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
Pfizer is not planning to launch second Remicade™ biosimilar, Ixifi™	12/14/2017	FDA approved a new biosimilar for Remicade™, Ixifi™, as a treatment for patients with rheumatoid arthritis, Crohn's disease, pediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Pfizer stated that it is not planning to launch Ixifi™ in the US as the company already has another Remicade™ biosimilar on the market, known as Inflectra™. Pfizer acquired Inflectra™ when it bought Hospira in 2015. At the time, the drugmaker elected not to discontinue development of Ixifi™, which was already under way. But the company has no plans to commercialize Ixifi™. Pfizer is currently evaluating their options for Ixifi™. But they are continuing to commercialize Inflectra™ in the US. There is also a third Remicade™ biosimilar currently on the market, Renflexis™ (manufactured by Merck and Samsung Bioepis).
Long-Acting Beta agonists (LABAs) and Inhaled Corticosteroids (ICS): Boxed warning about asthma-related death removed	12/20/2017	The FDA's boxed warning about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A FDA review of 4 large clinical safety trials (involving 41,297 patients) shows that treating asthma with LABAs in combination with ICS does not result in significantly more serious asthma-related side effects than treatment with ICS alone. A description of the 4 trials is now also included in the Warnings and Precautions section of the drug labels. These trials showed that LABAs, when used with ICS, did not significantly increase the risk of asthma-related hospitalizations, the need to insert a breathing tube known as intubation, or asthma-related deaths, compared to ICS alone. Health care professionals should refer to the most recently approved drug labels for recommendations on using ICS/LABA medicines.
Tasigna™ (nilotinib) labeling update	12/26/2017	Tasigna™ is currently approved for the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). The FDA updated the product label to include information for patients and health care providers regarding the conditions under which patients may be eligible to discontinue treatment and notes that if treatment is stopped patients must be regularly monitored for disease recurrence. The updated labeling for Tasigna (nilotinib) makes it the first BCR-ABL tyrosine kinase inhibitor to have treatment-free remission (TFR) data in the prescribing information. TFR refers to the ability to maintain a sustained molecular response after discontinuing TKI therapy in patients with Ph+ CML.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ogivri™ (trastuzumab-dkst), for intravenous use/ Mylan GmbH	HER2/neu receptor antagonist Biosimilar to Herceptin	Treatment of HER2-overexpressing breast cancer and the treatment of HER2-overexpressing stomach cancer (metastatic gastric or gastroesophageal junction adenocarcinoma) **Black box warning** Cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity	12/01/2017	**DOSAGE AND ADMINISTRATION** <u>Adjuvant treatment of HER2-overexpressing breast cancer</u> Administer at either: • Initial dose of 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel/carboplatin). One week after the last weekly dose of Ogivri, administer 6 mg/kg as an IV infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy, or • Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30 to 90 minutes IV infusion every three weeks for 52 weeks. <u>Metastatic HER2-overexpressing breast cancer</u> • Initial dose of 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions. <u>Metastatic HER2-overexpressing gastric cancer</u> • Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks. **DOSAGE FORMS AND STRENGTHS** For Injection: 420 mg lyophilized powder in a multiple-dose vial for reconstitution **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ogivri™ (trastuzumab-dkst), for intravenous use/ Mylan GmbH (continuation)	HER2/neu receptor antagonist Biosimilar to Herceptin	Treatment of HER2-overexpressing breast cancer and the treatment of HER2-overexpressing stomach cancer (metastatic gastric or gastroesophageal junction adenocarcinoma) **Black box warning** Cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity	12/01/2017	**WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Cardiomyopathy and cardiac failure (subclinical and clinical) have been reported; increased risk and severity with concurrent anthracycline-containing chemotherapy regimens; monitoring recommended and interruption or discontinuation may be required. (2) Serious and sometimes fatal infusion reactions have been reported during or within 24 hours of administration; monitoring recommended and interruption or discontinuation may be required. (3) Fetal harm has been reported, including oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death; verify pregnancy status prior to initiation, avoid pregnancy, and advise female patients to use adequate contraception during treatment and for at least 7 months after last dose. (4) Serious pulmonary toxicity, sometimes fatal, has been reported; increased risk with symptomatic intrinsic lung disease or extensive tumor involvement causing dyspnea at rest; monitoring recommended and interruption or discontinuation may be required. • **Cardiovascular:** (1) Asymptomatic decreases in left ventricular ejection fraction have been reported; monitoring recommended and interruption or discontinuation may be required. (2) Symptomatic myocardial dysfunction has been reported; monitoring recommended and interruption or discontinuation may be required. (3) Anthracycline-based therapy after trastuzumab-dkst discontinuation may increase the risk of cardiac dysfunction. • **Hematologic:** Exacerbation of chemotherapy-induced neutropenia, including grade 3 or 4 neutropenia and febrile neutropenia, has been reported. • **Immunologic:** Septic death has been reported.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ogivri™ (trastuzumab-dkst), for intravenous use/ Mylan GmbH (continuation)	HER2/neu receptor antagonist Biosimilar to Herceptin	Treatment of HER2-overexpressing breast cancer and the treatment of HER2-overexpressing stomach cancer (metastatic gastric or gastroesophageal junction adenocarcinoma) **Black box warning** Cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity	12/01/2017	**ADVERSE REACTIONS** Most common adverse reactions: anemia, chills, congestive heart failure, cough, diarrhea, dysgeusia, fatigue, fever, headache, infections, insomnia, mucosal inflammation, nasopharyngitis, nausea, neutropenia, rash, stomatitis, thrombocytopenia and weight loss. **DRUG INTERACTIONS** • **Anthracycline:** Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm when administered to a pregnant woman. Monitor women who received Ogivr™i during pregnancy or within 7 months prior to conception for oligohydramnios. If oligohydramnios occurs, perform fetal testing that is appropriate for gestational age and consistent with community standards of care. • **Females and Males of Reproductive Potential:** Verify the pregnancy status of females prior to initiation of Ogivri™. Advise females of reproductive potential to use effective contraception during treatment with Ogivri™ and for 7 months following the last dose of Ogivri™. • **Pediatric use: S**afety and effectiveness in pediatric patients have not been established. • **Geriatric use:** Elderly patients may be at increased risk of cardiac dysfunction.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ozempic™ (semaglutide) Injection, for subcutaneous use / Novo Nordisk	Glucagon-like peptide-1 (GLP-1) analog	Treatment of adults with type 2 diabetes. **Limitations of use** • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise. • Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy. • Not indicated for use in type 1 diabetes mellitus or treatment of diabetic ketoacidosis. **Black box warning** Risk of thyroid C-cell tumors	12/05/2017	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 0.25 mg once weekly. After 4 weeks, increase the dose to 0.5 mg once weekly. If after at least 4 weeks additional glycemic control is needed, increase to 1 mg once weekly. • Administered as subcutaneous injection in the abdomen, thigh, or upper arm. **DOSAGE FORMS AND STRENGTHS** Injection: 2 mg/1.5 mL (1.34 mg/mL) available in: • Single-patient-use pen that delivers 0.25 mg or 0.5 mg per injection. • Single-patient-use pen that delivers 1 mg per injection. **CONTRAINDICATIONS** • Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. • Known hypersensitivity to Ozempic™ or any of the product components. **WARNINGS AND PRECAUTIONS** • **Pancreatitis:** Has been reported in clinical trials. