: acalabrutinib+ pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q2 2016 Data anticipated: H2 2017
Phase II ACE-ST-007 NCT02448303	≥ 2L advanced or metastatic NSCLC	74	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: acalabrutinib+ pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD Q2 2016 Data readout: Q2 2017
Phase II ACE-ST-208 NCT02537444	Recurrent ovarian cancer	76	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: acalabrutinib+ pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD Q2 2016 Data anticipated: H2 2017
Phase II ACE-ST-003 NCT02362048	≥ 2L advanced or metastatic pancreatic cancer	73	<ul style="list-style-type: none"> Arm A: acalabrutinib Arm B: acalabrutinib+ pembrolizumab 	• Safety	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q1 2016 Data readout: Q2 2017
Phase II ACE-ST-005 NCT02351739	Platinum-resistant urothelial bladder cancer	75	<ul style="list-style-type: none"> Arm A: pembrolizumab Arm B: acalabrutinib+ pembrolizumab 	• ORR	<ul style="list-style-type: none"> FPCD: Q2 2015 LPCD: Q1 2016 Data anticipated: H2 2017
Phase Ib/II ACE-ST-209 NCT02586857	≥ 2L glioblastoma multiforme	72	<ul style="list-style-type: none"> Arm A: acalabrutinib 200 mg BID Arm B: acalabrutinib 400 mg QD 	<ul style="list-style-type: none"> Safety, ORR Secondary Endpoints: DOR, PFS, PFS-6, OS 	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2018



Cediranib (VEGF-inhibitor)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb CONCERTO	PRR heavily pre-treated BRCAwt	100	<ul style="list-style-type: none">Cediranib 30 mg + <i>Lynparza</i> 200 mg bd	<ul style="list-style-type: none">ORR DoR, DCR, QoL, OS; Safety	<ul style="list-style-type: none">FPCD: Q1 2017



Moxetumomab pasudotox (CD22 mAb)

Blood cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III PLAIT NCT01829711	Adults with relapsed or refractory hairy cell leukemia (HCL)	77	<ul style="list-style-type: none"> Multicentre, single-arm, open-label Phase III trial Moxetumomab pasudotox IV at the recommended dose 	<ul style="list-style-type: none"> Primary endpoint: Rate of durable CR: CR maintained for > 180 days Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS Safety and tolerability PK and immunogenicity 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: H2 2017
Phase I NCT00586924	Adults with relapsed refractory HCL	49	<ul style="list-style-type: none"> Open-label dose escalation Phase I trial Moxetumomab pasudotox IV 	<ul style="list-style-type: none"> MTD and efficacy 	<ul style="list-style-type: none"> FPCD: Q2 2007 LPCD: Q1 2014 Data readout: Q2 2015



Savolitinib (AZD6094) (MET)

Papillary renal cell and other cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT03091192	MET-Driven, Papillary renal cell cancer	180	<ul style="list-style-type: none"> Arm 1: savolitinb 600mg Arm 2: sunitinib 50mg Global trial	<ul style="list-style-type: none"> Primary endpoint: PFS 	<ul style="list-style-type: none"> initiating
Phase II NCT02127710	Papillary renal cell cancer	109	<ul style="list-style-type: none"> Single arm trial: savolitinib 600mg QD Conducted in UK, Spain, US, Canada	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q4 2015 Data readout: Q2 2017
Phase I NCT01985555 Partnered	Advanced cancer (all comers)	~70	<ul style="list-style-type: none"> Dose escalation trial Conducted in China	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: 2018
Phase I NCT02374645	Non-Small Cell Lung Cancer	~53	<ul style="list-style-type: none"> Dose escalation trial Conducted in China	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data anticipated: 2018
Phase II NCT02897479 Partnered	Lung Pulmonary Sarcomatoid Carcinoma (PSC)	45	<ul style="list-style-type: none"> Single arm trial: savolitinib 600mg QD Conducted in China	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2018



Selumetinib (MEK-inhibitor)

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase III ASTRA NCT01843062	Differentiated thyroid cancer	304	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Primary endpoint: Complete remission (CR) rate at 18 months post-radioactive iodine 	<ul style="list-style-type: none"> FPCD: Q3 2013 LPCD: Q1 2016
Phase II NCT01362803 Partnered	Paediatric Neurofibromatosis type 1	minimum of 50	<ul style="list-style-type: none"> Single Arm: selumetinib 25mg/m² BID with 2 strata: <ul style="list-style-type: none"> Stratum 1: PN related morbidity present at enrolment Stratum 2: No PN related morbidity present at enrolment 	<ul style="list-style-type: none"> Complete partial and complete response rate measured by volumetric MRI; Duration of response and functional outcomes/QoL 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q4 2016
Phase I NCT02586987	Advanced solid tumours	90	<ul style="list-style-type: none"> Dose escalation trial: Starting dose selumetinib 50mg bd 1 week on/1 week off – <i>Imfinzi</i> 20mg/kg Q4 – after 7 days of selumetinib dosing Note: No escalation in <i>Imfinzi</i> dose; selumetinib escalation with 25mg bd increment / dose cohort 	<ul style="list-style-type: none"> Safety and tolerability PK of selumetinib and <i>Imfinzi</i> and preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2018



Roxadustat (HIF-PHI)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase III ANDES NCT01750190	Anaemia in CKD patients not receiving dialysis	900	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Placebo Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2012 Data anticipated: 2018 Sponsored by FibroGen
Phase III ALPS NCT01887600		597	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Placebo Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: 2018 Sponsored by Astellas
Phase III DOLOMITES NCT02021318		570	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: darbepoetin alfa Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q1 2014 Data anticipated: H2 2017 Sponsored by Astellas
Phase III OLYMPUS NCT02174627		2,700	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Placebo Global trial	Primary endpoint: MACE	<ul style="list-style-type: none"> FPCD: Q3 2014 Data anticipated: 2018 Sponsored by AstraZeneca
Phase III ROCKIES NCT02174731	Anaemia in CKD in patients receiving dialysis	2,100	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Epoetin alfa Global trial	Primary endpoint: MACE	<ul style="list-style-type: none"> FPCD: Q3 2014 Data anticipated: 2018 Sponsored by AstraZeneca
Phase III SIERRAS NCT02273726		820	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Epoetin alfa Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2018 Sponsored by FibroGen
Phase III PYRENEES NCT02278341		838	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: erythropoiesis stimulating agent Arm 3: darbepoetin alfa Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2017 Sponsored by Astellas

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor



Roxadustat (HIF-PHI)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase III HIMALAYAS NCT02052310	Anaemia in newly initiated dialysis patients	750	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: epoetin alfa Global trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2013 Data anticipated: 2018 Sponsored by FibroGen
Phase III NCT02652819	Anaemia in CKD patients not receiving dialysis	150	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: Placebo China trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2016 Data readout: Q1 2017 Primary endpoint met Sponsored by FibroGen
Phase III NCT02652806	Anaemia in CKD patients receiving dialysis	300	<ul style="list-style-type: none"> Arm 1: roxadustat Arm 2: epoetin alfa China trial	Primary endpoint: Haemoglobin response	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q2 2016 Data readout: Q1 2017 Primary endpoint met Sponsored by FibroGen

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor



ZS-9 (Sodium zirconium cyclosilicate)

Hyperkalaemia

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT01493024	Hyperkalaemia and moderate chronic kidney disease (CKD)	90	<ul style="list-style-type: none"> Arm 1: Escalating TID doses (0.3g, 3g and 10g) of ZS Arm 2: Placebo TID US	<ul style="list-style-type: none"> Primary endpoint: Change in serum potassium levels from baseline 	<ul style="list-style-type: none"> FPCD: Q4 2011 LPCD: Q2 2012 Data readout: Q2 2012
Phase III NCT01737697	Hyperkalaemia	754	<ul style="list-style-type: none"> Arm 1: ZS 1.25g TID for 48 hrs followed by QD for 12 days Arm 2: ZS 2.5g TID for 48 hrs followed by QD for 12 days Arm 3: ZS 5g TID for 48 hrs followed by QD for 12 days Arm 4: ZS 10g TID for 48 hrs followed by QD for 12 days Arm 5: Placebo TID for 48 hrs followed by QD for 12 days Global trial – three countries	<ul style="list-style-type: none"> Primary endpoint: Change in serum potassium levels from baseline 	<ul style="list-style-type: none"> FPCD: Q4 2012 LPCD: Q4 2013 Data readout: Q4 2013 Primary endpoint met
Phase III NCT02088073	Hyperkalaemia	258	Open-label ZS 10g TID for 48 hrs followed by: <ul style="list-style-type: none"> Arm 1: ZS 5g QD for 28 days Arm 2: ZS 10g QD for 28 days Arm 3: ZS 15g QD for 28 days Arm 4: Placebo QD for 28 days Global trial – three countries	<ul style="list-style-type: none"> Primary endpoint: Maintenance of normokalaemia 	<ul style="list-style-type: none"> FPCD: Q1 2014 LPCD: Q3 2014 Data readout: Q4 2014 Primary endpoint met
Phase III Open-label Extension to Study NCT02088073 NCT02107092	Participation in study NCT02088073	123	<ul style="list-style-type: none"> Arm 1: ZS 10g QD for 11 months. Option to uptitrate to 15g QD or downtitrate to 5g QD and 5g QOD Global trial – three countries	<ul style="list-style-type: none"> Primary endpoint: Maintenance of normokalaemia 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q3 2015 Data readout: Q3 2015
Phase III NCT02163499	Hyperkalaemia	751	<ul style="list-style-type: none"> Arm 1: ZS 5g QD for 12 months. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD Global trial – seven countries	<ul style="list-style-type: none"> Primary endpoint: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q4 2016 Data readout: Q2 2017 Primary endpoint met
Phase III NCT02875834	Hyperkalaemia	255	Open-label ZS 10g TID for 48 hrs followed by: <ul style="list-style-type: none"> Arm 1: ZS 5g QD for 28 days Arm 2: ZS 10g QD for 28 days Arm 3: Placebo QD for 28 days Global trial – four countries	<ul style="list-style-type: none"> Primary endpoint: Maintenance of normokalaemia 	<ul style="list-style-type: none"> FPCD: Q1 2017
Phase II/III NCT03127644	Hyperkalaemia	102	Arm 1: ZS 5g TID for 48 hours Arm 2: ZS 10g TID for 48 hours Arm 3: Placebo TID for 48 hours Japan	<ul style="list-style-type: none"> Primary endpoint: Exponential rate of change in serum potassium 	<ul style="list-style-type: none"> FPCD: Q2 2017

