AstraZeneca

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AstraZeneca Patent Expiries of Key Marketed Products 2023

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		
						2023	2022	2021	**2023**	2022	2021
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	**1,815**	1,657	1,089	**699**	400	149
Enhertu[3] (trastuzumab deruxtecan)	A HER2-directed antibody drug conjugate indicated for HER2-positive and HER2-low 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	[4]	**–**	–	–	**261**	79	17
Faslodex (fulvestrant)	An injectable oestrogen receptor antagonist used for the treatment of hormone receptor positive advanced breast cancer that has progressed following treatment with prior endocrine therapy.	expired	expired	expired	2025-2026	**31**	17	30	**266**	317	401
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 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	**2,171**	1,539	1,245	**1,848**	1,232	1,167
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	2026	**146**	13	–	**72**	–	–
Iressa (gefitinib)	An epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI) that acts to block signals for cancer cell growth and survival in advanced NSCLC.	expired	2023	2023	2023	**5**	9	11	**66**	105	172
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.	2022-2024, 2027[7], 2024-2031	2024, 2024-2029	2029, 2024-2029	2029, 2024-2034	**1,254**	1,226	1,087	**1,557**	1,412	1,261

For more information, see Risk Overview from page 54 of AstraZeneca's Annual Report and Form 20-F Information 2023 and the Risk Supplement on our website, www.astrazeneca.com/annualreport2023. Details of material challenges by third parties can be found in Note 30 to the Financial Statements from page 204 of AstraZeneca's Annual Report and Form 20-F Information 2023.

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		
						2023	2022	2021	**2023**	2022	2021
Orpathys (savolitinib)	An oral, potent and highly selective MET-TKI indicated for NSCLC with MET gene alterations.	2030	2030	2030	2030	**–**	–	–	**44**	33	16
Tagrisso (osimertinib)	An EGFR-TKI indicated for early- and late-stage EGFRm NSCLC.	2032, 2035	2032, 2035	2032, 2035	2034, 2035	**2,276**	2,007	1,780	**3,523**	3,437	3,235
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	**6**	–	–	**–**	–	–
Zoladex[7] (goserelin acetate implant)	A luteinising hormone-releasing hormone (LHRH) agonist used to treat prostate cancer, breast cancer and certain benign gynaecological disorders.	expired	expired	expired	expired	**14**	15	13	**938**	912	935
CVRM											
Andexxa/ *Ondexxya* (andexanet alfa)	A factor Xa inhibitor reversal agent.	2032, 2028-2037	2028, 2030-2035	2028, 2030-2037	2028, 2030-2037	**75**	77	50	**107**	73	18
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	expired	2025	2023-2024, 2025-2030	**744**	744	735	**580**	614	737
Bydureon/ *Bydureon BCise* (exenatide XR injectable suspension)	An injectable glucagon-like peptide-1 receptor agonist (GLP-1RA) available as a single-dose tray, a single-dose pen or autoinjector device indicated for use in adults with type-2 diabetes (T2D).	2024-2028, 2031[8]	2024-2028, 2029[8]	2024-2028, 2029[8]	2024-2028, 2029[8]	**133**	242	321	**30**	38	64
Byetta (exenatide injection)	An injectable GLP-1RA indicated for adults with T2D.	expired	expired	expired	expired	**8**	14	26	**11**	17	30
Crestor (rosuvastatin calcium)	A statin for dyslipidaemia and hypercholesterolaemia.	expired	expired	expired	2023	**55**	65	80	**1,052**	983	1,016
Farxiga/ *Forxiga* (dapagliflozin)	A sodium-glucose cotransporter 2 (SGLT-2 inhibitor) indicated for adult patients with T2D or in adults with or without T2D with heart failure with reduced ejection fraction or chronic kidney disease (CKD).	2025, 2025-2040	2023, 2028-2041	2027	2024-2025, 2028	**1,339**	960	644	**3,795**	2,711	1,770
Komboglyze/ *Kombiglyze* XR[9] (saxagliptin/ metformin)	Combines saxagliptin and metformin as either *Komboglyze*, for T2D, or *Kombiglyze* XR, an extended release tablet for T2D.	2023, 2025	2025	2026, 2025	[4]	**17**	25	32	**94**	88	92
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[10]-2034	2032[2]	2032-2037	**214**	170	115	**198**	119	60
Onglyza (saxagliptin)	An oral dipeptidyl peptidase 4 inhibitor for T2D.	2023, 2028	2025	2024, 2025	[4]	**32**	51	56	**84**	93	179
Roxadustat[11]	An oral hypoxia-inducible factor prolyl hydroxylase inhibitor indicated for the treatment of anaemia from CKD.	2024, 2024-2034	2024, 2024-2033	[4]	[4]	**–**	–	–	**271**	197	174
Wainua (eplontersen)	*Wainua* injection, for subcutaneous use, is a prescription medicine used to treat adults with polyneuropathy of hereditary transthyretin-mediated amyloidosis.	2034	2034	2034	2034	**–**	–	–	**–**	–	–
Xigduo/ *Xigduo XR*[12] (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.	2025, 2025-2030	2023	2028	2024-2025, 2030	**112**	111	88	**717**	599	498

