

Specialty Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

March 2020

NEW DRUG INFORMATION

- **Sarclisa™ (isatuximab):** The U.S. Food and Drug Administration (FDA) approved Sanofi's Sarclisa for relapsed/refractory multiple myeloma (RRMM) in combination with pomalidomide and dexamethasone (pom-dex). Patients who are eligible to take Sarclisa must have previously received at least two prior therapies including Celgene's Revlimid® (lenalidomide) and a proteasome inhibitor. Sarclisa is an intravenous 10mg/kg injection, administered in combination with pom-dex every week for four weeks and then once every two weeks, until disease progression or unacceptable toxicity. The FDA approved Sarclisa based on its only Phase 3 trial (ICARIA-MM), which demonstrated that Sarclisa in combination with pom-dex significantly reduced the risk of disease progression or death by 40% compared to pom-dex alone. ICARIA-MM also demonstrated Sarclisa added to pom-dex improved progression free survival with median of 11.53 months, compared to 6.47 months with pom-dex alone.¹ Sarclisa wholesale acquisition cost (WAC) is \$650 per 100mg vial and \$3,250 per 500mg vial, averaging \$5,200 per infusion for a patient weighing 70-80kg.² Sanofi is planning Sarclisa launch shortly.
- **Isturisa™ (osilodrostat):** Recordati's Isturisa (submitted by Novartis) has been approved by the FDA as a cortisol synthesis inhibitor of 11-beta-hydroxylase for treatment of endogenous Cushing's syndrome. Isturisa is indicated for patients whom pituitary surgery is not an option or patients where surgery was unsuccessful. The FDA's approval is based on a Phase 3 study that demonstrated patients treated with Isturisa maintained a normal mean urinary free cortisol (mUFC) at higher proportions than those treated with placebo (86% vs. 29%).³ The FDA has awarded Isturisa with seven years of market exclusivity. Recordati is planning on launching Isturisa second or third quarter of 2020 with pricing to follow.

NEW INDICATIONS

- **Ofev® (nintedanib):** The FDA granted approval of Boehringer Ingelheim's Ofev to treat patients with chronic fibrosing interstitial lung diseases (ILD) with a progressive phenotype. Ofev is also indicated for treatment of idiopathic pulmonary fibrosis.

MARCH NEWS

- “The FDA gave an experimental medicine called remdesivir to treat COVID-19 what’s called orphan drug status. To qualify for an orphan designation, drug companies must show that their product will treat a population of fewer than 200,000 patients or that it would be unprofitable. With more than 52,000 confirmed U.S. cases of COVID-19 reported, the illness is under the technical threshold for a rare disease. But cases are rising quickly and it seems inevitable that they will surpass 200,000. Remdesivir is an intravenous, antiviral medicine that is being studied in clinical trials around the world as a possible treatment for COVID-19.”⁴
- “Novo Nordisk announced it would stop treating patients enrolled in clinical trials evaluating an investigational hemophilia drug it developed after three of those receiving the drug reported “thrombotic events.” In the meantime, the company is halting recruitment for the trials—two Phase 3 studies and one Phase 2 study—and stopping treatment of the 109 patients currently receiving concizumab. The affected trials enrolled patients with the two most common forms of hemophilia, A and B, which are caused by a lack or decrease in different clotting factors.”⁵
- “AstraZeneca’s badly damaged CTLA-4 strategy on the immuno-oncology front has taken another hit. The pharma giant put out word that the second leg of its CASPIAN study failed to demonstrate a significantly improved rate of overall survival among patients given a triplet of Imfinzi, standard of care and the CTLA-4 tremelimumab among frontline small cell lung cancer patients with extensive disease.”⁶
- “The medical journal the Lancet published an article highlighting the potential of hydroxychloroquine, citing early positive preliminary outcomes from a small Chinese study. The results are not conclusive in terms of clinical management due to the study’s small sample size, the author warned, adding that published data are still to come. The data are now available, and the findings are not positive,” noted Evercore ISI analyst Umer Raffat in a note.”⁷
- “Bluebird Bio’s ultra-pricey flagship gene therapy Zynteglo was finally cleared for launch in Germany just weeks ago. Now, with a manufacturing green light in hand, Bluebird is hoping to make good on its commercial hopes in the coming months.”⁸
- “Cell therapy trials at Bristol Myers Squibb are grinding to a halt as the pharma giant temporarily suspends all screening, enrollment and apheresis. As for its other clinical trials, no new sites will be activated until April 13, 2020, although existing sites can continue to recruit new patients — contrasting with Eli Lilly’s strategy to pause enrollment for most studies. Bristol Myers emphasized that the new policies, designed to ensure safety of patients, staff and investigators, do not impact the ongoing BLA activities for ide-cel (bb2121) or liso-cel (JCAR017). The timely approval of these two CAR-T therapies are imperative for Celgene stockholders to claim the \$9 CVR tucked into the \$74 billion acquisition. The FDA is supposed to hand down its decision on the third component of the CVR, ozanimod, March 25, 2020.”⁹

