pharmpiX 10 YEARS

POWERED BY ONEARK

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.
From: DECEMBER 2018

Date: 1/4/2019

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2019

Table of Contents

NEWS……

Drug Issue	Date	News/Event
Increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients	12/20/2018	The FDA is warning that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the aorta, which can lead to dangerous bleeding or even death. These complications can occur with fluoroquinolones for systemic use given by mouth or through an injection. For this reason, fluoroquinolones should not be used in patients at increased risk for an aortic aneurysm, unless there are no other treatment options available. People at increased risk include those with a history of blockages or aneurysms of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly. The FDA is requiring that a new warning about this risk be added to the prescribing information and patient Medication Guide for all fluoroquinolones. Recommendations for healthcare providers: • Avoid prescribing fluoroquinolone antibiotics to patients who have an aortic aneurysm or are at risk for an aortic aneurysm. Prescribe fluoroquinolones to these patients only when no other treatment options are available. • Advise all patients to seek immediate medical treatment for any symptoms associated with aortic aneurysm. • Stop fluoroquinolone treatment immediately if a patient reports side effects suggestive of aortic aneurysm or dissection. • Encourage patients to read the Medication Guide they receive with their fluoroquinolone antibiotic prescription. • Report adverse events involving fluoroquinolone antibiotics or other medicines to the FDA MedWatch program.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Herzuma™ (trastuzumab-pkrb) Injection, for intravenous use / Celltrion, Inc. and Teva Pharmaceutical Industries Ltd.	Antineoplastic agent HER2/neu receptor antagonist Note: Biosimilar to Herceptin™.	Treatment of HER2-overexpressing breast cancer **Black box warning** Cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity	12/14/2018	**DOSAGE AND ADMINISTRATION** • Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product. • Do not substitute Herzuma™ (trastuzumab-pkrb) for or with ado-trastuzumab emtansine. Adjuvant Treatment of HER2-Overexpressing Breast Cancer • The recommended initial dose is 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 and carboplatin). One week after the last weekly dose of Herzuma™, administer 6 mg/kg as an IV infusion over 30–90 minutes every three weeks to complete a total of 52 weeks of therapy. Metastatic HER2-Overexpressing Breast Cancer • The recommended dose is initially 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions. **DOSAGE FORMS AND STRENGTHS** For Injection: 420 mg lyophilized powder in a multiple-dose vial for reconstitution. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Exacerbation of chemotherapy-induced neutropenia. **ADVERSE REACTIONS** Adjuvant Breast Cancer Most common adverse reactions: headache, diarrhea, nausea, and chills.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Herzuma™ (trastuzumab-pkrb) Injection, for intravenous use / Celltrion, Inc. and Teva Pharmaceutical Industries Ltd. (continuation)	Antineoplastic agent HER2/neu receptor antagonist Note: Biosimilar to Herceptin™.	Treatment of HER2-overexpressing breast cancer **Black box warning** Cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity	12/14/2018	**ADVERSE REACTIONS** (continuation) Metastatic Breast Cancer Most common adverse reactions: fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash. **DRUG INTERACTIONS** • 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. • **Females of reproductive potential:** Verify the pregnancy status of females of reproductive potential prior to the initiation. Advise females of reproductive potential to use effective contraception during treatment and for 7 months following the last dose. • **Pediatric use:** Safety and effectiveness of trastuzumab products in pediatric patients have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Motegrity™ (prucalopride) Tablets, for oral use / Shire plc	Selective serotonin type 4 (5-HT4) receptor agonist	Treatment of chronic idiopathic constipation (CIC) in adults	12/14/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 2 mg once daily. Dose adjustment is recommended for patients with severe renal impairment (CrCL less than 30 mL/min: 1 mg once daily. **DOSAGE FORMS AND STRENGTHS** Tablets: 1 mg, 2 mg of prucalopride. **CONTRAINDICATIONS** • Hypersensitivity to Motegrity™. • Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum. **WARNINGS AND PRECAUTIONS** • **Psychiatric:** Suicides, suicide attempts, and suicidal ideation have been reported; monitoring recommended and discontinue therapy immediately for any symptoms. **ADVERSE REACTIONS** Most common adverse reactions: headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety and effectiveness observed between elderly and younger patients. • **Renal impairment:** Motegrity™ is substantially excreted by the kidney. A decreased dosage is recommended in patients with severe renal impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Asparlas™ (calaspargase pegol-mknl) Injection, for intravenous use / Servier Pharmaceuticals LLC	Antineoplastic agent Asparagine specific enzyme Note: Orphan drug designation	As a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years	12/20/2018	**DOSAGE AND ADMINISTRATION** The recommended dose 2,500 units/m2 intravenously no more frequently than every 21 days. **DOSAGE FORMS AND STRENGTHS** Injection: 3,750 units/5 mL (750 units/mL) in a single-dose vial. **CONTRAINDICATIONS** • History of serious hypersensitivity reactions to pegylated L-asparaginase. • History of serious thrombosis during L-asparaginase therapy. • History of