pharmpiX POWERED BY ONEARK 10 YEARS

PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: APRIL 2019

Date: 5/6/2019

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2019

Table of Contents

NEWS……

Drug Issue	Date	News/Event
Harm reported from sudden discontinuation of opioid pain medicines	04/09/2019	The FDA has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased, including serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. As a result, the FDA required changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued. Recommendations for health care professionals: • Do not abruptly discontinue opioids in a patient who is physically dependent. When both the health care provider and the patient have agreed to taper the dose of opioid analgesic, a variety of factors must be considered, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. • No standard opioid tapering schedule exists that is suitable for all patients. A patient-specific plan has to be created to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress. For tapering and additional recommendations, see additional information available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes
Drug Safety Communication and New Boxed Warning for Certain Prescription Medicines for Insomnia	04/30/2019	The FDA advised that rare but serious injuries and deaths have happened with certain common prescription medicines for insomnia because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep. As a result, the FDA required a Boxed Warning to be added to the prescribing information and the patient Medication Guides for these medicines. The FDA also required a Contraindication to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem. Recommendations for healthcare professionals: • Do not prescribe eszopiclone, zaleplon, or zolpidem to patients who have previously experienced complex sleep behaviors after taking any of these medicines. • Advise all patients that although rare, the behaviors caused by these medicines have led to serious injuries or death, and the use of these medicines must be discontinued if they experience an episode of complex sleep behavior.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Asceniv™ (immune globulin intravenous, human – slra) Injection, for intravenous use / ADMA Biologics, Inc.	Immunological Agent	Treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).	04/01/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 300-800 mg/kg every 3- 4 weeks. • Initial infusion rate: 0.5 mg/kg/min (0.005 mL/kg/min) for the first 15 minutes • Maintenance infusion rate: Increase gradually every 15 minutes (if tolerated) up to 8 mg/kg/min (0.08 mL/kg/min) Ensure that patients with pre-existing renal insufficiency are not volume depleted; discontinue ASCENIV if renal function deteriorates. For patients at risk of renal dysfunction or thrombotic events, administer ASCENIV at the minimum infusion rate practicable. **DOSAGE FORMS AND STRENGTHS** Asceniv™ is a liquid solution containing 10% IgG (100 mg/mL) for intravenous infusion; (5g in 50 mL solution). **CONTRAINDICATIONS** • History of anaphylactic or severe systemic reactions to human immunoglobulin. • IgA-deficient patients with antibodies to IgA and a history of hypersensitivity **WARNINGS AND PRECAUTIONS** • IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have medications such as epinephrine available to treat any acute severe hypersensitivity reactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Asceniv™ (immune globulin intravenous, human – slra) Injection, for intravenous use / ADMA Biologics, Inc. (continuation)	Immunological Agent	Treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).	04/01/2019	**WARNINGS AND PRECAUTIONS** (continuation) • Thrombotic events have occurred in patients receiving IGIV treatments. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for patients at risk of hyperviscosity. • In patients at risk of developing acute renal failure. monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output. • Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudo-hyponatremia can occur in patients receiving IGIV treatment. • Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments, especially with high doses or rapid infusion. • Hemolytic anemia can develop subsequent to IGIV treatment. Monitor patients for hemolysis and hemolytic anemia. • Monitor patients for pulmonary adverse reactions (Transfusion-related acute lung injury [TRALI]). If transfusion-related acute lung injury is suspected, test the product and patient for anti-neutrophil antibodies. • Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. **ADVERSE REACTIONS** Most common adverse reactions: headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea. **DRUG INTERACTIONS** • **Live vaccines:** Passive transfer of antibodies may transiently interfere with the immune response to live virus vaccines, such as measles, mumps, rubella, and varicella.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Asceniv™ (immune globulin intravenous, human – slra) Injection, for intravenous use / ADMA Biologics, Inc. (continuation)	Immunological Agent	Treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age).	04/01/2019	**DRUG INTERACTIONS** (continuation) • **Serological testing:** Passive transfer of antibodies may confound the results of serological testing. **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse Asceniv™ at the minimum infusion rate practicable.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Evenity™ (romosozumab-aqqg) Injection, for subcutaneous use /Amgen Inc.	Endocrine-Metabolic Agent; Sclerostin inhibitor	Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy **Limitations of use** Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.	04/09/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 210 mg subcutaneously once every month for 12 doses in the abdomen, thigh, or upper arm. Two separate subcutaneous injections are needed to administer the total dose of 210 mg. Inject two syringes, one after the other. Evenity™ should be administered by a healthcare provider. Adequately supplement calcium and vitamin D during treatment. **DOSAGE FORMS AND STRENGTHS** Injection: 105 mg/1.17 mL solution in a single-use prefilled syringe. A full dose of Evenity™ requires two single-use prefilled syringes. **CONTRAINDICATIONS** • Hypocalcemia. • Known hypersensitivity to Evenity™. **WARNINGS AND PRECAUTIONS** • **Major Adverse Cardiac Events (MACE):** Monitor for symptoms of MI and stroke and seek prompt medical attention if symptoms occur. • **Hypersensitivity:** Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria. Discontinue if a clinically significant allergic reaction occurs. • **Hypocalcemia:** Adequately supplement calcium and vitamin D during treatment. • **Osteonecrosis of the Jaw:** Monitor for symptoms. Consider discontinuation of therapy based on benefit-risk assessment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Evenity™ (romosozumab-aqqg) Injection, for subcutaneous use /Amgen Inc. (continuation)	Endocrine-Metabolic Agent; Sclerostin inhibitor	Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy **Limitations of use** Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.	04/09/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Atypical Femoral Fracture:** Evaluate new or unusual thigh, hip, or groin pain to rule out an incomplete femur fracture. **ADVERSE REACTIONS** Most common adverse reactions: arthralgia and headache. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or efficacy were observed between older and younger subjects, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. • **Renal impairment:** No dose adjustment is required in patients with renal impairment. Patients with severe renal impairment or receiving dialysis are at greater risk of developing hypocalcemia. Monitor serum calcium and supplement with calcium and vitamin D.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Balversa™ (erdafitinib) Tablets, for oral use / Janssen Pharmaceuticals, Inc.	