SPECIALTY NEW PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
osilodrostat	Isturisa™	Recordati	Cushing's syndrome	Oral	March 2020
peanut (Arachis hypogaea) allergen powder-dnfp	Palforzia™	Aimmune Therapeutics	Peanut allergy	Oral	February 2020
octreotide acetate	Bynfezia pen™	Sun Pharmaceuticals	Acromegaly	SC	February 2020
teprotumumab- trbw	Tepezza™	Horizon	Thyroid eye disease	IV	January 2020
golodirsen	Vyondys 53™	Sarepta Therapeutics	Duchenne muscular dystrophy (DMD)	IV	December 2019
methotrexate	Reditrex™	Cumberland Pharmaceuticals	Rheumatoid arthritis/ psoriasis	SC	December 2019
voxelotor	Oxbryta™	Global Blood Therapeutics	Sickle cell disease (SCD)	Oral	November 2019
riluzole	Exservan™	Aquestive	Adjunctive therapy for the treatment of ALS	Oral	November 2019
givosiran	Givlaari™	Alnylam	Acute hepatic porphyria (AHP)	SC	November 2019
crizanlizumab-tmca	Adakveo™	Novartis	Reduce the frequency of vaso-occlusive crises (VOCs) with sickle cell disease	IV	November 2019
luspatercept-aamt	Reblozyl™	Celgene Corp	Beta-thalassemia-associated anemia who require red blood cell transfusions	SC	November 2019
elexacaftor/ivacaftor/tezacaftor	Trikafta™	Vertex	Cystic fibrosis	Oral	October 2019
diroximel fumarate	Vumerity™	Alkermes and Biogen	Relapsing forms of MS	Oral	October 2019
afamelanotide	Scenesse™	Clinuvel Pharmaceuticals	Erythropoietic protoporphyria	SC	October 2019
brolocizumab-dbll	Beovu™	Novartis	Wet age-related macular degeneration	Intravitreal injection	October 2019
teriparatide	Bonsity™	Pfenex and Alvogen	Osteoporosis	SC	October 2019
ledipasvir and sofosbuvir pellets	Harvoni®	Gilead	Hepatitis C	Oral	September 2019
sofosbuvir pellets	Sovaldi®	Gilead	Hepatitis C	Oral	September 2019
lefamulin	Xenleta™	Nabriva	Community acquired bacterial pneumonia	Oral and IV	August 2019
upadacitinb	Rinvoq™	Abbvie	Rheumatoid arthritis	Oral	August 2019
pretomanid	Pretomanid™	Global Alliance for TB Drug Development	Tuberculosis	Oral	August 2019
immune globulin subcutaneous, human-klhw	Xembify™	Grifols SA	Primary humoral immunodeficiency	SC	July 2019
bremelanotide	Vyleesi™	AMAG Pharmaceuticals and Palatin Technologies	Generalized hypoactive sexual desire disorder	SC	June 2019
onasemnogene abeparvovec-xioi	Zolgensma™	Novartis/Avexis	Spinal muscular atrophy (SMA) in pediatrics < 2 years of age	IV	May 2019

continued

SPECIALTY NEW PRODUCT APPROVALS IN THE PAST TWELVE MONTHS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
amifampridine	Ruzurgi™	Jacobus Pharmaceutical Company	Lambert-Eaton myasthenic syndrome (LEMS)	Oral	May 2019
tafamidis meglumine	Vyndaqel™	Pfizer	Heart disease caused by transthyretin mediated amyloidosis (ATTR-CM)	Oral	May 2019
tafamidis	Vydamax™	Pfizer	ATTR-CM	Oral	May 2019
risankizumab-rzaa	Skyrizi®	Abbvie	Plaque psoriasis	SC	April 2019
romosozumab-aqqg	Evenity®	Amgen and UCB	Osteoporosis	SC	April 2019
immune globulin intravenous human-slra)	Asceniv®	ADMA Biologics	Primary humoral immunodeficiency	IV	April 2019

