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
Labeling changes for fluoroquinolones antibiotics	07/10/2018	Fluoroquinolone antibiotics are approved to treat certain serious bacterial infections. The FDA requires changes for the current warnings in the prescribing information of fluoroquinolone antibiotics to add that they may cause significant decreases in blood sugar and certain mental health side effects. The new label changes will add that low blood sugar levels can lead to coma and the new label will also make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are: • disturbances in attention • Disorientation • Agitation • Nervousness • memory impairment • serious disturbances in mental abilities called delirium Pharmacists should: • Be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. • Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat themselves if they have symptoms of hypoglycemia. • Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
TPOXX™ (tecovirimat) Capsules, for oral use / SIGA Technologies, Inc.	Anti-infective agent Orthopoxvirus-specific antiviral	Treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg **Limitations of use** • The effectiveness for treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible, and inducing smallpox disease in humans to study the drug's efficacy is not ethical. • Efficacy may be reduced in immunocompromised patients based on studies demonstrating reduced efficacy in immunocompromised animal models.	07/13/2018	**DOSAGE AND ADMINISTRATION** The recommended dose for adult patients is 600 mg twice daily for 14 days. The recommended dose for pediatric patients weighing 13 kg or more vary depending on patient weight: • 13 kg to less than 25 kg: 200 mg twice daily for 14 days. • 25 kg to less than 40 kg: 400 mg twice daily for 14 days. • 40 kg or more: 600 mg twice daily for 14 days. **DOSAGE FORMS AND STRENGTHS** Capsule: 200 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Hypoglycemia with the co-administration of repaglinide and tecovirimat has been reported; monitoring recommended. **ADVERSE REACTIONS** Most common adverse reactions: headache, nausea, abdominal pain, and vomiting. **DRUG INTERACTIONS** • **Repaglinide:** TPOXX™ may increase repaglinide concentrations. Monitor blood glucose and monitor for hypoglycemic symptoms in patients when TPOXX™ is co-administered with repaglinide. • **Midazolam:** TPOXX™ may decrease midazolam concentrations. Monitor for effectiveness of midazolam.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Symtuza™ (cobicistat, darunavir, emtricitabine and tenofovir alafenamide) Tablets, for oral use / Janssen Pharmaceuticals, Inc.	Anti-infective agent
	
	Antiretroviral
		Treatment of human immunodeficiency virus type 1 (HIV-1) in adults who:
		• have no prior antiretroviral treatment history, or
		• are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir
		
		Black box warning
		Post-treatment acute exacerbation of Hepatitis B
			07/17/2018	**DOSAGE AND ADMINISTRATION**
				The recommended dose is one tablet taken once daily.
				
				• Prior to or when initiating, test patients for HBV infection.
				• Prior to or when initiating, and during treatment with Symtuza™, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
				
				DOSAGE FORMS AND STRENGTHS
				Tablets: 800 mg of darunavir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide (equivalent to 11.2 mg of tenofovir alafenamide fumarate).
				
				CONTRAINDICATIONS
				• Concomitant use with the following:
				  • Alpha1-adrenoceptor antagonist: Alfuzosin.
				  • Antianginal: Ranolazine.
				  • Antiarrhythmic: Dronedarone.
				  • Anticonvulsants: Carbamazepine, phenobarbital, phenytoin.
				  • Anti-gout: Colchicine, in patients with renal/and or hepatic impairment.
				  • Antimycobacterial: Rifampin.
				  • Antipsychotics: Lurasidone, pimozide.
				  • Ergot derivatives.
				  • Gastrointestinal motility agent: Cisapride.
				  • Herbal product: St. John's wort (Hypericum perforatum).
				  • Hepatitis C direct acting antiviral: Elbasvir/grazoprevir.
				  • HMG-CoA reductase inhibitors: Lovastatin, simvastatin.
				  • PDE-5 inhibitor: Sildenafil when used for treatment of pulmonary arterial hypertension.