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		
						2023	2022	2021	**2023**	2022	2021
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	**–**	–	–	**–**	–	–
Bevespi Aerosphere (glycopyrrolate/ formoterol)	A combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta2-agonist (LABA) delivered in an Aerosphere pressurised metered-dose inhaler (pMDI) used for the long-term maintenance treatment of airflow obstruction in chronic obstructive pulmonary disease (COPD).	2030-2031	2030	2030	2030-2034	**34**	42	39	**24**	16	15
Breztri/Trixeo Aerosphere (PT010) (budesonide/ glycopyrrolate/ formoterol)	A fixed-dose triple combination of an inhaled corticosteroid (ICS), a LAMA and a 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	**383**	239	115	**294**	159	88
Daliresp/ Daxas (roflumilast)	An oral phosphodiesterase-4 inhibitor for adults with severe COPD to decrease their number of exacerbations.	2023-2024	2023	2023	expired	**42**	176	207	**12**	13	20
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.	2024, 2028-2034	2028	2025, 2028-2034	2025, 2034	**992**	906	790	**561**	490	468
Pulmicort (budesonide)	An ICS for maintenance treatment of asthma available as *Turbuhaler* and as *Respules*.	expired	expired	expired	expired	**28**	65	72	**685**	580	890
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	**260**	111	8	**20**	5	–
Symbicort (budesonide/ formoterol)	A combination of an inhaled corticosteroid and a fast-onset LABA to treat asthma and/or COPD either as *Symbicort Turbuhaler* or *Symbicort* pMDI.	2023-2029[13]	expired	expired	expired	**726**	973	1,065	**1,636**	1,565	1,663
Tezspire[14] (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	**–**	–	–	**86**	4	–
Vaccines & Immune Therapies											
Beyfortus (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		2035	2035, 2038	**87**	–	–	**19**	–	–
Evusheld (tixagevimab co-packaged with cilgavimab)	A combination of two long-acting antibodies, developed for the prevention and treatment of COVID-19.	2041				**–**	1,067	–	**132**	1,118	85

