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AstraZeneca

AstraZeneca Patent Expiries of Key Marketed Products as at 6 February 2025

Patent Expiries of Key Marketed Products

Key

Expiry dates in mulberry relate to new molecular entity patents. The remaining dates relate to other patents.

Patents covering our products are, or may be, challenged by third parties. Generic products may be launched 'at risk' and our patents may be revoked, circumvented or found not to be infringed. The expiry dates shown below include granted Supplementary Protection Certificate (SPC) and Patent Term Extension (PTE) and/or Paediatric Exclusivity periods (as appropriate). In Europe, the exact SPC situation may vary by country as different Patent Offices grant SPCs at different rates. The expiry dates of relevant regulatory data exclusivity periods are not represented in the table below. A number of our products are subject to generic competition in one or more markets. There may be agreements permitting generic or biosimilar entry prior to the expiry dates shown below.

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales $m			Aggregate Product Sales Ex-US $m		
						2024	2023	2022	**2024**	2023	2022
Oncology											
Calquence (acalabrutinib)	A selective inhibitor of Bruton's tyrosine kinase indicated for the treatment of chronic lymphocytic leukaemia (CLL) and mantle cell lymphoma (MCL) and in development for the treatment of multiple B-cell malignancies.	2026-2032, 2032-2036	2032, 2036	2032-2035, 2036[2]	2037, 2036	**2,190**	1,815	1,657	**939**	699	400
Datroway (datopotamab deruxtecan)	A TROP2-directed antibody drug conjugate (ADC) comprised of a humanised anti-TROP2 IgG1 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers, indicated for patients with previously treated metastatic HR-positive, HER2-negative breast cancer.	2034	2034	2034	[3]	**–**	–	–	**–**	–	–
Enhertu[4] (trastuzumab deruxtecan)	A HER2-directed ADC indicated for HER2-positive, HER2-low and HER2-ultralow advanced breast cancers, for HER2-mutant metastatic non-small cell lung cancer (NSCLC), and for HER2-positive advanced gastric cancer.	2033, 2035	2033-2035	2033-2035	[3]	**–**	–	–	**545**	261	79
Imfinzi (durvalumab)	A human monoclonal antibody (mAb) that blocks PD-1 and CD80 on T-cells indicated for unresectable, Stage III NSCLC, for extensive-stage small cell lung cancer (SCLC) in combination with chemotherapy, for advanced biliary tract cancer in combination with chemotherapy, for unresectable hepatocellular carcinoma (uHCC) in combination with *Imjudo*, for NSCLC in combination with *Imjudo* and chemotherapy, and for advanced bladder cancer.	2031	2030	2030	2033	**2,603**	2,171	1,539	**2,114**	1,848	1,232
Imjudo[5] (tremelimumab)	A cytotoxic T-lymphocyte-associated antigen 4 blocking antibody indicated for uHCC in combination with *Imfinzi* and for NSCLC in combination with *Imfinzi* and chemotherapy.	2031	2026	2026	2031	**180**	146	13	**101**	72	–

For more information, see Risk Overview from page 64 of AstraZeneca's Annual Report and Form 20-F Information 2024 and the Risk Supplement on our website, www.astrazeneca.com/annualreport2024.

Details of material challenges by third parties can be found in Note 30 to the Financial Statements from page 203 of AstraZeneca's Annual Report and Form 20-F Information 2024.