				  • Sedatives/hypnotics: Orally administered midazolam, triazolam.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symtuza™ (cobicistat, darunavir, emtricitabine and tenofovir alafenamide) Tablets, for oral use / Janssen Pharmaceuticals, Inc. (continuation)	Anti-infective agent Antiretroviral	Treatment of human immunodeficiency virus type 1 (HIV-1) in adults who: • have no prior antiretroviral treatment history, or • are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir **Black box warning** Post-treatment acute exacerbation of Hepatitis B	07/17/2018	**WARNINGS AND PRECAUTIONS** • **Dermatological:** Severe skin reactions have been reported with darunavir use; discontinue therapy if symptoms of reactions develop. • **Endocrine and metabolic:** (1) Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including emtricitabine and tenofovir disoproxil fumarate alone or in combination with other antiretrovirals; interruption of therapy may be necessary. (2) New onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus, and hyperglycemia have been reported with HIV protease inhibitor therapy. (3) Diabetic ketoacidosis has occurred. (4) Redistribution/accumulation of body fat, including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and cushingoid appearance have been reported in patients receiving antiretroviral therapy. • **Hematologic:** Increased bleeding, including spontaneous skin hematomas and hemarthrosis, in patients with hemophilia type A and B has been reported with HIV protease inhibitors. • **Hepatic:** (1) Drug-induced hepatitis (e.g. acute hepatitis, cytolytic hepatitis) has been reported with darunavir; monitoring and baseline laboratory testing recommended. (2) Increased risk of liver function abnormalities including severe and potentially fatal hepatic adverse reactions in patients with preexisting liver dysfunction (including hepatitis B or C); monitoring and baseline laboratory testing recommended. (3) Liver injury, including some fatalities, have been reported with darunavir and generally occurred in patients with advanced HIV-1 disease taking multiple concomitant medications, having comorbidities including hepatitis B or C coinfection, and/or developing immune reconstitution syndrome; monitoring and baseline laboratory testing recommended. (4) New or worsening liver dysfunction may occur; therapy interruption or discontinuation may be necessary.

New FDA Approved Products

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Symtuza™ (cobicistat, darunavir, emtricitabine and tenofovir alafenamide) Tablets, for oral use / Janssen Pharmaceuticals, Inc. (continuation)	Anti-infective agent Antiretroviral	Treatment of human immunodeficiency virus type 1 (HIV-1) in adults who: • have no prior antiretroviral treatment history, or • are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir **Black box warning** Post-treatment acute exacerbation of Hepatitis B	07/17/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) Immune reconstitution syndrome has been reported with combination antiretroviral therapy, leading to an inflammatory response in patients with asymptomatic or residual opportunistic infections. (2) Autoimmune disorders such as Graves' disease, polymyositis, and Guillain-Barré syndrome have been reported in the setting of immune reconstitution and may occur many months after initiation of therapy. • **Renal:** (1) Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of tenofovir prodrugs; monitoring and baseline laboratory testing recommended. Discontinuation may be necessary. (2) Increased risk of developing renal-related adverse reaction in patients taking tenofovir prodrugs who have impaired renal function and those taking nephrotoxic agents including nonsteroidal anti-inflammatory drugs; monitoring and baseline laboratory testing recommended. Discontinuation may be necessary. • **Sulfonamide allergy:** Sulfonamide moiety present in darunavir; monitoring recommended in patients with a known sulfonamide allergy. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea, rash, nausea, fatigue, headache, abdominal discomfort, and flatulence. **DRUG INTERACTIONS** • **Other antiretroviral medications:** Symtuza™ is a complete regimen for HIV-1 infection and coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended. • Co-administration of Symtuza™ with other drugs can alter the concentration of other drugs and other drugs may alter the concentrations of Symtuza™ components. Consult the full prescribing information prior to and during treatment for potential drug interactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symtuza™ (cobicistat, darunavir, emtricitabine and tenofovir alafenamide) Tablets, for oral use / Janssen Pharmaceuticals, Inc. (continuation)	Anti-infective agent Antiretroviral	Treatment of human immunodeficiency virus type 1 (HIV-1) in adults who: • have no prior antiretroviral treatment history, or • are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir **Black box warning** Post-treatment acute exacerbation of Hepatitis B	07/17/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Not recommended during pregnancy due to substantially lower exposures of darunavir and cobicistat during pregnancy. • **Lactation:** Breastfeeding is not recommended. • **Geriatric use:** Use caution due to possible decreased hepatic function, concomitant disease, or other therapies. • **Renal impairment:** Not recommended in patients with estimated creatinine clearance below 30 mL/min • **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nivestym™ (filgrastim-aafi) Injection, for subcutaneous or intravenous use / Pfizer Inc.	