pharmpiX

RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.
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NEWS……

Drug Issue	Date	News/Event
Uloric™ (febuxostat): Increased Risk of Heart-related Death	11/15/2017	Uloric™ (febuxostat) is FDA-approved to treat gout in adults. Gout happens uric acid builds up and causes sudden attacks of redness, swelling, and pain in one or more joints. Febuxostat works by lowering uric acid levels in the blood. The Uloric™ drug labels already carry a Warning and Precaution about cardiovascular events because the clinical trials conducted before approval showed a higher rate of heart-related problems in patients treated with Uloric™ compared to allopurinol. As a result, FDA required an additional safety clinical trial after the drug was approved in and on the market to better understand these differences, and that trial was finished recently. The FDA is alerting that the preliminary results from the safety clinical trial show an increased risk of heart-related death with Uloric™ compared to allopurinol. Once the final results from the manufacturer are received, FDA will conduct a comprehensive review and will update the public with any new information. The safety trial was conducted in over 6,000 patients with gout treated with either Uloric™ or allopurinol. The primary outcome was a combination of heart-related death, non-deadly heart attack, non-deadly stroke, and a condition of inadequate blood supply to the heart requiring urgent surgery. The preliminary results show that overall, Uloric™ did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, Uloric™ showed an increased risk of heart-related deaths and death from all causes. Health care professionals should consider this safety information when deciding whether to prescribe or continue patients on Uloric™. Patients should talk to your health care professionals if they have any questions or concerns. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of Uloric™ to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyzulta™ (latanoprostene bunod) Ophthalmic Solution, for topical ophthalmic use / Valeant Pharmaceuticals International, Inc.	Nitric oxide donating prostaglandin receptor agonist; Antiglaucoma; Ophthalmic agent	Treatment of patients with open angle glaucoma or ocular hypertension.	11/02/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is one drop in the affected eye(s) once daily in the evening. **DOSAGE FORMS AND STRENGTHS** Topical ophthalmic solution: 0.24 mg/mL latanoprostene bunod (0.024%) . **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Ophthalmic:** (1) Increased pigmentation of the iris has been reported, which is usually permanent and may not be noticeable for months or years. Monitoring recommended. (2) Darkening of eyelid or periorbital tissue has been reported, which may be reversible. (3) Increased length, thickness, and the number of lashes or hairs may occur in the treated eye; usually reversible upon discontinuation. (4) Use caution in patients with history of intraocular inflammation, including iritis or uveitis. (5) Avoid use in patients with active intraocular inflammation; exacerbation may occur. (6) Macular edema, including cystoid macular edema, has been reported. (7) Use caution in pseudophakic patients with a torn posterior lens capsule or in patients with known risk factors for macular edema. (8) Bacterial keratitis has ben reported with use of multiple-dose containers. **ADVERSE REACTIONS** Most common adverse reactions: conjunctival hyperemia, eye irritation, eye pain, and instillation site pain **DRUG INTERACTIONS** No major drug-drug interactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyzulta™ (latanoprostene bunod) Ophthalmic Solution, for topical ophthalmic use / Valeant Pharmaceuticals International, Inc. (continuation)	Nitric oxide donating prostaglandin receptor agonist; Antiglaucoma; Ophthalmic agent	Treatment of patients with open angle glaucoma or ocular hypertension.	11/02/2017	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Use in pediatric patients aged 16 years and younger is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use. • **Geriatric use:** No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Prevymis™ (letermovir) Tablets and Injection, for oral and intravenous use, respectively / Merck & Co., Inc.	DNA terminase complex inhibitor; Antiviral; Anti-infective agent	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult allogeneic stem cell transplant patients.	11/08/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 480 mg administered once daily orally or as an intravenous infusion over 1 hour through 100 days post-transplant. **DOSAGE FORMS AND STRENGTHS** • Tablet: 240 mg; 480 mg. • Injection: 240 mg/12 mL (20 mg/mL) or 480 mg/24 mL (20 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** • Concomitant use with pimozide. • Concomitant use with the following ergot alkaloids: Ergotamine, dihydroergotamine. • Concomitant use with pitavastatin or simvastatin when letermovir is co-administered with cyclosporine. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** (1) Concomitant use with repaglinide, atorvastatin, or lovastatin is not recommended when letermovir is coadministered with cyclosporine. (2) Concomitant use with rifampin, pitavastatin, or simvastatin is not recommended. • **Hepatic:** Use not recommended in patients with severe hepatic impairment (Child-Pugh Class C). • **Renal:** Hydroxypropyl betadex IV vehicle accumulation may occur in patients with IV administration and creatinine clearance less than 50 mL/min; monitoring recommended. **ADVERSE REACTIONS** Most common adverse reactions: nausea, diarrhea, vomiting, peripheral edema, cough, headache, fatigue, and abdominal pain.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Prevymis™ (letermovir) Tablets and Injection, for oral and intravenous use, respectively / Merck & Co., Inc. (continuation)	DNA terminase complex inhibitor; Antiviral; Anti-infective agent	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult allogeneic stem cell transplant patients.	