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		
						2023	2022	2021	**2023**	2022	2021
Fluenz Tetra/ *FluMist* Quadrivalent (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[15]	**23**	21	27	**193**	154	226
Synagis (palivizumab)	A humanised mAb used to prevent serious lower respiratory tract disease caused by RSV in infants at high risk of acquiring RSV disease.	2023[16]	expired	2023	2023	**(1)**	1	23	**547**	577	387
Vaxzevria[17] (ChAdOx1-S Recombinant)	An adenoviral vector vaccine, based on a weakened version of the common cold virus, for active immunisation against COVID-19.	2032	2032	2032	2032	**–**	79	64	**12**	1,719	3,853
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	**85**	77	32	**86**	83	30
Koselugo (selumetinib)	A specific enzyme-inhibitor which blocks mitogen-activated protein kinases (MEK1 and MEK2) which are involved in stimulating cells to grow. In neurofibromatosis type 1, these enzymes are overactive, causing tumour cells to grow in an unregulated way. By blocking these enzymes, *Koselugo* slows down the growth of tumour cells.	2023, 2023-2029	2023, 2026-2029	2023, 2026-2029	2023, 2023-2029	**195**	162	104	**136**	46	4
Soliris (eculizumab)	A C5 inhibitor for the treatment of paroxysmal nocturnal haemoglobinuria, atypical haemolytic uraemic syndrome, generalised myasthenia gravis and neuromyelitis optica spectrum disorder.	2027, 2025-2032[18]	2029	2029[19]	2027, 2029	**1,734**	2,180	1,068	**1,411**	1,582	806
Strensiq (asfotase alfa)	A targeted enzyme replacement therapy for patients with hypophosphatasia.	2025-2029, 2035-2038		2025-2031, 2036	2028, 2035-2036	**937**	769	297	**215**	189	81
Ultomiris (ravulizumab)	A long-acting C5 inhibitor for the treatment of paroxysmal nocturnal haemoglobinuria, atypical haemolytic uraemic syndrome, generalised myasthenia gravis and neuromyelitis optica spectrum disorder.	2035, 2038	2035, 2038	2035, 2038-2039	2037, 2038	**1,750**	1,136	381	**1,251**	829	307
Voydeya (danicopan)	An oral, Factor D inhibitor developed as add-on to proven standard-of-care *Ultomiris* or *Soliris* to address the needs of the subset of patients with PNH who experience clinically significant extravascular haemolysis while treated with a C5 inhibitor.	2035	2035	2035	2035	**–**	–	–	**–**	–	–
Other											
Nexium[20] (esomeprazole)	A proton pump inhibitor used to treat acid-related diseases.	expired	expired	expired	expired	**115**	120	128	**830**	1,165	1,198

* Date represents expiry of a pending SPC/PTE and/or Paediatric Exclusivity period.
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). The patentee successfully defended the patent in that proceeding, but the opponents have appealed.
3 AstraZeneca has recorded $1,022 million of Alliance Revenue in relation to this product in 2023 (2022: $523 million; 2021: $197 million), as per Note 1 to the Financial Statements on page 160.
4 AstraZeneca does not have commercialisation rights.
5 *Imjudo* Product Sales are included in the *Imfinzi* Product Sales figure.
6 In addition to any Product Sales, AstraZeneca has also recorded $245 million of Collaboration Revenue in relation to this product in 2023 (2022: $355 million; 2021: $400 million), as per Note 1 to the Financial Statements on page 160.
7 Rights licensed to TerSera Therapeutics LLC in the US.
8 Patent expiry date relates to *BCise*.
9 *Komboglyze*/*Kombiglyze* XR revenue is included in the *Onglyza* Product Sales figure.
10 The patent is the subject of a pending invalidation proceeding at China National Intellectual Property Administration.
11 AstraZeneca has recorded $5 million of Collaboration Revenue in relation to this product in 2023 (2022: $5 million; 2021: $6 million), as per Note 1 on page 160.
12 *Xigduo*/*Xigduo XR* Product Sales are included in the *Farxiga* Product Sales figure.
13 Patent expiry information relates to the *Symbicort* pMDI product, including any granted Paediatric Exclusivity term.
14 AstraZeneca has recorded $259 million of Alliance Revenue in relation to this product in 2023 (2022: $79 million; 2021: $nil), as per Note 1 to the Financial Statements on page 160.
15 Rights licensed to Daiichi Sankyo, Inc.
16 Rights sold to Sobi.
17 AstraZeneca has recorded $nil of Alliance Revenue in relation to this product in 2023 (2022: $76 million; 2021: $64 million), as per Note 1 to the Financial Statements on page 160.
18 Settled with Amgen for licensed biosimilar entry date of 1 March 2025. The patents expiring in 2027 are the subject of pending inter partes review proceedings before the United States Patent Office.
19 The patent is the subject of a pending opposition proceeding at the EPO. Alexion has consented to revocation of this patent in the UK and has withdrawn this patent in the Netherlands.
20 AstraZeneca has recorded $nil of Collaboration Revenue in relation to this product in 2023 (2022: $62 million; 2021: $75 million), as per Note 1 to the Financial Statements on page 160.

Updated on 26 February 2024