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……

- No security warning published during January 2018.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Balcoltra™ (ethinyl estradiol/levonorgestrel and ferrous bisglycinate) Tablets, for oral use / Avion Pharmaceuticals, LLC	Progestin/estrogen combination oral contraceptive (COC)	To prevent pregnancy in female patients of reproductive potential
		
		Black box warning
		Cigarette smoking and serious cardiovascular events - Balcoltra™ is contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use.
			01/09/2018	**DOSAGE AND ADMINISTRATION**
				The recommended dose is one tablet by mouth at the same time every day (taken in the order directed on the blister pack).
				
				DOSAGE FORMS AND STRENGTHS
				Balcoltra consists of 28 tablets in the following order:
				• 21 orange tablets (active), each containing 0.10 mg levonorgestrel and 0.02 mg ethinyl estradiol.
				• 7 blue tablets (inactive placebo) each containing ferrous bisglycinate 36.5 mg. The ferrous bisglycinate tablets do not serve any therapeutic purpose.
				
				CONTRAINDICATIONS
				• A high risk of arterial or venous thrombotic diseases
				  ○ Smoke, if over age 35
				  ○ Current or history of deep vein thrombosis or pulmonary embolism,
				  ○ Cerebrovascular disease
				  ○ Coronary artery disease
				  ○ Thrombogenic valvular or thrombogenic rhythm diseases of the heart (e.g. subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
				  ○ Uncontrolled hypertension
				  ○ Diabetes mellitus with vascular disease
				  ○ Headaches with focal neurological symptoms or have migraine headaches with aura (e.g. women over age 35 with any migraine headaches)
				• Liver tumors or liver disease
				• Undiagnosed abnormal uterine bleeding
				• Pregnancy
				• Breast cancer or other estrogen- or progestin-sensitive cancer
				• Hypersensitivity of any of the components
				• Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir

New FDA Approved Products

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Balcoltra™ (ethinyl estradiol/levonorgestrel and ferrous bisglycinate) Tablets, for oral use / Avion Pharmaceuticals, LLC (continuation)	Progestin/estrogen combination oral contraceptive (COC)	To prevent pregnancy in female patients of reproductive potential **Black box warning** Cigarette smoking and serious cardiovascular events - Balcoltra™ is contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use.	01/09/2018	**WARNINGS AND PRECAUTIONS** • **Black box warning:** Cigarette smoking increases risk for serious cardiovascular events (ie, arterial and venous thromboembolic events) especially in women over 35 years of age and with number of cigarettes smoked. • **Cardiovascular:** (1) Use caution in women with cardiovascular disease risk factors. (2) Hypertension may occur, especially in older women with extended duration of use; monitoring recommended and discontinuation may be required. • **Dermatologic:** Chloasma may occur, especially with history of chloasma gravidarum; avoid exposure to sunlight or ultraviolet light. • **Endocrine and metabolic:** (1) Glucose tolerance may be impaired in patients with diabetes (including prediabetic women); monitoring recommended. (2) Consider alternative contraception method in patients with uncontrolled dyslipidemia. (3) Increased serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin may occur. • **Gastrointestinal:** (1) Increased risk of pancreatitis in women with hypertriglyceridemia or a family history of hypertriglyceridemia. (2) New-onset or exacerbation of gallbladder disease may occur. (3) Increased risk of recurrence of cholestasis in patients with history of cholestasis related to pregnancy or hormonal contraceptive use. • **Hematologic:** Venous and arterial thrombotic events may occur, with highest risk during first year of use and when restarting after a break of 4 weeks or longer, and gradual disappearance after discontinuation; discontinue use. • **Hepatic:** (1) Acute or chronic disturbances of liver function may occur; discontinuation may be necessary. (2) Jaundice may occur; discontinue use. (3) Hepatic adenoma may occur.

