

## A Mini Review on New Drugs Approved in 2021

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### ABSTRACT

In 2021, the US Food and Drug Administration approved 50 novel drugs. Twenty three of the 50 (46%) drugs were categorized as orphan drug, and 9 of the 50 (18%) were approved under accelerated approval. This review includes a summary of the novel drugs approved by the US Food and Drug Administration in 2021.

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In 2020, the US Food and Drug Administration (FDA) approved 50 novel drugs. Several expedited review methods, such as accelerated approval, priority review, fast track, and breakthrough therapy, provide for approval processes that allow medications to be released sooner than they would be if they followed the regular route. As a result, medications that treat a critical ailment or meet an unmet medical need can be approved more quickly [1].

In terms of drug approvals, oncology was the most active therapeutic area in 2021, with 10 new drugs in this class hitting the market, including four new drugs for the treatment of Non-Small Cell Lung Cancer (NSCLC) and one new drug approved for identification of ovarian cancer lesions. In the United States, the number of oncology drug approvals and spending continues to rise. According to an economic analysis of cancer drug approvals in 2018, the United States would see a \$39.5 billion rise in drug expenditures if those drugs were used in all eligible patients, a 75 percent increase over overall 2017 oncology drug expenses. The average cost of newly approved oncology medicines per patient per treatment course was \$150,384 [2].

The FDA faces a tremendous difficulty in striking the right balance between rigorous testing and the necessity for drug approval in a rapid manner. Since the implementation of the 21st Century Cures Act in 2016, the FDA has increasingly accepted less data and more surrogate indicators to approve new medications. In 1992,

Congress passed the Prescription Medication User Fee Act, which enabled the collection of fees from the pharmaceutical industry when a new drug application is submitted in order to raise the funds needed to speed up review processes [3].

In addition, eight hematologic medicines and seven neurological treatments were approved. Out of 50 new drugs, nine were monoclonal antibody. It is worth noting that Atogepant (Qulipta®) is the first oral calcitonin gene-related peptide (CGRP) receptor antagonist approved for migraine. Twenty three of the 50 (46%) drugs were categorized as orphan drug, and 9 of the 50 (18%) were approved under accelerated approval. Table 1 summarized the 50 new drugs that will be approved in 2021. In 2021, the FDA approved biologicals, which are not considered medications and are not discussed in detail here.

Notable among the approved biologicals are Prehevbrio Prehevbrio (Hepatitis B Vaccine (Recombinant); VBI Vaccines (Delaware) Inc), for prevention of infection caused by hepatitis B virus, Rethymic (Allogeneic processed Thymus Tissue; Enzyvant Therapeutics GmbH), for immune reconstitution in pediatric patients with congenital athymia, Comirnaty (COVID-19 Vaccine, mRNA; BioNTech manufacturing GmbH Pfizer Inc.) for active immunization to prevent coronavirus disease 2019 (COVID-19), Abecma (idecabtagene vicleucel; Celgene Corporation) for treatment of adult patients with relapsed or refractory multiple myeloma [4].