Benralizumab (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	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	1,026 HD + ~200 MD	<ul style="list-style-type: none"> • Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 56-week trial Global trial – 11 countries	<ul style="list-style-type: none"> • Primary endpoint: Annual asthma exacerbation rate • Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM 	<ul style="list-style-type: none"> • FPCD: Q4 2013 • Data readout: Q2 2016 • Primary endpoint met
Phase III SIROCCO NCT01928771	Severe, uncontrolled asthma, despite background controller medication HD ICS + LABA ± chronic OCS Age 12-75 years	1,134	<ul style="list-style-type: none"> • Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 48-week trial Global trial – 17 countries	<ul style="list-style-type: none"> • Primary endpoint: Annual asthma exacerbation rate • Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM 	<ul style="list-style-type: none"> • FPCD: Q4 2013 • Data readout: Q2 2016 • Primary endpoint met
Phase III ZONDA NCT02075255	Severe, uncontrolled asthma on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18-75 years	210	<ul style="list-style-type: none"> • Arm 1: 30mg Q8w SC • Arm 2: 30mg Q4w SC • Arm 3: Placebo SC 46-week trial Global trial – 12 countries	<ul style="list-style-type: none"> • Primary endpoint: Reduction of oral corticosteroid dose 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • Data readout: Q3 2016 • Primary endpoint met
Phase III MELTEMI NCT02808819	A multi-centre, open-label, safety extension trial with benralizumab for asthmatic adults on Inhaled Corticosteroid plus Long-acting Beta2 Agonist Age 18-75 years	770	<ul style="list-style-type: none"> • Arm 1: 30mg Q4W SC • Arm 2: 30mg Q8W SC 	<ul style="list-style-type: none"> • Primary endpoint: Safety and tolerability 	<ul style="list-style-type: none"> • FPCD: Q2 2016 • Data anticipated: 2019
Phase III ALIZE NCT02814643	A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of benralizumab on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years	100	<ul style="list-style-type: none"> • 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 	Primary endpoints: <ul style="list-style-type: none"> • Post-dose strain-specific hemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs) • Post-dose strain-specific serum HAI antibody geometric mean titers (GMTs) • Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer 	<ul style="list-style-type: none"> • FPCD: Q3 2016 • Data anticipated: H2 2017



Benralizumab (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III BISE NCT02322775	Asthmatic with FEV ₁ (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18-75 years	200	<ul style="list-style-type: none"> Arm 1: 30mg Q4W SC Arm 3: Placebo SC 12-week trial Global trial – six countries	<ul style="list-style-type: none"> Primary endpoint: Pulmonary function (FEV₁) 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data readout: Q1 2016 Primary endpoint met
Phase III BORA NCT02258542	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years	2,550	<ul style="list-style-type: none"> Arm 1: 30mg Q4W SC Arm 2: 30mg Q8W SC* <ul style="list-style-type: none"> Placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global trial	<ul style="list-style-type: none"> Primary endpoint: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2018
Phase III GREGALE NCT02417961	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 18-75 years	120	<ul style="list-style-type: none"> Arm 1: 30mg Q4W SC 28-week (adults) Global trial – two countries	<ul style="list-style-type: none"> Primary endpoint: Functionality, reliability, and performance of a pre-filled syringe with benralizumab administered at Home 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data readout: Q2 2016 Primary endpoint met
Phase III ARIA NCT02821416	A Double-Blind, randomised, parallel group, placebo-controlled multi-centre trial to evaluate the effect of benralizumab on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years	38	<ul style="list-style-type: none"> Arm 1 : 30mg Q4W SC Arm 2: Placebo SC 	<ul style="list-style-type: none"> Primary endpoint: Safety and tolerability 	<ul style="list-style-type: none"> FPCD Q4 2016 Data anticipated: 2019

ICS = Inhaled corticosteroids

LABA = Long Acting Beta Agonist



Benralizumab (IL-5R mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III SOLANA NCT02869438	Severe asthma Age 18-75 years	230	<ul style="list-style-type: none"> Arm 1: 30mg Q4W SC Arm 2: Placebo SC 16-week trial Global trial – six countries	<ul style="list-style-type: none"> Primary endpoint: Onset and maintenance of effect on lung function 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: 2018
Phase III GRECO NCT02918071	Severe asthma Age 18-75 years	120	Open label 30mg Q4w 28-week trial Global trial - two countries	<ul style="list-style-type: none"> Primary endpoint: % of patients/ caregivers who successfully self administer at home 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: 2018
Phase IIIb ANDHI NCT03170271	A Multicenter, Randomized, Double-blind, Parallel Group, Placebo Controlled, Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients With Severe Asthma Uncontrolled on Standard of Care Treatment. Age 18-75	800	<ul style="list-style-type: none"> Arm 1: 30mg Q8W SC Arm 2: placebo SC 	<ul style="list-style-type: none"> Primary Endpoint: rate of asthma exacerbations. Secondary Outcome Measures: Saint George Respiratory Questionnaire (SGRQ) 	<ul style="list-style-type: none"> Data anticipated 2019
Phase I AMES NCT02968914	Healthy Volunteer Age 18-55 years	162	Open label study to compare 30 mg benralizumab PK administered by APFS or AI device 8-week study Global study – two countries	<ul style="list-style-type: none"> Primary endpoint: PK Comparability 	<ul style="list-style-type: none"> FPCD: H1 2017 Data anticipated: H2 2017



Benralizumab (IL-5R mAb)

Chronic Obstructive Pulmonary Disease (COPD)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase III TERRANOVA NCT02155660	Moderate to very severe COPD with exacerbation history	2,168	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Primary endpoint: Rate of COPD exacerbation	<ul style="list-style-type: none">• FPCD: Q3 2014• Data anticipated: H2 2018
Phase III GALATHEA NCT02138916	Moderate to very severe COPD with exacerbation history	1,626	<ul style="list-style-type: none">• Arm 1: 30mg Q4W SC• Arm 2: 100mg Q8W SC• Arm 3: Placebo SC 48-week trial Global trial – 17 countries	<ul style="list-style-type: none">• Primary endpoint: Rate of COPD exacerbation	<ul style="list-style-type: none">• FPCD: Q3 2014• Data anticipated: H2 2018

Oncology

CVMD

Respiratory

Other



Tralokinumab (IL-13 mAb)

Severe, uncontrolled asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III STRATOS 1 NCT02161757	Adults with severe, uncontrolled asthma	1,140	Cohort 1: <ul style="list-style-type: none"> • Arm 1: Tralokinumab dose regimen 1, SC • Arm 2: Placebo SC Cohort 2: <ul style="list-style-type: none"> • Arm 1: Tralokinumab dose regimen 2, SC • Arm 2: Placebo SC 2:1 randomisation in both cohorts Global trial – 14 countries	<ul style="list-style-type: none"> • Primary endpoint: Asthma exacerbation rate reduction • Secondary endpoint: 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) 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q1 2016 • Data readout: Q2 2017 • Primary endpoint not met
Phase III STRATOS 2 NCT02194699	Adults with severe, uncontrolled asthma	770	<ul style="list-style-type: none"> • Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – 12 countries including Japan	<ul style="list-style-type: none"> • Primary endpoint Asthma exacerbation rate reduction • Secondary endpoint: 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) 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • LPCD: Q1 2016 • Data anticipated: H2 2017
Phase III TROPOS NCT02281357	Adults with oral corticosteroid dependent asthma	120	<ul style="list-style-type: none"> • Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – seven countries	<ul style="list-style-type: none"> • Primary endpoint: % Change in OCS dose Secondary endpoints: <ul style="list-style-type: none"> • Proportion of subjects achieving final daily OCS dose ≤5 mg • Proportion of subjects achieving ≥50% reduction in OCS dose 	<ul style="list-style-type: none"> • FPCD: Q1 2015 • LPCD: Q3 2016 • Data anticipated: H2 2017
Phase II MESOS NCT02449473	Adults with uncontrolled asthma	80	<ul style="list-style-type: none"> • Arm 1: Tralokinumab SC • Arm 2: Placebo SC 1:1 randomisation Global trial – three countries	Primary endpoints: <ul style="list-style-type: none"> • Change in number of airway • Sub-mucosal eosinophils Secondary endpoints: <ul style="list-style-type: none"> • Change in blood eosinophils levels • Change in eosinophil cationic protein as a measure of activated eosinophils in blood and sputum 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • LPCD: Q4 2016 • Data anticipated: H2 2017



PT010 (LAMA/LABA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02536508	Moderate to very severe COPD	500	Treatments (52-week Treatment Period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg GFF MDI 14.4/9.6µg BFF MDI 320/9.6µg <i>Symbicort Turbuhaler</i> 400/1 µg Randomised, double-blind, chronic-dosing, multi-centre Country – US	Primary endpoints: <ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPD: Q3 2016 Data anticipated: H2 2017
Phase III NCT02465567	Moderate to very severe COPD	8,000 (possible increase by 4,000 after blinded sample size re-assessment)	Treatments (1-year Treatment Period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg BID BGF MDI 160/14.4/9.6µg BID BFF MDI 320/9.6µg BID GFF MDI 14.4/9.6µg BID Randomised, double-blind, multi-centre and parallel-group Multi-country	<ul style="list-style-type: none"> Primary endpoint: Rate of moderate or severe COPD exacerbations Secondary endpoint: Time to first moderate or severe COPD exacerbation 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: 2019
Phase III KRONOS NCT02497001	Moderate to very severe COPD	1,800	Treatments (24-week Treatment Period) <ul style="list-style-type: none"> BGF MDI 320/14.4/9.6µg GFF MDI 14.4/9.6µg BFF MDI 320/9.6µg <i>Symbicort Turbuhaler</i> 400/12µg Randomised, double-blind, parallel-group, and chronic dosing and multi-centre Multi-country	Primary Endpoints: <ul style="list-style-type: none"> FEV₁ area under curve from 0 to 4 hours (AUC0-4) over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs <i>Symbicort Turbuhaler</i>) 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) 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: 2018



PT010 (LAMA/LABA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02105012	Adult mild to moderate persistent asthma	150	<ul style="list-style-type: none"> • 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 <p>Randomised, four-period, five-treatment incomplete-block and cross-over</p> <p>US</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • FPCD: Q2 2014 • LPCD: Q1 2015 • Data readout: Q3 2015
Phase II NCT02433834	Intermittent asthma/mild to moderate persistent asthma	200	<p>Treatment (18-week Treatment Period)</p> <ul style="list-style-type: none"> • 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 <p>Randomised, double-blind, chronic-dosing, placebo controlled, incomplete block, cross-over, multi-centre, dose-ranging trial</p>	<ul style="list-style-type: none"> • Peak change from baseline in FEV₁ within three hours post-dosing on Day 15 	<ul style="list-style-type: none"> • FPCD: Q2 2015 • LPCD: Q4 2015 • Data readout: Q2 2016



PT010 (LAMA/LABA/ICS)

