

# What science can do

AstraZeneca Development Pipeline as at 8 February 2024



## AstraZeneca-sponsored or -directed trial

### New Molecular Entities (NMEs) and significant indications

First major market regulatory submission date and submission status is provided for assets in Phase III or beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

#### Phase I

Compound	Mechanism	Additional Information	Area Under Investigation
<b>Oncology</b>			
AZD0305	GPRC5D ADC		relapsed/refractory multiple myeloma
AZD0486	CD19-CD3 TCE		R/R B-cell non-Hodgkin lymphoma
AZD0486	CD19-CD3 TCE		B-cell acute lymphoblastic leukaemia
AZD1390	ATM inhibitor		glioblastoma
AZD3470	PRMT5 inhibitor		classic Hodgkin lymphoma, solid tumours
AZD5335	anti-folate receptor alpha topoisomerase 1 inhibitor ADC		ovarian cancer, lung adenocarcinoma
AZD5851	GPC3 CAR-T		hepatocellular carcinoma
AZD5863	CLDN18.2 x CD3 bi-specific antibody (HBM7022)		solid tumours
AZD6422	CLDN18.2 CAR-T		solid tumours
AZD8421	CDK2 inhibitor		solid tumours
AZD9592	EGFR/cMET		solid tumours
AZD9829	CD123 TOP1i ADC		acute myeloid leukemia, myelodysplastic syndromes
NT-125	autologous, fully-individualised, multi-specific TCR-T targeting neoantigens		solid tumours
NT-175	TGFBR2 KO armoured TCR-T targeting TP53 R175H/HLA-A*02:01		solid tumours
volrustomig + lenvatinib	PD-1/CTLA-4 bispecific mAb + VEGF		advanced renal cell carcinoma
<b>CVRM</b>			
AZD2373	podocyte health		nephropathy
AZD2389	anti-fibrotic mechanism		metabolic dysfunction-associated steatohepatitis
AZD4144	inflammation modulator		cardiorenal disease
AZD5462	RXFP1 agonist	PP	heart failure
AZD6234	peptide		obesity with related comorbidities
AZD7503	ASO		non-alcoholic steatohepatitis
AZD9550	GLP-1R glucagon dual agonist		non-alcoholic steatohepatitis
<b>Respiratory &amp; Immunology</b>			
AZD1163	bispecific antibody		rheumatoid arthritis
AZD5055	porcupine inhibitor		idiopathic pulmonary fibrosis
AZD6793	IRAK4 inhibitor		inflammatory diseases
AZD6912	siRNA		rheumatoid arthritis
AZD7798	humanised monoclonal antibody targets T cells subset		Crohn's disease
AZD8630	inhaled TSLP FAb	PP	asthma
<b>Vaccine and Immune Therapies</b>			
COVID mRNA VLP vaccine	Vaccine		COVID-19
<b>Other Medicines</b>			
AZD4041	orexin 1 receptor antagonist	PP	opioid use disorder
MEDI0618	PAR2 antagonist mAb	Phase I/IIa	migraine
MEDI1814	amyloid beta mAb	PP	Alzheimer's disease
<b>Rare Disease</b>			
ALXN1910	next generation TNSALP ERT		bone metabolism
ALXN1920	kidney-targeted factor H fusion protein		nephrology
ALXN2030	siRNA targeting complement C3		nephrology
ALXN2080	oral factor D inhibitor		healthy volunteers

#### Phase II

Compound	Mechanism	Additional Information	Area Under Investigation
<b>Oncology</b>			
AZD0171 + <i>Imfinzi</i> + CTx	anti-LIF mAb + PD-L1 mAb + CTx		1st-line metastatic pancreatic ductal adenocarcinoma
AZD0901	CLDN18.2 MAAE ADC		solid tumours
AZD8205	B7-H4 targeting ADC		solid tumours
AZD9574	PARP inhibitor		advanced solid malignancies
camizestrant	selective estrogen receptor degrader		estrogen receptor +ve breast cancer
cerlasertib	ATR inhibitor		solid tumours
IPH5201 + <i>Imfinzi</i>	CD39 + PD-L1	PP	neoadjuvant/adjuvant NSCLC
rilvegostomig ARTEMIDE-01	PD-1/TIGIT bispecific mAb	PP	solid tumours