NEW INDICATIONS FOR APPROVED SPECIALTY PRODUCTS

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION(S)	DATE APPROVED
nintedanib	Ofev®	Boehringer Ingelheim	Fibrosing interstitial lung diseases (ILD) with a progressive phenotype	March 2020
benralizumab	Fasenra®	AstraZeneca	Prefilled auto-injector administration in a non-clinical setting for treatment of severe eosinophilic asthma	October 2019
ustekinumab	Stelara®	Johnson & Johnson	Moderately to severely active ulcerative colitis in adults	October 2019
ravulizumab-cwvz	Ultomiris®	Alexion Pharmaceuticals	Atypical hemolytic uremic syndrome (aHUS)	October 2019
von Willebrand factor/coagulation factor VIII complex	Wilate®	Octapharma	Hemophilia A for routine prophylaxis	October 2019
emtricitabine/tenofovir alafenamide	Descovy®	Gilead	HIV pre-exposure prophylaxis (PrEP)	October 2019
glecaprevir and pibrentasvir	Mavyret®	AbbVie	Pediatric patients 12 years and above	September 2019
ledipasvir and sofosbuvir pellets	Harvoni®	Gilead	Pediatric patients 3 years and above	September 2019
sofosbuvir pellets	Sovaldi®	Gilead	Pediatric patients 3 years and above	September 2019
mepolizumab	Nucala®	GlaxoSmithKline	Pediatric patients 6-11 years	September 2019
nintedanib	Ofev®	Boehringer Ingelheim	Systemic sclerosis-associated interstitial lung disease	September 2019
ixekizumab	Taltz®	Lilly	Active ankylosing spondylitis	August 2019
bedaquiline	Sirturo®	Johnson & Johnson	Pediatric patients 12 years and older	August 2019
apremilast	Otezla®	Celgene Corp	Oral ulcers associated with Behcet's disease	July 2019
deflazacort	Emflaza®	PTC Therapeutics	Expanded age range for the corticosteroid to include pediatric patients with Duchenne muscular dystrophy who are between two and five years old	June 2019

continued

NEW INDICATIONS FOR APPROVED SPECIALTY PRODUCTS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION(S)	DATE APPROVED
tezacaftor/ivacaftor	Symdeko®	Vertex Pharmaceuticals	CF patients ages 6 and older who are homozygous for the F508del mutation or who have at least 1 mutation in the CF transmembrane conductance regulator gene that is responsive to Symdeko	June 2019
dupilumab	Dupixent®	Regeneron/Sanofi	Severe chronic rhinosinusitis with nasal polyps	June 2019
avatrombopag	Doptelet®	Dova	Immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	June 2019
eculizumab	Soliris®	Alexion Pharmaceuticals	Neuromyelitis optica spectrum disorder (NMOSD)	June 2019
ruxolitinib	Jakafi®	Incyte	Steroid-refractory acute graft-versus-host disease (GVHD)	May 2019
teduglutide, rDNA origin	Gattex®	Shire	Pediatric patients aged 1 to 17 years old with short bowel syndrome (SBS)	May 2019
aflibercept	Eylea®	Regeneron	Diabetic retinopathy	May 2019
ivacaftor	Kalydeco®	Vertex Pharmaceuticals	Children as young as six months old with cystic fibrosis (CF) who have at least one mutation in the CFTR gene	May 2019
glecaprevir and pibrentasvir	Mavyret®	AbbVie	Treatment of six genotypes of hepatitis C virus (HCV) in children ages 12 to 17	May 2019
belimumab	Benlysta®	GSK	Children aged 5 years and older with systemic lupus erythematosus (SLE)	May 2019
certolizumab pegol	Cimzia®	UCB	Radiographic axial spondyloarthritis (nr-axSpA)	April 2019