11/08/2017	**DRUG INTERACTIONS** • **Dosage adjustment:** If Prevymis™ is co-administered with cyclosporine, the dosage of Prevymis™ should be decreased to 240 mg once daily. • **Plasma concentration alteration:** Co-administration of Prevymis™ may alter the plasma concentrations of other drugs and other drugs may alter the plasma concentrations of Prevymis™. Consult the full prescribing information prior to and during treatment for potential drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy of Prevymis™ in patients below 18 years of age have not been established. • **Geriatric use:** Safety and efficacy were similar across older and younger subjects. No dosage adjustment of Prevymis™ is required based on age. • **Renal Impairment:** Closely monitor serum creatinine levels in patients with CrCl less than 50 mL/min using Prevymis™ injection. • **Hepatic Impairment:** Prevymis™ is not recommended for patients with severe (Child-Pugh C) hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cinvanti™ (aprepitant) Injection, for intravenous use / Heron Therapeutics, Inc.	Substance P/neurokinin-1 (NK 1) receptor antagonist; Antiemetic	Prevention of chemotherapy-induced nausea and vomiting (CINV), in combination with other antiemetic agents: • Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. • Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). **Limitations of Use** Cinvanti™ has not been studied for treatment of established nausea and vomiting	11/09/2017	**DOSAGE AND ADMINISTRATION** • For HEC (Single Dose Regimen): The recommended dosage in adults is 130 mg on Day 1 as an intravenous infusion over 30 minutes approximately 30 minutes prior to chemotherapy. • For MEC (3-Day Regimen): The recommended dosage in adults is 100 mg administered on Day 1 as an intravenous infusion over 30 minutes approximately 30 minutes prior to chemotherapy. Aprepitant capsules (80 mg) are given orally on Days 2 and 3. **DOSAGE FORMS AND STRENGTHS** Injectable emulsion: 130 mg aprepitant in single-dose vial. **CONTRAINDICATIONS** • Concomitant use of pimozide. • Hypersensitivity to aprepitant or any component of the product. **WARNINGS AND PRECAUTIONS** • **CYP3A4 Interactions:** Aprepitant is a substrate, weak-to-moderate (dosedependent) inhibitor and an inducer of CYP3A4; see Full Prescribing Information for recommendations regarding contraindications, risk of adverse reactions, and dosage adjustment of Cinvanti™ and concomitant drugs. • **Hypersensitivity Reactions** (including anaphylaxis and anaphylactic shock): Reported during or soon after infusion with fosaprepitant, a prodrug of aprepitant, and with oral aprepitant. If symptoms occur, discontinue Cinvanti™. Do not reinitiate if symptoms occur with first time use. • **Warfarin (a CYP2C9 substrate):** Risk of decreased INR of prothrombin time; monitor INR in 2–week period, particularly at 7 to 10 days, following initiation of Cinvanti™. • **Hormonal Contraceptives:** Efficacy of contraceptives may be reduced during and for 28 days following administration of aprepitant. Use effective alternative or back-up methods of non-hormonal contraception.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cinvanti™ (aprepitant) Injection, for intravenous use / Heron Therapeutics, Inc. (continuation)	Substance P/neurokinin-1 (NK 1) receptor antagonist; Antiemetic	Prevention of chemotherapy-induced nausea and vomiting (CINV), in combination with other antiemetic agents: • Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin. • Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). **Limitations of Use** Cinvanti™ has not been studied for treatment of established nausea and vomiting	11/09/2017	**ADVERSE REACTIONS** Most common adverse reactions: fatigue, eructation, and headache. **DRUG INTERACTIONS** • Aprepitant is a substrate, weak-to-moderate (dose-dependent) inhibitor, and an inducer of CYP3A4. Aprepitant is also an inducer of CYP2C9. Some substrates of CYP3A4 are contraindicated with Cinvanti™. Consult the full prescribing information prior to and during treatment for potential drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness of Cinvanti™ have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or effectiveness were observed between older and younger subjects. In general, use caution when dosing elderly patients as they have a greater frequency of decreased hepatic, renal or cardiac function and concomitant disease or other drug therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Heplisav-B™ (hepatitis B vaccine, recombinant (adjuvanted)), for intramuscular use / Dynavax Technologies Corporation	Vaccine	Immunization against infection caused by all known subtypes of hepatitis B virus, for use in adults 18 years of age and older.	11/10/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is to administer two doses (0.5 mL each) of Heplisav-B™ intramuscularly one month apart. **DOSAGE FORMS AND STRENGTHS** Solution for injection supplied as a single-dose vial. A single dose of Heplisav-B™ is 0.5 mL. **CONTRAINDICATIONS** • Severe allergic reaction, such as anaphylaxis, after a previous dose of any hepatitis B vaccine or to any component of Heplisav-B™, including yeast. **WARNINGS AND PRECAUTIONS** • **Managing Allergic Reactions:** Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Heplisav-B™. • **Immunocompromised Individuals:** Immunocompromised persons, including individualsreceiving immunosuppressant therapy, may have a diminished immune response to Heplisav-B™. • **Limitations of Vaccine Effectiveness:** Hepatitis B has a long incubation period. Heplisav-B™ may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration. **ADVERSE REACTIONS** Most common adverse reactions: injection site pain, fatigue, and pain. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** A pregnancy registry is available for Heplisav-B™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Abilify MyCite™ (aripiprazole), for oral use / Otsuka Pharmaceutical Co., Ltd	Atypical antipsychotic	• Treatment of adults with schizophrenia. • Treatment of bipolar I disorder: (1) Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate; (2) Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate. • Adjunctive treatment of adults with major depressive disorder (MDD). **Limitations of Use** (1) The ability of Abilify MyCite™ to improve patient compliance or modify aripiprazole dosage has not been established. (2) The use of Abilify MyCite™ to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur. **Black Box Warning** Increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.	