# Development Pipeline

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### Phase II continued

Compound	Mechanism	Additional Information	Area Under Investigation
sabestomig	PD-1/TIM3 bispecific mAb	solid tumours (Phase II), haematological malignancies (Phase I)	solid tumours, haematological malignancies
saruparib	PARP1SeI		solid tumours
volrustomig	PD-1/CTLA-4 bispecific mAb		solid tumours
<b>CVRM</b>			
AZD0780	PCSK9		dyslipidaemia
AZD2693	NASH resolution		non-alcoholic steatohepatitis
AZD3427	relaxin mimetic		heart failure
balcinenone/dapagliflozin	MR modulator + SGLT2 inhibitor		heart failure with CKD
MEDI6570	LOX-1 mAb		cardiovascular disease
mitiperstat	myeloperoxidase		heart failure with a preserved ejection fraction/NASH
zibotentan/dapagliflozin	endothelin A receptor antagonist/ SGLT2 inhibitor		liver cirrhosis
<b>Respiratory &amp; Immunology</b>			
atuliflapon	FLAP inhibitor		asthma
AZD4604	inhaled JAK1 inhibitor		asthma
mitiperstat	myeloperoxidase		COPD
tozorakimab FRONTIER 3	IL-33 mAb		asthma
<b>Other Medicines</b>			
MEDI1341	alpha synuclein mAb	PP	multiple system atrophy/Parkinson's disease
MEDI7352	NGF/TNF bispecific mAb		osteoarthritis pain and painful diabetic neuropathy
<b>Rare Disease</b>			
vemircopan	oral factor D inhibitor		generalised myasthenia gravis
vemircopan	oral factor D inhibitor		proliferative lupus nephritis or immunoglobulin A nephropathy
Voydeya (danicopan)	oral factor D inhibitor		geographic atrophy

### Phase III/Pivotal Phase II/Registration (listed until launched in all applicable major markets)

Compound	Mechanism	Area Under Investigation	Additional Information	Estimated submission/ submission status
<b>Oncology</b>				
camizestrant + CDK4/6i SERENA-6	selective estrogen receptor degrader + CDK4/6 inhibitors	1st-line HR+ HER2- ESR1m breast cancer		2025
camizestrant + palbociclib SERENA-4	selective estrogen receptor degrader + CDK4/6 inhibitor	1st-line HR+ HER2- breast cancer		2025
camizestrant CAMBRIA-1	selective estrogen receptor degrader	HR+ HER2- extended adjuvant breast cancer		>2025
camizestrant CAMBRIA-2	selective estrogen receptor degrader	ER+/HER2- early breast cancer		>2025
ceralasertib + Imfinzi LATIFY	ATR inhibitor + PDL-1 mAb	NSCLC		>2025
datopotamab deruxtecan AVANZAR	TROP2 ADC	1L NSCLC, squamous and non-squamous 1L NSCLC, TROP2 BM+	PP	2025
datopotamab deruxtecan TROPION-Breast01	TROP2 ADC	2-3L HR+ HER2- breast cancer	PP	H1 2024
datopotamab deruxtecan TROPION-Breast02	TROP2 ADC	1st-line triple negative breast cancer	PP	2025
datopotamab deruxtecan TROPION-Breast03	TROP2 ADC	adjuvant residual disease triple negative breast cancer	PP	>2025
datopotamab deruxtecan TROPION-Breast04	TROP2 ADC	neoadjuvant/adjuvant triple negative or HR-low/HER2-negative breast cancer	PP	>2025
datopotamab deruxtecan TROPION-Breast05	TROP2 ADC	1L PD-L1+ triple negative breast cancer	PP	>2025
datopotamab deruxtecan TROPION-Lung01	TROP2 ADC	2L+ NSCLC with or without actionable genomic alterations	PP	H1 2024
datopotamab deruxtecan TROPION-Lung07	TROP 2 ADC	1L NSCLC PD-L1 <50% non-squamous	PP	>2025
datopotamab deruxtecan TROPION-Lung08	TROP2 ADC	1L metastatic NSCLC without actionable genomic alterations and PD-L1 TPS ≥50%	PP	2025
Imfinzi + Imjudo HIMALAYA	PD-L1 mAb + CTLA-4 mAb	1st-line hepatocellular carcinoma	PP	Launched

