FDA Approvals of Novel Brand-Name Prescription Drugs in 2018

I. New Molecular Entities and New Biologic License Applications

**Aemcolo (NME)**
(Rifamycin; Cosmo Technologies/Aries Pharmaceuticals)
Class/route: Antibacterial drug; delayed-release oral tablets
Indication: For treatment of adults with traveler's diarrhea that is caused by noninvasive *Escherichia coli* strains and is not complicated by fever or blood in the stool
Limitations of use: Not indicated for diarrhea complicated by fever or bloody stool or from pathogens other than noninvasive strains of *Escherichia coli*
Approval considerations: Fast track, priority review
Approval date: November 16, 2018

**Aimovig (BLA)**
(Erenumab-aooe; Amgen)
Class/route: First-in-class calcitonin gene-related peptide receptor antagonist; subcutaneous injection
Indication: For the prevention of migraine in adults
Approval date: May 17, 2018

**Ajovy (BLA)**
(Fremanezumab-vfrm; Teva)
Class/route: Calcitonin gene-related peptide antagonist; subcutaneous injection
Indication: For the prevention of migraine in adults
Approval considerations: Priority review
Approval date: September 14, 2018

**Akynzeo (NME)**
(Fosnetupitant and palonosetron; Helsinn)
Class/route: Serotonin-3 receptor antagonist and substance P/neurokinin-1 receptor antagonist; intravenous injection
Indication: For the prevention, in combination with dexamethasone, of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy in adults: palonosetron prevents nausea and vomiting during the acute phase; fosnetupitant (a prodrug of netupitant) prevents nausea and vomiting during the acute and the delayed phases after chemotherapy
Limitations of use: This agent has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy
Approval considerations: Akynzeo (netupitant and palonosetron) oral capsules were initially approved in 2014 for the same indication
Approval date: April 19, 2018

**Annovera (NME)**
(Segesterone acetate and ethinyl estradiol; Population Council)
Class/route: Progestin plus estrogen combination hormonal contraception; vaginal system
Indication: To prevent pregnancy in females of reproductive potential
Limitations of use: Not adequately evaluated in females with a body mass index of >29 kg/m²
Approval date: August 10, 2018

**Asparlas (BLA)**
(Calaspargase pegol-mknl; Servier Pharmaceuticals)
Class/route: L-asparaginase; intravenous injection
Indication: For treatment of acute lymphoblastic leukemia, as part of a chemotherapeutic regimen, in patients aged 1 month to 21 years
Approval considerations: Orphan drug
Approval date: December 20, 2018