Chronic Obstructive Pulmonary Disease (COPD) & Asthma

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02189304	Healthy subjects	60	<ul style="list-style-type: none"> • Arm 1: BGF MDI 320/14.4/9.6µg • Arm 2: BFF MDI 320/9.6µg • Arm 3: <i>Symbicort Turbuhaler</i> 400/12µg Randomised, double-blind, single-dose, three-period, three-treatment and cross-over US	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q3 2014 • Data readout: Q4 2014
Phase I NCT02197975	Japanese healthy subjects	28	Treatment (2-week Treatment Period) <ul style="list-style-type: none"> • 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 cross-over Japan	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q3 2014 • Data readout: Q4 2014
Phase I NCT02196714	Japanese healthy subjects	24	Treatment (four-day Treatment Period) <ul style="list-style-type: none"> • 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 Japan	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPCD: Q3 2014 • LPCD: Q3 2014 • Data readout: Q4 2014

LAMA = Long Acting Muscarinic Agonist

LABA = Long Acting Beta Agonist

ICS = Inhaled corticosteroids



Anifrolumab (type I IFN receptor mAb)

Systemic Lupus Erythematosus (SLE)

Trial	Population	Patients	Design	Endpoints	Status
Phase III NCT02446912	Moderate to severe SLE TULIP SLE 1	450	<ul style="list-style-type: none"> Arm 1: 300mg IV anifrolumab Q4W for 48 weeks Arm 2: 150mg IV anifrolumab Q4W for 48 weeks Arm 3: Placebo IV Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: Response in SLE responder index at week 52 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: H2 2018
Phase III NCT02446899	Moderate to severe SLE TULIP SLE 2	360	<ul style="list-style-type: none"> Arm 1: 300mg IV anifrolumab Q4W for 48 weeks Arm 2: Placebo IV Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: Response in SLE responder index at week 52 	<ul style="list-style-type: none"> FPCD: Q3 2015 Data anticipated: H2 2018
Phase II NCT01438489	Moderate to severe SLE patients	307	<ul style="list-style-type: none"> Arm 1: 300mg IV anifrolumab Q4W for 48 weeks Arm 2: 1000mg IV anifrolumab Q4W for 48 weeks Arm 3: Placebo IV Q4W for 48 weeks 	<ul style="list-style-type: none"> Primary endpoint: Response in SLE responder index at 6 months 	<ul style="list-style-type: none"> FPCD: Q1 2012 LPCD: Q1 2015 Data readout: Q3 2014
Phase II NCT01753193	Moderate to severe SLE patients	218	<ul style="list-style-type: none"> Arm 1: anifrolumab, IV Q4W for 104 weeks 	<ul style="list-style-type: none"> Primary endpoint: Open-label extension to evaluate long-term safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2013 Data anticipated: H2 2018
Phase II NCT01559090	Japanese SLE patients	17	<p>Open-label, dose escalation trial:</p> <ul style="list-style-type: none"> 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 then 1000mg IV Q4W for 104 weeks 	<ul style="list-style-type: none"> Safety, tolerability, PK/PD 	<ul style="list-style-type: none"> FPCD: Q1 2012 Data readout: Q1 2015
Phase I NCT02601625	Healthy subjects	30	<ul style="list-style-type: none"> Arm 1: 300mg SC single dose Arm 2: 300mg IV single dose Arm 3: 600 mg SC single dose 	<ul style="list-style-type: none"> Safety, tolerability, PK/PD 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: H1 2016 Data readout: Q3 2016
Phase II NCT02962960	Moderate to severe SLE patients	32	<ul style="list-style-type: none"> Arm 1: 150mg SC every other week Arm 2: 300mg SC every other week Arm 3: Placebo SC every other week 	<ul style="list-style-type: none"> PK/PD, Safety, tolerability, Primary analysis at week 12, Secondary analysis at week 52 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: H1 2018



Anifrolumab (type I IFN receptor mAb)

Lupus Nephritis (LN)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02547922	Active Proliferative LN (TULIP-LN1)	150	<ul style="list-style-type: none">• Arm 1: 900 mg IV Q4W for 12 weeks then 300mg IV anifrolumab Q4W for 36 weeks• Arm 2: 300 mg IV anifrolumab Q4W for 48 weeks• Arm 3: Placebo IV Q4W for 48 weeks	Response in proteinuria at week 52	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: 2019

Oncology

CVMD

Respiratory

Other



Lanabecestat (AZD3293, BACE inhibitor)

Alzheimer's disease

Trial	Population	Patients	Design	Endpoints	Status
Phase III AMARANTH NCT02245737	Early Alzheimer's disease patients	2,202	<ul style="list-style-type: none"> • Arm 1: lanabecestat 20mg once daily • Arm 2: lanabecestat 50mg once daily • Arm 3: Placebo once daily <p>24-month treatment duration</p> <p>Global trial – 14 countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale <p>Secondary endpoints:</p> <ul style="list-style-type: none"> • Changes in cognitive and functional (ADCS-ADL) scales • Changes in composite scales (CDR-SB) • Changes in biomarkers and imaging assays • Safety and tolerability 	<ul style="list-style-type: none"> • FPCD: Q4 2014 • Data anticipated: 2019
Phase III AMARANTH - EXTENSION NCT02972658 Partnered	Early Alzheimer's disease patients	1400	<ul style="list-style-type: none"> • lanabecestat 20mg or 50mg once daily <p>12-month delayed start treatment extension</p> <p>Global trial – 14 countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Delayed start analysis 	<ul style="list-style-type: none"> • FPCD: Q1 2017 • Data anticipated: 2020
Phase III DAYBREAK-ALZ NCT02783573	Mild Alzheimer's disease patients	1,899	<ul style="list-style-type: none"> • Arm 1: lanabecestat 20 mg once daily • Arm 2: lanabecestat 50 mg once daily • Arm 3: placebo once daily <p>18-month treatment duration + 18-month delayed start extension</p> <p>Global trial – 18 countries</p>	<ul style="list-style-type: none"> • Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale <p>Secondary endpoints:</p> <ul style="list-style-type: none"> • Changes in cognitive and functional (ADCS-ADL) scales • Changes in composite scales (CDR-SB) • Changes in biomarkers and imaging assays • Safety and tolerability 	<ul style="list-style-type: none"> • FPCD: Q3 2016 • Data anticipated: 2019



Acalabrutinib (ACP-196)

Rheumatoid Arthritis

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoint(s)	Status
Phase II ACE-RA-001 NCT02387762	Rheumatoid Arthritis	31	<ul style="list-style-type: none">• Arm A: acalabrutinib + methotrexate• Arm B: methotrexate	Disease Activity Score 28-CRP at week 4	FPCD: Q2 2015 LPCD: Q2 2016 Data readout: Q2 2016

Oncology

CVMD

Respiratory

Other



Early development - IMED



AZD0156 (ATM)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02588105	Solid tumours	130	<ul style="list-style-type: none">• Arm 1: AZD0156 + <i>Lynparza</i>• Arm 2: AZD0156 + irinotecan <p>Trial conducted in North America, Europe and South Korea</p>	<ul style="list-style-type: none">• Safety, tolerability, pharmacokinetics and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: 2018



AZD1775 (WEE-1)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02272790	PR ovarian cancer	97	<ul style="list-style-type: none"> Arm B: paclitaxel + AZD1775 Arm C: carboplatin + AZD1775 <p>Global trial</p>	<ul style="list-style-type: none"> Primary endpoint: ORR Secondary endpoints: Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2015
Phase I/II NCT02482311	Advanced solid tumours	152	<ul style="list-style-type: none"> Monotherapy Safety Run-in (part A, N=12); solid tumours Expansions into specific tumour types, inc. ovarian cancer (BRCAm PARP failures and BRCAwt with three or more prior lines of treatment), triple negative breast cancer (TNBC) and SCLC <p>Conducted in US, Canada</p>	<ul style="list-style-type: none"> Safety and tolerability Secondary endpoints: Overall response rate, Disease Control Rate, Duration of Response, PFS 	<ul style="list-style-type: none"> FPCD: Q3 2015
Phase I NCT02610075	Advanced solid tumours	98	<ul style="list-style-type: none"> Monotherapy Dose escalation trial to determine MTD <p>Conducted in US</p>	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2015
Phase I NCT02511795	Advanced solid tumours	102	<ul style="list-style-type: none"> Dose escalation trial to determine MTD (AZD1775 + <i>Lynparza</i>) followed by expansions into specific tumour types, inc ovarian cancer, triple negative breast cancer (TNBC) and small cell lung cancer (SCLC) <p>Conducted in US, Canada</p>	<ul style="list-style-type: none"> Safety and tolerability Secondary endpoints: Overall response rate, Disease Control Rate, Duration of Response, PFS 	<ul style="list-style-type: none"> FPCD: Q3 2015
Phase I NCT02617277	Advanced solid tumours	55	<ul style="list-style-type: none"> Dose escalation trial to determine MTD (AZD1775 + <i>Imfinzi</i>) <p>Conducted in US</p>	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2015
Phase I NCT02341456	Advanced solid tumours	20	<ul style="list-style-type: none"> Dose escalation trial to determine MTD (AZD1775 + carboplatin + paclitaxel: AZD1775 + Carbo) <p>Conducted in Australia, Japan and Republic of Korea</p>	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPD: Q2 2016 Data readout Q1 2017



Vistusertib (AZD2014) (TORC 1/2)

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

Trial	Population	Patients	Design	Endpoints	Status
Phase II MANTA NCT02216786 Partnered	2L ER+ metastatic breast cancer	316	<ul style="list-style-type: none"> Arm 1: <i>Faslodex</i> Arm 2: <i>Faslodex</i> + vistusertib 50mg BD continuous dosing Arm 3: <i>Faslodex</i> + vistusertib 125mg BD two days on, 5 off Arm 4: <i>Faslodex</i> + everolimus Multicentre: European sites	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPD: H2 2016 Data anticipated: 2018
Phase I NCT02398747	Japanese Patients with Advanced Solid Malignancies	18	Open label Monotherapy and combination with paclitaxel cohorts	<ul style="list-style-type: none"> Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel PK 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data anticipated: H2 2017
Phase I/II PASTOR NCT02599714	Postmenopausal women with locally advanced/metastatic estrogen receptor positive (ER+) breast cancer	225	Part A – Phase I triplet dose finding to determine the maximum tolerated dose (MTD) of the triplet (vistusertib + palbociclib + fulvestrant) Part B – Phase I single arm expansions (vistusertib + palbociclib + <i>Faslodex</i>) Part C – randomised, double-blind, placebo-controlled, stratified, parallel group extension at RP2D for triplet combination (vistusertib + palbociclib + <i>Faslodex</i> vs matching vistusertib placebo + palbociclib + <i>Faslodex</i>)	Primary endpoints: <ul style="list-style-type: none"> Part A: Safety and tolerability of the triplet. MTD and recommended dose for Parts B and C Part B: Safety and tolerability Part C: PFS Secondary endpoints: Best Objective Response Rate (BOR) and Objective Response Rate (ORR)	<ul style="list-style-type: none"> FPCD: Q1 2016 Data anticipated: 2019