serious pancreatitis related to previous L-asparaginase treatment. • History of serious hemorrhagic events during previous L-asparaginase therapy. • Severe hepatic impairment. **WARNINGS AND PRECAUTIONS** • **Hypersensitivity:** Observe patients for one hour after administration. Discontinue Asparlas™ in patients with serious hypersensitivity reactions. • **Pancreatitis:** Discontinue Asparlas™ in patients with pancreatitis. Monitor blood glucose. • **Thrombosis:** Discontinue Asparlas™ for severe or life-threatening thrombosis. Provide anticoagulation therapy as indicated. • **Hemorrhage:** Discontinue Asparlas™ for severe or life-threatening hemorrhage. Evaluate for etiology and treat. • **Hepatotoxicity:** Monitor for toxicity through recovery from cycle. **ADVERSE REACTIONS** Most common adverse reactions: elevated transaminase, bilirubin increased, pancreatitis and abnormal clotting studies.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Asparlas™ (calaspargase pegol-mknl) Injection, for intravenous use / Servier Pharmaceuticals LLC (continuation)	Antineoplastic agent Asparagine specific enzyme Note: Orphan drug designation	As a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years	12/20/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on published literature studies in pregnant animals, Asparlas™ can cause fetal harm when • administered to a pregnant woman. • **Females of reproductive potential:** Conduct pregnancy testing in females of reproductive potential prior to starting treatment. Advise females of reproductive potential to avoid becoming pregnant while receiving Asparlas™. Females should use effective contraceptive methods, including a barrier method, during treatment and for at least 3 months after the last dose. • **Lactation:** Advise women not to breastfeed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Elzonris™ (tagraxofusp-erzs) Injection, for intravenous use / Stemline Therapeutics, Inc.	Antineoplastiv agent CD123-directed cytotoxin Note: Orphan drug designation	Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older **Black box warning** Capillary leak syndrome	12/21/2018	**DOSAGE AND ADMINISTRATION** The recommended dose 12 mcg/kg over 15 minutes once daily on days 1 to 5 of a 21-day cycle. • Administer the first cycle in the inpatient setting. Subsequent cycles may be administered in the inpatient or appropriate outpatient setting. • Premedicate with an H1-histamine antagonist, acetaminophen, corticosteroid and H2-histamine antagonist prior to each Elzonris™ infusion. **DOSAGE FORMS AND STRENGTHS** Injection: 1,000 mcg in 1 mL in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hypersensitivity:** Monitor patients for signs/symptoms and treat appropriately. • **Hepatotoxicity:** Monitor ALT and AST. Interrupt ELZONRIS if the transaminases rise to greater than 5 times the upper limit of normal. **ADVERSE REACTIONS** Most common adverse reactions: capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia and weight increase. **DRUG INTERACTIONS** No drug-drug interaction studies have been conducted.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Elzonris™ (tagraxofusp-erzs) Injection, for intravenous use / Stemline Therapeutics, Inc. (continuation)	Antineoplastiv agent CD123-directed cytotoxin Note: Orphan drug designation	Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older **Black box warning** Capillary leak syndrome	12/21/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • No drug-drug interaction studies have been conducted. • **Females of reproductive potential:** Conduct pregnancy testing in females of reproductive potential within 7 days prior to initiating. Advise females to use acceptable contraceptive methods during treatment and for at least 1 week after the last dose. • **Lactation:** Advise women not to breastfeed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ultomiris™ (ravulizumab-cwvz) Injection, for intravenous use / Alexion Pharmaceuticals, Inc.	Blood modifier agent C5 complement inhibitor Note: Orphan drug designation	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) **Black box warning** Serious meningococcal infections	12/21/2018S	**DOSAGE AND ADMINISTRATION** The recommended dose is weight-based: • For patient greater or equal to 40kg to less than 60kg - Loading dose: 2,400mg; Maintenance dose: 3,000mg. • For patient greater than or equal to 60kg to less than 100kg - Loading dose: 2,700mg; Maintenance dose: 3,300mg. • For patient greater than or equal to 100kg - Loading dose: 3,000mg; Maintenance dose: 3,600mg. Starting 2 weeks after the loading dose administration, begin maintenance doses at a once every 8-week interval. The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose) but the subsequent dose should be administered according to the original schedule. **DOSAGE FORMS AND STRENGTHS** Injection: 300 mg/30 mL (10 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** • Unresolved Neisseria *Meningitidis* infection. **WARNINGS AND PRECAUTIONS** • Use caution when administering to patients with any other systemic infection. **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory infection and headache. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in pediatric patients have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Vaxelis™ (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, haemophilus b conjugate [meningococcal protein conjugate] and hepatitis B [recombinant] vaccine) Suspension, for Intramuscular Injection / Merck and Sanofi	Hexavalent combination vaccine	Immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b in children from 6 weeks through 4 years of age (prior to the 5th birthday)	12/21/2018	**DOSAGE AND ADMINISTRATION**
				The recommended regimen is a 3-dose immunization series consisting of a 0.5 mL intramuscular injection, administered at 2, 4, and 6 months of age.
				