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. • **Diabetic retinopathy complications:** Has been reported in a clinical trial. Patients with a history of diabetic retinopathy should be monitored. • **Do not share:** Never share pen between patients, even if the needle is changed. • **Hypoglycemia:** When Ozempic™ is used with an insulin secretagogue or insulin, consider lowering the dose of the secretagogue or insulin to reduce the risk of hypoglycemia. • **Acute kidney injury:** Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ozempic™ (semaglutide) Injection, for subcutaneous use / Novo Nordisk	Glucagon-like peptide-1 (GLP-1) analog	Treatment of adults with type 2 diabetes. **Limitations of use** • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise. • Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy. • Not indicated for use in type 1 diabetes mellitus or treatment of diabetic ketoacidosis. **Black box warning** Risk of thyroid C-cell tumors	12/05/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hypersensitivity reactions:** Discontinue if suspected and promptly seek medical advice. • **Macrovascular outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with semaglutide. **ADVERSE REACTIONS** Most common adverse reactions: nausea, vomiting, diarrhea, abdominal pain and constipation. **DRUG INTERACTIONS** • **Oral medications:** Ozempic™ delays gastric emptying. May impact absorption of concomitantly administered oral medications. **USE IN SPECIFIC POPULATIONS** • **Females and males of reproductive potential:** Discontinue Ozempic™ in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide. • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or efficacy were detected between older and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution, for oral use / Sunovion Pharmaceuticals Inc.	Long-acting muscarinic antagonist (LAMA) bronchodilator	Maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema	12/05/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is the contents of one vial twice-daily. • For oral inhalation only. Do not swallow. • Only use Lonhala™ vials with Magnair™. **DOSAGE FORMS AND STRENGTHS** Inhalation Solution: Supplied as a sterile solution for inhalation in a unit-dose single-use low-density polyethylene (LDPE) vial. Each 1 mL vial contains 25 mcg of glycopyrrolate. **CONTRAINDICATIONS** • Known hypersensitivity to glycopyrrolate or any of the ingredients in the product. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Immediate hypersensitivity reactions have been reported; discontinue immediately if signs occur (e.g. angioedema, urticaria, skin rash). • **Ophthalmic:** Use with caution in preexisting or new onset, narrow-angle glaucoma; monitoring recommended. • **Renal:** Use with caution in patients with urinary retention and monitoring recommended. • **Respiratory:** (1) Do not initiate for acute deterioration of disease or use to treat acute symptoms. (2) Paradoxical bronchospasm, potentially life-threatening, has been reported with other inhalation therapy; discontinue immediately. **ADVERSE REACTIONS** Most common adverse reactions: dyspnea and urinary tract infection.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lonhala™ Magnair™ (glycopyrrolate) Inhalation Solution, for oral use / Sunovion Pharmaceuticals Inc. (continuation)	Long-acting muscarinic antagonist (LAMA) bronchodilator	Maintenance treatment of airflow obstruction in people with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema	12/05/2017	**DRUG INTERACTIONS** • **Anticholinergics:** May interact additively with concomitantly used anticholinergic medications. Avoid administration of Lonhala™ Magnair™ with other anticholinergic containing drugs. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Not indicated for use in children. The safety and efficacy in pediatric patients have not been established. • **Geriatric use:** Based on available data, no adjustment of the dosage in geriatric patients is warranted. Lonhala™ Magnair™ can be used at the recommended dose in elderly patients 75 years of age and older. • **Renal impairment:** No dose adjustment is required for patients with mild or moderate renal impairment. Use in patients with severe renal impairment should be considered if the potential benefit of the treatment outweighs the risk. • **Hepatic impairment:** No dose adjustment is required for patients with hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Sinuva™ (mometasone furoate) Sinus Implant / Intersect ENT, Inc.	Corticosteroid-eluting sinus implant	Treatment of recurrent nasal polyp disease in patients ≥ 18 years of age who have had ethmoid sinus surgery	12/08/2017	**DOSAGE AND ADMINISTRATION** The Sinuva™ sinus implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. • Sinuva™ is to be inserted by physicians trained in otolaryngology. • Repeat administration has not been studied. **DOSAGE FORMS AND STRENGTHS** One Sinuva™ sinus implant system contains 1350 mcg of mometasone furoate and a sterile delivery system **CONTRAINDICATIONS** • Known hypersensitivity to mometasone furoate and any of the ingredients of the product. **WARNINGS AND PRECAUTIONS** • Endocrine and metabolic: Adrenal suppression or hypercorticism may occur. If appear, consider sinus implant removal. • **Immunologic:** (1) Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported. (2) Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex. More serious or even fatal course of chickenpox or measles in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections. • **Local effects:** Monitor nasal mucosa adjacent to the SSinuva™ sinus implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma. • **Ophtalmic:** Monitor patients with changes in vision, glaucoma, increased intraocular pressure, an/or cataracts.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Sinuva™ (mometasone furoate) Sinus Implant / Intersect ENT, Inc. (continuation)	Corticosteroid-eluting sinus implant	Treatment of recurrent nasal polyp disease in patients ≥ 18 years of age who have had ethmoid sinus surgery	12/08/2017	**ADVERSE REACTIONS** Most common adverse reactions: bronchitis, nasopharyngitis, otitis media, headache, presyncope, asthma, and epistaxis. **DRUG INTERACTIONS** Formal drug-drug interaction studies have not been conducted. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness have not been established in children or adolescents less than 18 years of age. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. • **Hepatic Impairment:** Concentrations of mometasone furoate appear to increase with severity of hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Admelog™ (insulin lispro) Injection, for subcutaneous use / Sanofi-Aventis U.S. LLC	Rapid-acting insulin	Treatment of type 1 (in adults and pediatric patients aged 3 years and older) and type 2 diabetes (in adults)	12/11/2017	**DOSAGE AND ADMINISTRATION** Individualize and adjust the dosage based on route of administration, individual's metabolic needs, blood glucose monitoring results and glycemic control goal. **DOSAGE FORMS AND STRENGTHS** Injection: 100 units/mL (U-100) is available as: • 10 mL multiple-dose vials • 3 mL single patient use SoloStar® prefilled pens **CONTRAINDICATIONS** • Do not use during episodes of hypoglycemia. • Do not use in patients with hypersensitivity to insulin lispro or any of the excipients. **WARNINGS AND PRECAUTIONS** • **Do not share:** Never share disposable prefilled pens or syringes between patients, even if the needle is changed. • **Hyperglycemia or hypoglycemia with changes in insulin regimen:** Changes should be made under close medical supervision and the frequency of blood glucose monitoring should be increased. • **Hypoglycemia:** May be life-threatening. Monitor blood glucose and increase monitoring frequency with changes to insulin dosage, use of glucose lowering medications, meal pattern, and physical activity; in patients with renal or hepatic impairment; and in patients with hypoglycemia unawareness. • **Hypoglycemia due to medication errors:** Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection. • **Hypersensitivity reactions:** Severe, life-threatening, generalized allergic, including anaphylaxis can occur. Discontinue, monitor and treat if indicated.