# Development Pipeline

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### Phase III/Pivotal Phase II/Registration (listed until launched in all applicable major markets) continued

Compound	Mechanism	Area Under Investigation	Additional Information	Estimated submission/ submission status
<i>Imfinzi</i> +/- oleclumab +/- monalizumab PACIFIC-9	PD-L1 + NKG2A or PD-L1 + CD73	unresectable Stage III NSCLC	PP	>2025
rilvegostomig ARTEMIDE-Biliary01	PD-1/TIGIT bispecific mAb	adjuvant biliary tract cancer	PP	>2025
saruparib EvoPAR-Prostate01	PARP1Sel	metastatic castration-sensitive prostate cancer		>2025
<i>Truqap</i> (capiwasertib) + <i>Faslodex</i> CAPItello-291	AKT inhibitor + fulvestrant	2nd-line and beyond in AI resistant locally advanced (inoperable) or metastatic breast cancer	PP	Launched
volrustomig eVOLVE-Cervical	PD-1/CTLA-4 bispecific mAb	locally advanced cervical cancer		>2025
volrustomig eVOLVE-HNSCC	PD-1/CTLA-4 bispecific mAb	unresected locally advanced head and neck squamous cell carcinoma		>2025
volrustomig eVOLVE-Lung02	PD-1/CTLA-4 bispecific mAb	1L metastatic NSCLC		>2025
volrustomig eVOLVE-Meso	PD-1/CTLA-4 bispecific mAb	1L unresectable malignant pleural mesothelioma		>2025
<b>CVRM</b>				
<i>Andexxa</i>	anti-factor Xa reversal	acute major bleed		Launched
baxdrostat	aldosterone synthase inhibitor	hypertension		>2025
roxadustat OLYMPUS ROCKIES	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in chronic kidney disease/end-stage renal disease	PP	Launched
<i>Wainua</i> (eplontersen)	ligand-conjugated antisense	patients with hereditary transthyretin-mediated amyloid polyneuropathy (ATTRv-PN)	PP	Launched
zibotentan/ dapagliflozin	endothelin A receptor antagonist/SGLT2 inhibitor	CKD with high proteinuria		>2025
<b>Respiratory &amp; Immunology</b>				
<i>Fasenra</i> CALIMA SIROCCO ZONDA MIRACLE	IL-5R mAb	severe uncontrolled asthma	PP	Launched
<i>Saphnelo</i> TULIP 1 & TULIP 2 AZALEA (China)	type I IFN receptor mAb	systemic lupus erythematosus	PP	Launched
<i>Tezspire</i> NAVIGATOR DIRECTION (China)	TSLP mAb	severe uncontrolled asthma	PP	Launched
tozorakimab OBERON TITANIA PROSPERO MIRANDA	IL-33 mAb	chronic obstructive pulmonary disease		>2025
tozorakimab TILIA	IL-33 mAb	severe viral lower respiratory tract disease		2025
<b>Vaccine and Immune Therapies</b>				
<i>Beyfortus</i>	RSV mAb-YTE	passive RSV immunisation	PP	Launched
sipavibart (AZD3152) SUPERNOVA	SARS-CoV-2 LAAB	prevention of COVID-19		H1 2024
<b>Rare Disease</b>				
acoramidis	oral TTR stabiliser	transthyretin amyloid cardiomyopathy	PP	H1 2024
ALXN2220	transthyretin depleter	transthyretin amyloid cardiomyopathy	PP	>2025
anselamimab	fibril-reactive mAb	amyloid light chain amyloidosis		2025
efzimofase alfa (ALXN1850)	next generation TNSALP ERT	hypophosphatasia		>2025
gefurulimab	humanised bispecific VHH antibody	generalised myasthenia gravis		>2025
<i>Voydeya</i> (danicopan) ALPHA	oral factor D inhibitor	paroxysmal nocturnal haemoglobinuria with clinically significant extravascular haemolysis		Approved

# Development Pipeline

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### Significant Life-cycle Management

First major market regulatory submission date and submission status is provided for assets in Phase III or beyond. Projects in Phase III unless otherwise noted.

