PRIME THERAPEUTICS®

Specialty Pipeline **MONTHLY UPDATE**

Critical updates in an ever changing environment

September 2021

NEW DRUG INFORMATION

- **Welireg™ (belzutifan):** The U.S. Food and Drug Administration (FDA) has granted approval of Merck's Welireg, an oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery. VHL is a rare genetic disease that causes tumors and cysts to grow throughout the body, putting patients at risk for benign blood vessel tumors and several cancers, including renal cell carcinoma. The approval is based on the Phase 2 study that demonstrated that treatment with Welireg was associated with an overall response rate (ORR) of 49% in patients with VHL-associated RCC. For patients with CNS hemangioblastomas and pNET, the ORR was 63% and 83%, respectively.[1] Welireg has launched and has a wholesale acquisition cost (WAC) of $26,400 for 30 days.
- **Skytrofa™ (lonapegsomatropin-tcgd):** Ascendis' Skytrofa has been approved by the FDA for the treatment of pediatric patients one year and older who weigh at least 25.4 pounds, who have growth failure due to inadequate secretion of endogenous growth hormone (GH). Skytrofa is a once-weekly subcutaneous injection. Skytrofa was approved based off an open-label, Phase 3, clinical trial that demonstrated Skytrofa once weekly was noninferior to once daily somatropin subcutaneous injection in terms of annualized height velocity at 52 weeks.[2] Skytrofa is supplied as a single-dose, dual-chamber, prefilled cartridge and a diluent for subcutaneous injection in the following strengths: 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 7.6mg, 9.1mg, 11mg and 13.3mg. The cartridges are for use only with the Skytrofa Auto-Injector, which is packaged separately. Skytrofa launch and price are pending.

- **Exkivity™ (mobocertinib):** The FDA has granted accelerated approval to Takeda's Exkivity for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Exkivity is a first-in-class oral tyrosine kinase inhibitor (TKI) whose approval represents the first oral therapy specifically designed to selectively target EGFR exon 20 insertion mutations. Exkivity was approved based on results from a Phase 1/2 study of mobocertinib which was evaluated by an independent review committee (IRC) as well as an investigator assessment. The IRC confirmed an ORR of 28% with all responses being partial responses (PRs). The investigator assessment, the confirmed ORR was 35%, with complete responses (CRs) in fewer than 1% of patients, and PRs in 34%. The median duration of response (DOR) observed with mobocertinib treatment in the study was 17.5 months by IRC and 11.2 months by investigator assessment. The confirmed disease control rate was 78% by IRC and investigator assessment.[3] Exkivity has launched with an average wholesale price (AWP) of $30,000 per 30 days.
- **Tivdak™ (tisotumab vedotin-tftv):** The FDA has granted accelerated approval of Seagen's Tivdak for treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tivdak is an antibody-drug conjugate composed of Genmab's tissue factor (TF)-directed monoclonal antibody linked to the microtubule disrupting drug monomethyl auristatin E. Tivdak was approved based on a single arm, Phase 2 innovaTV204 trial that demonstrated a 24% confirmed ORR with 7% of patients achieving complete response and 17% having partial response. The median DOR was 8.3 months.[4] Patients received Tivdak 2mg/kg intravenously once every three weeks until disease progression or unacceptable toxicity. Tivdak launch and price are pending.
- **Byooviz™ (ranibizumab-nuna):** Samsung Bioepis' Byooviz is the first FDA-approved biosimilar of Genentech's Lucentis for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization. Byooviz was approved based on a Phase 3 study comparing the safety, efficacy, pharmacokinetic and immunogenicity profiles of Byooviz with Lucentis.[5] Results were comparable between the two products. The FDA did not grant interchangeable status for Byooviz. Byooviz will launch in June 2022 with pricing to follow. Currently, there is one additional Lucentis biosimilar that is seeking FDA approval in 2022.
- **Opzelura™ (ruxolitinib) cream:** The FDA has approved Incyte's Opzelura cream for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Opzelura is the first topical formulation of a JAK inhibitor approved in the United States. Opzelura was approved based on a Phase 3 trial, TRuE-AD that evaluated safety and efficacy Opzelura compared to vehicle. Opzelura demonstrated that 53.8% of patients had a clear or almost clear Investigator's Global Assessment (IGA) Treatment Success compared to 15.1% of patients treated with vehicle. Significantly more patients treated with Opzelura experienced a clinically meaningful reduction in itch from baseline at week eight, as measured by a ≥4-point reduction in the itch Numerical Rating Scale: 52.2% compared to 15.4% of patients treated with vehicle.[6] Opzelura will have a boxed warning which is seen across the JAK class of drugs, highlighting risks of serious infections, heart attack, stroke or cardiac death. Opzelura is scheduled to launch with a WAC of $1,950 per 60-gram tube.