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Balcoltra™ (ethinyl estradiol/levonorgestrel and ferrous bisglycinate) Tablets, for oral use / Avion Pharmaceuticals, LLC (continuation)	Progestin/estrogen combination oral contraceptive (COC)	To prevent pregnancy in female patients of reproductive potential **Black box warning** Cigarette smoking and serious cardiovascular events - Balcoltra™ is contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use.	01/09/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) May induce or exacerbate angioedema symptoms in patients with hereditary angioedema. (2) Contains tartrazine, which may cause allergic-type reactions, including bronchial asthma, in susceptible persons, frequently including those with aspirin hypersensitivity. • **Neurologic:** Evaluate and consider discontinuation in patients with new-onset headaches that are recurrent, persistent, or severe. • **Ophthalmic:** Retinal vein thrombosis may occur; discontinue use if unexplained ocular symptoms emerge (eg, loss of vision, diplopia, proptosis, papilledema). • **Postpartum use:** Increased risk of thromboembolism; do not initiate therapy earlier than 4 weeks after delivery in women who are not breastfeeding. • **Psychiatric:** Depression may be exacerbated; discontinuation may be warranted. • **Reproductive:** (1) Vaginal bleeding abnormalities may occur, including breakthrough bleeding and spotting. (2) Amenorrhea or oligomenorrhea may occur after discontinuation, especially if these conditions preexist before therapy. • **Surgery:** Interrupt therapy at least 4 weeks before and through 2 weeks after major surgery or other surgeries with elevated risk of venous thromboembolic events or during and following prolonged immobilization. **ADVERSE REACTIONS** Most common adverse reactions headache, metrorrhagia, dysmenorrhea and nausea, abdominal pain and breast pain, emotional lability and acne, and depression, amenorrhea, and vaginal moniliasis

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Balcoltra™ (ethinyl estradiol/levonorgestrel and ferrous bisglycinate) Tablets, for oral use / Avion Pharmaceuticals, LLC (continuation)	Progestin/estrogen combination oral contraceptive (COC)	To prevent pregnancy in female patients of reproductive potential **Black box warning** Cigarette smoking and serious cardiovascular events - Balcoltra™ is contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use.	01/09/2018	**DRUG INTERACTIONS** • **Drugs or herbal products that induce certain enzymes (e.g. CYP3A4):** May decrease the plasma concentrations of COCs and potentially diminish the effectiveness of COCs or increase breakthrough bleeding. • **Human immunodeficiency virus (HIV)/ Hepatitis C virus (HCV) protease inhibitors and nonnucleoside reverse transcriptase inhibitors:** Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin have been noted in some cases of co-administration with HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors. See Full Prescribing Information for more details regarding this and other possible drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Contraindicated in pregnancy. • **Lactation:** Can reduce milk production in breast-feeding females. When possible, advise the nursing female to use other methods of contraception until she discontinues breast-feeding. • **Pediatric use:** Safety and efficacy of Balcoltra™ have been established in women of reproductive age. Efficacy is expected to be the same in post-pubertal adolescents under the age of 18 years as for users 18 years and older. Use of this product before menarche is not indicated. • **Geriatric use:** Has not been studied in postmenopausal women and is not indicated in this population.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lutathera™ (lutetium Lu 177 dotatate) Injection, for intravenous use / Advanced Accelerator Applications S.A.	Lu-177-labeled somatostatin analogue Antineoplastic agent --- Note: Orphan drug designation	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults	01/26/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. • Verify pregnancy status in females of reproductive potential prior to initiating. • Administer long-acting octreotide 30m intramuscularly 4 to 24 hours after each Lutathera™ dose and short-acting octreotide for symptomatic management. • Continue long-acting octreotide 30mg intramuscularly every 4 weeks after completing Lutathera™ until disease progression or for up to 18 months following treatment initiation. • Pre-medicate with antiemetics 30 minutes before recommended amino acid solution. • Initiate recommended intravenous amino acid solution 30 minutes before Lutathera™ infusion, continue during and for 3 hours after Lutathera™ infusion. Do not reduce dose of amino acid solution if Lutathera™ dose is reduced. • Modify Lutathera™ dose based on adverse reactions. **DOSAGE FORMS AND STRENGTHS** Injection: 370 MBq/mL (10 mCi/mL) in single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Endocrine and metabolic:** Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm and hypotension, has been reported typically during or within 24 hours following the initial dose; monitoring recommended and institute appropriate therapy if necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lutathera™ (lutetium Lu 177 dotatate) Injection, for intravenous use / Advanced Accelerator Applications S.A. (continuation)	Lu-177-labeled somatostatin analogue Antineoplastic agent --- Note: Orphan drug designation	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults	01/26/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Hematologic:** (1) Myelosuppression, including anemia, thrombocytopenia, and neutropenia, has been reported; monitoring recommended. Dose adjustment, therapy interruption or discontinuation may be necessary depending on the severity. (2) Secondary myelodysplastic syndrome and acute leukemia have been reported. • **Hepatic:** Hepatic tumor hemorrhage, edema, necrosis, intrahepatic congestion, and cholestasis have been reported with increased risk in patients with hepatic metastasis; monitoring recommended. Dose adjustment, therapy interruption or discontinuation may be necessary depending on the severity. • **Radiation exposure:** Increased risk for cancer with long-term cumulative radiation exposure; minimize exposure to patients during and after treatment. • **Renal:** Renal failure has been reported with increased risk of toxicity in patients with baseline impairment; monitoring recommended. Dose adjustment, therapy interruption or discontinuation may be necessary depending on the severity. • **Reproductive:** (1) May cause fetal harm; verify pregnancy status prior to initiation. Effective contraceptive recommended for females of reproductive potential during therapy and for at least 7 months after final dose. Effective contraceptive recommended for males with female partners of reproductive potential during therapy and for at least 4 months after final dose. (2) Temporary or permanent infertility may occur **ADVERSE REACTIONS** Most common adverse reactions: lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia and hypokalemia