Blood modifier agent Granulocyte colony-stimulating factor Note: Biosimilar to Neupogen™	Treatment of neutropenia associated with chemotherapy and related conditions	07/20/2018	**DOSAGE AND ADMINISTRATION** For patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML, the recommended starting dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion. Refer to the Full Prescribing Information for recommended dosage adjustments and timing of administration. For patients with cancer undergoing bone marrow transplantation, the recommended dose is 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. Refer to the Full Prescribing Information for recommended dosage adjustments and timing of administration. For patients undergoing autologous peripheral blood progenitor cell collection and therapy, the recommended dose is 10 mcg/kg/day subcutaneous injection. For patients with congenital neutropenia, the recommended starting dose is 6 mcg/kg subcutaneous injection twice daily. For patients with cyclic or idiopathic neutropenia, the recommended starting dose is 5 mcg/kg subcutaneous injection daily. **DOSAGE FORMS AND STRENGTHS** Vial: • Injection: 300 mcg/mL in a single-dose vial. • Injection: 480 mcg/1.6 mL in a single-dose vial. Prefilled Syringe: • Injection: 300 mcg/0.5 mL in a single-dose prefilled syringe. • Injection: 480 mcg/0.8 mL in a single-dose prefilled syringe.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nivestym™ (filgrastim-aafi) Injection, for subcutaneous or intravenous use / Pfizer Inc. (continuation)	Blood modifier agent Granulocyte colony-stimulating factor Note: Biosimilar to Neupogen™	Treatment of neutropenia associated with chemotherapy and related conditions	07/20/2018	**CONTRAINDICATIONS** • History of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim products or pegfilgrastim products. **WARNINGS AND PRECAUTIONS** • **Bone imaging:** Bone-imaging results may be altered. • **Cardiovascular:** (1) Aortitis has been reported as early as during the first week of therapy; evaluation required if generalized symptoms are present and discontinue therapy if suspected. (2) Capillary leak syndrome has been reported and may be life-threatening if treatment is delayed; monitoring is recommended and treatment may be necessary. • **Concomitant use:** Simultaneous use with chemotherapy and radiation therapy may interfere with myeloid cell division; avoid use within 24 hours before or after chemotherapy or simultaneously with radiation therapy. • **Dermatologic:** Moderate or severe cutaneous vasculitis has been reported, most often in patients with severe chronic neutropenia receiving long-term therapy; reduction of dose or interruption may be necessary. • **Hematologic:** (1) Splenic rupture, including fatal cases, has been reported. (2) Severe and sometimes fatal sickle cell crises have been reported; discontinuation required. (3) Alveolar hemorrhage presenting as pulmonary infiltrates and hemoptysis requiring hospitalization has been reported in healthy donors undergoing peripheral blood progenitor cell mobilization (unapproved use). (4) Risk of cytogenetic abnormalities, transformation to myelodysplastic syndrome or acute myeloid leukemia, have been reported, particularly in patients with congenital neutropenia. (5) Thrombocytopenia has been reported; monitoring recommended. (6) Leukocytosis has been reported; monitoring recommended and discontinuation may be necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nivestym™ (filgrastim-aafi) Injection, for subcutaneous or intravenous use / Pfizer Inc. (continuation)	Blood modifier agent Granulocyte colony-stimulating factor Note: Biosimilar to Neupogen™	Treatment of neutropenia associated with chemotherapy and related conditions	07/20/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** Serious allergic reactions, including anaphylaxis, have been reported and can recur within days after discontinuation of initial antiallergic treatment; treatment may be necessary and permanent discontinuation may be required. • **Renal:** Glomerulonephritis has been reported; reduction of dose or interruption may be necessary. • **Respiratory:** Acute respiratory distress syndrome has been reported; discontinue use. • **Tumor growth:** Growth factor activity on any tumor type may occur **ADVERSE REACTIONS** Most common adverse reactions*: pyrexia, pain, rash, cough, dyspnea, epistaxis, headache, anemia, among others. *Most common adverse reaction vary depending on patient diagnosis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tibsovo™ (ivosidenib) Tablets, for oral use / Agios Pharmaceuticals, Inc.	