Patent Expiries of Key Marketed Products *continued*

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales $m			Aggregate Product Sales Ex-US $m		
						2024	2023	2022	**2024**	2023	2022
Lynparza[6] (olaparib)	An oral poly (ADP-ribose) polymerase (PARP) inhibitor indicated for platinum-sensitive relapsed and for BRCA-mutated (BRCAm) ovarian cancers, for homologous recombination repair deficient (HRD)-positive advanced ovarian cancer in combination with bevacizumab, for gBRCAm, HER2-negative early and metastatic breast cancers, for gBRCAm metastatic pancreatic cancer, for HRR gene-mutated and BRCAm metastatic castration-resistant prostate cancers (mCRPC), and for 1st-line mCRPC in combination with abiraterone.	2024, 2027, 2024-2041	2024, 2024-2029	2029, 2024-2029	2029, 2024-2034	**1,332**	1,254	1,226	**1,740**	1,557	1,412
Orpathys (savolitinib)	An oral, potent and highly selective MET-TKI indicated for NSCLC with MET gene alterations.	2030	2030	2030	2030	**–**	–	–	**44**	44	33
Tagrisso (osimertinib)	An EGFR-TKI indicated for early- and late-stage EGFRm NSCLC.	2032, 2035	2032, 2035	2032, 2035	2034, 2035	**2,763**	2,276	2,007	**3,817**	3,523	3,437
Truqap (capivasertib)	A first-in-class, potent, adenosine triphosphate (ATP)-competitive inhibitor approved in combination with *Faslodex* for HR-positive, HER2-negative advanced breast cancer with certain gene alterations.	2028-2030, 2025-2033	2028, 2033	2028, 2025-2033	2028	**408**	6	–	**22**	–	–
CVRM											
Andexxa/ *Ondexxya* (andexanet alfa)	A factor Xa inhibitor (apixaban and rivaroxaban) reversal agent.	2032, 2028-2037	2028, 2030-2035	2028, 2030-2037	2028, 2030-2037	**81**	75	77	**138**	107	73
Brilinta/*Brilique* (ticagrelor)	An oral P2Y12 platelet inhibitor for acute coronary syndromes (ACS) (ticagrelor 90mg) or continuation therapy in high-risk patients (ticagrelor 60mg) with a history of myocardial infarction (MI). An oral P2Y12 platelet inhibitor for the prevention of atherothrombotic events in adult patients with ACS or high-risk patients with history of MI, high-risk patients with coronary artery disease or stroke.	2025, 2030-2036	2037	2025, 2037	2024, 2025-2030	**751**	744	744	**582**	580	614
Farxiga/ *Forxiga* (dapagliflozin)	A sodium-glucose cotransporter 2 (SGLT-2 inhibitor) indicated for adult patients with type-2 diabetes (T2D) or in adults with or without T2D with heart failure with reduced ejection fraction or chronic kidney disease (CKD). Approved in the US to improve glycaemic control in paediatric patients with T2D aged 10 years and older.	2026, 2025-2040	2027-2041[7]	2028, 2027, 2028[2]	2024-2025, 2028-2040	**1,750**	1,451	1,071	**5,906**	4,512	3,310
Xigduo/Xigduo XR[8] (dapagliflozin/ metformin)	Combines dapagliflozin and metformin as either *Xigduo* – to improve glycaemic control in adults with T2D who are inadequately controlled on metformin alone, or *Xigduo XR* – an extended release tablet for adults with T2D who are inadequately controlled on metformin alone.	2026, 2027-2030	2027, 2030[7]	2028, 2027[2], 2030	2024-2025, 2027-2030	**–**	–	–	**–**	–	–