AZD2811 (AURN)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02579226	Solid tumours	72	<ul style="list-style-type: none">• Arm 1: AZD2811 dose escalation• Arm 2: AZD2811 dose expansion AZD2811 + irinotecan <p>Trial conducted in North America</p>	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetics and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: 2019



AZD4547 (FGFR)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase II GLOW NCT01202591	Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy	40	<ul style="list-style-type: none"> Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane Part B: <ul style="list-style-type: none"> Arm 1: AZD4547 (dose from part A) + <i>Faslodex</i> Arm 2: placebo + <i>Faslodex</i> Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients) Conducted in eight countries in Europe	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q4 2010 LPCD: Q1 2014 Data readout: Q3 2014
Phase II SHINE NCT01457846	Advanced gastro-oesophageal cancer	71	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Primary endpoint: PFS Secondary endpoint: OS/Tumour size 	<ul style="list-style-type: none"> FPCD: Q4 2011 LPCD: Q2 2013 Data readout: Q1 2015
Phase I NCT01213160	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	33	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B and C Part B: Safety and tolerability and preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2010 LPCD: Q4 2012 Data readout: Q2 2013
Phase I NCT00979134	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	94	<ul style="list-style-type: none"> Part A: Ascending oral doses of AZD4547 to define maximum tolerated dose (MTD) and /or continuous, tolerable recommended dose (RD) Part B: Dose expansion phase at RD defined in Part A Part C: Expansion phase in patients with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A Conducted in seven countries across North America and Europe	<ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B and C Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2009 LPCD: Q4 2013 Data readout: Q1 2015
Phase I BISCAY NCT02546661	2L Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy	110	<ul style="list-style-type: none"> Multi-drug biomarker-directed trial Arm 1: AZD4547 Arm 2: AZD4547 + <i>Imfinzi</i> Arm 3: <i>Lynparza</i> + <i>Imfinzi</i> Arm 4: AZD1775 + <i>Imfinzi</i> Arm 5: <i>Imfinzi</i> Arm 6: <i>vistusertib</i> + <i>Imfinzi</i> Planned in North America and Europe	<ul style="list-style-type: none"> Safety and tolerability of the combinations PK and preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: 2018



AZD4635 (A_{2A}R)

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

Oncology

Solid tumours and Non-Small Cell Lung Cancer (NSCLC)

Trial	Population	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	36 (estimated) 15	<ul style="list-style-type: none">Phase 1a: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4635 given as monotherapy and in combination with <i>Imfinzi</i>. 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 activityPhase 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: <ul style="list-style-type: none">Pharmacokinetics of AZD4635 as monotherapy and combination with <i>Imfinzi</i>Preliminary assessment of anti-tumour activity	<ul style="list-style-type: none">FPCD: Q2 2016Data anticipated: 2018

CVMD

Respiratory

Other



AZD4785 (KRAS antisense oligonucleotide)

Solid tumours and Non-Small Cell Lung Cancer (NSCLC)

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03101839	Phase Ia: patients with advanced solid tumours which harbour mutations of KRAS. Phase Ib: patients with advanced NSCLC with tumours harbouring mutations of KRAS.	30 (estimated) 20	<ul style="list-style-type: none"> Phase Ia: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4785 given as monotherapy. When the MTD is determined, additional patients with advanced solid malignancies may be enrolled to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity Phase Ib will consist of an expansion phase in patients with KRASm NSCLC at the MTD or maximum feasible dose. <p>To be conducted at sites in the USA and UK</p>	<p>Primary Outcome Measure: Safety and tolerability</p> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"> Pharmacokinetics of AZD4785 Change in KRAS mRNA from baseline Objective clinical response 	<ul style="list-style-type: none"> FPCD: Q2 2017 Data anticipated: 2019



AZD5069 (CXCR2)

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II NCT02499328	Squamous Cell Carcinoma of the Head & Neck (HNSCC)	233	Dose Escalation advanced solid and blood cancers <ul style="list-style-type: none"> • Arm A1: AZD9150/<i>Imfinzi</i> • Arm A2 : AZD5069/<i>Imfinzi</i> • Arm A4: AZD9150/<i>Imfinzi</i>/treme • Arm A5: AZD5069/<i>Imfinzi</i>/treme Dose Expansion 2L HNSCC: <ul style="list-style-type: none"> • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/<i>Imfinzi</i> • Arm B4: AZD5069/<i>Imfinzi</i> • Arm B5: AZD9150 Mono • Arm B6: AZD5069 Mono • Arm B7: AZD9150/<i>Imfinzi</i> (1L HNSCC) 	<ul style="list-style-type: none"> • Safety/Efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • Data anticipated: 2019
Phase Ib/II NCT02583477	Metastatic Pancreatic Ductal Carcinoma	19	Dose escalation and expansion Arms: <i>Imfinzi</i> in combination with nab-paclitaxel and gemcitabine <i>Imfinzi</i> in combination with AZD5069	<ul style="list-style-type: none"> • Safety/Efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q1 2016 • Data anticipated: 2018



AZD5363 (AKT)

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase IIb NCT01625286	ER+ breast cancer receiving 1 st treatment with paclitaxel in the advanced setting	100	<ul style="list-style-type: none"> Arm 1: AZD5363 + paclitaxel Arm 2: AZD5363 placebo + paclitaxel <p>Two strata (50 points per stratum): PIK3CA mutation positive vs Mutation not detected</p>	<ul style="list-style-type: none"> PFS ORR & OS are secondary endpoints 	<ul style="list-style-type: none"> FPCD: Q1 2014 Data anticipated: H2 2017
Phase I NCT01226316	Breast and gynaecological cancers with PIK pathway mutation	12-24 per arm (Parts E & F)	AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant [initially 12 patients per arm with option to expand to 24 patients in one or more arms] <ul style="list-style-type: none"> Part E arm 1: ER+ Breast with AKT-1 mutation (prior <i>Faslodex</i> resistance) Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to <i>Faslodex</i>) Part F arm 1: ER+ Breast with PTEN mutation (prior <i>Faslodex</i> resistance) Part F arm 2: ER+ Breast with PTEN mutation (first exposure to <i>Faslodex</i>) 	<ul style="list-style-type: none"> Safety and tolerability ORR Clinical Benefit Rate at 24 weeks (CBR24) [Parts E & F only] 	<ul style="list-style-type: none"> Data anticipated: H2 2017



AZD6738 (ATR)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02264678	Solid tumours	160	<ul style="list-style-type: none">• Arm 1: AZD6738 + carboplatin• Arm 2: AZD6738 dose escalation, AZD6738 + <i>Lynparza</i>• Arm 3: AZD6738 + <i>Imfinzi</i> <p>Trial conducted in North America, Europe and South Korea</p>	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetics and efficacy	<ul style="list-style-type: none">• FPCD: Q4 2014• Data anticipated: H2 2017



AZD8186 (PI3Kb/d)

Solid tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT01884285	Advanced Castrate Resistant Prostate Cancer /sqNSCLC /TNBC and patients with known PTEN-deficient/ mutated or PIK3CM mutated/ amplified advanced solid malignancies	153	<ul style="list-style-type: none"> Part A: AZD8186 monotherapy in ascending intermittent doses in 3 schedules Part B: AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer Part C: Combination AZD8186 added to abiraterone acetate (with prednisone) in PTEN deficient mCRPC patients. Initial dose/ schedule confirmation phase using AZD8186 monotherapy recommended dose/ schedule from Part A and the labelled dose of abiraterone followed by an expansion cohort to explore clinical activity Part D: Combination AZD8186 and AZD2014 (a novel dual mTORC 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 <p>Trial conducted in Canada, US, Spain & UK</p>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q2 2013 Data anticipated: 2018



AZD9150 (STAT3)

Solid tumours and blood cancers

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II NCT02499328	Squamous Cell Carcinoma of the Head & Neck (HNSCC)	233	Dose Escalation advanced solid and blood cancers <ul style="list-style-type: none"> • Arm A1: AZD9150/<i>Imfinzi</i> • Arm A2 : AZD5069/<i>Imfinzi</i> • Arm A4: AZD9150/<i>Imfinzi</i>/treme • Arm A5: AZD5069/<i>Imfinzi</i>/treme Dose Expansion 2L HNSCC: <ul style="list-style-type: none"> • Arm B1: AZD9150 • Arm B2: AZD5069 • Arm B3: AZD9150/<i>Imfinzi</i> • Arm B4: AZD5069/<i>Imfinzi</i> • Arm B5: AZD9150 Mono • Arm B6: AZD5069 Mono • Arm B7: AZD9150/<i>Imfinzi</i> (1L HNSCC) 	<ul style="list-style-type: none"> • Safety/Efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • Data anticipated: 2019
Phase Ib/II NCT02549651	Diffuse Large B-cell Lymphoma	190	Dose escalation and expansion Arms: <ul style="list-style-type: none"> • Experimental Arm: <i>Imfinzi</i> monotherapy • Experimental Arm: <i>Imfinzi</i> and tremelimumab • Experimental Arm: <i>Imfinzi</i> and AZD9150 	<ul style="list-style-type: none"> • Safety/Efficacy trial 	<ul style="list-style-type: none"> • FPCD: Q3 2016 • Data anticipated: 2021

* clinicaltrials.gov being updated



AZD9496 (SERD)

Breast cancer

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02248090	ER+ Breast Cancer	~50	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Primary Outcome Measures: Safety and tolerability Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood Anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2016 Data readout: Q2 2017
Phase I NCT02780713	Healthy subjects	14	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites Secondary Outcome Measures: Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q3 2016 Data readout: Q2 2017



AZD4076 (anti-miR 103/107)

Non-alcoholic steatohepatitis (NASH)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02612662	Healthy subjects	40	SAD trial (one trial site in US) <ul style="list-style-type: none">• 5 different dose levels investigated vs placebo• Sub-cutaneous injection	<ul style="list-style-type: none">• Safety and tolerability• PK parameters	<ul style="list-style-type: none">• FPCD: Q4 2015• LPCD: Q3 2016
Phase I/IIa NCT02826525	Type-2 diabetic patients with non-alcoholic fatty liver disease	14	MAD trial (one trial site in US) <ul style="list-style-type: none">• Up to 3 different dose levels investigated vs placebo• Sub-cutaneous injection	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• FPCD: Q3 2016• LPCD: Q1 2017



AZD4831 (MPO)