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lutathera™ (lutetium Lu 177 dotatate) Injection, for intravenous use / Advanced Accelerator Applications S.A. (continuation)	Lu-177-labeled somatostatin analogue Antineoplastic agent --- Note: Orphan drug designation	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults	01/26/2018	**DRUG INTERACTIONS** • **Somatostatin Analogs:** Somatostatin and its analogs competitively bind to somatostatin receptors and may interfere with the efficacy of Lutathera™. Discontinue long-acting analogs for at least 4 weeks and short-acting octreotide at least 24 hours prior to each Lutathera™ dose. Administer short- and long-acting octreotide during Lutathera™ treatment as recommended. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. • **Females and Males of Reproductive Potential:** Verify pregnancy status of females of reproductive potential prior to initiating. Advise females of reproductive potential to use effective contraception during treatment and for 7 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during and for 4 months following the final dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** Response rate and number of patients with a serious adverse event within patient 65 years and older were similar to that of younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Firvanq™ (vancomycin hydrochloride) Solution, for oral use / CutisPharma	Glycopeptide antibiotic	Treatment of *Clostridium difficile* associated diarrhea and *Staphylococcus aureus* enterocolitis in adults and pediatric patients **Limitations of use** Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections	01/29/2018	**DOSAGE AND ADMINISTRATION** For C. difficile-associated diarrhea: • Adult Patients (18 years of age and older): 125 mg orally 4 times daily for 10 days. • Pediatric Patients (less than 18 years of age): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g. For Staphylococcal enterocolitis: • Adult Patients (18 years of age and older): 500 mg to 2 g orally in 3 or 4 divided doses for 7 to 10 days. • Pediatric Patients (less than 18 years of age): 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g. **DOSAGE FORMS AND STRENGTHS** Each kit contains: vancomycin hydrochloride USP, powder for oral solution, equivalent to 3.75 g, 7.5 g, 10.5 g or 15 g vancomycin, and Grape-Flavored Diluent. **CONTRAINDICATIONS** • Hypersensitivity to vancomycin **WARNINGS AND PRECAUTIONS** • **For oral use only:** Must be given orally for treatment of C. difficile-associated diarrhea and staphylococcal enterocolitis. Orally administered vancomycin is not effective for treatment of other types of infections. Parenteral administration of vancomycin is not effective for treatment of C. difficile-associated diarrhea and staphylococcal enterocolitis. • **Elderly:** Elderly patients are at greater risk for nephrotoxicity during or after oral therapy; monitoring recommended. • **Otic:** Ototoxicity has occurred in patients receiving vancomycin hydrochloride. Assessment of auditory function may be appropriate in some instances.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Firvanq™ (vancomycin hydrochloride) Solution, for oral use / CutisPharma	Glycopeptide antibiotic	Treatment of *Clostridium difficile* associated diarrhea and *Staphylococcus aureus* enterocolitis in adults and pediatric patients **Limitations of use** Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections	01/29/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Renal:** Nephrotoxicity, including renal failure, renal impairment, and increased blood creatinine, has been reported; increased risk with underlying renal impairment or concomitant use with aminoglycosides; monitoring recommended. • **Systemic absorption:** Significant systemic absorption has been reported in some patients (e.g. patients with renal insufficiency and/or colitis) who have taken multiple oral doses of vancomycin hydrochloride for C. difficile-associated diarrhea. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for the development of adverse reactions associated with higher doses; therefore, monitoring of serum concentrations of vancomycin may be appropriate in some instances (e.g. in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug). **ADVERSE REACTIONS** Most common adverse reactions: nausea, abdominal pain (15%) and hypokalemia **DRUG INTERACTIONS** No drug interaction studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with vancomycin hydrochloride to detect potential vancomycin induced nephrotoxicity.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Xgeva™ (denosumab) Injection / Amgen Inc.	RANK ligand (RANKL) inhibitor Endocrine and metabolic agent; Bone density regulator	Approved for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. is also indicated for treatment giant cell tumor of bone and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. **New indication:** For the prevention of skeletal-related events in patients with bone metastases from solid tumors in patients with multiple myeloma.	01/04/2018	Xgeva™ is a fully human monoclonal antibody that binds to and neutralizes RANK ligand (RANKL) – a protein essential for the formation, function and survival of osteoclasts – thereby inhibiting osteoclast-mediated bone destruction. The approval is based on a Phase 3, randomized, double-blind, multicenter trial of Xgeva™ compared with zoledronic acid for the prevention of skeletal-related events in adult patients with newly diagnosed multiple myeloma and bone disease. A total of 1,718 patients (859 on each arm) were randomized to receive either subcutaneous Xgeva™ 120 mg and intravenous placebo every 4 weeks, or intravenous zoledronic acid 4 mg (adjusted for renal function) and subcutaneous placebo every four weeks. The primary endpoint of the study was non-inferiority of Xgeva™ versus zoledronic acid with respect to time to first on-study skeletal-related event (pathologic fracture, radiation to bone, surgery to bone or spinal cord compression). Secondary endpoints included superiority of Xgeva™ versus zoledronic acid with respect to time to first on-study skeletal-related event and first-and-subsequent on-study skeletal-related event and evaluation of overall survival. Pexploratory endpoint. The study met the primary endpoint, demonstrating non-inferiority of Xgeva™ to zoledronic acid in delaying the time to first on-study skeletal-related event in patients with multiple myeloma. The secondary endpoints, delaying time to first skeletal-related event and delaying time to first-and-subsequent skeletal-related events, did not demonstrate superiority.