**Table 1: Summary of 50 novel drugs approved in 2021 by US-FDA**

Generic (Brand)	Indication	Mechanism of Action	Adverse Effects	Package Insert
<b>Cardiology (1)</b> 1. Vericiguat (Verquvo®)	Reduce the risk of cardiovascular death and heart failure	Soluble guanylate cyclase (sGC) stimulator- Leading to smooth muscle relaxation & vasodilation	Hypotension ( $\geq 5\%$ ) and anemia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214377s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214377s000lbl.pdf</a>
<b>Dermatology (4)</b> 1. Odevixibat\$ (Bylvay®)	To treat pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)	Reversible inhibitor of the ileal bile acid transporter (IBAT), it decreases the reabsorption of bile acids (primarily the salt forms) from the terminal ileum	Liver test abnormalities, diarrhea, abdominal pain	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215498s000lbl.pdf?utm_medium=email&amp;utm_source=govdelivery">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215498s000lbl.pdf?utm_medium=email&amp;utm_source=govdelivery</a>
2. Difelikefalin (Korsuva®)	To treat moderate-to-severe pruritus associated with chronic kidney disease in certain populations	A kappa opioid receptor agonist	Diarrhea, dizziness, nausea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214916s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214916s000lbl.pdf</a>
3. Maralixibat\$ (Livmarli®)	To treat cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older	A reversible inhibitor of the ileal bile acid transporter (IBAT). It decreases the reabsorption of bile acids (primarily the salt forms) from the terminal ileum	Diarrhea, abdominal pain, vomiting	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214662s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214662s000lbl.pdf</a>
4. Tralokinumab-ldrm (Adbry®)	To treat moderate-to-severe atopic dermatitis	A human IgG4 monoclonal antibody that specifically binds to human interleukin 13 (IL-13) and inhibits its interaction with the IL-13 receptor $\alpha 1$ and $\alpha 2$ subunits (IL-13R $\alpha 1$ and IL13R $\alpha 2$ )	Upper respiratory tract infections, conjunctivitis, injection site reactions	<a href="https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/AdbryPI.pdf">https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/AdbryPI.pdf</a>
<b>Endocrine (4)</b> 1. Evinacumab-dgnb\$ (Evkeeza®)	To treat adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia	A recombinant human monoclonal antibody that binds to and inhibits ANGPTL3 (a member of the angiopoietin-like protein family) leads to reduction in LDL-C, HDL-C and TG.	Nasopharyngitis, influenza-like illness	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761181s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761181s000lbl.pdf</a>
2. Dasiglucagon (Zegalogue®)	To treat hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above	An antihypoglycemic agent, glucagon receptor agonist, which increases blood glucose concentration by activating hepatic glucagon receptors, thereby stimulating glycogen breakdown and release of glucose from the liver	Nausea, vomiting, headache	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214231s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214231s000lbl.pdf</a>
3. Finerenone (Kerendia®)	To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes	Nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription	Hyperkalemia, hypotension, hyponatremia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215341s000lbl.pdf</a>
4. Inclisiran (Legvio®)	To treat heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease as an add-on therapy	In hepatocytes, inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for PCSK9. This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation	Injection site reaction, arthralgia, urinary tract infection	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf</a>
<b>Genetic (3)</b> 1. Casimersen\$ (Amondys 45®)	To treat duchenne muscular dystrophy in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping	Antisense oligonucleotide, bind to exon 45 of dystrophin pre-mRNA	Upper respiratory tract infection, cough	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213026lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213026lbl.pdf</a>