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Admelog™ (insulin lispro) Injection, for subcutaneous use / Sanofi-Aventis U.S. LLC (continuation)	Rapid-acting insulin	Treatment of type 1 (in adults and pediatric patients aged 3 years and older) and type 2 diabetes (in adults)	12/11/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hypokalemia:** May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated. • **Fluid retention and heart failure with concomitant use of thiazolidinediones:** Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs. • **Hyperglycemia and ketoacidosis due to insulin pump device malfunction:** Monitor glucose and administer Admelog™ by subcutaneous injection if pump malfunction occurs. **ADVERSE REACTIONS** Most common adverse reactions: hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, and rash. **DRUG INTERACTIONS** • **Drugs that affect glucose metabolism:** Adjustment of insulin dosage may be needed. • **Antiadrenergic Drugs (e.g. beta-blockers, clonidine, guanethidine, and reserpine):** Signs and symptoms of hypoglycemia may be reduced or absent. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness not established in pediatric patients < 3 years of age with type 1 diabetes mellitus or in pediatric patients with type 2 diabetes mellitus. • **Renal impairment:** Patients with renal impairment may be at increased risk of hypoglycemia and may require more frequent dose adjustment and blood glucose monitoring. • **Hepatic impairment:** Patients with hepatic impairment may be at increased risk of hypoglycemia and may require more frequent dose adjustment and blood glucose monitoring.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xepi™ (ozenoxacin) Cream, for topical use / Medimetriks Pharmaceuticals, Inc.	Antimicrobial Non-fluorinated quinolone	Treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older	12/11/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is to apply a thin layer of Xepi™ topically to the affected area twice daily for 5 days. Affected area may be up to 100 cm2 in adult and pediatric patients 12 years of age and older or 2% of the total body surface area and not exceeding 100 cm2 in pediatric patients less than 12 years of age. **DOSAGE FORMS AND STRENGTHS** Cream: Each gram contains 10 mg of ozenoxacin (1%). **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Potential for microbial overgrowth:** Prolonged use of Xepi™ may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy. **ADVERSE REACTIONS** Most common adverse reactions: rosacea and seborrheic dermatitis (reported in 1 adult patient treated with Xepi™. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric** use: Safety and effectiveness of XEPI in the treatment of impetigo have been established in pediatric patients 2 months to 17 years of age. • **Geriatric use:** Studies of did not include sufficient numbers of subjects aged 65 and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ixifi™ (infliximab-qbtx) Injection, for intravenous use / Pfizer Inc.	Tumor necrosis factor (TNF) blocker Biosimilar to Remicade (infliximab)	Treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. **Black box warning** Serious infections and malignancy	12/13/2017	**DOSAGE AND ADMINISTRATION** For Crohn's Disease: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response. For Pediatric Crohn's Disease: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. For Ulcerative Colitis: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. For Rheumatoid Arthritis: In conjunction with methotrexate, 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks. For Ankylosing Spondylitis: 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks. Psoriatic Arthritis and Plaque Psoriasis: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Ixifi™ is administered by intravenous infusion over a period of not less than 2 hours. **DOSAGE FORMS AND STRENGTHS** For injection: 100 mg of lyophilized infliximab-qbtx in a 15 mL vial for intravenous infusion. **CONTRAINDICATIONS** • Doses > 5 mg/kg in moderate to severe heart failure. • Previous severe hypersensitivity reaction to infliximab products or known hypersensitivity to inactive components of Ixifi™ or to any murine proteins.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ixifi™ (infliximab-qbtx) Injection, for intravenous use / Pfizer Inc. (continuation)	Tumor necrosis factor (TNF) blocker Biosimilar to Remicade (infliximab)	Treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. **Black box warning** Serious infections and malignancy	12/13/2017	**WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens. (2) Discontinue if a patient develops a serious infection. (3) Perform test for latent TB; if positive, start treatment for TB prior to starting Ixifi™. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. (4) Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products. (5) Post-marketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including infliximab products. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of Ixifi™ cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult males. • **Immunologic:** (1) Do not initiate during an active infection. If an infection develops, monitor carefully and stop if infection becomes serious. (2) For patients who develop a systemic illness, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. (3) The incidence of malignancies, including invasive cervical cancer and lymphoma, was greater in Ixifi™ treated patients than in controls. Due to the risk of HSTCL carefully assess the risk/benefit especially if the patient has Crohn's disease or ulcerative colitis, is male, and is receiving azathioprine or 6-mercaptopurine treatment. (3) Test for HBV infection before starting. Monitor HBV carriers during and several months after therapy. If reactivation occurs, stopIxifi™ and begin anti-viral therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ixifi™ (infliximab-qbtx) Injection, for intravenous use / Pfizer Inc. (continuation)	Tumor necrosis factor (TNF) blocker Biosimilar to Remicade (infliximab)	Treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. **Black box warning** Serious infections and malignancy	12/13/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** Severe hepatic reactions, some fatal or necessitating liver transplantation. Stop IXIFI in cases of jaundice and/or marked liver enzyme elevations. • **Cardiovascular:** New onset heart failure or worsening symptoms may occur. • **Cytopenias:** Advise patients to seek immediate medical attention if signs and symptoms develop, and consider stopping IXIFI. • **Hypersensitivity:** Serious infusion reactions including anaphylaxis or serum sickness-like reactions may occur. • **Cardiovascular and cerebrovascular reactions:** Cerebrovascular accidents, myocardial infarctions (some fatal), and arrhythmias have been reported during and within 24 hours of initiation of IXIFI infusion. Monitor patients during IXIFI infusion and if serious reaction occurs, discontinue infusion. • **Demyelinating disease:** Exacerbation or new onset may occur. • **Lupus-like syndrome:** Stop IXIFI if syndrome develops. • **Live vaccines or therapeutic infectious agents:** Should not be given with IXIFI. Bring pediatric patients up to date with all vaccinations prior to initiating IXIFI. At least a six month waiting period following birth is recommended before the administration of live vaccines to infants exposed in utero to infliximab products. **ADVERSE REACTIONS** Most common adverse reactions: infections, infusion-related reactions, headache, and abdominal pain. **DRUG INTERACTIONS** • Use with anakinra or abatacept – increased risk of serious infections.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ixifi™ (infliximab-qbtx) Injection, for intravenous use / Pfizer Inc. (continuation)	Tumor necrosis factor (TNF) blocker Biosimilar to Remicade (infliximab)	Treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. **Black box warning** Serious infections and malignancy	12/13/2017	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness of infliximab products have been established in pediatric patients 6 to 17 years of age for induction and maintenance treatment of Crohn's disease. However, infliximab products have not been studied in children with Crohn's disease or ulcerative colitis < 6 years of age.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Eskata™ (hydrogen peroxide) Topical Solution / Aclaris Therapeutics, Inc.	