Compound	Mechanism	Area Under Investigation	Additional Information	Estimated submission/ submission status
<b>Oncology</b>				
Calquence + R-CHOP ESCALADE	BTK inhibitor + R-CHOP	1st-line diffuse large B cell lymphoma		>2025
Calquence + venetoclax + obinutuzumab AMPLIFY	BTK inhibitor + BCL-2 inhibitor + anti-CD20 mAb	1st-line chronic lymphocytic leukaemia	PP	>2025
Calquence ECHO	BTK inhibitor	1st-line mantle cell lymphoma	PP	>2025
Calquence ELEVATE-TN ChangE (China)	BTK inhibitor	1st-line chronic lymphocytic leukaemia	PP	Launched
Enhertu (platform) DESTINY-Breast07	HER2 targeting antibody drug conjugate	HER2+ breast cancer	PP Phase II LCM	
Enhertu (platform) DESTINY-Breast08	HER2 targeting ADC	HER2-low breast cancer	PP Phase I LCM	
Enhertu DESTINY-Breast02	HER2 targeting ADC	HER2+, unresectable and/or metastatic breast cancer pretreated with prior standard of care HER2 therapies, including T-DM1	PP	Approved
Enhertu DESTINY-Breast05	HER2 targeting ADC	HER2+ post-neoadjuvant high-risk breast cancer	PP	>2025
Enhertu DESTINY-Breast06	HER2 targeting ADC	post-ET HER2-low/HR+ breast cancer 2L	PP	H2 2024
Enhertu DESTINY-Breast09	HER2 targeting ADC	1st-line HER2+ breast cancer	PP	2025
Enhertu DESTINY-Breast11	HER2 targeting ADC	neoadjuvant HER2+ breast cancer	PP	2025
Enhertu DESTINY-Gastric01	HER2 targeting ADC	HER2-over-expressing advanced gastric or gastroesophageal junction adenocarcinoma patients who have progressed on two prior treatment regimens	PP	Launched
Enhertu DESTINY-Gastric04	HER2 targeting ADC	2nd-line HER2+ gastric cancer	PP	>2025
Enhertu DESTINY-Lung04	HER2 targeting ADC	1st-line HER2m NSCLC	PP	>2025
Enhertu DESTINY-PanTumour01	HER2 targeting ADC	HER2 mutant tumours	PP Phase II LCM	
Enhertu DESTINY-PanTumour02	HER2 targeting ADC	HER2 expressing solid tumours	PP Phase II LCM	Accepted
Imfinzi (platform) BEGONIA	PD-L1 mAb with paclitaxel and multiple novel oncology therapies	1st-line metastatic triple negative breast cancer		Phase II LCM
Imfinzi (platform) HUDSON	PD-L1 mAb + multiple novel oncology therapies	post IO NSCLC		Phase II LCM
Imfinzi + CRT KUNLUN	PD-L1 mAb + CRT	locally advanced oesophageal squamous cell carcinoma	PP	>2025
Imfinzi + CRT PACIFIC-5 (China)	PD-L1 mAb + CRT	locally-advanced (Stage III) NSCLC	PP	2025
Imfinzi + CTx neoadjuvant AEGEAN	PD-L1 mAb + CTx	locally-advanced (Stage II-III) NSCLC		Accepted
Imfinzi + CTx NIAGARA	PD-L1 mAb + CTx	muscle invasive bladder cancer		2025
Imfinzi + domvanalimab (AB154) PACIFIC-8	PD-L1 mAb + TIGIT	unresectable Stage III NSCLC	PP	>2025
Imfinzi + EV +/- Imjudo VOLGA	PD-L1 + nectin-4 targeting ADC +/- CTLA-4	muscle invasive bladder cancer		2025
Imfinzi + FLOT MATTERHORN	PD-L1 mAb + CTx	neoadjuvant/adjvant gastric cancer	PP	2025
Imfinzi + Imjudo + SoC NILE	PL-L1 mAb + CTLA-4 mAb + SoC	1st-line urothelial cancer		H2 2024
Imfinzi + Imjudo + TACE +/- lenvatinib EMERALD-3	PD-L1 + CTLA-4 + VEGF +/- chemoembolisation	locoregional hepatocellular carcinoma		>2025
Imfinzi + VEGF + TACE EMERALD-1	PD-L1 mAb + VEGF + TACE	locoregional hepatocellular carcinoma	PP	H1 2024
Imfinzi + VEGF EMERALD-2	PD-L1 mAb + VEGF	adjuvant hepatocellular carcinoma	PP	2025
Imfinzi +/- Imjudo + CRT ADRIATIC	PD-L1 mAb +/- CTLA-4 mAb + CRT	1st-line limited-stage small-cell lung cancer	PP	H2 2024
Imfinzi +/- Imjudo + CTx POSEIDON	PD-L1 mAb +/- CTLA-4 mAb + CTx	1st-line NSCLC		Launched
Imfinzi (platform) NeoCOAST-2	PD-L1 mAb + multiple novel oncology therapies	NSCLC	PP Phase II LCM	
Imfinzi post-SBRT PACIFIC-4	PD-L1 mAb post-SBRT	Stage I/II NSCLC	PP	>2025