NEW INDICATIONS

- **Opdivo® (nivolumab):** The FDA expanded the indication of Bristol-Myers Squibb's Opdivo (nivolumab) to include adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection.
- **Jemperli® (dostarlimab-gxly):** GlaxoSmithKline (Tesaro) and AnaptysBio's Jemperli (dostarlimab-gxly) expanded the FDA indication to include the treatment of adults with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternatives.
- **Xywav® (calcium, magnesium, potassium and sodium oxybates):** The FDA has approved an additional indication for Jazz Pharmaceuticals' Xywav (calcium, magnesium, potassium and sodium oxybates) to include idiopathic hypersomnia.
- **ibsovo® (ivosidenib, formerly AG-120):** Agios Pharmaceuticals' Tibsovo was approved by the FDA to include a new indication for previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation, which is a rare type of cancer in the bile ducts in the liver.
- **Brukinsa® (zanubrutinib):** The FDA approved a new indication for Beigene USA's Brukinsa to include the treatment of adults with the rare indolent B-cell lymphoma Waldenstrom's Macroglobulinemia (WM).

SEPTEMBER NEWS

- "The FDA finalized additional questions and answers related to biosimilar development and the *Biologics Price Competition and Innovation Act* (BPCIA) and made minor revisions to several other questions within the document. With this latest update, FDA has moved five questions from the draft guidance to the final one and updated seven others. The draft guidance has also been revised and contains just one question pertaining to how sponsors can demonstrate that their proposed injectable biosimilar or interchangeable product has the same strength as the reference product. The five newly finalized questions address sponsors responsibilities related to pediatric assessments for proposed biosimilar products; the types of information are needed to support post approval manufacturing changes; and clarifying that sponsors may not seek approval for a biosimilar with a different route of administration, dosage form, or strength than the reference product. The other two newly moved questions and answers provide clarification that biosimilars may not be approved for conditions of use that have not previously been approved for the reference product and explain that sponsors should provide data and information to support the approval of a proposed biosimilar for an indication that is still covered by unexpired orphan exclusivity, though the agency will not approve said indication until the orphan exclusivity expires."[7]
- "Bluebird bio announced it completed the rolling submission of its BLA to the FDA for betibeglogene autotemcel gene therapy. The therapy, designed for patients with beta-thalassemia who require regular red blood cell transfusions, was previously granted breakthrough therapy designation for treating transfusion-dependent beta-thalassemia (TDT). If approved, beti-cel will be the first hematopoietic stem cell ex-vivo gene therapy for patients in the U.S."[8]