				DOSAGE FORMS AND STRENGTHS
				Suspension for injection (0.5 mL dose) supplied in single dose vials.
				
				CONTRAINDICATIONS
				• Severe allergic reaction to a previous dose of Vaxelis™, any ingredient of Vaxelis™, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or Haemophilus influenzae type b vaccine.
				• Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.
				• Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.
				
				WARNINGS AND PRECAUTIONS
				• Carefully consider benefits and risks before administering Vaxelis™ to persons with a history of:
				  • fever ≥40.5°C (≥105°F), hypotonic-hyporesponsive episode (HHE) or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine.
				  • seizures within 3 days after a previous pertussis-containing vaccine.
				• If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Vaxelis™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vaxelis™ (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, haemophilus b conjugate [meningococcal protein conjugate] and hepatitis B [recombinant] vaccine) Suspension, for Intramuscular Injection / Merck and Sanofi (continuation)	Hexavalent combination vaccine	Immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b in children from 6 weeks through 4 years of age (prior to the 5th birthday)	12/21/2018	**WARNINGS AND PRECAUTIONS** (continuation) • Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including Vaxelis™, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. • Urine antigen detection may not have definitive diagnostic value in suspected H. influenzae type b disease following vaccination with Vaxelis™. **ADVERSE REACTIONS** Most common adverse reactions: irritability, crying, injection site pain, somnolence, injection site erythema, decreased appetite, fever ≥38.0°C, injection site swelling, and vomiting.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tecentriq™ (atezolizumab) Injection / Genentech, Inc.	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	**Previous indication(s):** Treatment of urothelial carcinoma and metastatic non-small cell lung cancer (with disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities) **New indication:** For the first-line treatment of people with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations	12/06/2018	The approval is based on results from a study that showed that Tecentriq™ in combination with Avastin™ and chemotherapy helped people live significantly longer compared to Avastin™ and chemotherapy (median overall survival [OS] = 19.2 versus 14.7 months; HR = 0.78; 95% CI: 0.64-0.96; p-value = 0.016). The safety profile of the Tecentriq™ combination was consistent with that observed in previous studies.
Nplate™ (romiplostim) / Amgen Inc.	Blood modifier agent; Thrombopoietin receptor agonist	**Previous indication(s):** Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) **Patient population altered:** For the treatment of pediatric patients one year of age and older with ITP for at least six months who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy	12/14/2018	The approval is based on two placebo-controlled studies evaluating the safety and efficacy of Nplate™ in pediatric patients. Rates of overall platelet response were increased with the Nplate™ group (71%) compared with placebo (20%). Additionally, durable platelet response occurred more frequently with Nplate™ (52%) compared with placebo (10%). Common adverse reactions were contusion, upper respiratory tract infection and oropharyngeal pain.