Antineoplastic Agent; Kinase Inhibitor	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has: • susceptible FGFR3 or FGFR2 genetic alterations and • progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials	04/12/2019	**DOSAGE AND ADMINISTRATION** The recommended initial dose is 8 mg orally once daily with a dose increase to 9 mg daily if criteria are met. Confirm the presence of FGFR genetic alterations in tumor specimens prior to initiation of treatment. **DOSAGE FORMS AND STRENGTHS** Tablets: 3 mg, 4 mg, and 5 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Ocular disorders:** Balversa™ can cause central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED). Perform monthly ophthalmological examinations during the first four months of treatment, every 3 months afterwards, and at any time for visual symptoms. Withhold Balversa™ when CSR/RPED occurs and permanently discontinue if it does not resolve within 4 weeks or if Grade 4 in severity. • **Hyperphosphatemia:** Increases in phosphate levels are a pharmacodynamic effect of Balversa™. Monitor for hyperphosphatemia and manage with dose modifications when required. • **Embryo-fetal toxicity:** Can cause fetal harm. Advise patients of the potential risk to the fetus and to use effective contraception.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Balversa™ (erdafitinib) Tablets, for oral use / Janssen Pharmaceuticals, Inc. (continuation)	Antineoplastic Agent; Kinase Inhibitor	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has: • susceptible FGFR3 or FGFR2 genetic alterations and • progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials	04/12/2019	**ADVERSE REACTIONS** Most common adverse reactions: phosphate increased, stomatitis, fatigue, creatinine increased, diarrhea, dry mouth, onycholysis, alanine aminotransferase increased, alkaline phosphatase increased, sodium decreased, decreased appetite, albumin decreased, dysgeusia, hemoglobin decreased, dry skin, aspartate aminotransferase increased, magnesium decreased, dry eye, alopecia, palmar-plantar erythrodysesthesia syndrome, constipation, phosphate decreased, abdominal pain, calcium increased, nausea, and musculoskeletal pain. **DRUG INTERACTIONS** • **Strong CYP2C9 or CYP3A4 inhibitors:** Consider alternative agents or monitor closely for adverse reactions. • **Strong CYP2C9 or CYP3A4 inducers:** Avoid concomitant use. • **Moderate CYP2C9 or CYP3A4 inducers:** Increase Balversa™ dose up to 9 mg. • **Serum phosphate level-altering agents:** Avoid concomitant use with agents that can alter serum phosphate levels before the initial dose modification period. • **CYP3A4 substrates:** Avoid concomitant use with sensitive CYP3A4 substrates with narrow therapeutic indices. • **OCT2 substrates:** Consider alternative agents or consider reducing the dose of OCT2 substrates based on tolerability. • **P-gp substrates:** Separate Balversa™ administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Balversa™ (erdafitinib) Tablets, for oral use / Janssen Pharmaceuticals, Inc. (continuation)	Antineoplastic Agent; Kinase Inhibitor	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has: • susceptible FGFR3 or FGFR2 genetic alterations and • progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials	04/12/2019	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on mechanism of action and findings in animal reproduction studies, can cause fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment. • **Females and males of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for one month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for one month after the last dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between older and younger patients. • **CYP2C9 poor metabolizers:** CYP2C9*3/*3 Genotype: Erdafitinib plasma concentrations were predicted to be higher in patients with the CYP2C9*3/*3 genotype. Monitor for increased adverse reactions in patients who are known or suspected to have CYP2C9*3/*3 genotype.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Skyrizi™ (risankizumab-rzaa) Injection, for subcutaneous use / AbbVie Inc.	Anti-psoriatic; Interleukin-23 (IL-23) inhibitor	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	04/23/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 150 mg (two 75 mg injections) administered by subcutaneous injection at Week 0, Week 4 and every 12 weeks thereafter. **DOSAGE FORMS AND STRENGTHS** Injection: 75 mg/0.83 mL in each single-dose prefilled syringe. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Infections:** Skyrizi™ may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer Skyrizi™ until the infection resolves. • **Tuberculosis (TB):** Evaluate for TB prior to initiating treatment. **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections. **DRUG INTERACTIONS** • **Live vaccines:** Avoid use of live vaccines in patients treated with Skyrizi™. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy of in pediatric patients have not yet been established. • **Geriatric use:** No overall differences were observed between older and younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Eticovo™ (etanercept-ykro) Injection, for subcutaneous use / Samsung Bioepis Co., Ltd.	Tumor necrosis factor (TNF) blocker Note: Biosimilar to Enbrel™	Treatment of: • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Plaque Psoriasis (PsO) in patients 4 years or older	04/25/2019	**DOSAGE AND ADMINISTRATION** • For adult RA and PsA: 50 mg once weekly with or without methotrexate (MTX). • For AS: 50 mg once weekly. • For adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly. • For pediatric PsO or JIA (patients who weigh 63 kg or more): 50 mg once weekly. **DOSAGE FORMS AND STRENGTHS** Injection: 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe. **CONTRAINDICATIONS** • Sepsis. **WARNINGS AND PRECAUTIONS** • Do not start Eticovo™ during an active infection. If an infection develops, monitor carefully and stop Eticovo™ if infection becomes serious. • Consider empiric anti-fungal therapy for patients at risk for invasive fungal infections who develop a severe systemic illness on Eticovo™ (those who reside or travel to regions where mycoses are endemic). • Demyelinating disease, exacerbation or new onset, may occur. • Cases of lymphoma have been observed in patients receiving TNF-blocking agents. • Congestive heart failure, worsening or new onset, may occur. • Advise patients to seek immediate medical attention if symptoms of pancytopenia or aplastic anemia develop, and consider stopping Eticovo™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Eticovo™ (etanercept-ykro) Injection, for subcutaneous use / Samsung Bioepis Co., Ltd. (continuation)	Tumor necrosis factor (TNF) blocker Note: Biosimilar to Enbrel™	Treatment of: • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Plaque Psoriasis (PsO) in patients 4 years or older	04/25/2019	**WARNINGS AND PRECAUTIONS** (continuation) • Monitor patients previously infected with hepatitis B virus for reactivation during and several months after therapy. If reactivation occurs, consider stopping Eticovo and beginning anti-viral therapy. • Anaphylaxis or serious allergic reactions may occur. • Stop Eticovo™ if lupus-like syndrome or autoimmune hepatitis develops. **ADVERSE REACTIONS** Most common adverse reactions: infections and injection site reactions. **DRUG INTERACTIONS** • **Live vaccines:** Should not be given with Eticovo™. • **Anakinra:** Increased risk of serious infection. • **Abatacept:** Increased risk of serious adverse events, including infections. • **Cyclophosphamide:** Use with Eticovo™ is not recommended.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Ibrance™ (palbociclib) Capsules / Pfizer Inc.	Antineoplastic agent; Cyclin-dependent kinase 4/6 (CDK4/6) inhibitor	**Previous indication(s):** Treatment of ER+, HER2- metastatic breast cancer **New indication:** In combination with an aromatase inhibitor or fulvestrant to include men with HR+, HER2- advanced or metastatic breast cancer	04/04/2019	The approval is based on data from electronic health records and post-marketing reports of the real-world use of Ibrance™ in male patients sourced from three databases: IQVIA Insurance database, Flatiron Health Breast Cancer database and the Pfizer global safety database.
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, and Merkel cell carcinoma **New indication:** As monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations	04/11/2019	This approval was based on results from a Phase 3 trial in which overall survival (OS) was sequentially tested as part of a pre-specified analysis plan. In the trial, Keytruda™ monotherapy demonstrated a statistically significant improvement in OS compared with chemotherapy alone in patients whose tumors expressed PD-L1 with a TPS ≥50%, with a TPS ≥20%, and then in the entire study population (TPS ≥1%).

