

Bristol-Myers Squibb Company's Products

The company's pharmaceutical products include chemically synthesized or small molecule drugs, products produced from biological processes, called "biologics" and chimeric antigen receptor (CAR) T-cell therapies. Small molecule drugs are typically administered orally in the form of a tablet or capsule, although other drug delivery mechanisms are used as well. Biologics are typically administered to patients through injections or by intravenous infusion. CAR-T therapies are administered to patients by intravenous infusion.

Below is a summary of Bristol-Myers Squibb's significant products, including approved indications:

Abecma (idecabtagene vicleucel) is a B-cell maturation antigen-directed genetically modified autologous CAR-T cell therapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Abraxane (paclitaxel albumin-bound particles for injectable suspension) is a solvent-free proteinbound chemotherapy product that combines paclitaxel with albumin using the proprietary Nab technology platform and is used to treat breast cancer, NSCLC, and pancreatic cancer, among others.

Breyanzi (lisocabtagene maraleucel) is a CD19-directed genetically modified autologous CAR-T cell therapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after one or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Camzyos (mavacamten) is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic obstructive HCM to improve functional capacity and symptoms.

Eliquis (apixaban) is an oral Factor Xa inhibitor indicated for the reduction in risk of stroke/systemic embolism in NVAf and for the treatment of DVT/PE and reduction in risk of recurrence following initial therapy.

Empliciti (elotuzumab), is a biological product that targets the SLAMF7 protein expressed in natural killer cells (NKC) and myeloma cells. Empliciti is a humanized monoclonal antibody for the treatment of multiple myeloma.

Inrebic (fedratinib) is an oral kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis.

Onureg (azacitidine) is an oral hypomethylating agent that incorporates into DNA and RNA, indicated for continued treatment of adult patients with AML who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete intensive curative therapy.

Opdivo (nivolumab), a biological product, is a fully human monoclonal antibody that binds to the PD1 on T and NKT cells. Opdivo has received approvals for several anti-cancer indications including bladder, blood, CRC, head, and neck, RCC, HCC, lung, melanoma, MPM, stomach and esophageal cancer. The Opdivo+Yervoy regimen also is approved in multiple markets for the treatment of NSCLC, melanoma, MPM, RCC, CRC and various gastric and esophageal cancers. There are several ongoing potentially registrational studies for Opdivo across other tumour types and disease areas, in monotherapy and combination with Yervoy and various anti-cancer agents.

Opdualag (nivolumab and relatlimab-rmbw) is a combination of nivolumab, a PD-1 blocking antibody, and relatlimab, a LAG-3 blocking antibody, indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Orencia (abatacept), a biological product, is a fusion protein indicated for adult patients with moderately to severely active RA and PsA, for reducing signs and symptoms in certain pediatric patients with moderately to severely active polyarticular JIA and for the treatment of aGVHD, in combination with a calcineurin inhibitor and methotrexate.

Pomalyst/Imnovid (pomalidomide) is a small molecule that is administered orally and modulates the immune system and other biologically important targets. Pomalyst/Imnovid is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Reblozyl (luspatercept-aamt), a biological product, is an erythroid maturation agent indicated for the treatment of anemia in adult patients with transfusion-dependent and non-transfusion-dependent beta thalassemia and for the treatment of anemia failing an erythropoiesis stimulating agent ("ESA") in adult patients with very low- to intermediate-risk MDS who have ring sideroblasts and require RBC transfusions.

Revlimid (lenalidomide) is an oral immunomodulatory drug that in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma. Revlimid as a single agent is also indicated as maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant. Revlimid has received approvals for several indications in hematological malignancies including lymphoma and MDS.

Sotyktu (deucravacitinib) is an oral, selective, allosteric tyrosine kinase 2 inhibitors indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Sprycel (dasatinib) is an oral inhibitor of multiple tyrosine kinase indicated for the first-line treatment of patients with Philadelphia chromosome-positive CML in the chronic phase, the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase CML with resistance or intolerance to prior therapy, including Gleevec* (imatinib mesylate) and the treatment of children and adolescents aged 1 year to 18 years with chronic phase Philadelphia chromosome-positive CML.

Yervoy (ipilimumab), is a biological product that is a CTLA4 immune checkpoint inhibitor. Yervoy is a monoclonal antibody for the treatment of patients with unresectable or metastatic melanoma.