11/13/2017	**DOSAGE AND ADMINISTRATION** The recommended dose varies depending on the diagnosis: • Schizophrenia: Initial dose – 10-15 mg/day; Recommended dose – 10-15 mg/day; Maximum dose: 30 mg/day. • Bipolar mania, monotherapy: Initial dose – 15 mg/day; Recommended dose – 15 mg/day; Maximum dose: 30 mg/day. • Bipolar mania – adults: adjunct to lithium or valproate: Initial dose – 10-15 mg/day; Recommended dose – 15 mg/day; Maximum dose: 30 mg/day. • Major Depressive Disorder, adjunct to antidepressant: Initial dose – 2-5 mg/day; Recommended dose – 5-10 mg/day; Maximum dose: 15 mg/day. **DOSAGE FORMS AND STRENGTHS** Tablets with sensor: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg. **CONTRAINDICATIONS** • Known hypersensitivity to aripiprazole tablets. **WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Abilify MyCite™ is not approved for the treatment of patients with dementia-related psychosis. (2) Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressanttreated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. (3) The safety and efficacy of Abilify MyCite™ have not been established in pediatric patients. • **Body temperature:** Inability to reduce core body temperature has been reported with antipsychotics especially following strenuous exercise, exposure to extreme heat, concomitant anticholinergic medication, or dehydration.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Abilify MyCite™ (aripiprazole), for oral use / Otsuka Pharmaceutical Co., Ltd (continuation)	Atypical antipsychotic	• Treatment of adults with schizophrenia. • Treatment of bipolar I disorder: (1) Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate; (2) Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate. • Adjunctive treatment of adults with major depressive disorder (MDD). **Limitations of Use** (1) The ability of Abilify MyCite™ to improve patient compliance or modify aripiprazole dosage has not been established. (2) The use of Abilify MyCite™ to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur. **Black Box Warning** Increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.	11/13/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Cardiovascular:** Orthostatic hypotension has been reported; increased risk with preexisting cardiovascular or cerebrovascular disease, conditions with predisposition to hypotension (eg, dehydration, hypovolemia), and concomitant use of antihypertensives. • **Gastrointestinal:** Dysphagia has been reported and may result in aspiration pneumonia due to esophageal dysmotility. • **Endocrine and metabolic:** (1) Patients with preexisting or risk factors for diabetes mellitus, including obesity and family history of diabetes, may experience hyperglycemia or worsening of glucose control; monitoring recommended. (2) Severe hyperglycemia, sometimes in association with ketoacidosis, hyperosmolar coma, or death, has been reported with atypical antipsychotics; monitoring recommended. (3) Dyslipidemia has been reported. (4) Weight gain has been reported; monitoring recommended. • **Falls:** Falls that may lead to fracture or other injuries may occur as a result of somnolence, postural hypotension, or motor or sensory instability. Assessment of risk of a fall recommended. • **Hematologic:** Agranulocytosis, leukopenia, and neutropenia have been reported in patients with risk factors (eg, history of low WBC, leukopenia, or neutropenia); monitoring recommended and discontinuation may be necessary. • **Neuroleptic Malignant Syndrome:** Has been reported; may require discontinuation of therapy and medical management; reinitiate therapy carefully with monitoring. • **Neurologic:** (1) Seizures have been reported; increased risk with a history of seizures and conditions that may lower seizure threshold. (2) Cerebrovascular adverse events, including stroke and transient ischemic attack, with fatalities has been reported in elderly patients with dementia-related psychosis. (3) Cognitive and motor impairment may occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Abilify MyCite™ (aripiprazole), for oral use / Otsuka Pharmaceutical Co., Ltd (continuation)	Atypical antipsychotic	• Treatment of adults with schizophrenia. • Treatment of bipolar I disorder: (1) Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate; (2) Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate. • Adjunctive treatment of adults with major depressive disorder (MDD). **Limitations of Use** (1) The ability of Abilify MyCite™ to improve patient compliance or modify aripiprazole dosage has not been established. (2) The use of Abilify MyCite™ to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur. **Black Box Warning** Increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.	11/13/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Tardive Dyskinesia:** Tardive dyskinesia may develop in patients treated with antipsychotic drugs, including Abilify MyCite™. It may require discontinuation of therapy; however, some patients may require treatment with Abilify MyCite™ despite the presence of the syndrome. **ADVERSE REACTIONS** Most common adverse reactions: akathisia, insomnia, sedation, restlessness, tremor, constipation, fatigue, blurred vision, and extrapyramidal disorder. **DRUG INTERACTIONS** • Strong CYP3A4 Inhibitors (e.g., itraconazole, clarithromycin) or strong CYP2D6 inhibitors (e.g., quinidine, fluoxetine, paroxetine) • Strong CYP3A4 Inducers (e.g., carbamazepine, rifampin) • Antihypertensive Drugs • Benzodiazepines (e.g., lorazepam) Dose adjustments are required for patients using Abilify MyCite™ concomitantly with the agents mentioned before. See Full Prescribing Information for recommendations. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Fasenra™ (benralizumab) Injection, for subcutaneous use / AstraZeneca	Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody	Add-on maintenance treatment of patients with severe eosinophilic asthma aged 12 years and older. Limitations of Use: (1) Not for treatment of other eosinophilic conditions. (2) Not for relief of acute bronchospasm or status asthmaticus.	