Antineoplastic agent Isocitrate dehydrogenase-1 (IDH1) inhibitor	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test **Black box warning** Differentiation syndrome	07/20/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 500 mg orally once daily with or without food until disease progression or unacceptable toxicity. **DOSAGE FORMS AND STRENGTHS** Tablets: 250 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** QTc interval prolongation and ventricular fibrillation have been reported. Increased risk in patients concomitantly taking drugs known to prolong the QTc interval (e.g. antiarrhythmic medicines, fluoroquinolones, triazole anti-fungals, 5-hydroxytryptamine-3 receptor antagonists) and CYP3A4 inhibitors; monitoring recommended and therapy interruption, reduction of dose or permanent discontinuation may be necessary. • **Concomitant use:** Avoid use of strong CYP3A4 inhibitors, strong CYP3A4 inducers, other QTc interval prolonging agents, sensitive CYP3A4 substrates, and sensitive CYP2C9 substrates. • **Neurologic:** Guillain-Barré syndrome has been reported; monitoring recommended and permanent discontinuation is necessary if diagnosed. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, leukocytosis, arthralgia, diarrhea, dyspnea, edema, nausea, mucositis, electrocardiogram QT prolonged, rash, pyrexia, cough, and constipation.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tibsovo™ (ivosidenib) Tablets, for oral use / Agios Pharmaceuticals, Inc. (continuation)	Antineoplastic agent Isocitrate dehydrogenase-1 (IDH1) inhibitor	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test **Black box warning** Differentiation syndrome	07/20/2018	**DRUG INTERACTIONS** • **Strong or Moderate CYP3A4 Inhibitors:** Reduce Tibsovo™ dose with strong CYP3A4 inhibitors. Monitor patients for increased risk of QTc interval prolongation. • Strong CYP3A4 Inducers: Avoid concomitant use with Tibsovo™. • **Sensitive CYP3A4 substrates:** Avoid concomitant use with Tibsovo™. • **QTc Prolonging Drugs:** Avoid concomitant use with Tibsovo™. If co-administration is unavoidable, monitor patients for increased risk of QTc interval prolongation. **USE IN SPECIFIC POPULATIONS** • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** No overall differences in effectiveness or safety were observed between patients 65 years and older and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Krintafel™ (tafenoquine) Tablets, for oral use / GlaxoSmithKline	Anti-infective agent Antimalarial	For the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection **Limitation of use** Not indicated for the treatment of acute *P. vivax* malaria	07/20/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is a single dose of 300 mg administered as two 150-mg tablets taken together. • All patients must be tested for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to prescribing Krintafel™. • Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment with Krintafel™. **DOSAGE FORMS AND STRENGTHS** Tablets: 150 mg of tafenoquine. **CONTRAINDICATIONS** • G6PD deficiency or unknown G6PD status. • Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown. • Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of Krintafel™. **WARNINGS AND PRECAUTIONS** • **Hematologic:** (1) Hemolytic anemia and hemolysis may occur in patients with G6PD deficiency and G6PD testing is required prior to therapy initiation; decline in hemoglobin may also occur in patients testing normal for G6PD activity; monitoring recommended. (2) Methemoglobinemia may occur and therapy is recommended if signs or symptoms develop; close monitoring recommended in patients with nicotinamide adenine dinucleotide (NADH)-dependent methemoglobin reductase deficiency. • **Immune:** Serious hypersensitivity reactions have been reported; due to long half-life (15 days), reaction may be delayed in onset or duration.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Krintafel™ (tafenoquine) Tablets, for oral use / GlaxoSmithKline (continuation)	Anti-infective agent Antimalarial	For the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection **Limitation of use** Not indicated for the treatment of acute *P. vivax* malaria	07/20/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Psychiatric:** Psychiatric adverse reactions including anxiety, abnormal dreams, and insomnia have been reported; psychosis and depression were also reported in patients taking a higher-than approved dose. Weigh risk/benefit for use in patients with a history of psychiatric illness; due to long half-life (15 days), reactions may be delayed in onset or duration. • **Reproductive:** (1) May cause fetal harm, including hemolytic anemia, if fetus is G6PD-deficient; avoid pregnancy during therapy and use effective contraception for 3 months after therapy. (2) Hemolytic anemia may occur in infants who are G6PD deficient and exposed through breastmilk; G6PD testing required; avoid breastfeeding during and for 3 months after therapy if infant G6PD status unknown. **ADVERSE REACTIONS** Most common adverse reactions: dizziness, nausea, vomiting, headache, and decreased hemoglobin. **DRUG INTERACTIONS** • Avoid co-administration with drugs that are substrates of organic cation transporter-2 (OCT2) or multidrug and toxin extrusion (MATE) transporters. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Use during pregnancy may cause hemolytic anemia in a fetus who is G6PD deficient. Treatment during pregnancy is not recommended. • **Females of reproductive potential:** Verify the pregnancy status in females of reproductive potential prior to initiating treatment. Advise females of reproductive potential that treatment with Krintafel™ during pregnancy is not recommended and to avoid pregnancy or use effective contraception for 3 months after the dose of Krintafel™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Krintafel™ (tafenoquine) Tablets, for oral use / GlaxoSmithKline (continuation)	Anti-infective agent Antimalarial	For the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection **Limitation of use** Not indicated for the treatment of acute *P. vivax* malaria	07/20/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Lactation:** Advise women not to breastfeed a G6PD-deficient infant or infant with unknown G6PD status for 3 months after the dose of Krintafel™. • **Pediatric use:** Safety and effectiveness in pediatric patients younger than 16 years have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Orilissa™ (elagolix) Tablets, for oral use / AbbVie Inc.	Endocrine and metabolic agent Gonadotropin-releasing hormone (GnRH) antagonist	Management of moderate to severe pain associated with endometriosis	07/23/208	**DOSAGE AND ADMINISTRATION** The recommended dose is 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months. For patients with moderate hepatic impairment, the recommended dose is 150 mg once daily for up to 6 months. **DOSAGE FORMS AND STRENGTHS** Tablets: 150 mg and 200 mg. **CONTRAINDICATIONS** • Pregnancy. • Known osteoporosis. • Severe hepatic impairment. • Strong organic anion transporting polypeptide (OATP) 1B1 inhibitor. **WARNINGS AND PRECAUTIONS** • **Hepatic:** Dose-depended elevations of serum alanine aminotransferase at least 3 times the upper limit of the reference range has been reported; use lowest effective dose and assess risks versus benefit of continuing therapy if transaminase elevations occur. • **Musculoskeletal:** Dose-dependent decrease in bone mineral density has been reported and may not be completely reversible after therapy discontinuation; consider assessment of bone mineral density in patients with a history of low-trauma fracture or other risk fractures for osteoporosis or bone loss. • **Psychiatric:** (1) Completed suicide, suicidal ideation and behavior have been reported; assess risks versus benefit of continuing therapy if suicidal ideation and behavior occur. (2) Depression and mood changes have been reported; increased risk in those with a history of suicidality or depression; assess risks versus benefit of continuing therapy if depressive symptoms occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Orilissa™ (elagolix) Tablets, for oral use / AbbVie Inc. (continuation)	Endocrine and metabolic agent Gonadotropin-releasing hormone (GnRH) antagonist	Management of moderate to severe pain associated with endometriosis	07/23/208	**WARNINGS AND PRECAUTIONS** (continuation) • **Reproduction:** (1) Reduction in menstrual bleeding, which may reduce the ability to recognize pregnancy in a timely manner, may occur; if suspected, perform pregnancy testing and discontinue therapy if confirmed. (2) Reduced efficacy with estrogen-containing contraceptive may occur and progesterone effects are not known; advise women to use non-hormonal contraceptive methods during therapy and for one week after discontinuing therapy. **ADVERSE REACTIONS** Most common adverse reactions: hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes. **DRUG INTERACTIONS** There is a potential for interaction with several drugs. Refer to Full Prescribing Information for clinically important interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Exposure early in pregnancy may increase the risk of early pregnancy loss. Use is contraindicated in pregnant women. Discontinue if pregnancy occurs during treatment. • **Females of reproductive potential:** Exclude pregnancy before initiating. Perform pregnancy testing if pregnancy is suspected during treatment. Advise women to use effective non-hormonal contraception during treatment and for one week after discontinuing. • **Pediatric use:** Safety and effectiveness have not been established. • **Hepatic impairment:** Dose adjustment is recommended for women with moderate hepatic impairment (Child-Pugh B) and the duration of treatment should be limited to 6 months. Orilissa™ is contraindicated in women with severe hepatic impairment (Child-Pugh C).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Perseris™ (risperidone) for Extended-Release Injectable Suspension, for subcutaneous use / Indivior Inc.	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	07/27/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 90 mg or 120 mg monthly by subcutaneous injection in the abdomen by a healthcare professional. • Tolerability with oral risperidone must be established. • Supplementation with oral risperidone is not recommended. • Do nor administer more than one dose per month. **DOSAGE FORMS AND STRENGTHS** Extended-release injectable suspension: 90 mg and 120 mg risperidone. **CONTRAINDICATIONS** • Known hypersensitivity to risperidone, paliperidone, or other components of Perseris™. **WARNINGS AND PRECAUTIONS** • **Beers Criteria:** Avoid use for behavioral problems of dementia and delirium (unless nonpharmacological measure fail and the patient is a threat to self or others) due to increased risk for