2. Avalglucosidase alfa-ngpt\$ (Nexviazyme®)	To treat late-onset Pompe disease	An exogenous source of $\alpha$ -glucosidase (GAA), exerts enzymatic activity in cleaving glycogen	Headache, fatigue, diarrhea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761194s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761194s000lbl.pdf</a>
3. Belzutifan\$ (Welireg®)	To treat von Hippel-Lindau disease under certain conditions	Inhibitor of hypoxia-inducible factor 2 alpha (HIF-2 $\alpha$ ), in vivo, belzutifan demonstrated anti-tumor activity in mouse xenograft models of renal cell carcinoma	Laboratory abnormalities, decreased hemoglobin, anemia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215383s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215383s000lbl.pdf</a>
<b>Infectious disease (6)</b> 1. Cabotegravir and rilpivirine (co-packaged) (Cabenuva®)	To treat HIV-1 infection in adults	Cabotegravir is a HIV-1 integrase strand transfer inhibitor (INSTI) & Rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI)	Injection Site Reaction ( $\geq 2\%$ ), pyrexia, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf</a>
2. Voclosporin (Lupkynis®)	To treat adult patients with active Lupus Nephritis	Calcineurin-inhibitor immunosuppressant	Decreased glomerular filtration rate, hypertension	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213716s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213716s000lbl.pdf</a>
3. Ibrexafungerp (Brexafemme®)	To treat adult and post-menarchal pediatric females with vulvovaginal candidiasis	A triterpenoid antifungal, inhibits glucan synthase, an enzyme involved in the formation of 1,3- $\beta$ -D-glucan, an essential component of the fungal cell wall	Diarrhea, nausea, abdominal pain	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214900s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214900s000lbl.pdf</a>
4. Fexinidazole\$ (Fexinidazole®)	To treat human African trypanosomiasis caused by the parasite <i>Trypanosoma brucei gambiense</i>	A nitroimidazole antimicrobial, leading in generation of reactive amines and damage to DNA and proteins	Headache, vomiting, insomnia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214429s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214429s000lbl.pdf</a>
5. Anifrolumab-fnia (Saphnelo®)	To treat adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy	A type I interferon (IFN) receptor antagonist	Nasopharyngitis, upper respiratory tract infections, bronchitis	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761123s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761123s000lbl.pdf</a>
6. Maribavir\$ (Livtency®)	To treat post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV	Antiviral activity of maribavir is mediated by competitive inhibition of the protein kinase activity of human CMV enzyme pUL97, which results in inhibition of the phosphorylation of proteins	Taste disturbance, nausea, diarrhea, vomiting	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215596s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215596s000lbl.pdf</a>
<b>Neurology (7)</b> 1. Fosdenopterin\$ (Nulibry®)	To reduce the risk of mortality in molybdenum cofactor deficiency Type A	An exogenous source of cyclic pyranopterin monophosphate (cPMP), which is converted to molybdopterin	Catheter-related complications, pyrexia, viral infection	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214018s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214018s000lbl.pdf</a>
2. Serdexmethylphenidate and dexmethylphenidate (Azstarys®)	To treat Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older	Dexmethylphenidate HCl is a central nervous system (CNS) stimulant. The mode of therapeutic action in ADHD is not known	Appetite decreased, insomnia, nausea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s000lbl.pdf</a>
3. Ponesimod (Ponvory®)	To treat relapsing forms of multiple sclerosis	A sphingosine 1-phosphate (S1P) receptor 1 modulator that binds with high affinity to S1P receptor 1	Upper respiratory tract infection, hepatic transaminase elevation	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213498s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213498s000lbl.pdf</a>
4. Viloxazine (Qelbree®)	To treat Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age	A selective norepinephrine reuptake inhibitor, however mechanism of action in the treatment of ADHD is unclear	Somnolence, decreased appetite, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf</a>
5. Olanzapine and samidorphan (Lybalvi®)	To treat schizophrenia and certain aspects of bipolar I disorder	A combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist	Weight increased, somnolence, dry mouth	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213378s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213378s000lbl.pdf</a>

6. Aducanumab-avwa (Aduhelm®)	To treat Alzheimer's disease	Human, immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta	Amyloid Related Imaging Abnormalities (ARIA)- Edema, headache	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf</a>
7. Atogepant (Qulipta®)	For preventive treatment of episodic migraine in adults	A calcitonin gene-related peptide (CGRP) receptor antagonist	Nausea, constipation, and fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215206Orig1s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215206Orig1s000lbl.pdf</a>
<b>Oncology (10)</b> 1. Tepotinib*\$ (Tepmetko®)	To treat adult patients with metastatic non-small cell lung cancer	A kinase inhibitor, inhibits hepatocyte growth factor (HGF)-dependent and -independent MET phosphorylation and MET-dependent downstream signaling pathways	Edema ( $\geq 20\%$ ), fatigue, nausea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf</a>
2. Tivozanib (Fotivda®)	To treat renal cell carcinoma	Kinase inhibitor, inhibits phosphorylation of vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2 and VEGFR-3 and inhibits other kinases including c-kit and PDGFR $\beta$	Fatigue, hypertension, diarrhea, decreased appetite	<a href="https://www.aveooncology.com/fotivdapi.pdf">https://www.aveooncology.com/fotivdapi.pdf</a>
3. Dostarlimab-gxly* (Jemperli®)	To treat adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer	A humanized monoclonal antibody of the IgG4 isotype that binds to the programmed death receptor-1 receptor (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response	Fatigue/asthenia, nausea, diarrhea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf</a>
4. Amivantamab-vmjw (Rybrevant®)	To treat adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations	A bispecific antibody that binds to the extracellular domains of EGFR and MET	Rash, infusion related reaction, paronychia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s000lbl.pdf</a>
5. Piflufolostat F 18 (Pylarify®)	To identify prostate-specific membrane antigen-positive lesions in prostate cancer	Binds to cells that express prostate-specific membrane antigen (PSMA), including malignant prostate cancer cells, which usually overexpress PSMA. Fluorine-18 (F 18) is a $\beta^+$ -emitting radionuclide that enables positron emission tomography	Headache, dysgeusia, and fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf</a>
6. Sotorasib\$ (Lumakras®)	To treat adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)	Inhibiting of KRASG12C, a tumor-restricted, mutant-oncogenic form of the RAS GTPase, KRAS.	Diarrhea, musculoskeletal pain, nausea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214665s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214665s000lbl.pdf</a>
7. Infigratinib*\$ (Truseltiq®)	To treat cholangiocarcinoma whose disease meets certain criteria	Kinase inhibitor, inhibits FGFR signaling and decreased cell proliferation in cancer cell lines with activating FGFR amplifications, mutations, or fusions	Nail toxicity, stomatitis, dry eye, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214622s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214622s000lbl.pdf</a>