Dermatological agent	Treatment of raised seborrheic keratoses	12/14/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is to apply 4 times, approximately 1 minute apart, to the targeted lesion(s) during a single in-office treatment session. Eskata™ is to be administered by a healthcare provider. **DOSAGE FORMS AND STRENGTHS** Topical solution: 40% (w/w) hydrogen peroxide. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Severe skin reaction, including erosion, ulceration, vesiculation and scarring, may occur in treatment area; do not initiate second treatment until skin has recovered from any reaction. • **Ophthalmic:** Corneal injury, chemical conjunctivitis, eyelid edema, severe eye pain, or permanent eye injury, including blindness may occur with direct eye contact; do not apply to eyes or mucosus membranes. **ADVERSE REACTIONS** Most common adverse reactions: erythema, stinging, edema, scaling, crusting, and pruritus. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy and lactatioc:** Hydrogen peroxide is not absorbed systemically following topical administration. Maternal use is not expected to result in fetal exposure to the drug. Breastfeeding is not expected to result in exposure of the child to hydrogen peroxide.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Rhopressa™ (netarsudil) Ophthalmic Solution / Aerie Pharmaceuticals, Inc.	Rho kinase inhibitor	Treatment of open-angle glaucoma or ocular hypertension	12/18/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is one drop into the affected eye(s) once daily in the evening. **DOSAGE FORMS AND STRENGTHS** Ophthalmic solution containing 0.2 mg/mL of netarsudil. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Ophthalmic:** Bacterial keratitis has been reported with multiple-dose containers. **ADVERSE REACTIONS** Most common adverse reactions: conjunctival hyperemia. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No overall 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
Luxturna™ (voretigene neparvovec) Intraocular Suspension, for sub-retinal injection / Spark Therapeutics	Adeno-associated viral (AAV) vector gene therapy	Treatment of patients with vision loss due to confirmed biallelic RPE65-mediated inherited retinal disease (IRD)	12/19/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for each eye is 1.5 x 10^11 vector genomes (vg), administered by sub-retinal injection in a total volume of 0.3mL. Administration to each eye should be performed on separate days within a close interval. Bu no fewer than 6 days apart. It is recommended the use of systemic oral corticosteroids in a dose equivalent to prednisone at 1 mg/kg/day (maximum of 40mg/day) for a total of 7 days (starting 3 days before the administration of Luxturna™ to each eye), and followed by a tapering dose during the next 100 days. **DOSAGE FORMS AND STRENGTHS** Suspension for sub-retinal injection: Supplied in a 0.5mL extractable volume in a single-dose 2mL vial for a single administration in one eye. The supplied concentration (5 x 10^12 vg/mL) requires a 1:10 dilution prior to administration. The diluent is supplied in 2 single-use 2mL vials. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cataract:** Sub-retinal injection of Luxturna™ may result in cataract formation or increase in the rate of cataract progression. • **Endophthalmitis:** Proper aseptic injection technique must be used and monitoring for signs and symptoms of infection is recommended. • **Expansion of intraocular air bubbles:** Air travel and/or scuba diving is not recommended until any intraocular air bubbles have been adsorbed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Luxturna™ (voretigene neparvovec) Intraocular Suspension, for sub-retinal injection / Spark Therapeutics (continuation)	Adeno-associated viral (AAV) vector gene therapy	Treatment of patients with vision loss due to confirmed biallelic RPE65-mediated inherited retinal disease (IRD)	12/19/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Increased intraocular pressure:** Monitoring and management of intraocular pressure elevations is recommended. • **Permanent decline in visual acuity:** Monitoring for visual disturbances is recommended. • **Retinal abnormalities:** Monitor for macular abnormalities, retinal tears or breaks. Do not inject in the immediate vicinity of the fovea. **ADVERSE REACTIONS** Most common adverse reactions: conjunctival hyperemia, cataract, increased intraocular pressure, retinal tear, dellen (thinning of the corneal stroma), macular hole, sub-retinal deposits, eye inflammation, eye irritation, eye pain, and maculopathy (wrinkling on the surface of the macula). **DRUG INTERACTIONS** No interaction studies have been performed. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Use in infants under 12 months of age is not recommended because of potential dilution or loss of Luxturna™ after administration due to the active retinal cells proliferation occurring in this age group.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Steglatro™ (ertugliflozin) Tablets, for oral use / Merck & Co., Inc.	Sodium-glucose co-transporter-2 (SGLT2) inhibitor	To improve glycemic control in adults with type 2 diabetes mellitus **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis	12/19/2017	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 5 mg once daily, taken in the morning, with or without food. Increase dose to 15 mg once daily in those tolerating Steglatro™ and needing additional glycemic control. **DOSAGE FORMS AND STRENGTHS** Tablets: 5 mg and 15 mg. **CONTRAINDICATIONS** • History of serious hypersensitivity reaction to Steglatro™. • Severe renal impairment, end-stage renal disease, or dialysis. **WARNINGS AND PRECAUTIONS** • **Hypotension:** May occur particularly in patients with renal impairment, the elderly, or patients on diuretics. Before initiating, assess and correct volume status. Monitor for signs and symptoms during therapy. • **Ketoacidosis:** Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If suspected, discontinue, evaluate, and treat promptly. Before initiating, consider risk factors for ketoacidosis. Patients may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis. • **Acute kidney injury and impairment in renal function:** Consider temporarily discontinuing in settings of reduced oral intake or fluid losses. If acute kidney injury occurs, discontinue and promptly treat. Monitor renal function. • **Urosepsis and pyelonephritis:** Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated. • **Lower limb amputation:** Before initiating, consider factors that may increase risk of amputation. Monitor patients for infections or ulcers of lower limbs, and discontinue if these occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Steglatro™ (ertugliflozin) Tablets, for oral use / Merck & Co., Inc. (continuation)	Sodium-glucose co-transporter-2 (SGLT2) inhibitor	To improve glycemic control in adults with type 2 diabetes mellitus **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis	12/19/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hypoglycemia:** Consider a lower dose of insulin or insulin secretagogue to reduce risk of hypoglycemia when used in combination. • **Genital mycotic infections:** Monitor and treat if indicated. • **Increased LDL-C:** Monitor and treat as appropriate. **ADVERSE REACTIONS** Most common adverse reactions: female genital mycotic infections **DRUG INTERACTIONS** • **Insulin and insulin secretagogues:** Concomitant use of Steglatro™ with insulin and insulin secretagogues may increase the risk of hypoglycemia. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Not recommended during the second and third trimesters of pregnancy. Advise females of the potential risk to a fetus especially during the second and third trimesters, • **Lactation:** Breastfeeding not recommended. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No dosage adjustment is recommended based on age. However, higher incidence of adverse reactions. related to reduced intravascular volume. • **Renal impairment:** Not recommended in patients with moderate renal impairment. Contraindicated in patients with severe renal impairment, ESRD, or receiving dialysis. No dose adjustment needed with mild renal impairment. • **Hepatic Impairment:** No dosage adjustment needed with mild or moderate hepatic impairment. However, it has not been studied in patients with severe hepatic impairment and is not recommended in this population.