Cardiovascular disease

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02712372	Healthy subjects	~96	SAD trial (one trial site in Germany) <ul style="list-style-type: none">Planned to investigate 6 different dose levels vs placebo but up to 10 cohort may be used	<ul style="list-style-type: none">Safety and tolerabilityPK parameters	<ul style="list-style-type: none">FPCD: Q3 2016LPCD: Q4 2016Data readout Q2 2017
Phase 1 NCT03136991	Healthy subjects	~40	MAD (one trial site in USA) <ul style="list-style-type: none">The planned number of cohorts is four but up to five cohorts may be included	<ul style="list-style-type: none">Safety and tolerabilityPK parameters	<ul style="list-style-type: none">FPCD: Q2 2017



AZD5718 (FLAP)

Cardiovascular disease

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

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02632526	Healthy subjects	96	SMAD trial (one trial site in UK) SAD <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> The planned number of cohorts is four but up to six cohorts may be included Once or twice daily oral administration of AZD5718 	<ul style="list-style-type: none"> Safety and tolerability PK parameters Pharmacodynamic analysis by ex-vivo stimulation of LTB4 production using calcium ionophore Pharmacodynamics of AZD5718 after single ascending doses and multiple ascending doses To evaluate the relative bioavailability between the amorphous and crystalline form of AZD5718 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q3 2016 Data readout: Q4 2016
Phase 1 NCT02963116	Healthy subjects	12	DDI/BA study (one trial site in UK) A Randomized, 5-Period, 5-Treatment, Single-Dose, open-label, cross-over study to <ul style="list-style-type: none"> estimate the effect of AZD5718 on the pharmacokinetics of rosuvastatin assess the relative bioavailability of AZD5718 oral suspension vs AZD5718 IR tablet formulation assess the food effect of AZD5718 	<ul style="list-style-type: none"> To evaluate the PK of rosuvastatin when administered alone and in combination with AZD5718, by assessment of AUC, AUC(0-last) and Cmax of rosuvastatin. To evaluate the relative bioavailability of an immediate release (IR) tablet vs oral suspension formulation of AZD5718. To examine the PK profiles of IR tablet formulation of AZD5718 when administered in fed and fasted conditions To further assess the safety of single doses of AZD5718 in healthy subjects 	<ul style="list-style-type: none"> FPCD: Q2 2016 LPCD: Q1 2017 Data readout Q2 2017



AZD8601 (VEGF-A)

Cardiovascular disease

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02935712	Type 2 diabetic patients	~60	SAD trial (one trial site in Germany) <ul style="list-style-type: none">Planned to investigate 3 different dose levels vs placebo but up to 5 cohort may be used	<ul style="list-style-type: none">Safety and tolerability	<ul style="list-style-type: none">FPCD: Q1 2017



Verinurad (RDEA3170 - SURI, URAT1 inhibitor)

CKD development programme

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT03118739	CKD patients with hyperuricaemia, albuminuria, and Type 2 diabetes	60	<ul style="list-style-type: none">• Arm A: verinurad 9 mg and febuxostat 80 mg• Arm B: Placebo The study is a multi-centre study conducted in the US	To assess the effects of intensive uric acid lowering therapy with RDEA3170 and febuxostat on albuminuria	<ul style="list-style-type: none">• FPCD: Q2 2017

Oncology

CVMD

Respiratory

Other



Abediterol (AZD0548, LABA)

Asthma

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02777827	Patients With Asthma on Inhaled Corticosteroids	36	Single-dose 6-way cross-over to investigate ultra-low doses of abediterol and to compare 2 different devices (pMDI and 3 DPI) <ul style="list-style-type: none">• Abediterol 0.156 µg• Drug: Abediterol 2.5 µg• Drug: Abediterol 0.05 µg• Other: Placebo	Primary Endpoint. <ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• FPCD: Q3 2016• LPCD: Q4 2016• Data readout: Q1 2017

Oncology

CVMD

Respiratory

Other



AZD1419 (TLR9 agonist)

Asthma

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa INCONTRO NCT02898662	Adults with eosinophilic, moderate to severe asthma on ICS + LABA background treatment	70	<ul style="list-style-type: none">• Arm 1: AZD1419, once-weekly adaptive dosing (4mg, 1mg, 8mg)• Arm 2: placebo Inhaled (nebulised) administration Trial conducted in EU	<ul style="list-style-type: none">• Time to loss of asthma control	<ul style="list-style-type: none">• FPCD: Q4 2016

ICS = Inhaled corticosteroids

LABA = Long Acting Beta Agonist

Oncology

CVMD

Respiratory

Other



AZD5634 (epithelial NaC inhibitor)

Cystic Fibrosis

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02679729	Healthy subjects	Part A: 57 Part B: 6	SAD. A Phase I, Randomized, Single-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of AZD5634 Following Single-Ascending Inhaled Doses (Part A) and After Single Inhaled and Intravenous Doses (Part B) in Healthy Subjects	Primary Endpoint • Safety and tolerability Secondary Endpoint • PK parameters	<ul style="list-style-type: none">• FPCD: Q1 2016• LPCD: Q3 2016• Data readout: Q2 2017

Oncology

CVMD

Respiratory

Other



AZD7594 (inhaled SGRM)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Asthma/Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT02479412	Patients with mild to moderate asthma	48	A randomised, double blind, multiple dosing (14 days), placebo-controlled, incomplete block cross-over, multi-centre trial to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma	<ul style="list-style-type: none"> Primary: morning trough forced expiratory volume in one second (FEV1) 	<ul style="list-style-type: none"> FPCD: Q3 2015 LPCD: Q4 2015 Data readout: Q3 2016
Phase I NCT02967159	Healthy subjects	32	A randomized open label cross-over study to evaluate pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination (FDC) and in free combination using DPI, in male healthy volunteers	<ul style="list-style-type: none"> PK, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2016 LPCD: Q1 2017 Data readout: Q2 2017
Phase I NCT02928354	Healthy subjects	12	This study is an open label, randomized, three-way cross-over study to assess the effect of particle size on the PK and safety of single inhaled doses of AZD7594 in healthy subjects (males aged 18 to 55 years [inclusive]). The study will be performed at a single study centre	<ul style="list-style-type: none"> PK and safety 	<ul style="list-style-type: none"> FPCD: Q4 2016 LPCD: Q1 2017 Data readout: Q2 2017
Phase I NCT01636024	Healthy subjects	73	SAD/MAD A Phase I, single centre, double-blind, randomised, placebo controlled, parallel-group trial to assess the safety, tolerability, Pharmacokinetics and Pharmacodynamics after single and multiple ascending inhaled doses of AZD7594 in healthy male Subjects – suspension inhaled via Spira nebuliser Trial conducted in the UK	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q4 2012 LPCD: Q2 2013 Data readout: Q4 2013
Phase I NCT02648438	Healthy subjects	30	An open label, partially randomised, four-period trial in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered intravenously, orally and inhaled via two different dry powder inhalers (DPI) and a pressurised metered-dose inhaler (pMDI)	<ul style="list-style-type: none"> Bioavailability and pharmacokinetics 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q2 2016 Data readout: Q3 2016
Phase I NCT02645253	Healthy subjects	27	A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of AZD7594 given once daily as inhaled formulation in healthy Japanese men	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: Q2 2016 Data readout: Q4 2016

Oncology

CVMD

Respiratory

Other

AZD7594 (inhaled SGRM)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Asthma/Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02928354	Healthy subjects	18	A Randomized Open Label Three-Way Cross-Over Study in Healthy Male Volunteers to Investigate the Effect of Particle Size on Pharmacokinetics Following a Single Inhaled Dose of AZD7594 Via a Dry Powder Inhaler	<ul style="list-style-type: none">PharmacokineticsSafety and tolerability	<ul style="list-style-type: none">FPCD: Q4 2016LPCD: Q1 2017
Phase I NCT02967159	Healthy subjects	32	A randomized open label cross-over study to evaluate the pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination and in free combination, using Dry Powder Inhaler, in male healthy volunteers	<ul style="list-style-type: none">PharmacokineticsSafety and tolerability	<ul style="list-style-type: none">FPCD: Q4 2016LPCD: Q1 2017

Oncology

CVMD

Respiratory

Other



AZD7986 (DPP1 inhibitor)

Chronic Obstructive Pulmonary Disease (COPD)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02303574	Healthy subjects	152	Part 1 (SAD) <ul style="list-style-type: none"> Five different dose levels investigated vs placebo oral administration 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q4 2014
			Part 2 (MAD) <ul style="list-style-type: none"> Three different dose levels investigated vs placebo in healthy subjects oral administration Trial conducted in the UK	<ul style="list-style-type: none"> Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses NE activity 	<ul style="list-style-type: none"> FPCD: Q1 2016
Phase I NCT02653872	Healthy subjects	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	<ul style="list-style-type: none"> Effect of verapamil and the effect of itraconazole/diltiazem on the pharmacokinetics (PK) of AZD7986 Safety and tolerability of AZD7986 	<ul style="list-style-type: none"> FPCD: Q1 2016



AZD8871 (MABA2)

Chronic Obstructive Pulmonary Disease (COPD)

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02573155	Part 1: Mild Asthmatic Part 2: Moderate to severe COPD	N (Part 1) = 16 N (Part 2) = 38	Part 1 SAD study 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) <ul style="list-style-type: none"> • 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 Study – 1 country (UK)	Part 1 Endpoints: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • As above to COPD subjects 	Part 1 <ul style="list-style-type: none"> • FPCD: Q4 2015 • LPCD: Q4 2015 Part 2 <ul style="list-style-type: none"> • FPCD: Q2 2016 • LPCD: Q3 2016 • Data readout: Q4 2016
Phase I NCT02814656	Healthy subjects	24	MAD study with 3 dose levels; 300 µg, 600µg, and 900 µg (TBC) and placebo Global Study – 1 country (UK)	Primary Endpoint: <ul style="list-style-type: none"> • The primary objective is to investigate the safety and tolerability of AZD8871 at steady state Secondary Endpoint: <ul style="list-style-type: none"> • To characterize the PK of AZD8871 and its metabolites LAS191861 and LAS34850 after multiple doses of AZD8871 and assess the time required to reach steady state, the degree of accumulation and the time dependency 	<ul style="list-style-type: none"> • FPCD: Q3 2016 • LPCD: Q4 2016 • Data readout: Q1 2017
Phase IIa NCT02971293	Moderate to severe COPD	42	Comprises 3 treatment periods of 14 days each separated by a washout period of 28 to 35 days <ul style="list-style-type: none"> • AZD8871 600 µg once daily (double-blind) • AZD8871 100 µg once daily (double-blind) • Placebo (double-blind) Global study – 2 countries (UK & Germany)	Primary Endpoint: <ul style="list-style-type: none"> • To evaluate the efficacy of inhaled AZD8871 in patients with moderate to severe COPD Secondary Endpoint: <ul style="list-style-type: none"> • To investigate the PK of AZD8871 and its metabolites after multiple dose administration of AZD8871 in patients with moderate to severe COPD 	<ul style="list-style-type: none"> • FPCD: Q1 2017