Fluarix Quadrivalent™ (influenza virus vaccine, inactivated) / GlaxoSmithKline	Influenza virus vaccine	For the prevention of influenza **Patient population altered:** To include use in persons 6 months and older.	01/11/2018	Prior to this, the vaccine was only approved for active immunization against influenza A subtype viruses and type B viruses, in persons 3 years of age and older. The approval was based on a Phase III pivotal study of the efficacy of Fluarix Quadrivalent™ in children 6 months through 35 months of age and on two supportive studies.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Lynparza™ (olaparib) Capsules and Tablets / AstraZeneca	Poly ADP ribose polymerase (PARP) inhibitor Antineoplastic agent	Treatment of BRCA-mutated, 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:** Treatment of germline BRCA-mutated metastatic breast cancer	01/12/2018	The FDA expanded the approved use of Lynparza™ to include the treatment of patients with certain types of breast cancer that have metastasized and whose tumors have a specific inherited (germline) genetic mutation. This approval makes Lynparza™ the first drug in its class (PARP inhibitor) approved to treat breast cancer, and it is the first time any drug has been approved to treat certain patients with metastatic breast cancer who have a BRCA gene mutation. Patients are selected for treatment with Lynparza™ based on an FDA-approved genetic test, called the BRACAnalysis CDx. The approval was based on a randomized clinical trial of 302 patients with HER2-negative metastatic breast cancer with a germline BRCA mutation. The trial measured the length of time the tumors did not have significant growth after treatment (progression-free survival). The median progression-free survival for patients taking Lynparza™ was 7 months compared to 4.2 months for patients taking chemotherapy only.
Gilotrif™ (afatinib) Tablets / Boehringer Ingelheim Pharmaceuticals, Inc.	Kinase inhibitor Antineoplastic agent	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) **New indication:** For the first-line treatment of patients with metastatic NSCLC whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.	01/12/2018	Gilotrif™ was previously approved in the US for the first-line treatment of patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations. The new label includes data on three additional EGFR mutations: L861Q, G719X and S768I. In addition, Gilotrif™ is approved in the US for patients with squamous cell carcinoma of the lung whose disease has progressed after treatment with platinum-based chemotherapy. The approval is based on a pooled analysis of three studies from the LUX-Lung clinical trial program (Phase II LUX-Lung 2 study and Phase III studies LUX-Lung 3 and LUX-Lung 6) that examined Gilotrif™ in NSCLC patients whose tumors have EGFR mutations, including L861Q, G719X or S768I. This analysis showed that Gilotrif was active in these EGFR mutations based on objective response rate, duration of response, disease control, progression-free survival and overall survival.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Programmed death receptor-1 (PD-1) blocking antibody Antineoplastic agent	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma **New indication:** For the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection	01/20/2018	The purpose of adjuvant therapy is to reduce the risk of recurrence following surgical removal of the tumor and lymph nodes that contain cancer. In the Phase 3 CheckMate - 238 trial, Opdivo™ significantly improved recurrence-free survival (RFS) versus an active comparator, Yervoy™ (ipilimumab), in patients with stage IIIB/C or stage IV melanoma after surgery. Opdivo™ demonstrated an 18-month RFS rate of 66.4% compared with 52.7% for Yervoy™. Opdivo™ reduced the risk of disease recurrence by 35% versus Yervoy™.
Trulance™ (plecanatide) Tablets / Synergy Pharmaceuticals Inc.	Guanylate cyclase-C agonist Gastrointestinal agent	Treatment of chronic idiopathic constipation, and irritable bowel syndrome with constipation **New indication:** Treatment of irritable bowel syndrome with constipation in adults	01/25/2018	This is the second indication for Trulance™, which is already approved for the treatment of adults with chronic idiopathic constipation (CIC). The approval was based on results of two randomized trials evaluating the efficacy and safety of Trulance™ in adult patients with irritable bowel syndrome with constipation (IBS-C). The primary endpoint for both trials was the percentage of patients who are Overall Responders during the 12-week treatment period. In both trials, Trulance™ met the primary endpoint as compared with placebo. In both studies, patients who received Trulance™ experienced significantly reduced abdominal pain and improvements in stool frequency, stool consistency, and straining with bowel movements during the 12-week treatment period as compared to placebo.

