AstraZeneca

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AstraZeneca Patent Expiries of Key Marketed Products 2021

Patent Expiries of Key Marketed Products

References to Notes and page numbers, and capitalised terms not defined in this supplement can be found in AstraZeneca's Annual Report and Form 20-F Information 2021 at www.astrazeneca.com/annualreport2021.

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 SPC/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. Expiry dates in mulberry relate to new molecular entity patents, the remaining dates relate to other patents. 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.

For more information, please see Risk Overview from page 48 and the Risk supplement at www.astrazeneca.com/annualreport2021. Many of our products are subject to challenges by third parties. Details of material challenges by third parties can be found in Note 30 to the Financial Statements from page 189.

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales ($m)			Aggregate Product Sales Ex-US ($m)		
						2021	2020	2019	**2021**	2020	2019
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, 2036[2]	2032	**1,089**	511	162	**149**	11	2
Enhertu[3] (trastuzumab deruxtecan)	A HER2-directed antibody drug conjugate (ADC) indicated for the treatment of unresectable or metastatic HER2-positive breast cancer following two or more prior anti-HER2 based regimens, and locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma following a prior trastuzumab-based regimen.	2033	2033–2035	2033–2035	[4]	**–**	–	–	**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.	2021[5]	expired	2021	2025–2026	**30**	55	328	**401**	525	564
Imfinzi (durvalumab)	A human monoclonal antibody that blocks PD-L1 interaction with PD-1 and CD80 on T-cells, countering the tumour's immune-evading tactics and inducing an immune response. It is currently indicated for the treatment of unresectable Stage III non-small cell lung cancer (NSCLC), extensive-stage small cell lung cancer and previously treated patients with advanced bladder cancer.	2031	2030	2030	2033	**1,245**	1,185	1,041	**1,167**	857	428
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[6]	2023	2023	2023	**11**	14	17	**172**	254	406
Koselugo (selumetinib)	An inhibitor of mitogen-activated protein kinases 1 and 2 (MEK1/2). MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway. Both MEK and ERK are critical components of the RAS-regulated RAF-MEK-ERK pathway, which is often activated in different types of cancers.	2023, 2023–2026	2023, 2026–2029	2023, 2026–2029	2023, 2023–2029	**104**	38	–	**4**	–	–
Lumoxiti (moxetumomab pasudotox-tdfk)	A CD22-directed cytotoxin and a first-in-class treatment in the US for adult patients with relapsed or refractory hairy cell leukaemia.	2022–2024, 2031–2032	2031	2022, 2031	2031	**1**	1	–	**–**	–	–
Lynparza[7] (olaparib)	An oral poly ADP-ribose polymerase (PARP) inhibitor that blocks DNA damage response (DDR) in cells/tumours harbouring a deficiency in homologous recombination repair, such as mutations in BRCA1 and/or BRCA2. It is indicated for platinum-sensitive relapsed ovarian cancer, regardless of BRCA status, 1st-line maintenance treatment of BRCA-mutated (BRCAm) advanced ovarian cancer, for germline BRCAm (gBRCAm) HER2-negative, metastatic breast cancer and for gBRCAm metastatic pancreatic cancer.	2022–2024, 2028*, 2024–2031	2021–2024, 2024–2029	2021–2029, 2024–2029	2021–2029, 2024–2034	**1,087**	876	626	**1,261**	900	572