SPECIALTY NEW PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
ruxolitinib cream	Opzelura®	Incyte Corporation	Atopic dermatitis	Topical	September 2021
lonapegsomatropin-tcgd	Skytrofa®	Ascendis	Growth hormone deficiency (GHD)	SC	September 2021
avalglucosidase alfa-ngpt	Nexviazyme®	Sanofi-Aventis	Pompe disease	IV	August 2021
anifrolumab-fnia	Saphnelo®	AstraZeneca	Systemic lupus erythematosus (SLE)	IV	August 2021
selexipag	Uptravi®	Johnson & Johnson	Pulmonary arterial hypertension	IV	July 2021
odevixibat	Bylvay®	Albireo	Progressive familial intrahepatic cholestasis	Oral	July 2021
belumosudil	Rezurock®	Kadmon	Chronic graft-versus-host disease (cGVHD)	Oral	July 2021
allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat	StrataGraft®	Mallinckrodt	Deep partial-thickness thermal burns	Topical	June 2021
sofosbuvir/velpatasvir	Epclusa® pellets	Gilead	Hepatitis C	Oral	June 2021
aducanumab-avwa	Aduhelm®	Biogen	Alzheimer's disease	IV	June 2021
plasminogen (human-tvmh)	Ryplazim®	Prometic Life Sciences Inc	Plasminogen deficiency type 1	IV	June 2021
pegcetacoplan	Empaveli®	Apellis	Paroxysmal nocturnal hemoglobinuria	SC infusion	May 2021
ponesimod	Ponvory®	Janssen	Multiple sclerosis	Oral	March 2021
fosdenopterin	Nulibry®	Origin Biosciences (BridgeBio)	Molybdenum cofactor deficiency (MoCD) Type A	IV	February 2021
casimersen	Amondys 45®	Sarepta Therapeutics	Duchenne muscular dystrophy (DMD)	IV	February 2021
evinacumab	Evkeeza™	Regeneron	Homozygous familial hypercholesterolemia (HoFH)	IV	February 2021
voclosporin	Lupkyis™	Aurinia	Lupus nephritis	Oral	January 2021
ansuvimab-zykl	Ebanga™	Ridgeback Biotherapeutics	Treatment of Zaire ebolavirus (Ebolavirus) infection	IV	December 2020
berotralstat	Orladeyo™	BioCryst	Prevention of hereditary angioedema (HAE) attacks	Oral	December 2020
lumasiran	Oxlumo™	Alnylam	Primary hyperoxaluria type 1 (PH1)	SC	December 2020
setmelanotide	Imcivree™	Rhythm Pharmaceuticals	Certain types of genetic obesity	SC	November 2020
lonafarnib	Zokinvy™	Eiger BioPharmaceuticals	Progeria and progeroid laminopathies	Oral	November 2020
mannitol for inhalation	Bronchitol™	Chiesi Group and Pharmaxis	Cystic fibrosis	Inhaled	November 2020
remdesivir	Veklury™	Gilead	COVID-19	IV	October 2020
atoltivimab, maftivimab and odesivimab-ebgn	Inmazeb™	Regeneron	Ebola	IV	October 2020