ONCOLOGY PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	DATE APPROVED
isatuximab	Sarclisa™	Sanofi	Multiple myeloma	IV	February 2020
tazemetostat	Tazverik™	Epizyme	Epithelioid sarcoma	Oral	January 2020
avapritinib	Ayvakit™	Blueprint Medicines	Unresectable or metastatic gastrointestinal stromal tumor (GIST)	Oral	January 2020
fam-trastuzumab deruxtecan-nxki	Enhertu™	Daiichi Sankyo and AstraZeneca	Breast cancer	IV	December 2019
enfortumab vedotin-ejfv	Padcev™	Astellas and Seattle Genetics	Advanced/metastatic/ urothelial cancer	IV	December 2019
zanubrutinib	Brukinsa™	BeiGene	Mantle cell lymphoma	Oral	November 2019
pemetrexed	Pemfexy™	Eagle Pharmaceuticals	In combination with cisplatin or as a single agent for certain types of cancer	IV	October 2019
bortezomib	Bortezomib™	Dr. Reddy's	Multiple Myeloma; Non-Hodgkin's Lymphoma; Mantle cell lymphoma	IV or SC	October 2019
eedratinib	Inrebic™	Celgene	Myelofibrosis	Oral	August 2019
entrectinib	Rozlytrek™	Genentech	ROS1-positive non-small cell lung cancer (NSCLC) and certain NTRK gene fusion cancers	Oral	August 2019
pexidartinib	Turalio™	Daiichi Sankyo	Symptomatic tenosynovial giant cell tumor	Oral	August 2019
darolutamide	Nubeqa™	Bayer and Orion	Non-metastatic castration-resistant prostate cancer	Oral	July 2019
selinexor	Xpovio™	Karyopharm	Multiple myeloma	Oral	July 2019
polatuzumab vedotin-piiq	Polivy™	Genentech	Relapsed or refractory diffuse large B-cell lymphoma	IV	June 2019
fulvestrant	Fulvestrant™	Kabi USA	Breast cancer	IV	May 2019
alpelisib	Piqray™	Novartis	Breast cancer	Oral	May 2019
erdafitinib	Balversa™	Janssen	Locally advanced or metastatic bladder cancer	Oral	April 2019

NEW INDICATIONS FOR APPROVED ONCOLOGY DRUGS

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION	DATE APPROVED
pembrolizumab	Keytruda®	Merck	Bacillus Calmette-Guerin (BCG)- non-muscle invasive bladder cancer (NMIBC)	January 2020
enzalutamide	Xtandi®	Pfizer/Astellas Pharma	Metastatic hormone-sensitive prostate cancer (mHSPC)	December 2019
atezolizumab	Tecentriq®	Genentech / Roche	Metastatic non-small cell lung cancer (NSCLC)	December 2019
olaparib	Lynparza®	AstraZeneca	Certain forms of advanced cancer	December 2019
acalabrutinib	Calquence®	AstraZeneca	Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	November 2019
niraparib	Zejula®	GSK	Certain forms of ovarian, fallopian tube, or peritoneal cancer	October 2019
neratinib	Nerlynx®	Puma	Certain forms of breast cancer	October 2019
rituximab	Rituxan®	Genentech /Roche	Granulomatosis with polyangiitis and microscopic polyangiitis in children 2 years of age and older	October 2019
pembrolizumab	Keytruda®	Merck	Certain forms of metastatic head and neck squamous cell carcinoma	October 2019
daratumumab	Darzalex®	Johnson & Johnson	Certain forms of multiple myeloma	September 2019
apalutamide	Erleada®	Janssen	Metastatic castration-sensitive prostate cancer	September 2019
pembrolizumab and lenvatinib	Keytruda® and Lenvima®	Merck and Eisai	Certain forms of advanced endometrial carcinoma	September 2019
pembrolizumab	Keytruda®	Merck	Certain types of squamous cell carcinoma of the esophagus	August 2019
lenalidomide	Revlimid®	Celgene	In combination with rituximab for follicular lymphoma or marginal zone lymphoma	June 2019
rituximab-abbs	Truxima®	Celltrion	CD20-positive non-Hodgkin's lymphoma	June 2019
ado-trastuzumab emtansine	Kadcyla®	Genentech/ Roche	HER2+ early breast cancer	June 2019
daratumumab	Darzalex®	Janssen	In combination with lenalidomide and dexamethasone for multiple myeloma	June 2019
pembrolizumab	Keytruda®	Merck	Head and neck squamous cell carcinoma	June 2019
ramucirumab	Cyramza®	Eli Lilly	Hepatocellular carcinoma (HCC)	May 2019
venetoclax	Venclexta®	Genentech and Abbvie	Untreated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	May 2019
ivosidenib	Tibsovo®	Agios	Individuals aged 75 years or older with newly diagnosed AML who have isocitrate dehydrogenase-1 (IDH1) mutations as detected by an FDA-approved test or are ineligible for intensive induction chemotherapy.	May 2019
avelumab	Bavencio®	EMD Serono	Combination with PF Prism CV's Inlyta® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma (RCC).	May 2019