Patent Expiries of Key Marketed Products *continued*

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales $m			Aggregate Product Sales Ex-US $m		
						2024	2023	2022	**2024**	2023	2022
Lokelma (sodium zirconium cyclosilicate)	An insoluble, non-absorbed sodium zirconium cyclosilicate, formulated as a powder for oral suspension, that acts as a highly selective potassium-removing agent for the treatment of hyperkalaemia.	2032-2035	2033, 2034[7]	2032	2035-2037	**256**	214	170	**286**	198	119
Roxadustat[9]	An oral hypoxia-inducible factor prolyl hydroxylase inhibitor indicated for the treatment of anaemia from CKD.	[3]	2024, 2024-2033	[3]	[3]	**–**	–	–	**331**	271	197
Wainua/ *Wainzua* (eplontersen)	*Wainua* injection, for subcutaneous use, is a prescription medicine used to treat adults with stage one or two polyneuropathy of hereditary transthyretin-mediated amyloidosis.	2025-2034	2034	2034	2034	**85**	–	–	**–**	–	–
Respiratory & Immunology											
Airsupra (albuterol/ budesonide)	A first-in-class, fixed-dose combination rescue medication for asthma in the US containing a short-acting beta2-agonist (SABA) and an anti-inflammatory inhaled corticosteroid (ICS), for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations, developed in a pressurised metered-dose inhaler (pMDI) using AstraZeneca's Aerosphere delivery technology.	2030	2030		2030	**66**	–	–	**–**	–	–
Breztri/*Trixeo* Aerosphere (budesonide/ glycopyrrolate/ formoterol)	A fixed-dose triple combination of an ICS, a long-acting muscarinic antagonist (LAMA) and a long-acting beta2-agonist (LABA) delivered in an Aerosphere pMDI, used for the long-term maintenance treatment of COPD.	2030-2031, 2038	2030, 2038	2030, 2038	2030-2034, 2038	**516**	383	239	**462**	294	159
Fasenra (benralizumab)	A mAb which directly targets and depletes eosinophils by recruiting natural killer cells and inducing apoptosis (programmed cell death). Approved as an add-on maintenance treatment for severe eosinophilic asthma and for eosinophilic granulomatosis with polyangiitis (EGPA).	2024, 2028-2034	2028	2025, 2028-2034	2025, 2034	**1,049**	992	906	**640**	561	490
Saphnelo (anifrolumab)	A first-in-class fully human mAb for moderate to severe systemic lupus erythematosus (SLE) that binds to subunit 1 of the type I IFN receptor, blocking the activity of type I IFNs. Type I IFNs such as IFN-alpha, IFN-beta and IFN-kappa are cytokines involved in driving the inflammatory pathways implicated in SLE.	2025-2029, 2033-2036	2025-2029	2025-2029, 2036	2030-2034, 2033-2036	**425**	260	111	**49**	20	5
Symbicort (budesonide/ formoterol)	A combination of an ICS and a fast-onset LABA to treat asthma and/or COPD, either as *Symbicort Turbuhaler* or *Symbicort* pMDI.	2025-2029[10]	expired	expired	expired	**1,187**	726	973	**1,692**	1,636	1,565
Tezspire[11] (tezepelumab)	A first-in-class human mAb that inhibits the action of TSLP, a key epithelial cytokine that sits at the top of multiple inflammatory cascades and is critical in the initiation and persistence of airway inflammation and airway hyperresponsiveness in severe asthma. Approved for a broad population of severe asthma patients, without phenotype and biomarker limitation. Developed in collaboration with Amgen.	2028, 2038	2028	2028	2028, 2038	**–**	–	–	**248**	86	4