NEW INDICATIONS FOR APPROVED SPECIALTY PRODUCTS

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION(S)	DATE APPROVED
calcium, magnesium, potassium and sodium oxybates	Xywav®	Jazz Pharmaceuticals	Idiopathic hypersomnia	August 2021
mepolizumab	Nucala®	Glaxo Smith Kline	Chronic rhinosinusitis with nasal polyps	July 2021
tacrolimus	Prograf®	Astellas Pharma	Prevent organ rejection in adult and pediatric patients receiving lung transplantation	July 2021
ravulizumab-cwvz	Ultomiris®	Alexion	Pediatric patients with paroxysmal nocturnal hemoglobinuria (PNH)	June 2021
elexacaftor, tezacaftor, and ivacaftor	Trikafta®	Vertex Pharmaceuticals	Ages 6 to 11 with at least one F508del mutation in the CFTR gene (the gene defective in CF) or a CFTR mutation that is responsive to the therapy	June 2021
ozanimod	Zeposia®	Bristol-Myers Squibb	Treatment of adults with moderately to severely active ulcerative colitis (UC)	May 2021
omalizumab	Xolair®	Genentech	New prefilled syringe for treatment of persistent asthma and chronic idiopathic urticaria	April 2021
risankizumab-rzaa	Skyrizi®	AbbVie	New autoinjector and a prefilled syringe with needle stock prevention for treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	April 2021
treprostinil	Tyvaso®	United Therapeutics Corp	Pulmonary hypertension associated with interstitial lung disease to improve exercise ability	March 2021
tocilizumab	Actemra®	Genentech	Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease	March 2021
adalimumab	Humira®	AbbVie	Moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older	February 2021
romiplostim	Nplate®	Amgen	Increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome, or HSARS)	January 2021
carglumic acid	Carbaglu®	Recordati Rare Diseases	Adjunctive therapy to standard of care for treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)	January 2021
ivacaftor	Kalydeco®	Vertex Diagnostics	Expanded population cystic fibrosis patients with additional rare CFTR mutations	December 2020
anakinra	Kineret®	Sobi	Treatment of patients with Deficiency of IL-1 Receptor Antagonist (DIRA)	December 2020
ocrelizumab	Ocrevus®	Genentech	Relapsing multiple sclerosis (RMS) and primary progressive MS (PPMS)	December 2020
tezacaftor and ivacaftor	Symdeko®	Vertical Pharmaceutical	Expanded population for the combination regimen of the cystic fibrosis transmembrane conductance regulator (CFTR) corrector and the CFTR potentiator for treatment of cystic fibrosis patient	December 2020
belimumab	Benlysta®	GlaxoSmithKline	Lupus nephritis	December 2020
rilonacept	Arcalyst®	Regeneron and Kiniksa	Deficiency of the interleukin-1 receptor antagonist (DIRA)	December 2020
pitolisant	Wakix®	Harmony Biosciences	Cataplexy in adults with narcolepsy	October 2020
ravulizumab-cwvz	Ultomiris®	Alexion	Higher concentrations formula for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS)	October 2020

ONCOLOGY PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	DATE APPROVED
tisotumab vedotin-tftv	Tivdak®	Seagen	Certain forms of cervical cancer	IV	September 2021
mobocertinib	Exkivity®	Takeda Pharmaceuticals	Metastatic non-small cell lung cancer (mNSCLC)	Oral	September 2021
belzutifan	Welireg®	Merck	Von Hippel-Lindau (VHL) disease	Oral	August 2021
asparaginase erwinia chrysanthemi-rywn	Rylaze®	Jazz Pharmaceuticals	Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)	IV	June 2021
sotorasib	Lumakras®	Amgen	Certain forms of lung cancer	Oral	May 2021
infigratinib	Truseltiq®	QED Therapeutics (BridgeBio)	Certain forms of cholangiocarcinoma	Oral	May 2021
leuprolide mesylate 50mg depot	Camcevi® 42mg	Foresee Pharmaceuticals	Palliative treatment of advanced prostate cancer	Injectable suspension	May 2021
amivantamab-vmjw	Rybrevant™	Johnson & Johnson	Certain forms of non-small cell lung cancer	IV	May 2021
dostarlimab-gxly	Jemperli™	GSK	Endometrial cancer	IV	April 2021
loncastuximab tesirine-lpyl	Zynlonta™	ADC Therapeutics	R/R diffuse large B-cell lymphoma (DLBCL)	IV	April 2021
tivozanib	Fotivda™	Aveo Oncology	Relapsed or refractory renal cell carcinoma (RCC)	Oral	March 2021
melphalan flufenamide	Pepaxto™	Oncopeptides	Certain forms of relapsed refractory multiple myeloma (RRMM)	IV	February 2021
trilaciclib	Cosela™	G1 Therapeutics	Myelopreservation	IV	February 2021
umbralisib	Ukoniq™	TG Therapeutics	Marginal zone lymphoma (MZL)	Oral	February 2021
tepotinib	Tepmetko®	EMD Serono	Certain forms of metastatic non-small cell lung cancer (NSCLC)	Oral	February 2021
relugolix	Orgovyx™	Myovant	Prostate cancer	Oral	December 2020
margetuximab-cmkb	Margenza™	MacroGenics	Breast cancer	IV	December 2020
naxitamab-gqgk	Danyelza™	Y-mAbs	Relapsed or refractory high-risk neuroblastoma	IV	November 2020