**Biktarvy (NME)**
(Bictegravir, emtricitabine, and tenofovir alafenamide; Gilead Sciences)
Class/route: 1 INSTI and 2 NRTIs; oral tablets
Indications: For treatment of HIV-1 infection, as a complete regimen, in adults who have not received antiretroviral therapy, and to replace current antiretroviral regimen in patients who are virologically suppressed (HIV-1 RNA <50 copies per mL) while receiving a stable antiretroviral regimen for ≥3 months and have no history of treatment failure or no known substitutions associated with resistance to the individual components of this regimen
Approval considerations: Priority review
Approval date: February 7, 2018
<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Approval considerations</th>
<th>Approval date</th>
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</thead>
<tbody>
<tr>
<td><strong>Braftovi</strong> (NME)</td>
<td>Kinase inhibitor targeting BRAF V600E; oral capsules</td>
<td>For treatment, in combination with</td>
<td>August 20, 2018</td>
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<tr>
<td></td>
<td>Indication: For treatment, in combination with</td>
<td>clobazam, of seizures associated with</td>
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<td>BRAF wild-type melanoma</td>
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<td></td>
<td>Limitations of use: Not indicated for BRAF wild-type melanoma</td>
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<tr>
<td><strong>Copiktra</strong> (NME)</td>
<td>Dual kinase inhibitor of PI3K-delta and</td>
<td>Accelerated approval, fast track, orphan</td>
<td>December 21, 2018</td>
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<tr>
<td></td>
<td>PI3K-gamma; oral capsules</td>
<td>drug, priority review, REMS program</td>
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<tr>
<td></td>
<td>Indications: For treatment of relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least 2 previous therapies; relapsed or refractory follicular lymphoma after at least 2 previous systemic therapies</td>
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<tr>
<td></td>
<td>Approval considerations: Breakthrough therapy, fast track, orphan drug, priority review</td>
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<tr>
<td><strong>Crysvita</strong> (NME)</td>
<td>First-in-class fibroblast growth factor</td>
<td></td>
<td>September 27, 2018</td>
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<td></td>
<td>23–blocking antibody; subcutaneous injection</td>
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<tr>
<td></td>
<td>Indications: For treatment of X-linked hypophosphatemia</td>
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<td>in patients aged ≥1 year</td>
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<td>Approval considerations: Breakthrough therapy, fast track, orphan drug</td>
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<tr>
<td><strong>Daurismo</strong> (NME)</td>
<td>Hedgehog pathway inhibitor; oral tablets</td>
<td></td>
<td>June 25, 2018</td>
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<tr>
<td></td>
<td>Indications: For treatment, in combination with low-dose cytarabine, of newly diagnosed AML in adults aged ≥75 years; and for patients with AML who have comorbidities that preclude the use of intensive induction chemotherapy</td>
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<tr>
<td><strong>Doptelet</strong> (NME)</td>
<td>Thrombopoietin receptor agonist; oral tablets</td>
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<td>September 27, 2018</td>
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<td></td>
<td>Indications: For the treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical procedure</td>
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<tr>
<td><strong>Elzonris</strong> (BLA)</td>
<td>First-in-class CD123-directed cytotoxin; intravenous injection</td>
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<td>December 21, 2018</td>
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<td></td>
<td>Indications: For treatment of blastic plasmacytoid dendritic-cell neoplasm in patients aged ≥2 years</td>
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<td>Approval considerations: Breakthrough therapy, orphan drug, priority review</td>
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<tr>
<td><strong>Emgality</strong> (NME)</td>
<td>Humanized monoclonal antibody specific to calcitonin gene-related peptide ligand; subcutaneous injection</td>
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<td>September 27, 2018</td>
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<td></td>
<td>Indications: For preventive treatment of migraine in adults</td>
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<td>Approval considerations: Fast track, orphan drug, priority review</td>
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<tr>
<td><strong>Epidiolex</strong> (NME)</td>
<td>Cannabinoid; oral solution</td>
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<td>June 25, 2018</td>
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<tr>
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<td>Indications: For treatment of seizures associated with 2 rare forms of epilepsy—Lennox-Gastaut syndrome and Dravet syndrome—in patients aged ≥2 years; this is the first drug approved for the treatment of Dravet syndrome</td>
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<td>Approval considerations: Fast track, orphan drug, priority review</td>
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<tr>
<td><strong>Erleada</strong> (NME)</td>
<td>Androgen receptor inhibitor; oral tablets</td>
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<td>February 14, 2018</td>
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<tr>
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<td>Indications: For the treatment of patients with nonmetastatic castration-resistant prostate cancer</td>
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<td>Approval considerations: Fast track, priority review</td>
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<td>This was the first time the FDA used the end point of metastasis-free survival to approve a drug</td>
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</table>
**Firdapse** (NME)
(Amifampridine; Catalyst Pharmaceuticals)
Class/route: Potassium channel blocker; oral tablets
*Indication:* For the treatment of Lambert-Eaton myasthenic syndrome (a rare autoimmune disorder) in adults
*Approval considerations:* Breakthrough therapy, orphan drug, priority review
*Approval date:* November 28, 2018

**Galafold** (NME)
(Migalastat; Amicus Therapeutics)
Class/route: First-in-class alpha-galactosidase A pharmacological chaperone; oral capsules
*Indication:* For treatment of adults with a confirmed diagnosis of Fabry disease and a GLA gene variant, based on in vitro assay data
*Approval considerations:* Accelerated approval, fast track, orphan drug, priority review
*Approval date:* August 10, 2018

**Gamifant** (NME)
(Emapalumab-lzsg; Novimmune/Sobi)
Class/route: First-in-class interferon gamma–blocking antibody; intravenous injection
*Indication:* For treatment of patients with primary hemophagocytic lymphohistiocytosis whose disease is refractory, recurrent, or progressive; and for patients who are intolerant to conventional hemophagocytic lymphohistiocytosis therapy
*Approval considerations:* Breakthrough therapy, orphan drug, priority review
*Approval date:* November 20, 2018

**Ilumya** (NME)
(Tildrakizumab-asmn; Sun Pharma)
Class/route: IL-23 antagonist; subcutaneous injection
*Indication:* For treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
*Approval date:* March 21, 2018