Zeposia (ozanimod) is an oral immunomodulatory drug used to treat moderately to severely active UC and relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Bristol-Myers Squibb Company estimates the minimum market exclusivity date for each of its products for business planning only. The length of market exclusivity for any of its products is impossible to predict with certainty because of the complex interaction between patent and regulatory forms of exclusivity and the inherent uncertainties regarding patent litigation. There can be no assurance that a particular product will enjoy market exclusivity for the full period that appears in the estimate or that the exclusivity will be limited to the estimate.

The following chart shows the company's key products together with the year in which the earliest basic exclusivity loss (patent rights or data exclusivity) is currently estimated to occur in the U.S., the EU and Japan (the "estimated minimum market exclusivity date"). The company also sells our pharmaceutical products in other countries; however, data is not provided on a country-by-country basis because individual country revenues are not significant outside the U.S., the EU and Japan.

	Estimated Minimum Market Exclusivity Date		
	U.S.	EU ^(a)	Japan
<i>Abecma</i> (idecabtagene vicleucel)	2036	2035	2035
<i>Abraxane</i> (paclitaxel) ^(a)	^^	^^	^^
<i>Breyanzi</i> (lisocabtagene maraleucel) ^(b)	2033	2033	2033
<i>Camzyos</i> (mavacamten) ^(c)	2034	++	++
<i>Eliquis</i> (apixaban) ^(d)	2026	^^	2026
<i>Empliciti</i> (elotuzumab)	2029	2029	2029
<i>Inrebic</i> (fedratinib) ^(e)	2026	2031	++
<i>Onureg</i> (azacitidine) ^(f)	2027	^^	++
<i>Opdivo</i> (nivolumab)	2028	2030	2031
<i>Opdualag</i> (nivolumab and relatlimab-rmbw) ^(g)	2034	2033	++
<i>Orencia</i> (abatacept) ^(h)	^^	^^	^^
<i>Pomalyst/Imnovid</i> (pomalidomide) ⁽ⁱ⁾	^^	2024	^^
<i>Reblozyl</i> (luspatercept-aamt) ^(j)	2031	2030	++
<i>Revlimid</i> (lenalidomide) ^(k)	^^	^^	^^
<i>Sotyktu</i> (deucravacitinib) ^(l)	2033	++	2033
<i>Sprycel</i> (dasatinib) ^(m)	^^	^^	^^
<i>Yervoy</i> (ipilimumab)	2025	2026	2025
<i>Zeposia</i> (ozanimod) ⁽ⁿ⁾	2029	2030	++

^^ See product footnote for more information.

++ We do not currently market the product in the country or region indicated.

(a) For Abraxane in the U.S., based on settlements, certain generics were permitted to enter the market in 2022. In the EU, generics have entered the market. For Japan, the estimated minimum market exclusivity date is 2023 based on a method of use patent.

(b) For Breyanzi in the U.S., a PTR application is pending and, if granted, the estimated patent expiry will be 2034.

(c) For Camzyos in the U.S., a PTR application is pending and, if granted, the estimated patent expiry will be 2036.

(d) For Eliquis, in the U.S., two patents listed in the FDA Orange Book, the composition of matter patent claiming apixaban specifically (expiring 2026) and a formulation patent (expiring 2031), were challenged by numerous generic companies. BMS, along with its partner Pfizer, settled with a number of these generic companies (settled generic companies) while continuing to litigate against three remaining generic companies (remaining generic companies). In August 2020, the U.S. District Court for the District of Delaware decided that the two challenged Eliquis patents are both valid and infringed by the remaining generic companies. The remaining generic companies appealed, and in

September 2021 the U.S. Court of Appeals for the Federal Circuit upheld the decision concerning both patents. Under the terms of previously executed settlement agreements with the settled generic companies, the permitted date of launch for the settled generic companies under these patents is April 1, 2028, subject to additional challenges. In the EU, the apixaban composition of matter patents and related Supplementary Protection Certificates (“SPCs”) expire in 2026. Generics have challenged the composition of matter patents and related SPCs in various jurisdictions and trials have taken place, or are scheduled to take place, in certain European countries. While these legal proceedings are pending, generic manufacturers have begun marketing generic versions of Eliquis in the UK and the Netherlands and may seek to market generic versions of Eliquis in other European countries before the expiration date of apixaban patents and related SPCs.