11/14/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter. **DOSAGE FORMS AND STRENGTHS** Injection: 30 mg/mL solution in a single-dose prefilled syringe. **CONTRAINDICATIONS** • Known hypersensitivity to benralizumab or excipients. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Do not abruptly discontinue use of systemic or inhaled corticosteroids with benralizumab therapy initiation. • **Immunologic:** Hypersensitivity reactions (eg anaphylaxis, angioedema, urticaria, rash) have been reported; generally occur within hours of administration but may have delayed onset. Discontinuation necessary if reactions occur. (2) Treat preexisting helminth infections before initiating therapy. If new infection occurs during therapy and does not respond to anti-helminth treatment, discontinue benralizumab until infection resolves. • **Respiratory:** Do not use for acute asthma symptoms or deteriorating disease. **ADVERSE REACTIONS** Most common adverse reactions: headache and pharyngitis. **DRUG INTERACTIONS** No formal drug interaction studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** No overall differences in safety or effectiveness were observed between older and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mepsevii™ (vestronidase alfa), for intravenous use / Ultragenyx Pharmaceutical, Inc.	Recombinant human lysosomal beta glucuronidase	Treatment of pediatric and adult patients with mucopolysaccharidosis type VII (MPS VII), also known as Sly syndrome. **Limitations of Use** The effect of Mepsevii™ on the central nervous system manifestations of MPS VII has not been determined. **Black box warning** Anaphylaxis has occurred with Mepsevii™ administration.	11/15/2017	**DOSAGE AND ADMINISTRATION** The recommended dose s 4 mg/kg administered every two weeks as an intravenous infusion. • Premedication with a non-sedating antihistamine with or without an anti-pyretic is recommended 30 to 60 minutes prior to the start of the infusion. • Administer the infusion over approximately 4 hours. In the first hour of infusion, infuse 2.5% of the total volume. After the first hour, the rate can be increased to infuse the remainder of the volume over 3 hours as tolerated. **DOSAGE FORMS AND STRENGTHS** Injection: 10 mg/5 mL (2 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Anaphylaxis has occurred. Mepsevii™ should be administered under the supervision of a healthcare professional with the capability to manage anaphylaxis. Patients should be observed for 60 minutes after administration. If severe systemic reactions occur, immediately discontinue the infusion and provide appropriate medical treatment. Prior to discharge, inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care if symptoms occur. Consider the risks and benefits of re-administering Mepsevii™ following anaphylaxis. **ADVERSE REACTIONS** Most common adverse reactions: infusion site extravasation, diarrhea, rash, anaphylaxis, infusion site swelling, peripheral swelling and pruritus. **DRUG INTERACTIONS** No major drug-drug interactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Hemlibra™ (emicizumab-kxwh) Injection, for subcutaneous use / Genentech, Inc.	Factor IXa- and factor X-directed antibody	Prevention or reduction of the frequency of bleeding episodes in in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.	11/16/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly. **DOSAGE FORMS AND STRENGTHS** Injection: • 30 mg/mL in a single-dose vial • 60 mg/0.4 mL in a single-dose vial • 105 mg/0.7 mL in a single-dose vial • 150 mg/mL in a single-dose vial **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Thrombotic Microangiopathy Associated (TMA) with Hemlibra™ and activated prothrombin complex concentrate (aPCC):** Consider the benefits and risks if aPCC must be used in a patient receiving Hemlibra™ prophylaxis. Monitor for the development of TMA when administering aPCC. • **Thromboembolism Associated with Hemlibra™ and aPCC:** Consider the benefits and risks if aPCC must be used in a patient receiving Hemlibra™ prophylaxis. Monitor for the development of thromboembolism when administering aPCC. • **Laboratory Coagulation Test Interference:** Hemlibra™ interferes with activated clotting time (ACT), activated partial thromboplastin time (aPTT), and coagulation laboratory tests based on aPTT, including one-stage aPTT-based single-factor assays, aPTT-based Activated Protein C Resistance (APC-R), and Bethesda assays (clotting-based) for factor VIII (FVIII) inhibitor titers. Intrinsic pathway clotting-based laboratory tests should not be used.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Hemlibra™ (emicizumab-kxwh) Injection, for subcutaneous use / Genentech, Inc. (continuation)	Factor IXa- and factor X-directed antibody	Prevention or reduction of the frequency of bleeding episodes in in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.	11/16/2017	**ADVERSE REACTIONS** Most common adverse reactions: injection site reactions, headache, and arthralgia. **DRUG INTERACTIONS** • **Hypercoagulability with Concomitant Use of aPCC, rFVIIa, or FVIII:** Clinical experience suggests that a drug interaction exists with Hemlibra™ and aPCC. See Warnings and Precautions section. • **Drug-Laboratory Test Interactions:** See Warnings and Precautions section. **USE IN SPECIFIC POPULATIONS** • **Females of reproductive potential:** Women of childbearing potential should use contraception while receiving Hemlibra™. • **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Juluca™ (dolutegravir and rilpivirine), for oral use / ViiV Healthcare	Combination of a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and a HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI); Antiretroviral agent	Maintenance treatment of virologically suppressed HIV-1 infection.	11/21/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is one tablet taken orally once daily. • Rifabutin coadministration: Take an additional 25-mg tablet of rilpivirine with Juluca™ once daily with a meal for the duration of the rifabutin co-administration. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg of dolutegravir (equivalent to 52.6 mg dolutegravir sodium) and 25 mg of rilpivirine (equivalent to 27.5 mg rilpivirine hydrochloride). **CONTRAINDICATIONS** • Hypersensitivity to dolutegravir or rilpivirine. • Concomitant use with the following antiarrhythmic: Dofetilide. • Concomitant use with the following anticonvulsants: Carbamazepine; oxcarbazepine; phenobarbital; or phenytoin. • Concomitant use with the following antimycobacterials: Rifampin or rifapentine. • Concomitant use with the following systemic glucocorticoid: Dexamethasone (more than a single-dose treatment). • Concomitant use with St. John's wort (Hypericum perforatum). • Concomitant use with the following proton pump inhibitors: Esomeprazole; lansoprazole; omeprazole; pantoprazole; and rabeprazole. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Severe skin and hypersensitivity reactions have been reported, including cases of drug reaction with eosinophilia and systemic symptoms including fever, organ dysfunction, and elevations in hepatic enzymes; discontinue immediately if signs or symptoms develop.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Juluca™ (dolutegravir and rilpivirine), for oral use / ViiV Healthcare (continuation)	Combination of a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and a HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI); Antiretroviral agent	Maintenance treatment of virologically suppressed HIV-1 infection.	11/21/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** (1) Underlying hepatitis B or C or elevated transaminases prior to initiation increase risk for new or worsening elevated transaminases (sometimes consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly if anti-hepatitis therapy was withdrawn); monitoring recommended. (2) Hepatotoxicity has been reported, including elevated serum liver enzyme levels and hepatitis, in patients with no preexisting hepatic disease or risk factors; monitoring recommended. (3) Liver injury leading to acute liver failure has been reported with dolutegravir-containing products including liver transplant with abacavir/dolutegravir/lamivudine; monitoring recommended. • **Immunologic:** Hypersensitivity reactions (characterized by rash, constitutional findings, and organ dysfunction, including liver injury) have been reported; discontinue use immediately if signs or symptoms develop. • **Psychiatric:** Depressive disorders have been reported with rilpivirine; immediate medical evaluation may be required for severe symptoms; evaluate benefit/risk of continued treatment. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea and headache. **DRUG INTERACTIONS** • **Concomitant use with other antiretroviral medicines:** Because Juluca™ is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Juluca™ (dolutegravir and rilpivirine), for oral use / ViiV Healthcare (continuation)	Combination of a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and a HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI); Antiretroviral agent	Maintenance treatment of virologically suppressed HIV-1 infection.	11/21/2017	**DRUG INTERACTIONS** (continuation) • **Potential for Juluca™ to affect other drugs:** Dolutegravir, a component of Juluca™, inhibits the renal organic cation transporters (OCT) 2 and multidrug and toxin extrusion transporter (MATE) 1, thus it may increase plasma concentrations of drugs eliminated via OCT2 or MATE1 such as dofetilide and metformin. • **CYP3A4 or UGT1A1 inducers or inhibitors:** Drugs that induce or inhibit CYP3A4 or UGT1A1 may affect the plasma concentrations of the components of Juluca™. • **Antacids:** Drugs that increase gastric pH or containing polyvalent cations may decrease plasma concentrations of the components of Juluca™. See Full Prescribing Information for more details regarding drug interactions with Juluca™. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** • **Lactation:** Breastfeeding is not recommended due to the potential for HIV transmission. • **Pediatric use:** The safety and efficacy have not been established in pediatric patients. • **Renal Impairment:** No dosage adjustment is necessary for patients with mild or moderate renal impairment (CrCl ≥ 30 mL/min). In patients with severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease, increased monitoring for adverse effects is recommended. • **Hepatic Impairment:** No dosage adjustment is necessary for patients with mild to moderate hepatic impairment (ChildPugh Score A or B). The effect of severe hepatic impairment (Child-Pugh Score C) on the pharmacokinetics of dolutegravir or rilpivirine is unknown.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Clenpiq™ (sodium picosulfate, magnesium oxide, and anhydrous citric acid) Oral Solution / Ferring Pharmaceuticals	Stimulant laxative and osmotic laxative combination	For cleansing of the colon as a preparation for colonoscopy in adults.	11/28/2017	**DOSAGE AND ADMINISTRATION** Clenpiq™ is ready to drink. It does not need to be diluted prior to administration. One bottle of CLENPIQ is equivalent to one dose. Two doses of Clenpiq™ are required for a complete preparation for colonoscopy. **DOSAGE FORMS AND STRENGTHS** Oral solution: Each bottle contains 10 mg of sodium picosulfate, 3.5 g of magnesium oxide, and 12 g of anhydrous citric acid in 160 mL of solution. **CONTRAINDICATIONS** • Allergy to any ingredient in the citric acid, magnesium oxide, and sodium picosulfate combination product. • Bowel perforation. • Gastric retention. • Gastrointestinal obstruction or ileus. • Severe renal impairment (CrCl < 30 mL/min); magnesium accumulation may occur. • Toxic colitis or toxic megacolon. **WARNINGS AND PRECAUTIONS** • **Risk of fluid and electrolyte abnormalities, arrhythmia, seizures, and renal impairment:** Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use. • **Use in patients with renal impairment or taking concomitant medications that affect renal function:** Use caution, ensure adequate hydration, and consider testing. • **Mucosal ulcerations:** Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. • **Suspected GI obstruction or perforation:** Rule out diagnosis before administration. • **Patients at risk for aspiration:** Observe during administration.