**Krintafel** (NME)
(Tafenoquine; GlaxoSmithKline)
Class/route: An 8-aminoquinoline antimalarial drug; oral tablets
*Indication:* For the radical cure (ie, prevention of relapse) of *Plasmodium vivax* malaria in patients aged ≥16 years who are receiving appropriate antimalarial therapy for acute *P vivax* infection
*Limitations of use:* Not indicated for treatment of acute *P vivax* malaria
*Approval considerations:* Breakthrough therapy, orphan drug, priority review
*Approval date:* July 20, 2018

**Libtayo** (BLA)
(Cemiplimab-rwlc; Regeneron/Sanofi)
Class/route: PD-1–blocking antibody; intravenous injection
*Indication:* For treatment of patients with locally advanced or metastatic cutaneous squamous-cell carcinoma who are not candidates for curative surgery or curative radiation
*Approval considerations:* Breakthrough therapy, priority review
*Approval date:* September 28, 2018

**Lokelma** (NME)
(Sodium zirconium cyclosilicate; AstraZeneca)
Class/route: Potassium binder; powder for oral suspension
*Indication:* For treatment of hyperkalemia in adults
*Limitations of use:* Should not be used as an emergency treatment for life-threatening hyperkalemia, because of its delayed onset of action
*Approval date:* May 18, 2018

**Lorbrena** (NME)
(Lorlatinib; Pfizer)
Class/route: Kinase (ALK) inhibitor; oral tablets
*Indications:* For treatment of patients with metastatic NSCLC and ALK mutation whose disease progressed during treatment with crizotinib and at least 1 other ALK inhibitor for metastatic disease, or for those whose disease progressed during treatment with alectinib as the first ALK inhibitor used for metastatic disease, or with ceritinib as the first ALK inhibitor used for metastatic disease
*Approval considerations:* Accelerated approval, breakthrough therapy, orphan drug, priority review
*Approval date:* November 2, 2018

**Lucemyra** (NME)
(Lofexidine; US WorldMeds)
Class/route: First-in-class central alpha-2 adrenergic agonist; oral tablets
*Indication:* For mitigation of opioid withdrawal symptoms in adults, to facilitate abrupt discontinuation of opioid therapy
*Limitations of use:* Not indicated for the treatment of opioid use disorder
*Approval considerations:* Fast track, priority review
*Approval date:* May 16, 2018
Onchocerca volvulus ≥ in patients aged ≥12 years:

**Indication**: For treatment of onchocerciasis caused by *O. volvulus* parasites; the safety and efficacy of repeated use is unknown

**Approval considerations**: Orphan drug, priority review

**Approval date**: June 13, 2018

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**Lumoxiti** (BLA)
(Moxetumomab pasudotox-tdk; AstraZeneca)

**Class/route**: CD22-directed cytotoxin; intravenous injection

**Indication**: For treatment of adults with relapsed or refractory hairy-cell leukemia who have received at least 2 systemic therapies, including a purine nucleoside analog; it is the first CD22-directed cytotoxin approved for this indication

**Limitations of use**: Not recommended for patients with severe renal impairment (creatinine clearance ≤29 mL/min)

**Approval considerations**: Fast track, orphan drug, priority review

**Approval date**: September 13, 2018

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**Lutathera** (NME)
(Lutetium Lu 177 dotatate; Advanced Accelerator Applications)

**Class/route**: First-in-class radiolabeled somatostatin analog; intravenous injection

**Indication**: For treatment of somatostatin receptor–positive gastroenteropancreatic NETs, including foregut, midgut, and hindgut NETs in adults

**Approval considerations**: Fast track, orphan drug, priority review

**Approval date**: January 26, 2018

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**Mektovi** (NME)
(Binimetinib; Array BioPharma)

**Class/route**: Kinase inhibitor; oral tablets

**Indication**: For treatment, in combination with encorafenib (Braftovi), of patients with unresectable or metastatic melanoma and a BRAF V600E or V600K mutation, as detected by an FDA-approved test

**Approval considerations**: Orphan drug

**Approval date**: June 27, 2018

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**Motegrity** (NME)
(Prucalopride; Shire US)

**Class/route**: Serotonin type 4 receptor agonist; oral tablets

**Indication**: For treatment of chronic idiopathic constipation in adults

**Approval date**: December 14, 2018

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**Moxidectin** (NME)
(Approved with no trade name; Medicines Development for Global Health)