(e) For Inrebic in the U.S., a PTR application is pending and, if granted, the estimated patent expiry will be 2031. In the EU, the estimated minimum market exclusivity date is based on RDP exclusivity.

(f) For Onureg in the U.S., the estimated minimum market exclusivity date of 2027 is based on seven years of orphan drug exclusivity. Formulation patents covering Onureg expire in 2030 in the U.S., and in 2029 in the EU and Japan. In the U.S., Accord Healthcare Inc. has challenged the formulation patent, which is listed in the FDA Orange Book, and litigation is ongoing. In the EU, three formulation patents (EP 2,299,984; EP 2,695,609; and EP 3,692,983) cover Onureg and they are in pending opposition proceedings. The EPO Opposition Division found two of these formulation patents invalid, and the decisions are being or will be appealed.

(g) For Opdualag in the U.S., a PTR application is pending and, if granted, the estimated patent expiry will be 2036. In the EU, an SPC application is pending and, if granted, the estimated patent expiry will be 2037.

(h) BMS is not aware of an Orenzia biosimilar on the market in the U.S., EU, or Japan. Formulation and additional patents expire in 2026 and beyond.

(i) For Pomalyst in the U.S., we currently do not expect generic entry before the first quarter of 2026. For Europe, the estimated minimum market exclusivity date is based on RDP exclusivity. For Japan, the estimated minimum market exclusivity date is 2026 based on a method of use patent.

(j) For Reblozyl in the U.S. and Europe, the estimated minimum market exclusivity date is based on RDP exclusivity. In the U.S., a PTR application on a method of treatment patent is pending and if granted, the estimated patent expiry will be 2033. In the EU, an SPC application on a method of treatment patent is pending and if granted, the estimated patent expiry will be 2034.

(k) For Revlimid, in the U.S., as part of the settlement with Natco Pharma Ltd. (“Natco”) and its partners and affiliates, Natco was granted a volume-limited license to sell generic lenalidomide in the U.S. commencing in March 2022. Certain other generic companies have been granted volume-limited licenses to sell generic lenalidomide in the U.S. beginning on confidential dates that are sometime after the March 2022 volume-limited license date provided to Natco. Natco and certain other generics have begun marketing generic lenalidomide products in the U.S. under those volumelimited licenses. In addition, Natco and other generic companies have been granted licenses to sell generic lenalidomide in the U.S. without volume limitation beginning on January 31, 2026. In the EU, licenses have been granted to third parties to market generic lenalidomide products before the expiry of patent and supplementary protection certificate (“SPC”) rights in the UK beginning on January 18, 2022, and in various other major market European countries (e.g., France, Germany, Italy and Spain) where SPC is in force beginning on February 18, 2022. In Japan, the composition of matter patent expired in July 2022, however, BMS is not aware of any generic approvals.

(l) For Sotyktu in the U.S., a PTR application is pending and, if granted, the estimated patent expiry will be 2036. In Japan, a PTR application is also pending and, if granted, the estimated patent expiry will be 2037.

(m) For Sprycel, in the U.S., BMS entered into settlement agreements with Apotex Inc. and certain other generic companies regarding patents covering certain polymorphic forms of dasatinib whereby the generic companies can launch their generic dasatinib ANDA products in September 2024, or earlier in certain circumstances. Lawsuits filed by BMS are pending against other companies that filed 505(b)(2) NDA applications containing paragraph IV certifications seeking approval of dasatinib products in the U.S. In the EU, the EPO's Opposition Division upheld the validity of the patent directed to the use of dasatinib to treat CML, which expires in 2024; however, further to settlement agreements certain generics have already launched generic dasatinib for all approved indications. In Japan, the composition of matter patent has been extended to 2024 for the treatment of nonimatinib-resistant CML, but generics have been approved for other indications.

(n) For Zeposia, in the U.S., a PTR application is pending and if granted, the estimated patent expiry will be 2033. In the EU, the estimated minimum market exclusivity date is based on RDP exclusivity. In the EU, an SPC application is pending and, if granted, the estimated patent expiry will be 2034.

(o) Estimated minimum market exclusivity dates for EU countries are based on France, Germany, Italy, Spain, and the UK.

Take note that this is a summarized version of the product information by [The Globetrotting Investor](#). For more information, please refer to the [Bristol-Myers Squibb Company website](#).

Updated on: 8 May 2023