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Clenpiq™ (sodium picosulfate, magnesium oxide, and anhydrous citric acid) Oral Solution / Ferring Pharmaceuticals (continuation)	Stimulant laxative and osmotic laxative combination	For cleansing of the colon as a preparation for colonoscopy in adults.	11/28/2017	**ADVERSE REACTIONS** Most common adverse reactions: nausea, headache, and vomiting. **DRUG INTERACTIONS** • **Drugs that may increase risks of fluid and electrolyte abnormalities:** Caution with other drugs that increase the risk for fluid and electrolyte disturbances or may increase the risk of renal impairment, seizures, arrhythmias or QT prolongation in the setting of fluid and electrolyte abnormalities. • Reduction of drug absorption: Clenpiq™ can reduce the absorption of other co-administered drugs. Administer oral medications at least 1 hour before starting Clenpiq™. Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine, and penicillamine at least 2 hours before and not less than 6 hours after administration of Clenpiq™ to avoid chelation with magnesium. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between geriatric patients and younger patients. • **Renal Impairment:** Clenpiq™ is contraindicated in patients with severe renal impairment (CrCl < 30 mL/min), as accumulation of magnesium in plasma may occur. Patients with less severe renal impairment or patients taking concomitant medications that may affect renal function may be at increased risk for renal injury. Advise these patients of the importance of adequate hydration before, during, and after the use of Clenpiq™. Consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Sublocade™ (buprenorphine extended-release) Injection, for subcutaneous use / Indivior PLC	Partial opioid agonist	Treatment of moderate to severe opioid use disorder (OUD) who have initiated treatment with trans-mucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. **Limitations of use** Prescription use of this product is limited under the Drug Addiction Treatment Act. **Black Box Warning** Risk of serious harm or death with intravenous administration. Sublocade™ is onlo available through a restricted program called the Sublocade™ REMS Program. Healthcare settings and pharmacies that order and dispense this product must be certified in this program and comply with REMS requirements.	11/30/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is two monthly initial doses of 300mg followed by 100mg monthly maintenance doses. **DOSAGE FORMS AND STRENGTHS** Injection: 100mg/0.5mL and 300mg/1.5mL provided in a prefilled syringe with a 19 Gauge 5/8-inch needle. **CONTRAINDICATIONS** • Hypersensitivity to buprenorphine or any other ingredients in Sublocade™. **WARNINGS AND PRECAUTIONS** • **Adiction, abuse, and misuse:** Buprenorphine can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. • **Respiratory depression:** Life-threatening respiratory depression and death have occurred in associations with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with Sublocade™. • **Neonatal opioid withdrawal syndrome (NOWS):** NOWS is an expected and treatable outcome of prolonged use of opioids during pregnancy. • **Adrenal insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. • **Risk of opioid withdrawal with abrupt discontinuation:** If treatment with Sublocade™ is discontinued, monitor patients for several months for withdrawal and treat appropriately. • **Risk of hepatitis, hepatic events:** Monitor liver function tests prior to and during treatment. • **Risk of withdrawal in patients dependent of full agonist opioids:** Verify if the patient is clinically stable on trans-mucosal buprenorphine before injecting Sublocade™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Sublocade™ (buprenorphine extended-release) Injection, for subcutaneous use / Indivior PLC (continuation)	Partial opioid agonist	Treatment of moderate to severe opioid use disorder (OUD) who have initiated treatment with trans-mucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. **Limitations of use** Prescription use of this product is limited under the Drug Addiction Treatment Act. **Black Box Warning** Risk of serious harm or death with intravenous administration. Sublocade™ is onlo available through a restricted program called the Sublocade™ REMS Program. Healthcare settings and pharmacies that order and dispense this product must be certified in this program and comply with REMS requirements.	11/30/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Treatment of emergent acute pain:** Trat pain with non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect. **ADVERSE REACTIONS** Most common adverse reactions: constipation, headaches, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain. **DRUG INTERACTIONS** • **CYP3A4 inhibitors and inducers:** Monitor patients starting or ending CYP3A4 inhibitors and inducers for potential over- or under-dosing. • **Serotonergic drugs:** If concomitant use is warranted, monitor for serotonin syndrome, particularly during treatment initiation, and during dose adjustment of the serotonergic drug. **USE IN SPECIFIC POPULATIONS** • **Lactation:** Buprenorphine passes into mother's milk. • **Geriatric use:** Monitor for sedation or respiratory depression. • **Moderate to severe hepatic impairment:** Not recommended.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Alecensa™ (alectinib) Capsules / Genentech, Inc.	Anaplastic lymphoma kinase (ALK) inhibitor; Antineoplastic agent	Treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). **New indication:** First-line treatment of ALK-positive metastatic NSCLC, as detected by an FDA-approved test.	11/06/2017	The approval is based on results from the Phase III ALEX study, which showed Alecensa significantly reduced the risk of disease worsening or death (progression-free survival, PFS) by 47% (HR=0.53, 95% CI: 0.38, 0.73, p<0.0001) compared to crizotinib as assessed by independent review committee (IRC). Median PFS was 25.7 months (95 percent CI: 19.9, not estimable) for people who received Alecensa compared with 10.4 months (95 percent CI: 7.7, 14.6) for people who received crizotinib.