8. Mobocertinib* (Exkivity®)	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations	Kinase inhibitor of the epidermal growth factor receptor (EGFR) that irreversibly binds to and inhibits EGFR exon 20 insertion mutations	Can cause life-threatening heart rate-corrected QT (QTc) prolongation, diarrhea, rash, nausea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215310s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215310s000lbl.pdf</a>
9. Tisotumab vedotin-tftv* (Tivdak®)	To treat adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	A tissue factor (TF)-directed antibody drug conjugate (ADC) and microtubule inhibitor conjugate	Laboratory abnormalities, hemoglobin decreased, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208s000lbl.pdf</a>
10. Pafolacianine\$ (Cytalux®)	To help identify ovarian cancer lesions	A fluorescent drug that targets folate receptor (FR) which may be overexpressed in ovarian cancer	Nausea, vomiting, abdominal pain	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214907s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214907s000lbl.pdf</a>
<b>Hematology (8)</b>				
1. Umbralisib*\$ (Ukoniq®)	To treat marginal zone lymphoma and follicular lymphoma	Inhibits multiple kinases, inhibits PI3Kδ and casein kinase CK1ε	Laboratory abnormalities, increased creatinine	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213176s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213176s000lbl.pdf</a>
2. Trilaciclib (Cosela®)	To mitigate chemotherapy-induced myelosuppression in small cell lung cancer	A transient inhibitor of CDK 4 and 6	Fatigue, hypocalcemia, hypokalemia	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214200s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214200s000lbl.pdf</a>
3. Melphalan flufenamide* (Pepaxto®)	To treat adult patients with relapsed or refractory multiple myeloma	An alkylating drug, inhibits proliferation and induced apoptosis of hematopoietic and solid tumor cells	Fatigue, nausea, diarrhea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214383s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214383s000lbl.pdf</a>
4. Loncastuximab tesirine-lpyl*\$ (Zynlonta®)	To treat adult patients with certain types of relapsed or refractory large B-cell lymphoma	An antibody-drug conjugate (ADC) targeting CD19, a transmembrane protein expressed on the surface of cells of B-lineage origin	Laboratory abnormalities, are thrombocytopenia, increased gamma-glutamyltransferase	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf</a>
5. Pegcetacoplan\$ (Empaveli®)	To treat adult patients with paroxysmal nocturnal hemoglobinuria (PNH)	Binds to complement protein C3 and its activation fragment C3b, thereby regulating the cleavage of C3 and the generation of downstream effectors of complement activation	Injection-site reactions, infections, diarrhea	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215014s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215014s000lbl.pdf</a>
6. Asparaginase erwinia chrysanthemi (recombinant)-rywn\$ (Rylaze®)	To treat acute lymphoblastic leukemia and lymphoblastic lymphoma in patients who are allergic to E. coli-derived asparaginase products, as a component of a chemotherapy regimen	An enzyme that catalyzes the conversion of the amino acid L-asparagine into aspartic acid and ammonia. Pharmacological effect is based on the killing of leukemic cells due to depletion of plasma asparagine	Abnormal liver test, nausea, musculoskeletal pain	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761179s000lbl.pdf</a>
7. Asciminib (Scemblix®)	To treat Philadelphia chromosome-positive chronic myeloid leukemia (CML) with disease that meets certain criteria	An ABL/BCR-ABL1 tyrosine kinase inhibitor	Upper respiratory tract infections, musculoskeletal pain, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig2lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215358s000Orig2lbl.pdf</a>
8. Rpeginterferon alfa-2b-njft\$ (Besremi®)	To treat polycythemia vera, a blood disease that causes the overproduction of red blood cells	Interferon alfa belongs to the class of type I interferons, which exhibit their cellular effects in polycythemia vera in the bone marrow by binding to a transmembrane receptor termed interferon alfa receptor (IFNAR)	Influenza-like illness, arthralgia, fatigue	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761166s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761166s000lbl.pdf</a>