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, 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, and hepatocellular carcinoma **New indication:** Treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC)	12/19/2018	The approval is based on results from a study in patients with recurrent locally advanced or metastatic MCC who had not received prior systemic therapy for their advanced disease. Keytruda™ monotherapy demonstrated an objective response rate of 56%, with a complete response rate of 24% and a partial response rate of 32%.
Lynparza™ (olaparib) Tablets / AstraZeneca	Antineoplastic agent; poly ADP ribose polymerase (PARP) inhibitor	**Previous indication(s):** Treatment of advanced ovarian cancer; for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer; and for the treatment of germline BRCA-mutated metastatic breast cancer **New indication:** Maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy	12/19/2018	This is the first FDA-approval for a PARP inhibitor in the 1st-line maintenance setting for BRCAm advanced ovarian cancer. The approval was based on positive results from a study in which Lynparza™ reduced the risk of disease progression or death by 70% in patients with BRCAm advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy compared to placebo. It is of note that patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer are selected for therapy based on an FDA-approved companion diagnostic for Lynparza™.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Envarsus XR™ (tacrolimus) Extended-Release Tablets / Veloxis Pharmaceuticals A/S	Immuno-suppressant	**Previous indication(s):** Prophylaxis of organ rejection in kidney transplant patients **New indication:** To prevent organ rejection in de novo kidney transplant patients in combination with other immunosuppressants	12/19/2018	Envarsus XR™ was already approved for the prophylaxis of organ rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus XR™. This new indication is commonly referred to as the de novo indication and provides new treatment option for kidney transplant patients and providers, where significant unmet need currently exists.
Ravicti™ (glycerol phenylbutyrate) Oral Liquid / Hyperion Therapeutics	Endocrine-Metabolic agent; Nitrogen-binding agent	**Previous indication(s):** Chronic management of patients with urea cycle disorders **Patient population altered:** To include infants younger than two months of age living with a urea cycle disorder	12/21/2018	Ravicti™ is now approved for use in adults and children of all ages who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

New FDA Approved Dosage Forms, Formulations, and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Dextenza™ (dexamethasone) Ophthalmic Insert / Ocular Therapeutix, Inc.	Corticosteroid	Treatment of post-surgical ocular inflammation and pain	11/30/2018	Dextenza™ is the first FDA-approved intra-canalicular insert delivering dexamethasone to treat post-surgical ocular pain for up to 30 days with a single administration.
Tolsura™ (itraconazole) Capsules / Mayne Pharma US	Anti-infective agent; Antifungal; Azole	Treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: • Blastomycosis, pulmonary and extrapulmonary, • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and • Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.	12/11/2018	Tolsura™ is a new formulation of itraconazole indicated for the treatment of certain systemic fungal infections in adult patients. Important note: Tolsura™ capsules are not interchangeable or substitutable with any other itraconazole formulation due to differences in dosing.
Ezallor™ (rosuvastatin) Capsules / Sun Pharma Global	Antihyperlipidemic; HMG Co-A reductase inhibitor	• Adult patients with hypertriglyceridemia as an adjunct to diet • Adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet • Adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB	12/18/2018	Rosuvastatin was previously available as: • Oral tablets - In generic and under the brand name Crestor™.
Licart™ (diclofenac epolamine) Topical System / Institut Biochimique	Nonsteroidal antiinflammatory drug (NSAID)	Topical treatment of acute pain due to minor strains, sprains, and contusions	12/19/2018	Diclofenac epolamine was previously available as: • Extended-release topical patch - Under the brand name Flector™