**Class/route**: A macrocyclic lactone, anthelmintic drug; oral tablets

**Indication**: For treatment of onchocerciasis caused by *Onchocerca volvulus* in patients aged ≥12 years

**Limitations of use**: Moxidectin tablets do not kill *O. volvulus* parasites; the safety and efficacy of repeated use is unknown

**Approval considerations**: Orphan drug, priority review

**Approval date**: June 13, 2018

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**Mulpleta** (NME)
(Lusutrombopag; Shionogi)

**Class/route**: Thrombopoietin receptor agonist; oral tablets

**Indication**: For treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical procedure

**Approval considerations**: Fast track, priority review

**Approval date**: July 31, 2018

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**Nuzyra** (NME)
(Omadacycline; Paratek Pharmaceuticals)

**Class/route**: Aminomethylcycline antibacterial within the tetracycline class; oral tablets and intravenous injection

**Indications**: For treatment of adults with community-acquired bacterial pneumonia caused by susceptible microorganisms, including *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*; and for treatment of adults with acute bacterial skin and skin structure infections caused by susceptible microorganisms, including *S. aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *K pneumoniae*

**Approval considerations**: Fast track, priority review

**Approval date**: October 2, 2018

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**Olumiant** (NME)
(Baricitinib; Eli Lilly)

**Class/route**: Janus kinase inhibitor; oral tablets

**Indication**: For treatment of adults with moderate-to-severe active rheumatoid arthritis who have had an inadequate response to treatment with ≥1 tumor necrosis factor antagonists

**Limitations of use**: The use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs, or potent immunosuppressants (eg, azathioprine, cyclosporine) is not recommended

**Approval considerations**: Orphan drug, priority review

**Approval date**: May 31, 2018
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Approval Date</th>
<th>Indication</th>
<th>Class/route</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Omegaven</strong> (NME)</td>
<td>July 27, 2018</td>
<td>For treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults</td>
<td>First-in-class lipid complex intravenous injection; intravenous injectable emulsion</td>
</tr>
<tr>
<td><strong>Pifelatro</strong> (NME)</td>
<td>August 30, 2018</td>
<td>For treatment, in combination with other antiretroviral agents, of HIV-1 infection in adults who have not received previous antiretroviral therapy</td>
<td>First-in-class NNRTI; oral tablets</td>
</tr>
<tr>
<td><strong>Poteligio</strong> (NME)</td>
<td>August 8, 2018</td>
<td>For treatment, after ≥1 previous systemic therapies, of adults with relapsed or refractory mycosis fungoides, or adults with Sézary syndrome; this is the first drug approved for Sézary syndrome</td>
<td>First-in-class CCR4-directed monoclonal antibody; intravenous injection</td>
</tr>
<tr>
<td><strong>Revcovi</strong> (BLA)</td>
<td>October 5, 2018</td>
<td>For treatment of pediatric patients and adults with adenosine deaminase severe combined immune deficiency</td>
<td>Recombinant adenosine deaminase; intramuscular injection</td>
</tr>
<tr>
<td><strong>Seysara</strong> (NME)</td>
<td>October 1, 2018</td>
<td>For treatment of patients with cystic fibrosis aged ≥12 years who are homozygous for the F508del mutation, or patients who have ≥1 CFTR genetic mutations that respond to therapy with tezacaftor</td>
<td>First-in-class CFTR corrector and CFTR modulator; oral tablets</td>
</tr>
</tbody>
</table>

**Approval considerations**: Fast track, orphan drug, priority review

**Limitations of use**: Fish oil triglycerides is not indicated to prevent parenteral nutrition-associated cholestasis

**Indication**: As a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis

**Approval considerations**: Priority review

**Indication**: For treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

**Approval considerations**: Breakthrough therapy, fast track, orphan drug, priority review

**Indication**: For treatment of neurotrophic keratitis, a degenerative disease of the cornea

**Approval considerations**: Breakthrough therapy, fast track, orphan drug, priority review

**Indication**: For treatment of inflammatory lesions of nonnodular moderate-to-severe acne vulgaris in patients aged ≥9 years

**Limitations of use**: Efficacy beyond 12 weeks and safety beyond 12 months have not been established, nor has this drug been evaluated for treatment of infections; to reduce drug-resistant bacteria and to maintain the efficacy of other antibacterial drugs, this medication should only be used as indicated