continued

NEW INDICATIONS FOR APPROVED ONCOLOGY DRUGS *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	NEW INDICATION	DATE APPROVED
pembrolizumab	Keytruda®	Merck	Patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation along with metastatic NSCLC patients, the PD-L1 threshold is now set at a tumor proportion score (TPS) of 1% or higher	April 2019
pembrolizumab	Keytruda®	Merck	Renal cell carcinoma	April 2019
albociclib	Ibrance®	Pfizer	Breast cancer in males	April 2019
ivosidenib	Tibsovo®	Agios Pharmaceuticals Inc	Acute myeloid leukemia (AML) for patients who are at least 75 years old or have comorbidities	April 2019
erdafitinib	Balversa®	Janssen Pharmaceuticals Companies	Urothelial carcinoma	April 2019

continued

BIOSIMILAR PRODUCT APPROVALS IN THE PAST TWELVE MONTHS

GENERIC NAME	BRAND NAME	REFERENCE PRODUCT	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
infliximab-axxq	Avsola™	Remicade®	Janssen	Crohn's disease, pediatric Crohn's, ulcerative colitis, Rheumatoid Arthritis in combination with methotrexate, Psoriatic Arthritis	IV	December 2019
adalimumab-afzb	Abrilada™	Humira®	Pfizer	Autoimmune	SC	November 2019
pegfilgrastim-bmez	Ziextenzo™	Neulasta®	Sandoz	Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drug	IV	November 2019
adalimumab-bwwd	Hadlima™	Humira®	Samsung Bioepis/ Merck	Certain forms of: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis	SC	July 2019
rituximab-pvvr	Ruxience™	Rituxan®	Pfizer	Certain forms of Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Granulomatosis with Polyangiitis	IV	July 2019
bevacuzynav-bvzr	Zirabev™	Avastin®	Pfizer	Certain forms of cancer	IV	July 2019
trastuzumab-anns	Kanjinti™	Herceptin®	Amgen/ Allergan	HER2-positive breast cancer or gastric or gastroesophageal junction cancer	IV	June 2019
etanercept-ykro	Eticovo®	Enbrel®	Samsung Bioepis	Rheumatoid Arthritis; Polyarticular Juvenile Idiopathic Arthritis Psoriatic Arthritis; Ankylosing Spondylitis; Plaque Psoriasis	SC	April 2019