cerebrovascular accident and mortality. Avoid use in patients with Parkinson disease, a history of falls, fractures, or cognitive impairment as ataxia, syncope, impaired psychomotor performance, and adverse CNS effects may occur. If prescribed, use with caution in elderly as SIADH or hyponatremia may be exacerbated or may occur; monitoring recommended when starting or changing doses. • **Cardiovascular:** Use caution in patients with cardiovascular or cerebrovascular disease or conditions that predispose to hypotension, including dehydration, hypovolemia, and antihypertensive medications because of increased risk of orthostatic hypotension; monitoring recommended in these patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Perseris™ (risperidone) for Extended-Release Injectable Suspension, for subcutaneous use / Indivior Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	07/27/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Endocrine and metabolic:** (1) Patients with diabetes mellitus or risk factors for diabetes mellitus, including obesity and family history, are at increased risk of worsening of glucose control or severe hyperglycemia; monitoring recommended. (2) Hyperglycemia, with some extreme cases associated with ketoacidosis, hyperosmolar coma, or death, has been reported with atypical antipsychotic use; monitoring recommended. (3) Hyperprolactinemia may occur and may result in galactorrhea, amenorrhea, and gynecomastia, and patients with longstanding hyperprolactinemia may experience impotence, hypogonadism, and decreased bone density; incidence of hyperprolactinemia appears to be higher with risperiDONE relative to other antipsychotic agents. (4) Dyslipidemia and weight gain, which may increase cardiovascular or cerebrovascular risk, have been reported. (5) Use caution in patients with conditions that may contribute to elevated body temperature since disruption of body temperature regulation has been reported with antipsychotic agents. (6) Hyperthermia and hypothermia have been reported; use caution in patients who will be exposed to temperature extremes. • **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. • **Gastrointestinal:** Esophageal dysmotility resulting in aspiration may occur; use cautiously in patients at risk for aspiration pneumonia. • **Hematologic:** Agranulocytosis, leukopenia, and neutropenia have been reported, especially with preexisting low WBC and history of drug-induced leukopenia or neutropenia; monitoring recommended and discontinue if significant WBC decline with no other causative factors or if patient has severe neutropenia (e.g. absolute neutrophil count less than 1000/mm(3)).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Perseris™ (risperidone) for Extended-Release Injectable Suspension, for subcutaneous use / Indivior Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	07/27/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Musculoskeletal:** Potentially irreversible tardive dyskinesia may occur and risk increases with increased duration of therapy or higher total cumulative dose; discontinue if appropriate. • **Neurologic:** (1) Neuroleptic malignant syndrome has been reported in association with antipsychotic drugs; immediately discontinue if suspected. (2) Patients with Parkinson disease or dementia with Lewy bodies are at increased sensitivity to antipsychotic medications. (3) Use caution in patients with history of seizure disorder or conditions that lower seizure threshold. • **Reproductive:** Priapism has been reported and severe cases may require surgical intervention. **ADVERSE REACTIONS** Most common adverse reactions: increased weight, sedation/somnolence, musculoskeletal pain, and injection site reactions (e.g. site pain and erythema). **DRUG INTERACTIONS** • **Carbamazepine and other strong CYP3A4 inducers:** Strong CYP3A4 inducers decrease plasma concentrations of risperidone. • **Fluoxetine, paroxetine, and other strong CYP2D6 inhibitors:** Strong CYP2D6 inhibitors increase plasma concentrations of risperidone. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. • **Females of reproductive potential:** Treatment may result in an increase in serum prolactin levels, which may lead to a reversible reduction in fertility.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Perseris™ (risperidone) for Extended-Release Injectable Suspension, for subcutaneous use / Indivior Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	07/27/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Lactation:** Infants exposed to Perseris™ through breastmilk should be monitored for excess sedation, failure to thrive, jitteriness, and extrapyramidal symptoms. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Clinical studies did not include patients aged 65 and older. However, in general, dose selection should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and od concomitant disease or other drug thrapy. • **Renal or hepatic impairment:** Carefully titrate on oral risperidone up to at lest 3 mg before initiating treatment with Perseris™ at a dose of 90 mg.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Azedra™ (iobenguane I 131) Injection, for intravenous use / Progenics Pharmaceuticals, Inc.	