**Approval date**: May 24, 2018
plus ivacaftor, based on in vitro data and/or clinical evidence; if the patient’s genotype is unknown, an FDA-approved test for cystic fibrosis mutations is indicated to detect the presence of a CFTR mutation

**Approval considerations:** Breakthrough therapy, fast track, orphan drug, priority review

**Approval date:** February 13, 2018

### Takhzyro (BLA)
(Lanadelumab-flyo; Dyax/Shire)

**Class/route:** Plasma kallikrein inhibitor; subcutaneous injection

**Indication:** Prophylaxis therapy to prevent attacks of hereditary angioedema in patients aged ≥12 years

**Approval considerations:** Breakthrough therapy, fast track, orphan drug, priority review

**Approval date:** August 23, 2018

### Talzenna (NME)
(Talazoparib; Pfizer)

**Class/route:** PARP inhibitor; oral capsules

**Indications:** For treatment of adults with HER2-negative locally advanced or metastatic breast cancer and deleterious or suspected deleterious germline BRCA mutation, as detected by the BRACAnalysis CDx, an FDA-approved test

**Approval considerations:** Priority review

**Approval date:** October 16, 2018

### Tavalisse (NME)
(Fostamatinib disodium hexahydrate; Rigel)

**Class/route:** First-in-class spleen tyrosine kinase inhibitor; oral tablets

**Indication:** For the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia who have had an insufficient response to previous treatment

**Approval considerations:** Orphan drug

**Approval date:** April 17, 2018

### Tegsedi (NME)
(Inotersen; Akcea Therapeutics)

**Class/route:** First-in-class transthyretin-directed antisense oligonucleotide inhibitor; subcutaneous injection

**Indication:** For treatment of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis in adults

**Approval considerations:** Fast track, orphan drug, priority review

**Approval date:** October 5, 2018

### Tibsovo (NME)
(Ivosidenib; Agios Pharmaceuticals)

**Class/route:** First-in-class IDH1 inhibitor; oral tablets

**Indication:** For treatment of adults with relapsed or refractory AML and a susceptible IDH1 mutation, as detected by an FDA-approved test

**Approval considerations:** Fast track, orphan drug, priority review

**Approval date:** July 20, 2018

### Tpoxx (NME)
(Tecovirimat/Catalent Pharma; SIGA Technologies)

**Class/route:** First-in-class orthopoxvirus-specific antiviral drug; oral capsules

**Indication:** For treatment of human smallpox disease caused by variola virus in adults and in pediatric patients weighing ≥13 kg; this is the first drug approved for the treatment of smallpox disease

**Limitations of use:** The efficacy of this drug for treatment of smallpox disease has not been determined in humans, because well-controlled clinical trials were not feasible; the drug’s efficacy may be reduced in immunocompromised patients

**Approval considerations:** Fast track, orphan drug, priority review

**Approval date:** July 13, 2018

### Trogarzo (NME)
(Ibalizumab-uiyk; TaiMed Biologics)

**Class/route:** First-in-class CD4-directed post-attachment HIV-1 inhibitor; intravenous injection

**Indication:** For treatment, in combination with other antiretroviral(s), of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection who are not responding to current antiretroviral regimen

**Approval considerations:** Breakthrough therapy, fast track, orphan drug, priority review

**Approval date:** March 6, 2018

### Ultomiris (BLA)
(Ravulizumab-cwvz; Alexion Pharmaceuticals)

**Class/route:** Complement inhibitor; intravenous injection

**Indication:** For treatment of adults with paroxysmal nocturnal hemoglobinuria

**Approval considerations:** Orphan drug, REMS program

**Approval date:** December 21, 2018
Vitrakvi (NME)
(Larotrectinib; Loxo Oncology)
Class/route: First-in-class tropomyosin receptor kinase inhibitor; oral capsules and oral solution
Indications: For treatment of pediatric patients and adults with solid tumors that are linked to an NTRK gene fusion and without a known acquired resistance mutation, are metastatic, or when surgical resection of the tumor is likely to result in severe morbidity, and the patient has no satisfactory alternative treatment or the tumor progressed after treatment; this is the second drug approved by the FDA based on a biologic marker rather than a tumor type Approval considerations: Accelerated approval, breakthrough therapy, orphan drug, priority review Approval date: November 26, 2018