<p><b>Pulmonary (1)</b> 1. Tezepelumab-ekko (Tezspire®)</p>	<p>To treat severe asthma as an add-on maintenance therapy</p>	<p>A thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2λ that binds to human TSLP with a dissociation constant of 15.8 pM and blocks its interaction with the heterodimeric TSLP receptor</p>	<p>Pharyngitis, arthralgia, and back pain</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s0001bl.pdf</a></p>
<p><b>Other (6)</b> 1. Drospirenone and estetrol (Nextstellis®)</p>	<p>For use by females of reproductive potential to prevent pregnancy</p>	<p>A combination of drospirenone, a progestin, and estetrol, an estrogen. Combined Hormonal Contraceptives (CHCs) prevent pregnancy primarily by suppressing ovulation</p>	<p>Bleeding irregularities, mood disturbance, headache</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214154s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214154s0001bl.pdf</a></p>
<p>2. Belumosudil\$ (Rezurock®)</p>	<p>To treat adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy</p>	<p>Inhibitor of rho-associated, coiled-coil containing protein kinase (ROCK) which inhibits ROCK2 and ROCK1</p>	<p>Laboratory abnormalities, infections, asthenia, nausea</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214783s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214783s0001bl.pdf</a></p>
<p>3. Lonapegsomatropin-tcgd\$ (Skytrofa®)</p>	<p>To treat pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH)</p>	<p>A pegylated human growth hormone (somatropin), somatropin stimulates skeletal growth in pediatric patients with growth hormone deficiency (GHD) as a result of effects on the growth plates (epiphyses) of long bones</p>	<p>Viral infection, pyrexia, cough</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/7611771bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/7611771bl.pdf</a></p>
<p>4. Avacopan\$ (Tavneos®)</p>	<p>To treat severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids</p>	<p>A complement 5a receptor (C5aR) antagonist that inhibits the interaction between C5aR and the anaphylatoxin C5a</p>	<p>Nausea, headache, hypertension</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s0001bl.pdf</a></p>
<p>5. Vosoritide*\$ (Voxzogo®)</p>	<p>To improve growth in children five years of age and older with achondroplasia and open epiphyses</p>	<p>Acts as a positive regulator of endochondral bone growth as it promotes chondrocyte proliferation and differentiation</p>	<p>Injection site erythema, injection site swelling, vomiting</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214938s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214938s0001bl.pdf</a></p>
<p>6. Efgartigimod alfa-fcab\$ (Vyvgart®)</p>	<p>To treat generalized myasthenia gravis</p>	<p>A human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG</p>	<p>Respiratory tract infections, headache, and urinary tract infection</p>	<p><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761195s0001bl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761195s0001bl.pdf</a></p>

Approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials  
\$Orphan Drug

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