New FDA Approved Dosage Forms, Formulations, and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Elepsia XR™ (levetiracetam) Extended-Release Tablets / Sun Pharma Global	Central nervous system agent; Anticonvulsant	Adjunctive therapy for the treatment of partial onset seizures in patients 12 years of age and older	12/20/2018	Levetiracetam was previously available as: • Intravenous solution – In generic and under the bran name Keppra™ • Oral solution – In generic and under the bran name Keppra™ • Oral tablet – In generic and under the brand names Keppra™, and Roweepra™ • Extended-release oral tablet – In generic and under the brand names Keppra XR™, and Roweepra XR™. • Oral tablet for suspension – Under the brand name Spritam™.
Inbrija™ (levodopa) Inhalation Powder / Acorda Therapeutics, Inc.	Central nervous system agent; Antiparkinsonian	Treatment of OFF episodes in people with Parkinson's disease taking a carbidopa/levodopa regimen	12/21/2018	OFF episodes, also known as OFF periods, are defined as the return of Parkinson's symptoms that result from low levels of dopamine between doses of oral carbidopa/levodopa, the standard oral baseline Parkinson's treatment.
ProAir Digihaler™ (albuterol sulfate) Inhalation Powder / Teva Pharmaceuticals USA, Inc.	Beta-2-adrenergic agonist	Treatment or prevention of bronchospasm in patients aged four years and older with reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm (EIB) in patients aged four years and older	12/21/2018	ProAir Digihaler™ the first digital inhaler that detect when the inhaler is used and measure inspiratory flow. It contains built-in sensors which connects to a companion mobile application and provides inhaler use information to people with asthma and COPD. Patients can review their data over time, and if desired, share it with their healthcare professionals

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Toremifene Citrate Tablets 60 mg (base) / Eirgen Pharma Ltd.	Antineoplastic agent	12/04/2018	Generic for: Fareston™
Pimecrolimus Topical Cream 1% / Actavis Laboratories UT, Inc.	Dermatological agent; Immunosuppresant	12/27/2018	Generic for: Elidel™

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
PF708 (teriparatide) / Pfenex Inc.	12/10/2018	Treatment for: Osteoporosis	PF708 is being developed as a therapeutic equivalent to Forteo®, which is approved and marketed by Eli Lilly and Company for the treatment of osteoporosis in certain patients with a high risk of fracture. Pfenex Inc. has submitted an NDA for PF708.	High
Lumateperone / Intra-Cellular Therapies Inc.	12/11/2018	Treatment for: Schizophrenia	Lumateperone is first-in-class antipsychotic in development for the treatment of schizophrenia. The FDA has accepted the NDA for lumateperone.	High
ABP 710 (biosimilar infliximab) / Amgen Inc.	12/17/2018	Treatment for: Rheumatoid Arthritis, Plaque Psoriasis, Crohn's Disease -- Maintenance, Ulcerative Colitis, Psoriatic Arthritis, Ankylosing Spondylitis	ABP 710 is a tumor necrosis factor (TNF) blocker biosimilar to Remicade™ (infliximab) in development for the treatment of rheumatoid arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and ankylosing spondylitis. Amgen has submitted an BLA for ABP 710.	High
UGN-101 (mitomycin) Gel / UroGen Pharma Ltd.	12/17/2018	Treatment for: Urothelial Carcinoma	UGN-101 for instillation is an investigational drug formulation of mitomycin in development for the treatment for patients with low-grade upper tract urothelial cancer. UroGen Pharma has initiated the submission of an NDA for UGN-101.	High
Vumerity (diroximel fumarate) / Alkermes plc and Biogen Inc.	12/17/2018	Treatment for: Multiple Sclerosis	Vumerity is a novel oral fumarate in development for the treatment of relapsing forms of multiple sclerosis (MS). Alkermes plc and Biogen Inc. has submitted an NDA for Vumerity.	Moderate
Xipere (triamcinolone acetonide) Injection / Clearside Biomedical, Inc.	12/19/2018	Treatment for: Macular Edema, Uveitis	Xipere is a proprietary corticosteroid suspension for suprachoroidal injection in development for the treatment of macular edema associated with uveitis. Clearside Biomedical has submitted an NDA for Xipere.	Moderate