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Prexxartan™ (valsartan) Solution, for oral use / Medicure Inc.	Cardiovascular agent Angiotensin II receptor blocker (ARB)	Treatment of hypertension, heart failure, and left ventricular dysfunction following myocardial infarction	12/19/2017	**DOSAGE AND ADMINISTRATION** Recommended dose for hypertension (adults) – Starting dose: 40 or 80 mg twice daily; Dose range: 40 -160 mg twice daily. Recommended dose for hypertension (6 to 16 years) – Starting dose: 0.65 mg/kg twice daily (up to 40 mg total); Dose range: 0.65-1.35 mg/kg twice daily (up to 40 mg-160 mg total). Recommended dose for heart failure – Starting dose: 40 mg twice daily; Dose range: 40 -160 mg twice daily; Target maintenance dose 160 mg twice daily. Recommended dose post-myocardial infarction – Starting dose: 20 mg twice daily; Dose range: 20 -160 mg twice daily; Target maintenance dose 160 mg twice daily. **DOSAGE FORMS AND STRENGTHS** Oral Solution: 4 mg /mL **CONTRAINDICATIONS** • Known hypersensitivity. • Patients with diabetes on aliskiren. **WARNINGS AND PRECAUTIONS** • Observe for signs and symptoms of hypotension. • Monitor renal function and potassium in susceptible patients. **ADVERSE REACTIONS** Most common adverse reactions: headache, dizziness, fatigue, abdominal pain, hypotension, diarrhea, arthralgia back pain, hyperkalemia, cough, and increased blood creatinine.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Prexxartan™ (valsartan) Solution, for oral use / Medicure Inc. (continuation)	Cardiovascular agent Angiotensin II receptor blocker (ARB)	Treatment of hypertension, heart failure, and left ventricular dysfunction following myocardial infarction	12/19/2017	**DRUG INTERACTIONS** • **Potassium-sparing diuretics, potassium supplements or salt substitutes:** May lead to increases in serum potassium, and in heart failure patients, increases in serum creatinine. • **NSAIDs:** Increase risk of renal impairment and loss of antihypertensive effect. • **Dual inhibition of the renin-angiotensin system:** Increased risk of renal impairment, hypotension, and hyperkalemia. • **Lithium:** Increases in serum lithium concentrations and lithium toxicity **USE IN SPECIFIC POPULATIONS** • **Lactation:** Breastfeeding not recommended. • **Pediatric use:** Efficacy and safety data support use in 6 to 16 year old patients; use is not recommended in patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Segluromet™ (ertugliflozin and metformin hydrochloride) Tablets, for oral use / Merck & Co., Inc.	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination	To improve glycemic control in adults with type 2 diabetes who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. **Black box warning** Lactic acidosis	12/19/2017	**DOSAGE AND ADMINISTRATION** The starting dose must be individualize based on the patient's current regimen. Maximum recommended dose is 7.5 mg ertugliflozin/1,000 mg metformin twice daily. Segluromet™ must be taken twice daily with meals, with gradual dose escalation. **DOSAGE FORMS AND STRENGTHS** Tablets: • Ertugliflozin 2.5 mg and metformin hydrochloride 500 mg • Ertugliflozin 2.5 mg and metformin hydrochloride 1,000 mg • Ertugliflozin 7.5 mg and metformin hydrochloride 500 mg • Ertugliflozin 7.5 mg and metformin hydrochloride 1,000 mg **CONTRAINDICATIONS** • History of serious hypersensitivity reaction to ertugliflozin or metformin. • Severe renal impairment, end stage renal disease, or dialysis. • Metabolic acidosis, including diabetic ketoacidosis. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Death, hypothermia, hypotension, and resistant bradyarrhythmias have been reported due to metformin-associated lactic acidosis. Onset may be subtle and include nonspecific symptoms. Increased risk with renal or hepatic impairment, use of certain medications (e.g. those that impair renal function, interfere with acid-base balance, increase metformin accumulation, or result in significant hemodynamic change), age 65 years or older, undergoing a radiological study with contrast, surgery, or other procedures, hypoxic states, and excessive alcohol intake; monitoring recommended. Discontinue if suspected and initiate supportive measures.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Segluromet™ (ertugliflozin and metformin hydrochloride) Tablets, for oral use / Merck & Co., Inc. (continuation)	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination	To improve glycemic control in adults with type 2 diabetes who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. **Black box warning** Lactic acidosis	12/19/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Cardiovascular:** (1) Hypoxic states, including cardiovascular shock, acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia increase risk of lactic acidosis and may cause prerenal azotemia; discontinuation may be necessary. (2) Symptomatic hypotension may occur with therapy initiation, especially in elderly patients (65 years and older), those with impaired renal function (GFR less than 60 mL/min/1.73 m(2)), low systolic blood pressure, and those receiving diuretics; correct volume status prior to therapy initiation and monitor. • **Contrast media:** Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and less than 60 mL/min/1.73 m(2), a history of hepatic impairment, alcoholism, or heart failure, or those who will receive intra-arterial iodinated contrast; monitoring recommended. • **Endocrine and metabolic:** (1) Ketoacidosis, including fatalities, has been reported with an increased risk in patients with alcohol abuse, pancreatic insulin deficiency, and caloric restriction. Patients should be assessed for ketoacidosis regardless of blood glucose level; monitoring is recommended and discontinue if suspected. (2) Hypoglycemia may occur with insufficient calorie intake, strenuous exercise, or concomitant use of hypoglycemic agents or ethanol; increased risk in elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency. (3) Increases in LDL-C may occur; monitoring recommended. • **Hematologic:** Low vitamin B12 levels may occur, especially in patients with inadequate vitamin B12 or calcium intake or absorption; monitoring recommended. • **Hepatic:** Avoid use in patients with clinical or laboratory evidence of hepatic disease due to increased risk of lactic acidosis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Segluromet™ (ertugliflozin and metformin hydrochloride) Tablets, for oral use / Merck & Co., Inc. (continuation)	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination	To improve glycemic control in adults with type 2 diabetes who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. **Black box warning** Lactic acidosis	12/19/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** Sepsis increases risk of lactic acidosis. • **Limb amputation:** Risk of lower limb amputation (primarily toe) may be increased; consider risk factors (peripheral vascular disease, neuropathy, diabetic foot ulcers, prior amputation) prior to initiation of therapy and monitor; discontinue if complications occur. • **Renal:** (1) Starting therapy in patients with an eGFR between 30 to less than 60 mL/min/1.73 m(2) is not recommended; if eGFR falls below 60 mL/min/1.73 m(2) persistently during treatment, continued use is not advisable; assess renal function prior to starting therapy and monitor. (2) Acute kidney injury, sometimes requiring dialysis and hospitalization, has been reported. Increased risk in patients with hypovolemia, chronic renal insufficiency, congestive heart failure, and concomitant use of medications (e.g. diuretics, ACE inhibitors, angiotensin II receptor blockers, and NSAIDs); monitoring recommended and discontinuation may be required. (3) Urinary tract infections resulting in urosepsis and pyelonephritis, some requiring hospitalization, have been reported; monitoring recommended. • **Reproductive:** Genital mycotic infections may occur, especially in patients with history of genital mycotic infections or if uncircumcised; monitoring recommended. • **Surgery:** Use caution in patients undergoing surgery due to increased risk of hypotension, volume depletion, and renal impairment; suspend therapy while food and fluid intake are restricted. **ADVERSE REACTIONS** Most common adverse reactions: • Associated with ertugliflozin: female genital mycotic infections. • Associated with metformin: diarrhea, nausea, vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Segluromet™ (ertugliflozin and metformin hydrochloride) Tablets, for oral use / Merck & Co., Inc. (continuation)	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination	To improve glycemic control in adults with type 2 diabetes who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin **Limitations of use** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. **Black box warning** Lactic acidosis	12/19/2017	**DRUG INTERACTIONS** • Carbonic anhydrase inhibitors may increase risk of lactic acidosis. Consider more frequent monitoring. (7.2) Drugs that reduce metformin clearance (such as ranolazine, vandetanib, dolutegravir, and cimetidine) may increase the accumulation of metformin. Consider the benefits and risks of concomitant use. (7.2) Alcohol can potentiate the effect of metformin on lactate metabolism. Warn patients against excessive alcohol intake. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Advise females of the potential risk to a fetus, especially during the second and third trimesters. • **Lactation:** Breastfeeding not recommended. • **Females and males of reproductive potential:** Advise premenopausal females of the potential for an unintended pregnancy. • **Geriatric use:** Higher incidence of adverse reactions related to reduced intravascular volume. • **Renal impairment:** Higher incidence of adverse reactions related to reduced intravascular volume and renal function. • **Hepatic impairment:** Avoid use in patients with hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Steglujan™ (ertugliflozin and sitagliptin) Tablets, for oral use / Merck & Co., Inc.	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor, and dipeptidyl peptidase-4 (DPP-4) inhibitor combination	To improve glycemic control in adults with type 2 diabetes when treatment with both ertugliflozin and sitagliptin is appropriate **Limitations of use** • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.	12/19/2017	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 5 mg ertugliflozin/100 mg sitagliptin once daily, taken in the morning, with or without food. Increase dose to 15 mg ertugliflozin/100 mg sitagliptin once daily in those tolerating Steglujan™ and needing additional glycemic control. **DOSAGE FORMS AND STRENGTHS** Tablets: • Ertugliflozin 5 mg and sitagliptin 100 mg • Ertugliflozin 15 mg and sitagliptin 100 mg **CONTRAINDICATIONS** • History of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema. • History of serious hypersensitivity reaction to ertugliflozin. • Severe renal impairment, end stage renal disease, or dialysis. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** (1) Symptomatic hypotension may occur with therapy initiation, especially in elderly patients (65 years and older), those with impaired renal function (GFR less than 60 mL/min/1.73 m(2)), low systolic blood pressure, and those receiving diuretics; correct volume status prior to therapy initiation and monitor is recommended. (2) Increased risk for heart failure in patients with a prior history of heart failure and a history of renal impairment; monitoring recommended and discontinuation may be necessary. • **Dermatologic:** Bullous pemphigoid may occur; discontinuation may be necessary. • **Gastrointestinal:** Acute pancreatitis, including fatal and nonfatal hemorrhagic or necrotizing pancreatitis, has been reported with use of sitagliptin; monitoring recommended and discontinue use immediately if suspected.

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Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Steglujan™ (ertugliflozin and sitagliptin) Tablets, for oral use / Merck & Co., Inc. (continuation)	Antidiabetic Sodium glucose co-transporter 2 (SGLT2) inhibitor, and dipeptidyl peptidase-4 (DPP-4) inhibitor combination	To improve glycemic control in adults with type 2 diabetes when treatment with both ertugliflozin and sitagliptin is appropriate **Limitations of use** • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Has not been studied in patients with a history of pancreatitis.	12/19/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Endocrine and metabolic:** (1) Ketoacidosis, including fatalities, has been reported with an increased risk in patients with acute febrile illness, insulin dose reduction, reduced caloric intake, pancreatic disorders suggesting insulin deficiency, and alcohol abuse. Monitoring is recommended and discontinue use if suspected. (2) Increases in low-density lipoprotein cholesterol may occur; monitoring recommended. • **Immunologic:** Serious hypersensitivity reactions, including anaphylaxis, angioedema, and exfoliative skin conditions (e.g. Stevens-Johnson syndrome) have been reported; discontinuation may be necessary. • **Limb amputation:** Risk of lower limb amputation (primarily toe) may be increased; consider risk factors (e.g. peripheral vascular disease, neuropathy, diabetic foot ulcers, prior amputation); monitoring is recommended and discontinuation may be necessary. • **Musculoskeletal:** Severe and disabling arthralgia may occur; discontinuation may be necessary. • **Renal:** (1) Acute kidney injury, sometimes requiring hospitalization and dialysis, has been reported with sodium glucose co-transporter-2 use and sitagliptin; increased risk in patients with hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications (e.g. diuretics, ACE inhibitors, angiotensin II receptor blockers, NSAIDs); monitoring recommended and discontinuation may be required. (2) Serum creatinine increases and decreases to eGFR may occur; increased risk in patient with moderate renal impairment (estimated GFR 30 to less than 60 mL/min/1.73 (m2)); monitoring recommended. (3) Use not recommended in patients with estimated GFR persistently between 30 and less than 60 mL/min/1.73 (m2). (4) Urinary tract infections resulting in urosepsis and pyelonephritis, some requiring hospitalization, have been reported; monitoring recommended. • **Reproductive:** Increased risk of genital mycotic infections with increased risk in patients with prior history of genital

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Macrilen™ (macimorelin) Solution, for oral use / Aeterna Zentaris Inc.	Endocrine-metabolic agent Growth hormone (GH) secretagogue receptor agonist	For the diagnosis of adult growth hormone deficiency **Limitations of use** The safety and diagnostic performance has not been established for subjects with BMI > 40kg/m2.	12/20/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 0.5 mg/kg as a single oral dose, after fasting for at least 8 hours. **DOSAGE FORMS AND STRENGTHS** For oral solution: 60 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Macimorelin prolongs the QT interval. Avoid use in patients who are taking drugs known to prolong the QT interval because additive QT/QTc interval prolongation, which can lead to ventricular tachycardia, may occur. • **Discontinuation:** Strong CYP3A4 inducers can decrease macimorelin plasma levels significantly, which may lead to a false positive result; discontinue strong CYP3A4 inducer to allow enough time prior to testing for washout. • **Endocrine and metabolic:** Recent hypothalamic disease onset may result in false negative test results for adult growth hormone; repeat testing may be warranted. **ADVERSE REACTIONS** Most common adverse reactions: dysgeusia, dizziness, headache, fatigue, nausea, hunger, diarrhea, upper respiratory tract infection, feeling hot, hyperhidrosis, nasopharyngitis, and sinus bradycardia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Macrilen™ (macimorelin) Solution, for oral use / Aeterna Zentaris Inc. (continuaion)	Endocrine-metabolic agent Growth hormone (GH) secretagogue receptor agonist	For the diagnosis of adult growth hormone deficiency **Limitations of use** The safety and diagnostic performance has not been established for subjects with BMI > 40kg/m2.	