Patent Expiries of Key Marketed Products *continued*

Key marketed products	Description	US	China	EU[1]	Japan	US Product Sales ($m) 2021	2020	2019	Aggregate Product Sales Ex-US ($m) 2021	2020	2019
Orpathys (savolitinib)	An oral, potent and highly selective MET TKI that blocks atypical activation of the MET receptor tyrosine kinase pathway.	2030	2030	2030	2030	**–**	–	–	**16**	–	–
Tagrisso (osimertinib)	An EGFR-TKI indicated for the adjuvant treatment of patients with early-stage EGFR-mutated NSCLC and for locally advanced or metastatic EGFR-mutated NSCLC.	2032, 2035	2032	2032, 2035	2034, 2035	**1,780**	1,566	1,268	**3,235**	2,762	1,921
Zoladex[8] (goserelin acetate implant)	A luteinising hormone-releasing hormone (LHRH) agonist used to treat prostate cancer, breast cancer and certain benign gynaecological disorders.	2022	2021	2021	2021	**13**	5	7	**935**	883	806
CVRM											
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 acute coronary syndromes (ACS) or high-risk patients with history of myocardial infarction (MI), high-risk patients with coronary artery disease (CAD) or stroke.	2024[9], 2021–2036	2021[10]	2024, 2021	2023–2024, 2025–2030	**735**	732	710	**737**	861	871
Bydureon/ *Bydureon BCise* (exenatide XR injectable suspension)	An injectable glucagon-like peptide-1 (GLP-1) receptor agonist available as a single-dose tray, a single-dose pen or auto-injector device indicated for use in adults with type-2 diabetes.	2022–2028, 2031[11]	2021–2028, 2029[11]	2021–2028, 2029[11]	2021–2028, 2029[11]	**321**	382	459	**64**	66	90
Byetta (exenatide injection)	An injectable GLP-1 receptor agonist indicated for adults with type-2 diabetes.	expired	expired	2021	expired	**26**	37	68	**30**	31	42
Crestor (rosuvastatin calcium)	A statin for dyslipidaemia and hypercholesterolaemia.	2021–2022[12]	2021	expired	2023	**80**	92	104	**1,016**	1,088	1,174
Farxiga/ *Forxiga* (dapagliflozin)	A sodium-glucose cotransporter 2 (SGLT-2 inhibitor) indicated for adult patients with type-2 diabetes or in adults with or without type-2 diabetes with heart failure with reduced ejection fraction or chronic kidney disease.	2025, 2025–2040	2023, 2028	2027	2024–2025, 2028	**644**	456	434	**1,770**	1,049	748
Komboglyze/ *Kombiglyze* XR[13] (saxagliptin/ metformin)	Combines saxagliptin and metformin as either *Komboglyze* – for type-2 diabetes, or *Kombiglyze* XR – an extended release tablet for type-2 diabetes.	2023, 2025	2021, 2025	2021–2026, 2025	[4]	**32**	56	–	**92**	82	87
Lokelma (sodium zirconium cyclosilicate)	An insoluble, non-absorbed sodium zirconium silicate, 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	2032[14]	2032–2037	**115**	57	13	**60**	19	1
Onglyza (saxagliptin)	An oral dipeptidyl peptidase 4 (DPP-4) inhibitor for type-2 diabetes.	2023, 2028	2021, 2025	2024, 2025	[4]	**56**	110	230	**179**	222	209
Roxadustat[15]	An oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) indicated for the treatment of anaemia from chronic kidney disease.	2024, 2024–2034	2024, 2024–2033	[4]	[4]	**–**	–	–	**174**	–	–
Qtern (dapagliflozin/ saxagliptin)	A once-daily oral treatment combination of dapagliflozin and saxagliptin indicated for use in adults with type-2 diabetes.	2025, 2025–2029	2023	2027	2024–2025	**4**	5	6	**37**	22	12
Xigduo/ *Xigduo* XR (dapagliflozin/ metformin)	Combines dapagliflozin and metformin as either *Xigduo* – to improve glycaemic control in adults with type-2 diabetes who are inadequately controlled on metformin alone or *Xigduo* XR – an extended release tablet for adults with type-2 diabetes who are inadequately controlled on metformin alone.	2025, 2025–2030	2023	2028	2024–2025, 2030	**88**	113	103	**498**	340	257

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)		
						2021	2020	2019	**2021**	2020	2019
Respiratory & Immunology											
Bevespi Aerosphere (glycopyrrolate/ formoterol)	A combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta2-agonist (LABA) used for the long-term maintenance treatment of airflow obstruction in COPD.	2030–2031	2030	2030	2030–2034	**39**	44	42	**15**	4	–
Breztri Aerosphere (PT010) (budesonide/ glycopyrrolate/ formoterol)	A fixed-dose triple combination of an inhaled corticosteroid (ICS), a LAMA and a LABA, used for the long-term maintenance treatment of COPD.	2030–2031	2030	2030	2030–2034	**115**	5	–	**88**	23	2
Daliresp/ Daxas (roflumilast)	An oral phosphodiesterase-4 inhibitor for adults with severe COPD to decrease their number of exacerbations.	2023–2024	2023	2023	expired	**207**	190	184	**20**	27	31
Duaklir/Brimica[16] (aclidinium/ formoterol)	A fixed-dose combination of a LAMA and a LABA for the maintenance treatment of COPD.	2025, 2022–2029	2022–2027	2025, 2022–2029	2025, 2021–2029	**–**	–	3	**77**	69	74
Fasenra (benralizumab)	A monoclonal antibody for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype, which directly targets and depletes eosinophils by recruiting natural killer cells and inducing apoptosis (programmed cell death).	2024, 2028–2034	2021, 2028	2025, 2028–2034	2025, 2034	**790**	603	482	**468**	346	222
Pulmicort (budesonide)	An inhaled corticosteroid for maintenance treatment of asthma.	expired	expired	expired	expired	**72**	71	110	**890**	925	1,356
Saphnelo (anifrolumab)	A first-in-class fully human monoclonal antibody 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 regulating the inflammatory pathways implicated in SLE.	2025–2029, 2033–2036	2025–2029	2025–2029, 2036	2025–2029, 2033–2036	**8**	–	–	**–**	–	–
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 (pressurised metered-dose inhaler).	2022–2029[17]	expired[18]	expired[18]	expired[18]	**1,065**	1,022	829	**1,663**	1,699	1,666
Tudorza/Eklira/ Bretaris[16] (aclidinium)	A LAMA for the maintenance treatment of COPD.	2025, 2022–2029	2022–2027	2025, 2022–2029	2025, 2021–2029	**18**	6	2	**44**	54	70
Rare Disease											
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[19], 2025–2029		2027[20]	2027, 2029	**1,068**	–	–	**806**	–	–
Ultomiris (ravulizumab)	A long-acting C5 inhibitor for the treatment of paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome.	2035, 2036–2042	2035, 2036–2042	2035, 2036–2042	2035, 2036–2042	**381**	–	–	**307**	–	–
Strensiq (asfotase alfa)	A targeted enzyme replacement therapy for patients with hypophosphatasia.	2025–2029, 2035–2038		2025–2031, 2036	2028, 2035–2036	**297**	–	–	**81**	–	–
Kanuma (sebelipase alfa)	A recombinant form of the human LAL enzyme, the enzyme replacement therapy is for the treatment of lysosomal acid lipase deficiency.	2031	2031	2031, 2026–2037	2031	**32**	–	–	**30**	–	–
Andexxa/ Ondexxya (andexanet alfa)	A factor Xa inhibitor reversal agent.	2028, 2030–2037	2028, 2030–2035	2028, 2030–2037	2028, 2030–2035	**50**	–	–	**18**	–	–