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, and Merkel cell carcinoma **New indication:** In combination with Inlyta™ (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma (RCC)	04/19/2019	This approval was based on findings from a Phase 3 trial that demonstrated significant improvements in overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) for Keytruda™ in combination with Inlyta™ compared to sunitinib. For the main efficacy outcome measures of OS and PFS, the combination of Keytruda™ and Inlyta™ reduced the risk of death by 47% compared to sunitinib (HR=0.53 [95% CI: 0.38-0.74]; p<0.0001); for PFS, the combination of Keytruda™ and Inlyta™ showed a reduction in the risk of progression of disease or death of 31% compared to sunitinib (HR=0.69 [95% CI: 0.57-0.84]; p=0.0001). The ORR was 59% for patients who received the combination of Keytruda™ and Inlyta™ (95% CI: 54-64) and 36% for those who received sunitinib (95% CI: 31-40) (p<0.0001). This is the first indication for Keytruda™ in advanced RCC, which is the most common type of kidney cancer, and the first anti-PD-1 therapy FDA-approved as part of a combination regimen that significantly improved OS, PFS, and ORR versus sunitinib in patients with advanced RCC.
Benlysta™ (belimumab) Injection	Immunological agent; B-lymphocyte stimulator-specific inhibitor	**Previous indication(s):** Treatment of patients with systemic lupus erythematosus **Patient population altered:** To include children with lupus from as young as five years of age	04/26/2019	Benlysta™ was approved in the U.S. in March 2011 for adults, and is currently the only medicine specifically approved in the U.S. for both adults and children with SLE.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Praluent™ (alirocumab) Injection / Sanofi and Regeneron Pharmaceuticals, Inc.	Anti-hyperlipidemic; Cardiovascular agent; PCSK9 (pro-protein convertase subtilisin/kexin type 9) inhibitor monoclonal antibody	**Previous indication(s):** Treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C **New indication:** To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease	04/26/2019	This approval was based on data from ODYSSEY OUTCOMES, which assessed the effect of adding Praluent™ to maximally-tolerated statins on CV outcomes in patients who had an acute coronary syndrome (ACS) within a year of enrolling in the trial. Patients who received Praluent™ in the trial experienced: • A 15% reduced risk for major CV events. The primary endpoint included time to first heart attack, stroke, death from coronary heart disease (CHD), or unstable angina requiring hospitalization (HR 0.85; 95% CI: 0.78 to 0.93; p=0.0003). • A 27% reduced risk of stroke, 14% reduced risk of non-fatal heart attack and 39% reduced risk of unstable angina requiring hospitalization. • A 15% reduced risk of death from any cause (also called all-cause mortality; HR 0.85; 95% CI, 0.73 to 0.98; nominal p=0.026) was also observed.
Mavyret™ (glecaprevir and pibrentasvir) Tablets / Abbvie	Anti-infective; Antiviral; Combination of an NS3/4A protease inhibitor, and pibrentasvir, an NS5A inhibitor	**Previous indication(s):** Treatment of all major genotypes (GT1-6) of chronic hepatitis C **Patient population altered:** To include children ages 12 to 17	04/30/2019	The safety and efficacy of Mavyret™ in pediatric patients was evaluated during clinical trials of 47 patients with genotype 1, 2, 3 or 4 HCV infection without cirrhosis or with mild cirrhosis. Results of the studies demonstrated that 100% of patients who received Mavyret™ for 8 or 16 weeks had no virus detected in the blood 12 weeks after finishing treatment, suggesting that patients' infection had been cured. In pediatric patients with cirrhosis, history of a kidney and/or liver transplant, or genotype 5 or 6 HCV infection, the safety and efficacy of Mavyret™ are supported by previous studies observed in glecaprevir and pibrentasvir in adults. The adverse reactions observed were consistent with those observed in clinical studies of Mavyret™ in adults