Radioactive therapeutic agent Note: Orphan drug desidnation	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy	07/30/2018	**DOSAGE AND ADMINISTRATION** Azedra™ must be administered intravenously as a dosimetric dose followed by two therapeutic doses administered 90 days apart. The recommended dosimetric dose vary depending on patients' weigh: • For patients greater than 50 kg: 185 to 222 MBq (5 to 6 mCi) • For patients 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg) The recommended therapeutic dose for each of the 2 doses vary depending on patients' weigh: • For patients greater than 62.5 kg: 18,500 MBq (500 mCi) • For patients 62.5 kg or less: 296 MBq/kg (8 mCi/kg) --- • Block thyroid prior to administering. • Do not administer if platelet count is less than 80,000/mcL or absolute neutrophil count is less than 1,200/mcL. • Adjust therapeutic doses based on radiation dose estimates results from dosimetry. **DOSAGE FORMS AND STRENGTHS** Injection: 555 MBq/mL (15 mCi/ml) at TOC as a clear solution in a singledose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Worsening of pre-existing hypertension has been reported; monitoring recommended. • **Endocrine and metabolic:** Hypothyroidism has been reported; initiate thyroid-blocking medication prior to administration; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Azedra™ (iobenguane I 131) Injection, for intravenous use / Progenics Pharmaceuticals, Inc. (continuation)	Radioactive therapeutic agent Note: Orphan drug desidnation	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy	07/30/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Hematologic:** Severe and prolonged myelosuppression, including anemia, thrombocytopenia, and neutropenia, has been reported; monitoring recommended. Dose adjustment, therapy interruption or discontinuation may be necessary depending on the severity. • **Hematologic:** Secondary myelodysplastic syndrome and acute leukemia have been reported. • **Radiation exposure:** Increased risk for cancer with long-term cumulative radiation exposure; minimize exposure to patient during and after treatment. • **Renal:** Renal toxicity has been reported with increased risk in patients with baseline impairment; monitoring recommended and dose adjustment may be necessary depending on the severity. • **Reproductive:** Temporary or permanent infertility may occur. • **Respiratory:** Pneumonitis, including a fatal case, has been reported; monitoring recommended. If pneumonitis occurs, treat appropriately. **ADVERSE REACTIONS** Most common adverse reactions: lymphopenia, neutropenia, thrombocytopenia, fatigue, anemia, increased international normalized ratio, nausea, dizziness, hypertension, and vomiting. **DRUG INTERACTIONS** • **Drugs that Reduce Catecholamine Uptake or Deplete Stores:** Discontinue these drugs prior to and following Azedra™ administration. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Advise pregnant women of the risk to a fetus.

New FDA Approved Products

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Azedra™ (iobenguane I 131) Injection, for intravenous use / Progenics Pharmaceuticals, Inc. (continuation)	Radioactive therapeutic agent Note: Orphan drug desidnation	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy	07/30/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating. Advise women of reproductive potential to use effective contraception during treatment and for 7 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months following the final dose. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients younger than 12 years old. • **Renal impairment:** The radiation dose to patients with renal impairment may be increased due to the delayed elimination of the drug. Adjust the therapeutic dose based on radiation exposure estimates from the dosimetry assessment. The safety of Azedra™ in patients with severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease has not been studied.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mulpleta™ (lusutrombopag) Tablets, for oral use / Shionogi Inc.	Blood modifier agent Thrombopoietin (TPO) receptor agonist	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	07/31/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 3 mg orally once daily for 7 days. • Begin dosing 8-14 days prior to a scheduled procedure. • Patients should undergo their procedure 2-8 days after the last dose. **DOSAGE FORMS AND STRENGTHS** Tablet: 3 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hemathologic:** TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Monitor platelet counts and for thromboembolic events and institute treatment promptly. **ADVERSE REACTIONS** Most common adverse reactions: headache. **USE IN SPECIFIC POPULATIONS** • **Lactation:** Breastfeeding is not recommended during treatment. • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Cinryze™ (C1 esterase inhibitor (human)) Injection / Shire US, Inc.	Immune modulator C1-esterase inhibitor	**Previous indication(s):** Prophylaxis against angioedema attacks in patients with hereditary angioedema (HAE) **Patient population altered:** Prophylaxis against angioedema attacks in children aged 6 years and older with HAE	06/20/2018	Cinryze™ has been approved in the U.S. since October 2008 for routine prophylaxis against attacks in adolescents and adults living with HAE.