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)		
						2021	2020	2019	**2021**	2020	2019
Other											
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[21]	**27**	70	20	**226**	225	93
Linzess (linaclotide)	A guanylate cyclase-C agonist for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.	[4]	2024, 2029	[4]	[4]	**–**	–	–	**–**	–	–
Nexium[23] (esomeprazole)	A proton pump inhibitor used to treat acid-related diseases.	expired	expired	expired	expired	**128**	169	218	**1,198**	1,323	1,265
Synagis (palivizumab)	A humanised mAb used to prevent serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in paediatric patients at high risk of acquiring RSV disease.	2023[22]	expired	2023	2023	**23**	47	46	**387**	325	312
Vaxzevria (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	**64**	–	–	**3,853**	2	–
Evusheld (tixagevimab co-packaged with cilgavimab)	A combination of two long-acting antibodies, developed for the prevention and treatment of COVID-19.					**–**	–	–	**85**	–	–

* 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).
3 AstraZeneca has recorded $193m of Collaboration Revenue in relation to this Product in 2021 as per Note 1 on page 146 and recorded $94m of Collaboration Revenue in relation to this Product in 2020.
4 AstraZeneca does not have commercialisation rights.
5 Settled with various generic companies for licensed entry dates of 25 March 2019 or later.
6 In the US, *Iressa* has seven years' Orphan Drug exclusivity to 13 July 2022.
7 In addition to any product sales, AstraZeneca has also recorded $400m of Collaboration Revenue in relation to this Product in 2021 as per Note 1 on page 146 and recorded $460m of Collaboration Revenue in relation to this Product in 2020.
8 Rights licensed to TerSera in the US. In addition to any product sales, AstraZeneca has also recorded $35m of Collaboration Revenue in relation to this Product in 2020 as per Note 1 on page 146.
9 Separate settlements with ANDA challengers for a licensed entry date corresponding to the expiry of US Patent No. RE46,276, subject to regulatory approval.
10 The patent was invalidated during invalidation proceedings at the CNIPA. The patentee has appealed that decision.
11 Patent expiry date relates to *BCise*.
12 A settlement agreement in the US permitted Watson Laboratories, Inc. and Actavis, Inc. (together, Watson) to begin selling its generic version of *Crestor* and its rosuvastatin zinc product from 2 May 2016.
13 *Komboglyze*/*Kombiglyze* XR revenue is included in the *Onglyza* revenue figure.
14 The patent is the subject of a pending opposition proceeding at the EPO. The patentee successfully defended the patent in that proceeding, but the opponents have appealed.
15 AstraZeneca has recorded $6m of Collaboration Revenue in relation to this Product in 2021 as per Note 1 on page 146 and recorded $30m of Collaboration Revenue in relation to this Product in 2020.
16 Rights to *Duaklir*/*Brimica* and *Tudorza*/*Eklira*/*Bretaris* sold to Covis Pharma GmbH.
17 Patent expiry information relates to the *Symbicort* pMDI product, including any granted Paediatric Exclusivity term.
18 Patent expiry information relates to the *Symbicort Turbuhaler* product.
19 Settled with biosimilar manufacturer Amgen for a licensed entry date of March 2025, or later, subject to regulatory approval.
20 The patent was revoked during opposition proceedings at the EPO. The patentee has appealed that decision.
21 Rights licensed to Daiichi Sankyo Company, Ltd.
22 Rights sold to Swedish Orphan Biovitrum AB (publ).
23 AstraZeneca has recorded $75m of Collaboration Revenue in relation to this Product in 2021 as per Note 1 on page 146.