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Dovato™ (dolutegravir and lamivudine) Tablets / ViiV Healthcare	Anti-infective agent; Antiviral	Treatment of HIV-1 infection in adults with no antiretroviral (ARV) treatment history and with no known resistance to either dolutegravir or lamivudine.	04/08/2019	Dovato™ is a once-daily, single-tablet, two-drug regimen of the approved drugs dolutegravir (Tivicay™) and lamivudine (Epivir™).
Corlanor™ (ivabradine) Oral Solution / Amgen Inc.	Cardiovascular agent; Hyperpolarization-activated cyclic nucleotide-gated channel blocker	• To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction. • For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older.	04/22/2019	Corlanor™ was already available as oral tablet.
Duobrii™ (halobetasol propionate and tazarotene) Lotion / Bausch Health Companies Inc.	Dermatological agent; Anti-inflammatory; Corticosteroid and retinoid combination	Treatment of plaque psoriasis in adults	04/25/2019	Duobrii™ is the first and only topical lotion that contains a combination of halobetasol propionate and tazarotene in one formulation.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Naftifine Hydrochloride Topical Gel 2% / Taro Pharmaceuticals Inc.	Dermatological agent; Antifungal	04/10/2019	Generic for: Naftin Gel 2%
Loteprednol Etabonate Ophthalmic Suspension 0.5% / Hi-Tech Pharmacal Co., Inc.	Ophthalmologic agent; Corticosteroid	04/17/2019	Generic for: Lotemax Ophthalmic Suspension 0.5%
Valrubicin Intravesical Solution 40mg/mL / Custopharm, Inc.	Antineoplastic agent; Anthracycline	04/19/2019	Generic for: Valstar
Naloxone Hydrochloride Nasal Spray 4mg/spray / Teva Pharmaceuticals USA, Inc.	Opioid antagonist	04/19/2019	Generic for: Narcan Nasal Spray
Everolimus Tablets for Oral Suspension 2 mg, 3 mg, and 5 mg / Mylan Pharmaceuticals, Inc.	Antineoplastic agent	04/19/2019	Generic for: Afinitor Disperz
Rufinamide Oral Suspension 40mg/mL / Bionpharma, Inc.; Hikma Pharmaceuticals USA Inc.	Central nervous system agent; Anticonvulsant	04/23/2019	Generic for: Banzel Oral Suspension
Pentamidine Isethionate for Inhalation Solution 300mg/vial / Seton Pharmaceuticals	Anti-infective agent; Antiprotozoal	04/24/2019	Generic for: Nebupent
Bosentan Tablets 62.5 mg and 125 mg / Alvogen Inc.; Amneal Pharmaceuticals LLC; Natco Pharma Ltd.; Par Pharmaceutical, Inc.; Sun Pharmaceutical Industries, Inc.; Watson Labs Inc.; West-Ward Pharmaceuticals Corp.; Zydus Pharmaceuticals (USA) Inc.	Anti-hypertensive agent; endothelin receptor antagonist	04/26/2019	Generic for: Tracleer