Xeomin™ (incobotulinumtoxin A) Injection / Merz Pharmaceuticals	Musculoskeletal agent Botulinum toxin type A	**Previous indication(s):** Treatment of cervical dystonia, blepharospasm, glabellar lines, upper limb spasticity **New indication(s):** Treatment of chronic sialorrhea, or excessive drooling, in adult patients	07/03/2018	Xeomin™ is the first and only neurotoxin with this approved indication in the U.S.
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb CompanyS	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking antibody	**Previous indication(s):** Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC), and hepatocellular carcinoma **New indication(s):** Opdivo™ in combination with Yervoy™ (ipilimumab) for the treatment of MSI-H or dMMR mCRC	07/11/2018	The Opdivo™ + Yervoy™ combination is also approved in two other tumor types: • Previously untreated patients with intermediate- or poor-risk advanced renal cell carcinoma • Unresectable or metastatic melanoma

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Xtandi™ (enzalutamide) Capsules / Astellas Pharma US, Inc.	Antineoplastic agent Androgen receptor inhibitor	**Previous indication(s):** Treatment of men with metastatic castration-resistant prostate cancer (CRPC) **New indication(s):** Treatment of men with non-metastatic CRPC	07/13/2018	This approval makes Xtandi™ the first and only oral medication FDA-approved for both non-metastatic and metastatic CRPC.
Kisqali™ (ribociclib) Tablets / Novartis Pharmaceuticals Corporation	Antineoplastic agent Inhibitor of cyclin-dependent kinase (CDK) 4 and 6 indicated	**Previous indication(s):** In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer **New indication(s):** (1) In combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women, with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy (2) In combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy	07/18/2018	The new approved indications have broaden the use of Kisqali™ as first-line.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Perseris™ (risperidone) for Extended-Release Injectable Suspension / Indivior Inc.	Atypical antipsychotic	Treatment of schizophrenia in adults	07/27/2018	Perseris™ is the first once-monthly subcutaneous risperidone-containing, long-acting injectable (LAI) for the treatment of schizophrenia in adults.
Remodulin™ (treprostinil) Injection / United Therapeutics	Antihypertensive Prostacyclin vasodilator	Treatment of pulmonary arterial hypertension (PAH)	07/30/2018	The FDA has approved the use of Remodulin™ in the Implantable System for Remodulin™ (ISR). Remodulin™ was originally approved to treat PAH by continuous subcutaneous and intravenous routes of administration, using external pumps. In the case of intravenous users, the therapy can be very burdensome and brings a risk of sepsis due to the use of a central indwelling catheter. The ISR provides patients a new option for delivery of intravenous Remodulin™, where the entire delivery system is implanted into the body and will be refilled by healthcare professionals at intervals of up to 16 weeks depending on the patient's dose, using a syringe needle through the patient's skin.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Emtricitabine Capsules 200 mg / Cipla USA Inc.	Antiretroviral	07/02/2018	Generic for: Emtriva
Budesonide Extended-Release Tablets 9 mg / Actavis Laboratories FL, Inc.	Steroid	07/05/2018	Generic for: Uceris Extended-Release Tablets
Roflumilast Tablets 500 mcg / Mylan Pharmaceuticals Inc.	Respiratory agent/ Phosphodiesterase inhibitor	07/13/2018	Generic for: Daliresp
Colesevelam Hydrochloride for Oral Suspension 1.875 grams/packet and 3.75 grams/packet / Glenmark Pharmaceuticals Inc.	Anti-hyperlipidemic; Bile acid sequestrant	07/16/2018	Generic for: Welchol for Oral Suspension
Asenapine Maleate Sublingual Tablets 5 mg (base) and 10 mg (base) / Sigmapharm Laboratories LLC	Antipsychotic	07/17/2018	Generic for: Saphris
Teriflunomide Tablets 7 mg and 14 mg / Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.	Psychotherapeutic and neurological agent	07/27/2018	Generic for: Aubagio
Temsirolimus Intravenous Solution 25 mg/mL / Accord Healthcare Inc.	Antineoplastic agent	07/30/2018	Generic for: Torisel

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Evenity (romosozumab) / Amgen Inc.	07/12/2018	Treatment for: Osteoporosis	Evenity is an anti-sclerostin monoclonal antibody in development for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. Amgen resubmits a BLA for Eventy.	High
Selinexor / Karyopharm Therapeutics Inc.	07/18/2018	Treatment for: Multiple Myeloma	Selinexor (KPT-330) is a first in class Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist in development for the treatment of patients with penta-refractory multiple myeloma. Karyopharma submits a NDA for selinexor. The FDA granted an orphan drug designation for selinexor.	High High

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

References:

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