Patent Expiries of Key Marketed Products *continued*

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales $m			Aggregate Product Sales Ex-US $m		
						2024	2023	2022	**2024**	2023	2022
Vaccines & Immune Therapies											
Beyfortus[12] (nirsevimab)	A long-acting anti-RSV F mAb used to prevent RSV lower respiratory tract disease in neonates and infants during their first RSV season. Jointly developed and commercialised with Sanofi.	2028-2035, 2038-2040	2038	2035	2035, 2038	**232**	87	–	**86**	19	–
FluMist (live attenuated influenza vaccine)	A live attenuated vaccine indicated for active immunisation for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.	2025-2026	2025	2025	2025[13]	**28**	23	21	**230**	193	154
Rare Disease											
Kanuma (sebelipase alfa)	A recombinant form of the human lysosomal acid lipase (LAL) enzyme. The enzyme replacement therapy is for the treatment of LAL deficiency.	2031	2031	2031, 2026-2037	2031, 2032	**100**	85	77	**109**	86	83
Koselugo[14] (selumetinib)	A kinase inhibitor that blocks specific enzymes (MEK1 and MEK2) for the treatment of patients with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas.	2028[15], 2026-2029	2026-2029	2026-2029	2029-2031	**212**	195	162	**319**	136	46
Soliris (eculizumab)	A C5 complement inhibitor for the treatment of paroxysmal nocturnal haemoglobinuria, atypical haemolytic uraemic syndrome, generalised myasthenia gravis and neuromyelitis optica spectrum disorder.	2027[16], 2025-2032	2029	2027, 2029	2027, 2029	**1,523**	1,734	2,180	**1,065**	1,411	1,582
Strensiq (asfotase alfa)	A targeted enzyme replacement therapy for patients with hypophosphatasia.	2025-2029, 2035-2038		2025-2031, 2036	2028, 2035-2036	**1,167**	937	769	**249**	215	189
Ultomiris (ravulizumab)	A long-acting C5 complement inhibitor for the treatment of paroxysmal nocturnal haemoglobinuria (PNH), atypical haemolytic uraemic syndrome (aHUS), generalised myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD).	2035, 2038	2035, 2038	2035, 2038-2040	2038, 2038	**2,261**	1,750	1,136	**1,663**	1,251	829
Voydeya[17] (danicopan)	A first-in-class oral, Factor D complement inhibitor for certain adults with PNH as add-on therapy to ravulizumab or eculizumab.	2035, 2038	2035	2035	2035	**–**	–	–	**–**	–	–

Notes

Crestor, Nexium, Pulmicort, Seloken, Synagis and *Zoladex* are key marketed products which have lost patent protection in all major markets.

1 Expiry in major EU markets, which includes the UK.
2 The patent is the subject of a pending opposition proceeding at the European Patent Office (EPO).
3 AstraZeneca does not have commercialisation rights.
4 AstraZeneca has recorded $1,437 million of Alliance Revenue in relation to this product in 2024 (2023: $1,022 million; 2022: $523 million), as per Note 1 to the Financial Statements on page 161.
5 Prior to 2024, *Imjudo* Product Sales were included in the *Imfinzi* Product Sales figure within Note 1 to the Financial Statements on page 160.
6 In addition to any Product Sales, AstraZeneca has also recorded $600 million of Collaboration Revenue in relation to this product in 2024 (2023: $245 million; 2022: $355 million), as per Note 1 to the Financial Statements on page 161.
7 The patent is the subject of a pending invalidation proceeding at China National Intellectual Property Administration.
8 *Xigduo/Xigduo XR* revenues are combined with *Farxiga/Forxiga*. Comparative revenues for years 2023 and 2022 have been revised to reflect this change.
9 AstraZeneca has recorded $6 million of Alliance Revenue in relation to this product in 2024 (2023: $5 million; 2022: $5 million), as per Note 1 to the Financial Statements on page 161.
10 Patent expiry information relates to the *Symbicort* pMDI product, including any granted Paediatric Exclusivity term.
11 AstraZeneca has recorded $436 million of Alliance Revenue in relation to this product in 2024 (2023: $259 million; 2022: $79 million), as per Note 1 to the Financial Statements on page 161.
12 AstraZeneca has recorded $237 million of Alliance Revenue in relation to this product in 2024 (2023: $57 million; 2022: $nil), as per Note 1 to the Financial Statements on page 161.
13 Rights licensed to Daiichi Sankyo, Inc.
14 In addition to any Product Sales, AstraZeneca has also recorded $100 million of Collaboration Revenue in relation to this product in 2024 (2023: $nil; 2022: $nil), as per Note 1 to the Financial Statements on page 161.
15 Date represents expiry of a pending SPC/PTE and/or Paediatric Exclusivity period.
16 Settled with Amgen and Samsung Bioepis for licensed biosimilar entry date of 1 March 2025.
17 *Voydeya* revenues are combined with *Ultomiris*.