# Development Pipeline

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### Significant Life-cycle Management continued

Compound	Mechanism	Area Under Investigation	Additional Information	Estimated submission/ submission status
<i>Imfinzi</i> POTOMAC	PD-L1 mAb	non-muscle invasive bladder cancer		2025
<i>Lynparza</i> (basket) LYNK002	PARP inhibitor	HRRm cancer	PP Phase II LCM	
<i>Lynparza</i> + abiraterone PROpel	PARP inhibitor + NHA	prostate cancer	PP	Launched
<i>Lynparza</i> + <i>Imfinzi</i> + bevacizumab DUO-O	PARP inhibitor + PD-L1 mAb + VEGF inhibitor	1st-line ovarian cancer	PP	H1 2024
<i>Lynparza</i> + <i>Imfinzi</i> DUO-E	PARP inhibitor + PD-L1 mAb	1st-line endometrial cancer	PP	Submitted
<i>Lynparza</i> MONO-OLA1	PARP inhibitor	1st-line BRCAwt ovarian cancer	PP	2025
<i>Lynparza</i> OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	PP	Launched
<i>Orpathys</i> + <i>Imfinzi</i> SAMETA	MET inhibitor + PD-L1 mAb	1st-line papillary renal cell carcinoma	PP	2025
<i>Tagrisso</i> + CTx FLAURA2	EGFR inhibitor + CTx	1st-line advanced EGFRm NSCLC		Accepted
<i>Tagrisso</i> + <i>Orpathys</i> SAFFRON	EGFR inhibitor + MET inhibitor	advanced EGFRm NSCLC	PP	2025
<i>Tagrisso</i> + <i>Orpathys</i> SAVANNAH	EGFR inhibitor + MET inhibitor	advanced EGFRm NSCLC	PP Phase II LCM	
<i>Tagrisso</i> +/- CTx neoadjuvant NeoADAURA	EGFR inhibitor +/- CTx	Stage II/III resectable EGFRm NSCLC		H2 2024
<i>Tagrisso</i> ADAURA2	EGFR inhibitor	adjuvant EGFRm NSCLC Stage Ia2-Ia3 following complete tumour resection		>2025
<i>Tagrisso</i> LAURA	EGFR inhibitor	Stage III EGFRm non-small cell lung cancer		H1 2024
<i>Tagrisso</i> ORCHARD platform study	EGFR inhibitor + multiple novel oncology therapies	2nd-line EGFRm osimertinib-resistant NSCLC	PP Phase II LCM	
<i>Truqap</i> (capiwasertib)	AKT inhibitor	prostate cancer	Phase II LCM	
<i>Truqap</i> (capiwasertib) + abiraterone CAPtello-281	AKT inhibitor + abiraterone	PTEN deficient metastatic hormone sensitive prostate cancer		2025
<i>Truqap</i> (capiwasertib) + CTx CAPtello-290	AKT inhibitor + CTx	1st-line metastatic triple negative breast cancer		H2 2024
<i>Truqap</i> (capiwasertib) + docetaxel CAPtello-280	AKT inhibitor + docetaxel	mCRPC prostate cancer		>2025