12/20/2017	**DRUG INTERACTIONS** • **Drugs that prolong QT interval:** Co-administration of with drugs that prolong the QT interval (such as antipsychotic medications (e.g. chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g. moxifloxacin), Class 1A (e.g. quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications or any other medications known to prolong the QT interval) may lead to development of torsade de pointes-type ventricular tachycardia. Avoid concomitant use of Macrilen™ with drugs that prolong the QT interval. Sufficient washout time of drugs that are known to prolong the QT interval prior to administration of Macrilen™ is recommended. • **Cytochrome P450 (CYP) 3A4 inducers:** Co-administration with a strong CYP3A4 inducer (e.g. carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, modafinil, armodafinil, rufinamide) may reduce the plasma macimorelin concentrations and may lead to false positive test results. Discontinue strong CYP3A4 inducers prior to Macrilen™ use. Sufficient washout time of strong CYP3A4 inducers prior to administration of Macrilen™ is recommended. • **Drugs affecting growth hormone release:** Some drugs may impact the accuracy of the Macrilen™ diagnostic test. Avoid concomitant use with the following: (1) Drugs that directly affect the pituitary secretion of growth hormone (e.g. somatostatin, insulin, glucocorticoids, and cyclooxygenase inhibitors such as aspirin or indomethacin); (2) Drugs that may transiently elevate growth hormone concentrations (e.g. clonidine, levodopa, and insulin; (3) Drugs that may blunt the growth hormone response to Macrilen™ (e.g. muscarinic antagonists: atropine, anti-thyroid medication: propylthiouracil, and growth hormone products). Discontinue growth hormone products at least one week before administering the Macrilen™ diagnostic test.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Giapreza™ (angiotensin II) Injection, for intravenous use / La Jolla Pharmaceutical Company	Cardiovascular agent Synthetic human angiotensin II vasoconstrictor	Treatment of hypotension in adults with septic or other distributive shock	12/21/2017	**DOSAGE AND ADMINISTRATION** It is recommended to start Giapreza™ intravenously at 20 nanograms (ng)/kg/min. Titrate as frequently as every 5 minutes by increments of up to 15 ng/kg/min as needed. During the first 3 hours, the maximum dose should not exceed 80 ng/kg/min. Maintenance dose should not exceed 40 ng/kg/min. **DOSAGE FORMS AND STRENGTHS** Injection: 2.5 mg/mL and 5 mg/2 mL (2.5 mg/mL) in a vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hematologic:** There is a potential for venous and arterial thrombotic and thromboembolic events in patients who receive Giapreza™. Use concurrent venous thromboembolism (VTE) prophylaxis. **ADVERSE REACTIONS** Most common adverse reactions: thromboembolic events. **DRUG INTERACTIONS** • **Angiotensin converting enzyme (ACE) inhibitors:** ACE inhibitors may increase response to Giapreza™. • **Angiotensin II Receptor Blockers (ARB):** ARBs may reduce response to Giapreza™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Siklos™ (hydroxyurea) Tablets, for oral use / Addmedica	Antimetabolite	To reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises **Black box warning** Myelosuppression and malignancies	12/21/2017	**DOSAGE AND ADMINISTRATION** The recommended initial dose is 20 mg/kg once daily. Monitor blood counts every two weeks. The dose may be increased by 5 mg/kg/day every 8 weeks, or sooner if a severe painful crisis occurs, until a maximum tolerated dose or 35 mg/kg/day is reached if blood counts are in an acceptable range. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg and functionally triple-scored 1,000 mg tablet. **CONTRAINDICATIONS** • Hypersensitivity to hydroxyurea or any component of the product. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Severe myelosuppression has been reported and may be life-threatening; monitoring required and interruption, dose reduction, or discontinuation may be required. • **Concomitant use:** (1) Avoid use with didanosine or stavudine; severe and sometimes fatal cases of hepatotoxicity, hepatic failure, pancreatitis, peripheral neuropathy have been reported. (2) Avoid use with live vaccinations; severe infection may occur. • **Dermatologic:** (1) Avoid use in patients with wounds on the legs (leg ulcers). (2) Cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, has occurred in patients with myeloproliferative disorders and receiving interferon therapy; discontinue use or reduce dose. (3) Exacerbation of postirradiation erythema may occur; monitoring recommended. • **Hematologic:** Macrocytosis may occur and may mask development pernicious anemia; prophylaxis with folic acid recommended. • **Hepatic:** Monitoring recommended in patients with preexisting hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Siklos™ (hydroxyurea) Tablets, for oral use / Addmedica (continuation)	Antimetabolite	To reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises **Black box warning** Myelosuppression and malignancies	12/21/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) Secondary leukemias and skin cancer have occurred with long-term therapy for myeloproliferative disorders; monitoring and sun protection recommended. (2) Patients with previous radiotherapy or chemotherapy have an increased risk for myelosuppression; monitoring recommended and dose reduction or discontinuation may be required. • **Renal:** Renal impairment (CrCl less than 60 mL/min or ESRD); monitoring recommended and dose reduction required. • **Reproductive:** Fetal harm has been reported with use during pregnancy; verify pregnancy status prior to initiation; adequate contraception required during therapy and after discontinuation. **ADVERSE REACTIONS** Most common adverse reactions: infections and neutropenia. **DRUG INTERACTIONS** • **Antiretroviral drugs:** Increased toxicity with concomitant use of antiretroviral drugs. Pancreatitis (including fatal cases), hepatotoxicity and hepatic failure resulting in death, and peripheral neurophaty have been reported in patient with HIV infection receiving antiretroviral therapy. • **Live virus vaccine:** Concomitant use of Siklos™ with a live virus vaccine may potentiate the replication of the vaccine virus and/or may increase the adverse reactions of the vaccine virus, because normal defense mechanisms may be suppressed by Siklos™ therapy. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. In case of an exposure to Siklos™ of pregnant female patients or pregnant partners of male patients, treated by Siklos™, a careful follow-up with adequate clinical, biological and ultrasonographic examinations should be considered.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Siklos™ (hydroxyurea) Tablets, for oral use / Addmedica (continuation)	Antimetabolite	To reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises **Black box warning** Myelosuppression and malignancies	12/21/2017	**USE IN SPECIFIC POPULATIONS** (continuation) • **Lactation:** Advise women to stop breastfeeding while taking Siklos™. • **Females and males of reproductive potential:** Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females of reproductive potential to use effective contraception during and after treatment with SIKLOS for at least 6 months after therapy. Advise females to immediately report pregnancy. Males with female sexual partners of reproductive potential should use effective contraception during and after treatment with SIKLOS for at least 6 months after therapy. • **Geriatric:** May have increased sensitivity to effects. • **Renal impairment:** Reduce the dose by 50% in patients with creatinine clearance less than 60 mL/min. • **Hepatic impairment:** Close monitoring of hematologic parameters is advised.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Taltz™ (ixekizumab) Injection / Eli Lilly	Humanized interleukin-17A antagonist	Approved for treatment of plaque psoriasis and psoriatic arthritis. **New indication:** Treatment of adults with active psoriatic arthritis	12/01/2017	The efficacy and safety of Taltz™ was determined from findings from 2 studies (SPIRIT-P1 and SPIRIT-P2) including more than 670 adult patients with active psoriatic arthritis (PsA). These studies evaluated the safety and efficacy compared to placebo in (1) patients with active PsA who had never been treated with a biologic disease-modifying antirheumatic drug and in (2) tumor necrosis factor (TNF) inhibitor-experienced patients with active PsA who failed one or two TNF inhibitors. In both studies, the primary efficacy endpoint was the proportion of patients at 24 weeks achieving ACR20 response, which represents a 20% reduction in a composite measure of disease activity as defined by the American College of Rheumatology (ACR). Results from both studies demonstrated that patients treated with Taltz™ achieved significant improvement in joint symptoms, as measured by ACR20, compared with placebo.