AZD9567 (oSGRM)

Respiratory

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02512575	Healthy subjects	72	SAD trial with 8 dose levels – single ascending doses (starting at 2 mg up to 155 mg)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q2 2016 Data readout: Q1 2017
Phase I NCT02760316	Healthy subjects	64	MAD trial with 4 dose levels: 10 mg, 20mg, 40mg, 80mg and prednisolone 20 mg	<p>Primary Endpoint:</p> <ul style="list-style-type: none"> 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) <p>Secondary Endpoints:</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q2 2016



AZD0284 (ROR γ)

Plaque Psoriasis Vulgaris

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02976831	Healthy subjects	80	Part 1 (SAD) <ul style="list-style-type: none"> Seven different dose levels investigated vs placebo oral administration 	<ul style="list-style-type: none"> Safety and tolerability and PK following oral administration with single ascending dose Preliminary assessment of the effect of food on the single dose PK parameters of AZD0284 	<ul style="list-style-type: none"> FPCD: Q3 2016 LPCD: Q2 2017
			Part 2 (MAD) <ul style="list-style-type: none"> Three different dose levels investigated vs placebo in healthy subjects oral administration 	<ul style="list-style-type: none"> Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses Proof of Mechanism (PoM) confirmed by demonstrating that oral dosing of AZD0284 reduces IL-17 secretion by ex vivo stimulated whole blood T cells 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2017
Phase I NCT03029741	Healthy subjects	6	A Phase I, single centre, open-label, non-randomized, single dose study performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The study will assess the absolute bioavailability of a single oral dose of AZD0284 and the pharmacokinetics (PK) of a single intravenous (IV) microdose of [14C]AZD0284 in healthy male and female subjects. Oral AZD0284 and [14C]AZD0284 intravenous solution are referred to as the investigational products in this study	<ul style="list-style-type: none"> Determination of absolute bioavailability of AZD0284 Safety and tolerability of AZD0284 	<ul style="list-style-type: none"> FPCD: Q1 2017 LPCD: Q1 2017

Oncology

CVMD

Respiratory

Other



AZD3241 (MPO)

Parkinson's disease

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

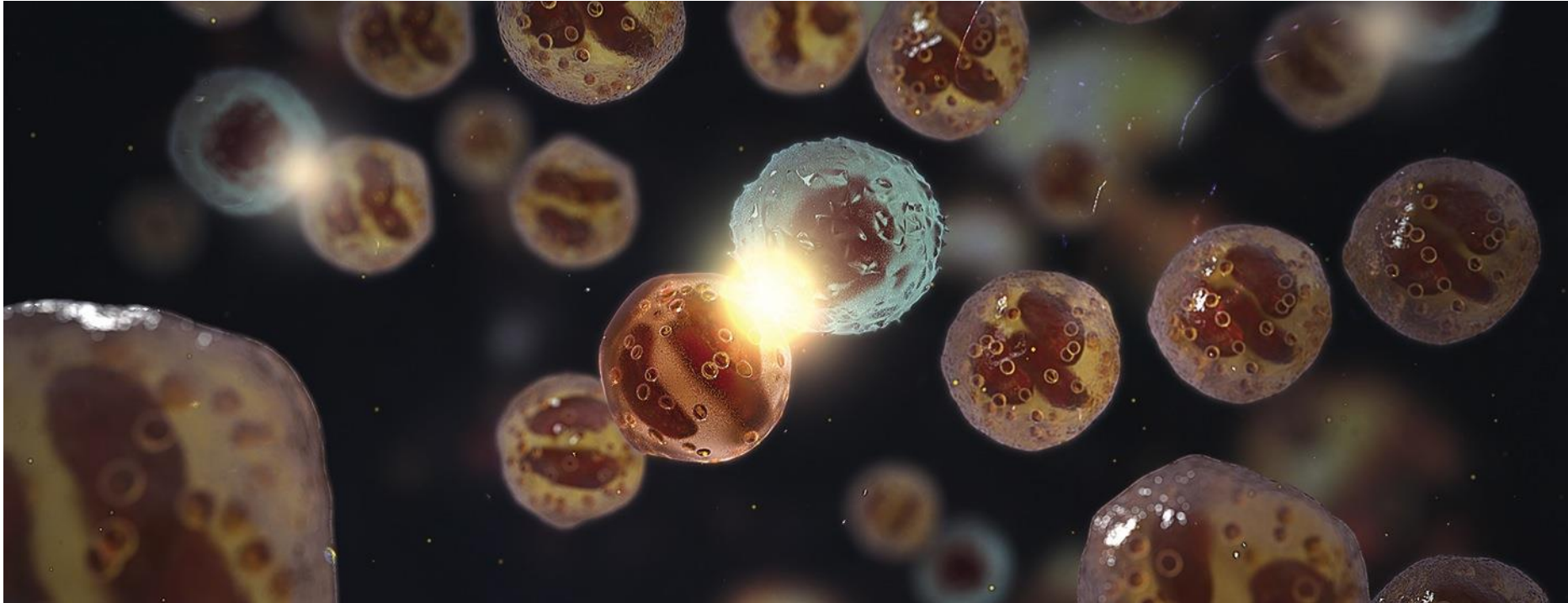
Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase II NCT01527695	Parkinson's disease patients	24	<ul style="list-style-type: none"> Arm 1: AZD3241 600mg BID for 8 weeks Arm 2: Placebo <p>Randomisation 3:1 active to placebo Three sites in Sweden and Finland</p>	<ul style="list-style-type: none"> Microglia activation represented by [11C]PBR28 binding <p>Secondary endpoints:</p> <ul style="list-style-type: none"> PD symptoms measured by UPDRS Plasma MPO activity 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2015
Phase II NCT01603069	Parkinson's disease patients	51	<ul style="list-style-type: none"> Arm 1: AZD3241 300mg BID for 12 weeks Arm 2: AZD3241 600mg BID for 12 weeks Arm 3: Placebo <p>Randomisation 1:1:1 across arms 13 sites in US</p>	<ul style="list-style-type: none"> AEs, labs, vital signs, ECGs <p>Secondary endpoints:</p> <ul style="list-style-type: none"> PD symptoms measured by UPDRS Plasma MPO activity 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2015
Phase I NCT00729443	Healthy subjects	46	<ul style="list-style-type: none"> Active ArmS: SAD Comparator Arm: placebo <p>One site in Sweden</p>	<ul style="list-style-type: none"> AEs, labs, vital signs, ECGs PK 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2015
Phase I NCT01457807	Healthy subjects	18	<ul style="list-style-type: none"> Active ArmS: MAD Comparator Arm: placebo <p>One site in UK</p>	<ul style="list-style-type: none"> AEs, labs, vital signs, ECGs PK 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2015
Phase I NCT00914303	Healthy subjects	59	<ul style="list-style-type: none"> Active ArmS: MAD Comparator Arm: placebo <p>One site in Sweden</p>	<ul style="list-style-type: none"> AEs, labs, vital signs, ECGs PK 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q2 2015



Early development - MedImmune



Imfinzi (durvalumab, PD-L1 mAb)

Immuno-oncology

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

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase I/II STUDY 1108 NCT01693562	<i>Imfinzi</i>	Solid tumours	1,014	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Safety Optimal biologic dose Secondary endpoints include PK, immunogenicity and anti-tumour activity 	<ul style="list-style-type: none"> FPCD: Q3 2012 LPD: Q4 2015 Data anticipated: H2 2017
Phase I NCT02117219	<i>Imfinzi</i> , azacitidine (Vidaza)	Myelodysplastic syndrome	41	Dose-escalation and dose-expansion trial <ul style="list-style-type: none"> Arm 1: <i>Imfinzi</i> Global trial – four countries	<ul style="list-style-type: none"> Safety and tolerability of monotherapy and combination Secondary endpoints include duration of response, PFS and OS 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPD: Q2 2015 Data anticipated: 2019
Phase 1 NCT02900157	<i>Imfinzi</i>	Solid tumours	30	Multi-centre, open-label, single-arm trial for adult subjects	<ul style="list-style-type: none"> Safety, PK, number of subjects reporting infusion related reaction 	<ul style="list-style-type: none"> FPCD: Q3 2016 Data anticipated: 2018



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

Solid and hematologic tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase Ib/II STUDY 21 NCT02340975	Gastric or GEJ adenocarcinoma	236	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab 2L Arm B: <i>Imfinzi</i> 2L Arm C: tremelimumab 2L Arm D: <i>Imfinzi</i> + tremelimumab 3L <p>US and ROW trial centres</p>	<ul style="list-style-type: none"> Primary endpoints: Safety & tolerability, ORR, PFS Secondary endpoints: DCR, OS, DoR, PD-L1 Expression 	<ul style="list-style-type: none"> FPCD: Q2 2015 Data anticipated: 2018
Phase Ib/II STUDY 22 NCT02519348	Hepatocellular Carcinoma	144	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> + tremelimumab Arm B: <i>Imfinzi</i> 2L Arm C: tremelimumab 2L 	<ul style="list-style-type: none"> Primary endpoints: Safety & tolerability, ORR, PFS Secondary endpoints: DCR, OS, DoR, PD-L1 Expression 	<ul style="list-style-type: none"> FPCD: Q4 2015 Data anticipated: 2018
Phase Ib STUDY 006 NCT02000947	NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	446	<ul style="list-style-type: none"> Dose Escalation: minimum 5 cohorts exploring various treme Q4W and <i>Imfinzi</i> 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 <p>North American trial centres, exploration of ex-US countries for expansion into EU and ROW</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Optimal biologic dose for the combination <p>Secondary endpoints include Antitumour activity, PK and immunogenicity</p>	<ul style="list-style-type: none"> FPCD: Q4 2013 LPCD: H1 2017 Data anticipated: 2018
Phase I STUDY 10 NCT02261220	Solid tumours (Basket trial)	380	<ul style="list-style-type: none"> Dose Exploration: 2 cohorts exploring various Q4W treme and <i>Imfinzi</i> dose combinations and 2 cohorts exploring various Q2W treme and <i>Imfinzi</i> dose combinations Dose Expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 7 tumour types <p>North American trial centres</p>	<p>Primary endpoints:</p> <ul style="list-style-type: none"> Safety Optimal biologic dose for the combination <p>Secondary endpoints include anti-tumour activity, PK/PD and immunogenicity</p>	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: H1 2017 Data anticipated: 2018
Phase I STUDY 11 NCT02262741	HNSCC	69	<ul style="list-style-type: none"> Arm A: treatment-naïve, PD-L1+, combo Arm B: treatment-naïve, PD-L1-, combo Arm C: PD-1/PD-L1 refractory, combo <p>North American trial centres</p>	<ul style="list-style-type: none"> Primary endpoint: Safety & tolerability Secondary endpoints: OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers 	<ul style="list-style-type: none"> FPCD: Q4 2014 LPCD: Q3 2016 Data anticipated: H2 2017
Phase Ib STUDY 23 NCT02549651	Diffuse Large B cell Lymphoma	186	<ul style="list-style-type: none"> Arm A: <i>Imfinzi</i> Arm B: <i>Imfinzi</i> + tremelimumab Arm C: tremelimumab + AZD9150 <p>US and European trial centres</p>	<ul style="list-style-type: none"> Primary endpoint: Safety & tolerability Secondary endpoints: OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers 	<ul style="list-style-type: none"> FPCD: Q3 2016 Data anticipated: 2021