<i>Truqap</i> (capiwasertib) + <i>Faslodex</i> + palbociclib CAPtello-292	AKT inhibitor + fulvestrant + CDK4/6 inhibitor	1st-line triplet in early relapse/ET resistant locally advanced (inoperable) or metastatic breast cancer	PhIb/III	>2025
<b>CVRM</b>				
<i>Andexxa</i>	anti-factor Xa reversal	urgent surgery		
<i>Farxiga/Forxiga</i> DAPA-MI	SGLT-2 inhibitor	prevention of heart failure and CV death following a myocardial infarction		n/a
roxadustat	hypoxia-inducible factor prolyl hydroxylase inhibitor	chemotherapy induced anaemia	PP	Accepted
<i>Wainua</i> (eplontersen)	ligand-conjugated antisense	patients with hereditary or wild-type transthyretin-mediated amyloid cardiomyopathy (ATTR CM)	PP	2025
<b>Respiratory &amp; Immunology</b>				
<i>Breztri/Trixeo</i> (PT010) KALOS LOGOS	LABA/LAMA/ICS	asthma		2025
<i>Breztri/Trixeo</i> ATHLOS	LABA/LAMA/ICS	COPD cardiopulmonary exercise test (CPET) trial		2025
<i>Fasenra</i> MANDARA	IL-5R mAb	eosinophilic granulomatosis with polyangiitis		Submitted
<i>Fasenra</i> NATRON	IL-5R mAb	hypereosinophilic syndrome		H2 2024
<i>Fasenra</i> ORCHID	IL-5R mAb	nasal polyps	PP	2025
<i>Fasenra</i> RESOLUTE	IL-5R mAb	chronic obstructive pulmonary disease	PP	>2025
<i>Saphnelo</i> DAISY	type I IFN receptor mAb	systemic sclerosis	PP	>2025
<i>Saphnelo</i> IRIS	type I IFN receptor mAb	lupus nephritis	PP	>2025
<i>Saphnelo</i> TULIP-SC	type I IFN receptor mAb	systemic lupus erythematosus (subcutaneous)	PP	2025
<i>Tezspire</i> COURSE	TSLP mAb	chronic obstructive pulmonary disease	PP Phase II LCM	
<i>Tezspire</i> CROSSING	TSLP mAb	eosinophilic esophagitis	PP	>2025

# Development Pipeline

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### Significant Life-cycle Management *continued*

Compound	Mechanism	Area Under Investigation	Additional Information	Estimated submission/ submission status
<i>Tezspire</i> WAYPOINT	TSLP mAb	nasal polyps	PP	2025
<b>Rare Disease</b>				
<i>Ultomiris</i>	anti-complement C5 mAb	proliferative lupus nephritis or immunoglobulin A nephropathy	Phase II LCM	
<i>Ultomiris</i>	anti-complement C5 mAb	haematopoietic stem cell transplant-associated thrombotic microangiopathy		2025
<i>Ultomiris</i>	anti-complement C5 mAb	generalised myasthenia gravis		Launched
<i>Ultomiris</i> ARTEMIS	anti-complement C5 mAb	cardiac surgery-associated acute kidney injury		>2025
<i>Ultomiris</i> CHAMPION- NMOSD	anti-complement C5 mAb	neuromyelitis optica spectrum disorder		Launched