NEW INDICATIONS FOR APPROVED ONCOLOGY DRUGS

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION	DATE APPROVED
ivosidenib	Tibsovo®	Agios Pharmaceuticals	Locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation, which is a rare type of cancer in the bile ducts in the liver	September 2021
zanubrutinib	Brukinsa®	Beigene USA	Rare indolent B-cell lymphoma Waldenstrom's Macroglobulinemia (WM)	August 2021
nivolumab	Opdivo®	Bristol-Myers Squibb	Certain forms of urothelial carcinoma (UC)	August 2021
pembrolizumab	Keytruda®	Merck	First-line treatment of patients with renal cell carcinoma	August 2021
dostarlimab-gxly	Jemperli™	GSK	Certain forms of solid tumors	August 2021
pembrolizumab	Keytruda®	Merck	Certain forms of triple negative breast cancer (TNBC) in combination with chemotherapy	July 2021
pembrolizumab and lenvatinib	Keytruda® and Lenvima®	Merck and Eisai	Certain forms of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)	July 2021
enfortumab vedotin-ejfy	Padcev®	Astellas and Seagen	Treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and are ineligible for cisplatin	July 2021
daratumumab and hyaluronidase-fihj	Darzalex Faspro®	Janssen Biotech and Genmab	Combination regimen with pomalidomide and dexamethasone (d-Pd) for treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy	July 2021
avapritinib	Ayvakit®	Blueprint Medicines Corp	Adults with advanced systemic mastocytosis (SM)	June 2021
pembrolizumab	Keytruda®	Merck	Certain combination for first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma	May 2021
nivolumab	Opdivo®	Bristol-Myers Squibb	Adjuvant treatment of patients with resected esophageal or gastroesophageal junction (GEJ) cancer after neoadjuvant chemoradiation therapy (CRT)	May 2021
nivolumab	Opdivo®	Bristol-Myers Squibb	Certain forms of advanced or metastatic gastric cancer, gastroesophageal junction cancer (GEJC) or esophageal adenocarcinoma (EAC)	May 2021
lorlatinib	Lorbrena®	Pfizer	Treatment of previously untreated advanced ALK-positive non-small cell lung cancer (NSCLC)	April 2021
sacituzumab govitecan-hziy	Trodelvy®	Gilead Sciences	Triple-negative breast cancer that has spread to other parts of the body	April 2021
nivolumab	Opdivo®	Bristol-Myers Squibb	Initial treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma	April 2021
pembrolizumab	Keytruda®	Merck	Certain forms of locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction (GEJ)	March 2021
axicabtagene ciloleucel	Yescarta®	Kite Pharm	Relapsed or refractory follicular lymphoma and marginal zone lymphoma after two or more prior lines of systemic therapy	March 2021