SPECIALTY PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
ozanimod	N/A	Celgene Corp	MS	Oral	March 2020
HTX-011 (bupivacaine and meloxicam)	N/A	Heron Therapeutics	Pain	Injectable	March 2020
UGN-101 (mitomycin gel)	N/A	UroGen Pharma	Urothelial Cancer	Topical	April 2020
trastuzumab deruxtecan	N/A	Daiichi Sankyo and AstraZeneca	HER2 expressing cancers	IV	April 2020
treprostinil for infusion with PatchPump device	Trevyent®	SteadyMed	Drug/Device for PAH	SC or IV	April 2020
selumetinib	N/A	Merck and AstraZeneca	Neurofibromatosis type 1 (NF1) and symptomatic, inoperable plexiform neurofibromas (PNs)	Oral	May 2020
APL-130277 (apomorphine)	N/A	Sunovion	Parkinson's disease	Sublingual film	May 2020
risdiplam	N/A	Genentech	Spinal muscular atrophy	Oral	May 2020
nadofaragene firadenovec	N/A	FerGene	Non-muscle invasive bladder cancer	IV	May 2020
pemigatinib	N/A	Incyte Corp.	Cholangiocarcinoma	Oral	May 2020
inebilizumab	N/A	Viela Bio	Neuromyelitis optica spectrum disorder (NMOSD)	IV	June 2020
sacituzumab govitecan	N/A	Immunomedics	Breast cancer	IV	June 2020
octreotide	Mycapssa™	Chiasma	Acromegaly	Oral	June 2020
abicipar pegol	N/A	Allergan	Macular degeneration	Eye injection	July 2020
UX007 (triheptanoin)	N/A	Ultragenyx	Long-chain fatty acid oxidation disorders	Oral	July 2020
belantamab mafodotin	N/A	GlaxoSmithKline	Multiple myeloma	IV	July 2020
selpercatinib (LOXO-292)	N/A	Lilly	RET-altered thyroid cancer, RET-altered non-small cell lung cancer (NSCLC)	Oral	August 2020
satralizumab	N/A	Roche	Neuromyelitis optica spectrum disorder (NMOSD)	SC	August 2020
Viaskin peanut	N/A	DBV Technologies	Peanut allergy	Patch	August 2020
KTE-X19 (Yescarta)	N/A	Kite	Mantle cell lymphoma	IV	August 2020
capmatinib	N/A	Novartis	Non-small cell lung cancer	Oral	August 2020
ASTX727 (cedazuridine and decitabine, C-DEC)	N/A	Astex Pharmaceuticals (Otsuka)	Myelodysplastic syndrome (MDS)	Oral	August 2020
ripretinib	N/A	Deciphera	Gastrointestinal stromal tumors (GIST)	Oral	August 2020
lurbnectedin	Zepsyre™	PharmaMar and Jazz Pharmaceuticals	Small cell lung cancer (SCLC)	IV	August 2020
lisocabtagene maraleucel (liso-cel, JCAR017)	N/A	Bristol-Myers Squibb (Celgene)	Relapsed or refractory large B-cell lymphoma (LBCL)	IV	August 2020
tucatinib	N/A	Seattle Genetics	Breast cancer	Oral	August 2020

SPECIALTY PIPELINE *(continued)*

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE*
tafasitamab	N/A	MorphoSys AG	Relapsed/refractory diffuse large B cell lymphoma	IV	August 2020
eflapregastim	Rolontis™	Spectrum Pharmaceuticals and Hanmi Pharmaceutical	Chemotherapy-induced neutropenia	SC	September 2020
tanezumab	N/A	Pfizer And Lilly	Osteoarthritis	SC	December 2020
roxadustat	N/A	FibroGen Inc. and AstraZeneca PLC	Anemia of chronic kidney disease (CKD)	Oral	December 2020

* 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					
SB8	N/A (Avastin® biosimilar)	Samsung Bioepis and Merck	Non-small cell lung cancer	IV	September 2020
Blood modifiers					
TX-01	N/A (Neupogen® biosimilar)	Tanvex BioPharma	Neutropenia	IV/SC	October 2020

FDA APPROVED GENE/CELL THERAPY NEW PRODUCT APPROVALS

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	MONTH APPROVED
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 2020 PIPELINE

GENERIC NAME	BRAND NAME	MANUFACTURER	INDICATION(S)	ROUTE OF ADMINISTRATION	ANTICIPATED APPROVAL DATE
nadofaragene firadenovec	Instiladrin™	FerGene	Non-muscle invasive urothelial bladder cancer	Intravesical	May 25, 2020
KTE-X19 (axicabtagene ciloleucel)	Yescarta™	Kite	Mantle cell lymphoma	CAR T-cell therapy	August 10, 2020
lisocabtagene maraleucel (liso-cel)	N/A	Bristol-Myers Squibb	R/R large B cell lymphoma	IV	August 17, 2020
valoctogene roxaparvovec (BMN 270)	valrox	BioMarin	Hemophilia A	IV	August 21, 2020
RVT-802	N/A	Enzyvant	Pediatric congenital athymia	IV	2020
remestemcel-L	Ryoncil™	Mesoblast	Children with acute graft-versus host disease (GVHD)	IV	2020
bb-2121 (idecabtagene vicleucel)	N/A	Celegene Bluebird Bio	Multiple myeloma	CAR T-cell therapy	2H2020

REFERENCES

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