Vizimpro (NME)
(Dacomitinib; Pfizer)
Class/route: Irreversible kinase EGFR inhibitor; oral tablets
Indication: For first-line treatment of patients with metastatic NSCLC and EGFR exon 19 deletion or exon 21 L858R substitution mutations, as detected by an FDA-approved test Approval considerations: Orphan drug, priority review Approval date: September 27, 2018

Xerava (NME)
(Eravacycline; Tetraphase Pharmaceuticals)
Class/route: Fluorocycline antibacterial in the tetracycline class; intravenous injection
Indications: For treatment of complicated intra-abdominal infections caused by susceptible microorganisms, including Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Klebsiella oxytoca, Enterococcus faecalis, Enterococcus faecium, Streptococcus anginosus group, Clostridium perfringens, Bacteroides species, and Parabacteroides distasonis, in patients aged ≥18 years Limitations of use: Eravacycline is not indicated for treatment of complicated urinary tract infections Approval considerations: Fast track, priority review Approval date: August 27, 2018

Xofluza (NME)
(Baloxavir marboxil; Genentech)
Class/route: First-in-class polymerase acidic endonuclease inhibitor; oral tablets
Indication: For treatment of acute uncomplicated influenza in patients aged ≥12 years whose symptoms have lasted for ≤48 hours Limitations of use: Influenza viruses change over time; change in their type or subtype, emerging resistance, or changes in viral virulence could diminish the benefit of antiviral drugs; verify drug susceptibility for influenza virus strains before using baloxavir marboxil Approval considerations: Priority review Approval date: October 24, 2018

Xospata (NME)
(Gilteritinib; Astellas Pharma)
Class/route: Multiple tyrosine kinases (including FLT3) inhibitor; oral tablets
Indication: For treatment of adults with relapsed or refractory AML and an FLT3 mutation, as detected by an FDA-approved test Approval considerations: Fast track, orphan drug, priority review Approval date: November 28, 2018

Yapelri (NME)
(Revefenacin; Mylan)
Class/route: Anticholinergic; oral inhalation solution
Indication: For maintenance treatment of patients with chronic obstructive pulmonary disease Approval date: November 8, 2018

Zemdri (NME)
(Plazomicin; Achaogen)
Class/route: Aminoglycoside antibacterial; intravenous injection
Indication: For treatment of patients aged ≥18 years with complicated urinary tract infections, including pyelonephritis caused by the susceptible microorganism that include Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Enterobacter cloacae; because only limited safety and efficacy data are available, reserve this drug for patients with no alternative options Approval considerations: Priority review Approval date: June 25, 2018

ALK indicates anaplastic lymphoma kinase; AML, acute myeloid leukemia; BLA, biologic license application; CCR4, CC chemokine receptor type 4; CFTR, cystic fibrosis transmembrane conductance regulator; FDA, US Food and Drug Administration; FLT3, FMS-like tyrosine kinase; GLA, amenable galactosidase alpha; GnRH, gonadotropin-releasing hormone; HER2, human epidermal growth factor receptor 2; IDH1, isocitrate dehydrogenase-1; IL, interleukin; ISTI, integrase strand transfer inhibitor; NETs, neuroendocrine tumors; NME, new molecular entity; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NTRK, neurotrophic receptor tyrosine kinase; NSCLC, non–small-cell lung cancer; PARP, poly (ADP-ribose) polymerase; PD, programmed cell death; PI3K, phosphatidylinositol 3-kinase; REMS, Risk Evaluation and Mitigation Strategies; RNA, ribonucleic acid.
II. New Biosimilars Approved in 2018

Fulphila (new biosimilar)
(pegfilgrastim-jndb; Mylan)
Class/route: Leukocyte growth factor (covalent conjugate of recombinant methionyl human G-CSF and monomethoxypolyethylene glycol); injection, for subcutaneous use
Reference drug: Neulasta (pegfilgrastim)
Approval considerations: First biosimilar to Neulasta
Indication: To reduce the risk for infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies who are receiving myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia (it is not indicated for mobilization of peripheral blood progenitor cells for hematopoietic stem-cell transplantation)
Approval date: June 4, 2018