Repatha™ (evolocumab) Injection / Amgen	Monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9)	Treatment of patients with heterozygous familial hypercholesterolemia; homozygous familial hypercholesterolemia; and to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease. **New indication:** To prevent heart attacks, strokes and coronary revascularizations in adults with established cardiovascular disease.	10/01//2017	The Repatha™ cardiovascular outcomes study (FOURIER) includd 21,564 patients. Results showed a statistically significant reduction in major adverse cardiovascular events. There was a 15% reduction in the risk of the primary composite endpoint, which included hospitalization for unstable angina, coronary revascularization, heart attack, stroke or cardiovascular death. Repatha™ reduced the risk of heart attack by 27%, the risk of stroke by 21% and the risk of coronary revascularization by 22%.

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Nucala™ (mepolizu-mab) Injection / GlaxoSmithKline	Interleukin-5 antagonist monoclonal antibody (IgG1 kappa)	Add-on maintenance treatment of patients with severe eosinophilic asthma **New indication:** To treat adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)	12/12/2017	EGPA is a rare autoimmune disease that causes vasculitis, an inflammation in the wall of blood vessels of the body. This new indication provides the first FDA-approved therapy specifically to treat EGPA. The approval was based on data from a 52-week treatment clinical trial that compared Nucala™ to placebo. Patients received 300mg of Nucala™ or placebo administered subcutaneously once every 4 weeks while continuing their stable daily oral corticosteroids (OCS) therapy. Starting at week 4, OCS was tapered during the treatment period. The primary efficacy assessment in the trial measured Nucala's treatment impact on disease remission (e.g. becoming symptom free) while on an OCS dose ≤ 4mg of prednisone. Patients receiving 300mg of Nucala™ achieved a significanlty greater accrued time in remission compared with placebo. A significantly higher proportion of patients receiving 300mg of Nucala™ achieved remission at both week 36 and week 48 compared with placebo. In addition, significantly more patients who received 300mg of Nucala™ achieved remission within the first 24 weeks and remained in remission for the remainder of the 52-week study treatment period compared with patients who received the placebo.
Omidria™ (ketorolac and phenylephrine) Injection / Omeros Corporation	Anti-inflammatory and mydriatic combination	It is added to irrigation solution during cataract surgery and intraocular lens replacement procedures. **Patient population altered:** To include use in pediatric patients (ages birth through 17 years old)	12/12/2017	Omidria™, used during cataract surgery or intraocular lens (IOL) replacement, prevents intraoperative miosis (pupil constriction) and reduces postoperative pain.

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Xeljanz and Xeljanz XR (tofacitinib citrate) / Pfizer	Antirheumatic agent Janus kinase (JAK) inhibitors	Treatment of rheumatoid arthritis. **New indication:** Treatment of active psoriatic arthritis (PsA) in adults who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).	12/15/2017	Xeljanz and Xeljanz XR are the first Janus kinase (JAK) inhibitors to be approved for both moderate to severe rheumatoid arthritis and now active PsA.
Cabometyx™ (cabozantinib malate)	Antineoplastic agent Tyrosine kinase inhibitor (TKI)	Treatment of advanced RCC in patients who had previously received anti-angiogenic therapy. **New indication:** First-line treatment for patients with advanced renal cell carcinoma (RCC)	12/19/2017	Available as 20mg, 40mg, and 60mg strength tablets.
Bosulif™ (bosutinib) Tablets / Pfizer	Antineoplastic agent Tyrosine kinase inhibitor (TKI)	Treatment of adults with chronic, accelerated or blast phase Philadelphia chromosome-positive myelogenous leukemia (Ph+ CML) with resistance or intolerance to prior therapy. **New indication:** Treatment of adults with newly-diagnosed chronic phase Ph+ CML	12/20/2017	Taken orally once a day with food, Bosulif™ blocks two different kinase groups that are involved with CML. Recommended dosing for patients new to treatment is 400mg daily. It is supplied as 100mg and 500mg strength tablets; the FDA recently approved a 400mg tablet strength.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Opdivo™ (nivoumab) Injection / Bristol-Myers Squibb	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking monoclonal antibody	Treatment of various renal, urothelial, head and neck carcinomas; hepatocellular carcinoma, microsatellite instability-high or mismatch repair deficient colorectal cancer, classical Hodgkin lymphoma, melanoma, and non-small cell lung cancer. **New indication:** Adjuvant treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection	12/21/2017	The recommended dose of Opdivo™ to treat melanoma is 3mg/ Kg once every two weeks until the disease worsens or the patient can no longer tolerate the drug's side effects.
Perjeta™ (pertuzumab) / Genentech Inc.	Antineoplastic agent Monoclonal antibody	For use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. **New indication:** For use in combination with trastuzumab (Herceptin™) and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.	12/21/2017	In addition, the FDA has converted the previously granted accelerated approval of the Perjeta-based regimen to full approval for neoadjuvant treatment of HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Prexxartan™ (valsartan) Oral Solution / Medicure Inc.	Cardiovascular agent Angiotensin II receptor blocker (ARB)	Treatment of hypertension, heart failure, and left ventricular dysfunction following myocardial infarction	12/20/2016	Prexxartan™ is the first oral liquid dosage form of the angiotensin II receptor blocker, valsartan. Prexxartan™ is not therapeutically equivalent to the tablet formulation of Diovan™; the peak concentration of valsartan with Prexxartan™ is higher than with Diovan™.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Efavirenz Capsules (50mg, 100mg and 200mg) / Aurobindo Pharma Limited	Antiretroviral agent	12/15/2017	Generic for: Sustiva
Atazanavir Sulfate Capsules / Teva	Antiretroviral agent	12/27/2017	Generic for: Reyataz

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Galcanezumab / Eli Lilly and Company	12/11/2017	Migraine Prophylaxis	Galcanezumab is a calcitonin gene-related peptide (CGRP) receptor antagonist in development for the prevention of migraine and cluster headache.	Moderate
Patisiran / Alnylam Pharmaceuticals, Inc.	12/12/2017	Treatment for amyloidogenic Transthyretin Amyloidosis	Patisiran is an investigational RNAi therapeutic targeting transthyretin (TTR) in development for the treatment of hereditary ATTR (hATTR) amyloidosis.	High

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

References:

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