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

Non-small cell lung cancer (NSCLC)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02088112	NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)	56	Escalation phase Standard 3+3 design with 28 days DLT period • <i>Iressa</i> (QD) + <i>Imfinzi</i> IV Expansion phase • <i>Iressa</i> (QD) + <i>Imfinzi</i> IV recommended dose Global trial – three countries	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints: tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression- free survival, immunogenicity, pharmacokinetics, pharmacodynamics	<ul style="list-style-type: none"> • FPCD: Q2 2014 • LPCD: Q2 2015 • Data anticipated: 2019



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

Advanced cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02118337	Advanced malignancies (escalation phase) RCC (expansion phase)	150	Dose-escalation phase <ul style="list-style-type: none"> Imfinzi IV + MEDI0680 IV Dose-expansion phase at selected dose from dose-escalation phase <ul style="list-style-type: none"> Imfinzi IV + MEDI0680 IV recommended dose 	Primary endpoints: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPCD: Q2 2014 Data anticipated: 2019
Phase I NCT02013804	Advanced malignancies (escalation phase)	58	Dose-escalation phase <ul style="list-style-type: none"> MEDI0680 IV 	<ul style="list-style-type: none"> Primary endpoint: Safety & Tolerability Secondary endpoints include tumour response such as objective response rate, immunogenicity, pharmacokinetics, pharmacodynamics	<ul style="list-style-type: none"> FPCD: Q4 2013 Data anticipated: H2 2017



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

Melanoma

Trial	Population	Patients	Design	Endpoints	Status
Phase I/II NCT02027961	Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&C)	69	Dose Escalation: <ul style="list-style-type: none"> Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ <i>Imfinzi</i> IV Cohort B trametinib 2mg QD/ <i>Imfinzi</i> IV Cohort C trametinib 2mg QD/ <i>Imfinzi</i> IV Dose Expansion: <ul style="list-style-type: none"> Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global trial – two countries	Primary endpoints: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPCD: Q1 2014 LPCD: Q2 2015 Data anticipated: 2018



Imfinzi (durvalumab, PD-L1 mAb) + Monalizumab (NKG2a mAb)

Advanced Solid Tumours

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02671435	Advanced solid tumours	175	Escalation phase • monalizumab + <i>Imfinzi</i> IV Expansion phase • monalizumab + <i>Imfinzi</i> IV recommended dose Global Trial	Primary endpoints: • Safety • Optimal biologic dose for the combination • Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2019



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

Advanced cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02318394	Advanced malignancies	106	Dose-escalation phase • MEDI0562 IV Dose-expansion phase • MEDI0562 IV recommended dose	Primary endpoints: • Safety • Determination of MTD • Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, biomarker activity, and immunogenicity	• FPCD: Q1 2015 • Data anticipated: 2020
Phase I NCT02705482	Advanced malignancies	161	• Arm A: MEDI0562 IV + <i>Imfinzi</i> IV • Arm B: MEDI0562 IV + tremelimumab IV	• Primary endpoint: Safety • Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, and immunogenicity and pharmacodynamics	• FPCD: Q2 2016 • Data anticipated: 2020



MEDI1873 (GITR agonist)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02583165	Adult subjects with select advanced solid tumours	42	Dose-escalation phase • MEDI1873 IV US trial centres	Primary endpoints: • Safety • Determination of MTD • Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	• FPCD: Q4 2015 • LPCD: Q4 2016 • Data anticipated: 2019



MEDI4276 (HER2 ADC mAb)

Advanced cancers

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02576548	Advanced HER2+ metastatic breast and gastric cancer	Dose escalation 21-36 Dose expansion 80	<ul style="list-style-type: none">First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	<ul style="list-style-type: none">Primary endpoint: safetySecondary endpoints: anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size	<ul style="list-style-type: none">FPCD: Q4 2015Data anticipated: 2019



MEDI5083 + *Imfinzi* (durvalumab, PD-L1 mAb)

Advanced Solid Tumours

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

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03089645	Advanced Solid Tumours	204	Dose-escalation phase <ul style="list-style-type: none"> Part 1: MEDI5083 Part 2: MEDI5083 + <i>Imfinzi</i> IV Dose expansion phase <ul style="list-style-type: none"> Part 3: MEDI5083 recommended dose + <i>Imfinzi</i> IV US and Australian trial centres	Primary endpoints: <ul style="list-style-type: none"> Safety Determination of MTD Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: 2022

Oncology

CVMD

Respiratory

Other



MEDI7247 (PBD ADC mAb)

Advanced cancers

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT03106428	Relapsed/Refractory Hematological Malignancies	228	First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects	<ul style="list-style-type: none">Primary endpoint: safetySecondary endpoints: Pharmacokinetics, immunogenicity and antitumor activity	<ul style="list-style-type: none">FPCD: Q2 2017Data anticipated: 2020



MEDI9197 (TLR7/8 agonist)

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02556463	Advanced solid tumour malignancies readily accessible for injection	78	Dose-escalation phase <ul style="list-style-type: none">• MEDI9197 IT• MEDI9197 IT + <i>Imfinzi</i>• MEDI9197 IT + <i>Imfinzi</i> + palliative radiation Global trial – three countries	Primary endpoints: <ul style="list-style-type: none">• Safety• Determination of MTD Secondary endpoints include: <ul style="list-style-type: none">– Objective response, disease control and duration of response– Intratumoural and systemic PK and PD profiles/relationships	<ul style="list-style-type: none">• FPCD: Q4 2015• Data anticipated: 2021



MEDI9447 (CD73 mAb) + *Imfinzi* (durvalumab, PD-L1 mAb)

Advanced cancers

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02503774	Advanced malignancies	188	Dose-escalation phase <ul style="list-style-type: none"> • MEDI9447 IV • MEDI9447 IV + <i>Imfinzi</i> IV Dose expansion phase <ul style="list-style-type: none"> • MEDI9447 IV recommended dose • MEDI9447 IV recommended dose + <i>Imfinzi</i> IV US and Australian trial centres	Primary endpoints: <ul style="list-style-type: none"> • Safety • Determination of MTD <ul style="list-style-type: none"> • Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity 	<ul style="list-style-type: none"> • FPCD: Q3 2015 • Data anticipated: 2020



Other biologics

Solid tumours

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Compound	Population	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	176	<ul style="list-style-type: none"> Arm 1: MEDI-573 IV and aromatase inhibitor Arm 2: aromatase inhibitor alone <p>Open label trial</p>	<ul style="list-style-type: none"> PFS Retrospective evaluation of predictive biomarker +ve subgroups 	<ul style="list-style-type: none"> FPCD: Q2 2012 LPCD: Q2 2013 Data anticipated: H2 2017
Phase I NCT01284231 Partnered	Anti-CEA BiTE mAb (MEDI-565)	<p>Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments</p> <p>Refractory pancreatic, colorectal and gastro-oesophageal cancers</p>	<p>51 max</p> <p>60 max, 20 in each cohort</p>	<ul style="list-style-type: none"> Dose-escalation (3+3), IV Dose expansion trial, IV 	<ul style="list-style-type: none"> MTD and safety profile 	<ul style="list-style-type: none"> FPCD: Q1 2011 LPCD Q3 2014 Data readout: Q1 2015
Phase I NCT01577745	Anti-DLL4 mAb (MEDI0639)	Adults with advanced solid tumours including SCLC	up to 28	<ul style="list-style-type: none"> Dose-escalation trial (3+3); IV 	<ul style="list-style-type: none"> MTD and safety profile 	<ul style="list-style-type: none"> FPCD: Q2 2012 LPCD: Q2 2015 Data readout: Q4 2015



Biologics

Cardiovascular & metabolic disease

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Oncology

CVMD

Respiratory

Other

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II NCT02601560	rhLCAT MEDI6012	Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL)	56	<ul style="list-style-type: none"> SAD in stable CAD patients 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q2 2016 Data readout: Q4 2016
Phase II NCT03004638		Adults with Stable Atherosclerotic Cardiovascular Disease (ACD)	24	<ul style="list-style-type: none"> MAD in stable ACD patients 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables Changes in baseline adjusted post dose HDL-C, HDL-CE, and CE AUC PK, immunogenicity, Apolipoprotein A,LDL, and Apolipoprotein B 	<ul style="list-style-type: none"> FPCD: Q1 2017 Data anticipated: H2 2017
Phase II NCT02394314	GLP-1-glucagon MEDI0382	Healthy male subjects	64	<ul style="list-style-type: none"> SAD SC administration Germany 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q4 2015 Data readout: Q4 2015
Phase II NCT02548585		Male Adults with type-2 diabetes	75	<ul style="list-style-type: none"> MAD SC administration Germany 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPCD: Q1 2016 LPCD: H2 2016 Data readout: Q2 2017
Phase I NCT03001297	MEDI5884 EL ACS	Healthy Volunteers	56	<ul style="list-style-type: none"> SAD SC administration 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables Changes in HDL-C over time 	<ul style="list-style-type: none"> FPCD Q1 2017 LPCD Q3 2017 Data anticipated: H2 2017



Tezepelumab (MEDI9929, TSLP mAb)

Asthma

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase II PATHWAY NCT02054130 Partnered	Adult subjects with inadequately controlled, severe asthma	552	<ul style="list-style-type: none">• Arm 1: Placebo• Arm 2: Low dose tezepelumumab 70mg SC• Arm 3: Medium dose tezepelumumab 210mg SC• Arm 4: High dose tezepelumumab 280mg SC	<ul style="list-style-type: none">• Reduction in the annualised asthma exacerbation rate (AER) measured at week 52	<ul style="list-style-type: none">• FPCD: Q2 2014• LPCD: Q4 2015• Data readout: Q1 2017
Phase II NCT02525094 Partnered	Adult subjects with moderate-to-severe atopic dermatitis	100	<ul style="list-style-type: none">• Arm 1: Placebo• Arm 2: Dose of tezepelumumab SC	<ul style="list-style-type: none">• 50% reduction from baseline in the eczema area and severity index measured at week 12	<ul style="list-style-type: none">• FPCD: Q2 2015• LPCD: Q2 2016• Data readout: Q4 2016