continued

NEW INDICATIONS FOR APPROVED ONCOLOGY DRUGS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION	DATE APPROVED
cytarabine and daunorubicin	Vyxeos®	Jazz Pharmaceuticals	Certain forms of acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)	March 2021
sacituzumab govitecan-hziy	Trodelvy®	Gilead Sciences	Adult patients with locally advanced or metastatic urothelial cancer (UC)	March 2021
isatuximab-irfc	Sarclisa®	Sanofi PS	Multiple myeloma who have received at least one prior therapy	March 2021
cemiplimab-rwlc	Libtayo®	Regeneron	Monotherapy for treatment of first line locally advanced or metastatic non-small cell lung cancer (NSCLC) with PD-L1 expression	February 2021
cemiplimab-rwlc	Libtayo®	Regeneron	Treatment of locally advanced or metastatic basal cell carcinoma (BCC)	February 2021
pralsetinib	Gavreto®	Blueprint medicines	Treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancers.	February 2021
darolutamide	Nubeqa®	Bayer Pharmaceutical	Non-metastatic castration-dependent prostate cancer	January 2021
daratumumab and hyaluronidase-fihj	Darzalex Faspro®	Janssen Biotech and Genmab	Light chain (AL) amyloidosis	January 2021
fam-trastuzumab deruxtecan-nxki	Enhertu®	Daiichi Pharmaceutical	Patients with HER2-positive metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma	January 2021
cabozantinib	Cabometyx®	Exelixis	In combination with the immuno-oncologic nivolumab (Bristol-Myers Squibb's Opdivo) for first-line treatment of advanced renal cell carcinoma (RCC)	January 2021
nivolumab	Opdivo®	Bristol-Myers Squibb	In combination with cabozantinib (Exelixis' Cabometyx) for first-line treatment of advanced renal cell carcinoma (RCC)	January 2021
crizotinib	Xalkori®	Pfizer	Pediatric patients with certain forms of relapsed or refractory systemic anaplastic large cell lymphoma	January 2021
selinexor	Xpovio®	Karyopharm	Treatment of patients with multiple myeloma after at least one prior line of therapy	December 2020
osimertinib	Tagrisso®	AstraZeneca	Adjuvant treatment of patients with early-stage (IB, II and IIIA) epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after complete tumor resection with curative intent	December 2020
ponatinib	Iclusig®	Takeda Pharmaceuticals	Chronic-phase (CP) chronic myeloid leukemia (CML) with resistance	December 2020
durvalumab	Imfinzi®	AstraZeneca	New four-week, fixed-dose regimen for the PD-L1 inhibitor immuno-oncologic, consistent with approved dosing in extensive-stage small cell lung cancer (ES-SCLC), for Imfinzi's approved indications in urothelial cancer and non-small cell lung cancer (NSCLC)	November 2020
pembrolizumab	Keytruda®	Merck	In combination with chemotherapy for treatment of patients with locally recurrent unresectable or metastatic triple negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10)	November 2020
pembrolizumab	Keytruda®	Merck	Monotherapy for treatment of adults with relapsed or refractory classical Hodgkin lymphoma (cHL)	October 2020
nivolumab and ipilimumab	Opdivo® and Yervoy®	Bristol-Myers Squibb	First line treatment for malignant pleural mesothelioma	October 2020

BIOSIMILAR PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	REFERENCE PRODUCT	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
ranibizumab-nuna (SB11)	Byooviz™	Lucentis® biosimilar	Samsung Bioepis	Age related macular degeneration	Injection into the eye	September 2021
insulin glargine-yfgn *First interchangeable status for Lantus*	Semglee™	Lantus®	Mylan and Biocon	Diabetes	SC	July 2021
rituximab-arrx	Riabni™	Rituxan®	Amgen	Oncology	IV	December 2020