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Cosyntropin Depot / Assertio Therapeutics, Inc.	12/20/2018	Treatment for: Adrenocortical Insufficiency	Cosyntropin Depot is an alcohol-free, long-acting formulation of a synthetic ACTH analogue in development for use as a diagnostic in the screening of patients presumed to have adrenocortical insufficiency.	Low
Golodirsen / Sarepta Therapeutics, Inc.	12/20/2018	Treatment for: Muscular Dystrophy	Golodirsen is a phosphordiamidate morpholino oligimer in development for the treatment of patients with Duchenne muscular dystrophy (DMD) who have genetic mutations subject to skipping exon 53 of the DMD gene. DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. Sarepta Therapeutics has completed the submission of its NDA for golodirsen.	High High
Lefamulin / Nabriva Therapeutics plc	12/20/2018	Treatment for: Pneumonia	Lefamulin is a first-in-class, semi-synthetic pleuromutilin antibiotic in development for the treatment of community-acquired bacterial pneumonia (CABP). Nabriva Therapeutics has submitted an NDA for lefamulin.	High
Upadacitinib / AbbVie Inc.	12/20/2018	Treatment for: Rheumatoid Arthritis	Upadacitinib is a JAK1-selective inhibitor in development for the treatment of adult patients with moderate to severe rheumatoid arthritis. Abbvie has submitted an NDA for upadacitinib.	Moderate
Pedmark (sodium thiosulfate) / Fennec Pharmaceuticals Inc.	12/20/2018	Treatment for: Prevention of Cisplatin-Induced Ototoxicity	Pedmark is a cisplatin neutralizing agent in development for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. Fennec Pharmaceuticals has initiated the submission of an NDA for Pedmark. The FDA has granted orphan drug designation for Pedmark.	High High

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Bronchitol (mannitol) / Pharmaxis	12/20/2018	Treatment for: Cystic Fibrosis	Bronchitol is an inhaled dry powder formulation of mannitol in development to improve lung function in patients with cystic fibrosis. Pharmaxis has announced the resubmission of an NDA for Bronchitol.	Moderate
FMX101 (minocycline) Foam / Foamix Pharmaceuticals	12/21/2018	Treatment for: Acne	FMX101 (minocycline) is a topical foam formulation of minocycline in development for the treatment of moderate-to-severe acne vulgaris. Foamix Pharmaceuticals has submitted an NDA for FMX101.	Moderate
AR101 (peanut immunotherapy) / Aimmune Therapeutics, Inc.	12/21/2018	Treatment for: Peanut Allergy	AR101 is an investigational biologic oral immunotherapy for desensitization of patients with peanut allergy in children and adolescents ages 4–17. Aimmune Therapeutics has submitted a BLA for AR101.	High
KPI-121 0.25% (loteprednol etabonate) / Kala Pharmaceuticals, Inc.	12/26/2018	Treatment for: Dry Eye Disease	KPI-121 0.25% is an ophthalmic corticosteroid formulation in development for the temporary relief of signs and symptoms of dry eye disease. The NDA for KPI-121 0.25% has been accepted by the FDA for revision.	Moderate

Soruce: 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)