Herzuma (new biosimilar)
(trastuzumab-pkrb; Celltrion)
Class/route: Humanized IgG1 kappa monoclonal antibody; injection, for subcutaneous use
Reference drug: Herceptin (trastuzumab)
Approval considerations: Second biosimilar to Herceptin
Indications: First-line treatment of HER2 overexpressing metastatic breast cancer, in combination with paclitaxel; as monotherapy in HER2 overexpressing (as detected by an FDA-approved test) metastatic breast cancer after ≥1 chemotherapy regimens for metastatic disease; for adjuvant treatment of HER2 overexpressing node-positive or node-negative breast cancer, in combination with doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, or in combination with doxetaxel and carboplatin
Approval date: December 14, 2018

Hyrimoz (new biosimilar)
(adalimumab-adaz; Sandoz)
Class/route: Inhibitor of tumor necrosis factor; injection, for subcutaneous use
Reference drug: Humira (adalimumab)
Approval considerations: Third biosimilar to Humira
Indications: Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active rheumatoid arthritis; reducing signs and symptoms of polyarticular juvenile idiopathic arthritis, in patients aged ≥4 years; reducing signs and symptoms, inhibiting progression, and improving physical function of adults with active psoriatic arthritis; reducing signs and symptoms of active ankylosing spondylitis; reducing signs and symptoms and inducing and maintaining remission of moderately to severely active Crohn’s disease in patients who have had an inadequate response to conventional therapy, including infliximab, or are intolerant of infliximab; inducing or sustaining remission in moderately to severely active ulcerative colitis in adults who have had an inadequate response to immunosuppressant therapy; treatment of moderate-to-severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate
Approval date: May 15, 2018

Nivestym (new biosimilar)
(filgrastim-aaf; Pfizer)
Class/route: Leukocyte growth factor (recombinant human G-CSF); injection, for subcutaneous or intravenous use
Reference drug: Neupogen (filgrastim)
Approval considerations: Second biosimilar to Neupogen
Indications: To reduce infections, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies who are receiving myelosuppressive therapies; to reduce the time to neutrophil recovery and fever duration after chemotherapy in patients with AML; to reduce the duration of neutropenia and its sequelae, such as febrile neutropenia, in patients with AML after bone marrow transplantation; to enhance the process of leukapheresis; and for long-term use to reduce the incidence and duration of severe neutropenia in symptomatic patients
Approval date: July 20, 2018

Retacrit (new biosimilar)
(epoetin alfa-epbx; Hospira/Pfizer)
Class/route: Erythropoiesis-stimulating factor; injection, for intravenous or subcutaneous use
Reference drug: Epogen and Procrit (epoetin alfa)
Approval considerations: First biosimilar to Epogen and Procrit
Indications: Treatment of anemia caused by chronic kidney disease (in patients who are or are not undergoing dialysis); treatment of anemia caused by the use of zidovudine in patients with HIV infection; treatment of anemia caused by the effects of concomitant myelosuppressive chemotherapy in patients who require at least 2 additional months of chemotherapy; and for the reduction of allogeneic red blood cell transfusions in patients undergoing elective noncardiac, nonvascular surgery
Approval date: May 15, 2018
Truxima (new biosimilar)  
(*rituximab-abbv; Celltrion*)  
*Class/route:* Chimeric murine/human monoclonal IgG1 kappa anti-CD20 antibody; injection, for intravenous use  
*Reference drug:* Rituxan (*rituximab*)  
*Approval considerations:* First biosimilar to Rituxan  
*Indications:* Treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive B-cell NHL as a single agent; for first-line treatment, in combination with chemotherapy, of patients with untreated follicular, CD20-positive B-cell NHL, and in patients achieving a complete or partial response to rituximab plus chemotherapy, as single-agent maintenance therapy; and for nonprogressing, low-grade, CD20-positive B-cell NHL, as a single agent after first-line treatment with cyclophosphamide, vincristine, and prednisone  
*Approval date:* November 28, 2018

Udenyca (new biosimilar)  
(*pegfilgrastim-cbqv; Coherus*)  
*Class/route:* Leukocyte growth factor (covalent conjugate of recombinant methionyl human G-CSF and monomethoxypolyethylene glycol); injection, for subcutaneous use  
*Reference drug:* Neulasta (*pegfilgrastim*)  
*Approval considerations:* Second biosimilar to Neulasta  
*Indication:* To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies who are receiving myelosuppressive anticancer drugs that are associated with a clinically significant incidence of febrile neutropenia  
*Approval date:* November 2, 2018

AML indicates acute myeloid leukemia; FDA, US Food and Drug Administration; G-CSF, granulocyte colony-stimulating factor; NHL, non-Hodgkin lymphoma.