SPECIALTY PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
CPP-1X/sul (eflornithine and sulindac)	N/A	Cancer Prevention Pharmaceuticals	Familial adenomatous polyposis (FAP)	Oral	Delayed
donislecel	Lantidra®	CellTrans	Brittle type 1 diabetes	IV	Delayed
abrocitinib	N/A	Pfizer And Lilly	Atopic dermatitis	Oral	Delayed
SH-111	N/A	Shorla Pharma	Pediatric patients with T-cell leukemia	IV	Delayed
inolimomab	Leukotac®	Farmaceutici Spa	Steroid-refractory acute graft-versus-host disease	IV	2H2021
tanezumab	N/A	Pfizer And Lilly	Osteoarthritis	SC	3Q2021
maralixibat	N/A	Mirum Pharmaceuticals	Alagille syndrome (ALGS)	Oral	September 2021
budesonide	Nefecon®	Calliditas Therapeutics	Nephropathy	Oral	September 2021
triamcinolone acetonide	Xipere®	Clearside Biomedical and Bausch + Lomb	Macular edema associated with uveitis	Suspension for suprachoroidal injection	October 2021
avacopan	Vynpenta®	Chemocentryx	ANCA-associated vasculitis	Oral	October 2021
somatrogon	N/A	Pfizer	Growth hormone deficiency	SC	October 2021
FT218 (sodium oxybate, controlled release)	N/A	Avadel Pharmaceuticals	Narcolepsy	Oral	October 2021
bimekizumab	N/A	UCB Pharma	Psoriasis	SC	October 2021
narsoplimab	N/A	Omeros	Hematopoietic stem cell transplant-associated thrombotic microangiopathy	IV	October 2021
ranibizumab port delivery system	N/A	Genentech	Age-related macular degeneration	Ophthalmic	October 2021
vosoritide	N/A	BioMarin	Achondroplasia	SC	November 2021
sodium thiosulfate, STS	Pedmark	Fennec Pharmaceuticals	Prevention of ototoxicity induced by cisplatin	IV	November 2021
ropeginterferon alfa-2b	N/A	PharmaEssentia	Polycythemia vera (PV)	SC	November 2021
plinabulin	N/A	BeyondSpring	Neutropenia	IV	November 2021
palovarotene	N/A	Ipsen	Fibrodysplasia ossificans progressiva (FOP)	Oral	November 2021

continued

SPECIALTY PIPELINE *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
pacritinib	N/A	CTI BioPharma	Myelofibrosis patients with severe thrombocytopenia	Oral	November 2021
oleogel-S10	Filsuvez®	Amryt Pharma	Dystrophic epidermolysis bullosa	Topical	November 2021
sirolimus albumin-bound nanoparticles for injectable suspension	Fyarro®	Aadi Bioscience	Metastatic or locally advanced malignant perivascular epithelioid cell tumor (PEComa)	IV	November 2021
LIQ861 (treprostinil for inhalation)	N/A	Liquidia	Pulmonary arterial hypertension	Inhaled dry powder	November 2021
efgartigimod	N/A	Argenx	Generalized myasthenia gravis	IV	December 2021
balstilimab	N/A	Agenus	Recurrent or metastatic cervical cancer	IV	December 2021
LV-101 (carbetocin)	N/A	Levo Therapeutics, Inc.	Hyperphagia and behavioral distress	Internasal	December 2021
levoketoconazole	Recorlev®	Strongbridge Biopharma	Cushing's syndrome	Oral	January 2022
mavacamten	N/A	Bristol-Myers Squibb	Symptomatic obstructive hypertrophic cardiomyopathy (oHCM)	Oral	January 2022
inclisiran	Leqvio®	Novartis	Hyperlipidemia	SC	January 2022
faricimab	N/A	Genentech	Diabetic macular edema	Intravitreal	January 2022
tezepelumab	N/A	AstraZeneca and Amgen	Asthma across phenotypes	SC	January 2022
bardoxolone	N/A	Reata Pharmaceuticals	Autosomal dominant polycystic kidney disease	Oral	February 2022
GC5107 (immune globulin intravenous [human], 10% liquid)	N/A	GC Pharma	Primary humoral immunodeficiency	IV	February 2022
mitapivat	N/A	Agios Pharmaceuticals	Pyruvate kinase (PK) deficiency	Oral	February 2022
sintilimab	N/A	Innovent Biologics and Lilly	Nonsquamous non-small cell lung cancer (NSCLC)	IV	March 2022
vadadustat	N/A	Akebia Therapeutics	Anemia due to chronic kidney disease (CKD)	Oral	March 2022
ublituximab	N/A	TG Therapeutics	Certain forms of chronic lymphocytic leukemia (CLL)	IV	March 2022
vutrisiran	N/A	Alnylam Pharmaceuticals	Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis	SC	April 2022
surufatinib	N/A	Hutchmed	Pancreatic and extra-pancreatic neuroendocrine tumor	Oral	April 2022
trientine tetrahydrochloride	N/A	Orphalan	Wilson's disease	Oral	May 2022
tapinarof	N/A	Dermavant (Roivant)	Plaque psoriasis	Topical	May 2022
tislelizumab	N/A	BeiGene and Novartis	Certain forms of esophageal squamous cell carcinoma (ESCC)	Injection	July 2022

* Anticipated approval dates are predictions made by Prime Therapeutics based on industry information.