Zelboraf™ (vemurafenib) Tablets / Genentech, Inc.	Kinase inhibitor; Antineoplastic agent	Treatment of patients with metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test, and for the treatment of patients with Erdheim-Chester Disease (ECD) with BRAF V600 mutation. **New indication:** Treatment of certain adult patients with ECD with BRAF V600 Mutation	11/06/2017	ECD is a rare cancer of the blood. **This is the first FDA-approved treatment for ECD.** The efficacy of Zelboraf™ for the treatment of ECD was studied in 22 patients with BRAF-V600-mutation positive ECD. The trial measured the percent of patients who experienced a complete or partial reduction in tumor size (overall response rate). In the trial, 11 patients (50%) experienced a partial response and 1 patient (4.5%) experienced a complete response.
Auryxia™ (ferric citrate) Tablets / Keryx Biopharmaceuticals, Inc.	Phosphate binder	As phosphate binder for the control of serum phosphorus levels in dialysis patients; and as iron replacement product for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD) who are not on dialysis. **New indication:** Treatment for people with iron deficiency anemia and CKD, not on dialysis.	11/07/2017	The approval was based on results from a 24-week placebo controlled Phase 3 clinical trial in 234 adults with stage 3-5 non-dialysis dependent CKD. In the study, treatment with Auryxia™ demonstrated significant increases in hemoglobin levels of >1 g/dL at any point during the 16-week efficacy period for the majority of patients (52.1%, n=61/117 compared to 19.1%, n=22/115 in the placebo group), a clinically meaningful result. In the trial, ferric citrate was generally well tolerated and adverse events were consistent with its known safety profile.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Adcetris™ (brentuximab vedotin) Injection / Seattle Genetics, Inc.	CD30-directed antibody-drug conjugate (ADC); Antineoplastic agent	Treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and CD30-expressing mycosis fungoides. **New indication:** Treatment of patients with primary Cutaneous Anaplastic Large Cell Lymphoma (ALCL) and CD30-Expressing Mycosis Fungoides (MF).	11/09/2017	Primary cutaneous ALCL and MF are the most common subtypes of cutaneous T-cell lymphoma (CTCL). The approval was based on data from the phase 3 ALCANZA trial comparing Adcetris™ monotherapy administered every 3 weeks versus physician's choice of representative standard of care options, methotrexate or bexarotene. The trial met its primary endpoint with the Adcetris™ treatment arm demonstrating a highly statistically significant improvement in the rate of objective response lasting at least four months (ORR4) versus the control arm as assessed by an independent review facility. ORR4 was 56.3% (95% CI: 44.1, 68.4) in the Adcetris arm compared to 12.5% (95% CI: 4.4, 20.6) in the control arm (p-value <0.001).
Sprycel™ (dasatinib) Tablets / Bristol-Myers Squibb Company	Kinase inhibitor; Antineoplastic agent	Treatment of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia and Philadelphia chromosome-positive acute lymphoblastic leukemia. **Patient population altered:** To include the treatment of children with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic phase.	11/09/2017	The indication received orphan drug designation.