Oncology

CVMD

Respiratory

Other



MEDI3506 (IL-33 mAb)

COPD

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I (Combined SAD / MAD) NCT03096795	SAD: Healthy subjects with mild atopy MAD: COPD	SAD: 56 MAD: 24	SAD: <ul style="list-style-type: none">7 sequential placebo-controlled single dose cohorts (active N=6 / placebo N = 2 within each cohort)Dose levels: 1mg SC, 3 mg SC, 10 mg SC, 30 mg SC, 100 mg SC, 300 mg SC and 300 mg IV MAD: <ul style="list-style-type: none">3 sequential placebo-controlled multiple dosing cohorts (active N=6 / placebo N = 2 within each cohort)Dose levels: 30 mg SC, 100 mg SC and 300 mg SC	<ul style="list-style-type: none">Safety and tolerability	<ul style="list-style-type: none">FPCD: Q2 2017LPCD: Q3 2018Data anticipated: 2019

Oncology

CVMD

Respiratory

Other



MEDI7836 (IL-13 mAb)

Asthma

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02388347	Healthy subjects	32	<ul style="list-style-type: none">• Arm 1: 30mg MEDI7836 (6) or placebo (2) as a single SC dose• Arm 2: 105mg MEDI7836 (6) or placebo (2) as a single SC dose• Arm 3: 300mg MEDI7836 (6) or placebo (2) as a single SC dose• Arm 4: 600mg MEDI7836 (6) or placebo (2) as a single SC dose	<ul style="list-style-type: none">• Safety and tolerability	<ul style="list-style-type: none">• FPCD: Q1 2015• LPCD: Q3 2015• Data readout: Q1 2016

Oncology

CVMD

Respiratory

Other



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

Systemic Lupus Erythematosus (SLE)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase Ia NCT02618967 Partnered	Healthy Subjects	40	Single Ascending Dose <ul style="list-style-type: none">• Arm 1: MEDI0700 administered as single SC dose• Arm 2: Dose levels of Placebo administered as single SC dose	<ul style="list-style-type: none">• Safety and tolerability• PK/PD	<ul style="list-style-type: none">• FPCD: Q1 2016• Data anticipated: H2 2017

Oncology

CVMD

Respiratory

Other



MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02036645	Alzheimer's disease & healthy elderly	121	<ul style="list-style-type: none">SAD & MADUp to 10 IV cohorts are planned vs placebo2 SC cohorts are planned vs placebo US only	<ul style="list-style-type: none">Safety, tolerability	<ul style="list-style-type: none">FPCD: Q2 2014LPCD: Q2 2016Data readout: Q4 2016

Oncology

CVMD

Respiratory

Other



MEDI5872 - AMG 557 (B7RP-1 mAb)

Systemic Lupus Erythematosus (SLE)

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase IIa NCT02334306 Partnered	Primary Sjögren's syndrome	42	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Safety and tolerability• Change in the ESSDAI score from baseline to Day 99	<ul style="list-style-type: none">• FPCD: Q3 2015• Data anticipated: H2 2017
Phase I NCT01683695 Partnered Completed	SLE and lupus related inflammatory arthritis	40	Dose escalation trial: <ul style="list-style-type: none">• Arm 1: MEDI5872 SC• Arm 2: placebo SC Global trial – eight countries	<ul style="list-style-type: none">• Safety and tolerability• Lupus Arthritis Response Rate	<ul style="list-style-type: none">• FPCD: Q2 2012• LPCD: Q4 2015• Data readout: Q2 2016

Oncology

CVMD

Respiratory

Other



MEDI7352 (NGF TNF Bispecific)

Osteoarthritis pain

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02508155	Painful osteoarthritis of the knee	160	<ul style="list-style-type: none">SAD & MADUp to 10 IV cohorts are planned vs placebo2 SC cohorts are planned vs placebo Europe only	<ul style="list-style-type: none">Safety, tolerability, PK, PD	<ul style="list-style-type: none">FPCD: Q1 2016Data anticipated: H1 2018

Oncology

CVMD

Respiratory

Other



MEDI9314 (IL-4Ra mAb)

Atopic Dermatitis

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Population	Patients	Design	Endpoints	Status
Phase I NCT02669667	Healthy subjects	44	<ul style="list-style-type: none">• Arm 1: 45mg MEDI9314 (4) or placebo (2) as a single SC dose• Arm 2: 150mg MEDI9314 (4) or placebo (2) as a single SC dose• Arm 3: 300mg MEDI9314 (6) or placebo (2) as a single SC dose• Arm 4: MEDI9314 (6) or placebo (2) as a single IV dose• Arm 5: 300300mg mg MEDI9314 (6) or placebo (2) as a single SC dose (Japanese subjects)• Arm 6: 450mg MEDI9314 (6) or placebo (2) as a single IV dose	<ul style="list-style-type: none">• Safety and tolerability• Pharmacokinetic and immunogenicity profile	<ul style="list-style-type: none">• FPCD: Q1 2016• LPCD: Q4 2016• Data readout: Q4 2016

Oncology

CVMD

Respiratory

Other



Other biologics

Autoimmunity

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

Oncology

CVMD

Respiratory

Other

Trial	Compound	Population	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)	212 (estimated)	<ul style="list-style-type: none"> Arm 1: inebilizumab 500mg IV Arm 2: placebo IV Open-label extension 300mg <p>Global trial – 26 Countries</p>	<ul style="list-style-type: none"> Primary: Time to attack Secondary: Attack rate, safety and tolerability 	<ul style="list-style-type: none"> FPCD: Q1 2015 Data anticipated: 2019
Phase I NCT02151110	Anti-CD40L (MEDI4920)	Healthy adults	56	<ul style="list-style-type: none"> Arm 1: 3mg MEDI4920 (2) or placebo (1) as a single IV dose Arm 2: 10mg MEDI4920 (2) or placebo (1) as a single IV dose Arm 3: 3mg MEDI4920 (3) or placebo (2) as a single IV dose Arm 4: 100mg MEDI4920 (8) or placebo (2) as a single IV dose Arm 5: 300mg MEDI4920 (8) or placebo (2) as a single IV dose Arm 6: 1000mg MEDI4920 (8) or placebo (2) as a single IV dose Arm 7: 2000mg MEDI4920 (8) or placebo (2) as a single IV dose 	<ul style="list-style-type: none"> Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q4 2015 Data readout: Q2 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	36	<ul style="list-style-type: none"> Arm 1: 1mg MEDI7734 (3) or placebo (1) as a single SC dose Arm 2: 5mg MEDI7734 (6) or placebo (2) as a single SC dose Arm 3: 15mg MEDI7734 (6) or placebo (2) as a single SC dose Arm 4: 50mg MEDI7734 (6) or placebo (2) as a single SC dose Arm 5: 150mg MEDI7734 (6) or placebo (2) as a single SC dose 	<ul style="list-style-type: none"> Safety, tolerability Pharmacokinetics and pharmacodynamics 	<ul style="list-style-type: none"> FPCD Q3 2016 Data anticipated: H2 2017



Other biologics

Infections

Approved medicines

Late-stage development

Early development - IMED

Early development - MedImmune

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase II EudraCT 2014-001097-34	Anti-Staph AT (MEDI4893)	Intubated ICU	462	<ul style="list-style-type: none"> Placebo-controlled, single-dose, dose-ranging Route of administration: intravenous 	<ul style="list-style-type: none"> Efficacy and safety 	<ul style="list-style-type: none"> FPCD: Q4 2014 Data anticipated: 2018
Phase IIb NCT02878330	Anti-Respiratory Syncytial Virus mAb-YTE (MEDI8897)	32-35 WK GA infants	1,500	<ul style="list-style-type: none"> Randomised, double-blind, placebo-controlled trial Route of administration: IM 	<ul style="list-style-type: none"> Safety and efficacy 	<ul style="list-style-type: none"> FPCD: Q4 2016 Data anticipated: 2018
Phase Ib/Ia NCT02290340		32-35 WK GA infants	89	<ul style="list-style-type: none"> Randomised, double-blind, placebo-controlled, Dose-escalation trial Route of administration: IM 	<ul style="list-style-type: none"> Evaluate Safety, tolerability, PK and ADA 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q3 2015 Data readout: Q3 2016
Phase Ia NCT02114268 Completed		Healthy adults	136	<ul style="list-style-type: none"> Randomised, double-blind, placebo-controlled, Dose-escalation trial Route of administration: IV and IM 	<ul style="list-style-type: none"> Evaluate Safety, tolerability, PK and ADA 	<ul style="list-style-type: none"> FPCD: Q2 2014 LPCD: Q2 2014 Data readout: Q2 2015

Oncology

CVMD

Respiratory

Other



Other biologics

Infections

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

Trial	Compound	Population	Patients	Design	Endpoints	Status
Phase Ib/Ila NCT02603952	Anti-influenza A mAb (MEDI8852)	Adults	160	<ul style="list-style-type: none"> Randomised, partial double-blind, single dose, active-controlled, dose ranging trial Route of administration: intravenous 	<ul style="list-style-type: none"> Evaluate safety in adults with acute, uncomplicated Influenza 	<ul style="list-style-type: none"> FPCD: Q4 2015 LPCD: Q4 2016 Data readout: Q4 2016
Phase I NCT02350751 Completed		Healthy adults	40	<ul style="list-style-type: none"> Double-blind, single-dose, placebo-controlled, dose-escalation trial Route of administration: intravenous 	<ul style="list-style-type: none"> Evaluate the safety and pharmacokinetics 	<ul style="list-style-type: none"> FPCD: Q1 2015 LPCD: Q1 2015 Data readout: Q2 2015
Phase I NCT02255760 Completed	Anti-Pseudomonas A mAb (MEDI3902)	Healthy adults	56	<ul style="list-style-type: none"> Randomised, double-blind, placebo-controlled, dose-escalation trial Route of administration: intravenous 	<ul style="list-style-type: none"> Evaluate the safety, tolerability, and pharmacokinetics 	<ul style="list-style-type: none"> FPCD: Q3 2014 LPCD: Q1 2015 Data readout: Q2 2015
Phase II NCT02696902		Intubated ICU	429	<ul style="list-style-type: none"> Placebo-controlled, single-dose, dose-ranging Route of administration: intravenous 	<ul style="list-style-type: none"> Efficacy and safety 	<ul style="list-style-type: none"> FPCD: Q2 2016 Data anticipated: 2021



Clinical trials appendix

Q2 2017 Results update