BIOSIMILAR PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
Oncology					
MYL-1402O	N/A (Avastin® biosimilar)	Mylan NV and Biocon Ltd.	Oncology	IV	2021
SB8	N/A (Avastin® biosimilar)	Samsung Bioepis and Merck	Oncology	IV	2021
FKB238	N/A (Avastin® biosimilar)	Centus Biotherapeutics	Oncology	IV	2021
BAT-1706	N/A (Avastin® biosimilar)	Bio-thera solutions	Oncology	IV	November 2021
BEVZ92	N/A (Avastin® biosimilar)	mAbxience, Insud Pharma; Amneal	Oncology	IV	2Q2022
Blood modifiers					
MSB11455	Stimufend® (Neulasta® biosimilar)	Fresenius Kabi	Neutropenia	IV or SC	2021
TPI-120	N/A (Neulasta® biosimilar)	Amneal and Kashiv (Adello)	Neutropenia	IV or SC	2022
lupifil-p	N/A (Neulasta® biosimilar)	Lupin	Neutropenia	SC	April 2022
filgrastim kashiv	N/A (Neupogen® biosimilar)	Adello Biologics	Neutropenia	IV	2021
TX-01	N/A (Neupogen® biosimilar)	Tanvex BioPharma	Neutropenia	SC	2021
Ophthalmology					
FYB201	N/A (Lucentis® biosimilar)	Coheres biosciences/bioeq	Age related macular degeneration	Injection into the eye	2022
Autoimmune					
AVT02	N/A (Humira® biosimilar)	Alvotech	Autoimmune	SC	2021
CHS-1420	N/A (Humira® biosimilar)	Coherus	Autoimmune	SC	December 2021
CT-P17	N/A (Humira® biosimilar)	Celltrion	Autoimmune	SC	4Q2021

FDA APPROVED GENE/CELL THERAPY NEW PRODUCT APPROVALS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
idecabtagene vicleucel (bb2121, ide-cel)	Abecma™	Bristol-Myers Squibb and bluebird bio	Multiple myeloma	CAR-T	March 2021
lisocabtagene maraleucel (liso-cel)	Breyanzi™	Bristol-Myers Squibb	R/R large B cell lymphoma	IV	February 2021
brexucabtagene autoleucel	Tecartus™	Kite	Mantle cell lymphoma	CAR T-cell therapy	July 2020
onasemnogene abeparvovec-xioi	Zolgensma™	AveXis	Spinal Muscular Atrophy	IV	May 2019
voretigene neparvovec-rzyl	Luxturna®	Spark Therapeutics	Biallelic RPE65 mutation-associated retinal dystrophy	Subretinal injection	December 2017
axicabtagene ciloleucel	Yescarta®	Kite	Large B-cell lymphoma	IV	October 2017
tisagenlecleucel	Kymriah®	Novartis	Acute lymphoblastic leukemia	IV	August 2017

GENE/CELL THERAPY 2021 PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE
RVT-802	N/A	Enzyvant	Pediatric congenital athymia	IV	October 2021
ciltacabtagene autoleucel (cilta-cel)	N/A	Johnson & Johnson (Janssen)	Relapsed and refractory multiple myeloma	CAR-T	November 2021
betibeglogene autotemcel	Lentiglobin-TDT™	Bluebird Bio	Transfusion-dependent β-thalassemia	IV	2022

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