Vraylar™ (cariprazine) Capsules / Allergan plc	Dopamine D_3/D_2 receptor partial agonist atypical antipsychotic	Acute treatment of manic or mixed episodes associated with bipolar I disorder and for the acute and maintenance treatment of schizophrenia. **New indication:** Maintenance treatment of adults with schizophrenia.	11/09/2017	The efficacy of Vraylar™ in the maintenance treatment of schizophrenia was based on an up to 72-week, multinational, double-blind, placebo-controlled, randomized withdrawal study in the prevention of relapse in adult patients with schizophrenia. The primary endpoint was time to relapse. The study demonstrated that Vraylar™ significantly delayed the time to relapse compared to placebo (P=0.0010). Relapse occurred in nearly twice as many placebo-treated patients (49.5%, n=49/99) as Vraylar™-treated (29.7%, n=30/101) patients. The safety results were consistent with the profile observed to-date for Vraylar™.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Faslodex™ (fulvestrant) Injection / AstraZeneca	Estrogen receptor antagonist; Antineoplastic agent	Treatment of hormone receptor positive metastatic breast cancer. **New indication:** Treatment in combination with abemaciclib (a CDK4/6 inhibitor) of hormone receptor-positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in women with disease progression after endocrine therapy.	11/14/2017	The FDA approval is based on data from the Phase III MONARCH 2 trial. The results showed a statistically significant increase in investigator-assessed median PFS of 7.1 months (16.4 months vs 9.3 months) in patients who received Faslodex™ 500 mg and abemaciclib 150 mg over Faslodex™ and placebo (HR: 0.553; 95% CI: 0.449-0.681; p<0.0001).
Gazyva™ (obinutuzumab) Injection / Genentech, Inc.	CD20-directed cytolytic antibody; Antineoplastic agent	Combination treatment of patients with chronic lymphocytic leukemia and follicular lymphoma (FL). **New indication:** For people with previously untreated advanced FL.	11/16/2017	The approval is based on results from the Phase III GALLIUM study, which showed superior progression-free survival (PFS) for patients who received this Gazyva™-based regimen compared with those who received a Rituxan™ (rituximab)-based regimen as an initial (first-line) therapy.
Sutent™ (sunitinib malate) Capsules / Pfizer Inc.	Multi-kinase inhibitor; Antineoplastic agent	Treatment of gastrointestinal stromal tumors, advanced renal cell carcinoma (RCC), adjuvant treatment of patients at high risk of recurrent RCC following nephrectomy, and the treatment of pancreatic neuroendocrine tumors. **New indication:** Adjuvant treatment of adult patients who are at a high risk of RCC returning after a nephrectomy.	11/16/2017	The approval of Sutent™ for the adjuvant treatment of RCC was based on a randomized trial of 615 patients with high risk of recurrent RCC following nephrectomy. The study measured the amount of time after the start of the trial that it took for the cancer to come back, for the patient to develop another unrelated cancer, or for death to occur from any cause (disease-free survival). After 5 years, 59.3% of patients treated with Sutent™ had not experienced cancer recurrence or death compared with 51.3% of patients receiving placebo.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Auvi-Q™ (epinephrine) Injection / Sanofi	Adrenergic agent	Emergency treatment of life-threatening allergic reactions in people who are at risk for or have a history of anaphylaxis. **Patient population altered:** To include infants and small children weighing 16.5 to 33 pounds (7.5 to 15 kilograms) who are at risk for or have a history of serious allergic reactions.	11/17/2017	Only Auvi-Q™ 0.1 mg has a dose and needle length designed specifically for treating anaphylaxis in infants and small children weighing 16.5 – 33 pounds.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tekturna™ (aliskiren) Tablets and Oral Pellets / Noden Pharma	Direct renin inhibitor	Treatment of high blood pressure.	11/14/2017	FDA have approved Tekturna™ (aliskiren) oral pellets for the treatment of hypertension in adults and children six years of age and older.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Butenafine Hydrochloride Topical Cream 1% (OTC) / Taro Pharmaceuticals U.S.A., Inc.	Antifungal	11/16/2017	Generic for: Lotrimin Ultra
Darunavir Ethanolate Tablets 600 mg (base) / Teva Pharmaceuticals USA, Inc.	Protease inhibitor; Antiretroviral agent	11/21/2017	Generic for: Prezista Tablets 600 mg
Capreomycin Sulfate Injection 1 gram (base) /vial / Mylan Pharmaceuticals Inc.	Aminoglycoside; Anti-infective agent	11/27/2017	Generic for: Capastat Sulfate
Praziquantel Tablets 600mg / Par Pharmaceutical, Inc.	Anthelmintic; Anti-infective agent	11/27/2017	Generic for: Biltricide

Source: https://www.drugs.com/generic-approvals.html

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Drug/Manufacturer	Date	Indications	Comments	Impact
Dasotraline / Sunovion Pharmaceuticals Inc.	11/10/2017	Treatment of attention deficit hyperactivity disorder (ADHD).	Dasotraline is a dual dopamine and norepinephrine reuptake inhibitor (DNRI) in development. FDA has accepted for review the NDA for dasotraline, a novel dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) being evaluated for the treatment of ADHD in children, adolescents and adults.	Moderate
Revefenacin / Theravance Biopharma, Inc.	11/13/2017	Treatment of chronic obstructive pulmonary disease (COPD).	Revefenacin is an investigational long-acting muscarinic antagonist (LAMA) in development. An NDA was submitted for the treatment of COPD.	Moderate
Avatrombopag / Dova Pharmaceuticals, Inc.	11/27/2017	Treatment of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure.	Avatrombopag is a second generation orally administered thrombopoietin receptor agonist (TPO-RA) in development.	

Soruce: https://www.drugs.com/new-drug-applications.html

References:

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- Micromedex® Solutions - Truven Health Analytics (www.micromedexsolutions.com)
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