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
KW-6002 (istradefylline) / Kyowa Kirin, Inc.	04/04/2019	Treatment for: Parkinson's Disease	Istradefylline is an investigational adenosine A2A receptor antagonist intended for use as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "OFF" episodes. Kyowa Kirin announced the FDA acceptance of the NDA resubmission for Istradefylline.	High
Luspatercept / Celgene Corporation	04/05/2019	Treatment for: Anemia associated to myelodysplastic syndromes (MDS) and beta-thalassemia	Luspatercept is a first-in-class erythroid maturation agent (EMA) in development for the treatment of myelodysplastic syndromes (MDS)-associated anemia and beta-thalassemia-associated anemia. Celgene announced the submission of the BLA for luspatercept.	High
Remimazolam / Cosmo Pharmaceuticals NV	04/09/2019	Treatment for: Anesthesia	Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic in development for use during gastrointestinal procedures. Cosmo pharmaceuticals announced the submission of the NDA for remimazolam.	Low
Brolucizumab / Novartis	04/15/2019	Treatment for: Macular Degeneration	Brolucizumab (RTH258) is an anti-vascular endothelial growth factor (VEGF) single-chain antibody fragment in development for the treatment of wet age-related macular degeneration (AMD). Novartis announced the FDA acceptance of the BLA for brolucizumab.	High

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

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)