New FDA Approved Formulations

- No new FDA-approved formulations.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Remifentanil Hydrochloride Injection 1 mg base/vial, 2 mg base/vial and 5mg base/vial / Fresenius Kabi USA, LLC	Opioid analgesic	01/16/2018	Generic for: Ultiva

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Eravacycline / Tetraphase Pharmaceuticals, Inc.	01/02/2018	Treatment of complicated intra-abdominal infections (cIAI)	Eravacycline is a fluorocycline antibiotic. The NDA submission includes data from the IGNITE1 and IGNITE 4 phase 3 clinical trials, in which twice-daily IV eravacycline was well tolerated and achieved high clinical cure rates in patients with cIAI. Both studies demonstrated statistical non-inferiority of eravacycline to two widely used comparators – ertapenem in IGNITE1 and meropenem in IGNITE4 – for the primary efficacy endpoint of clinical response at the test-of-cure (TOC) visit.	Moderate
Plazomicin / Achaogen, Inc.	01/02/2018	Treatment of complicated urinary tract infections	Plazomicin is a next generation aminoglycoside. FDA has accepted for review the NDA for plazomicin.	Moderate
Olinvo (oliceridine) / Trevena, Inc.	01/02/2018	For the management of moderate to severe acute pain	Olinvo (oliceridine) is a G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator. FDA has accepted for review the NDA for Olinvo.	Moderate
Stannsoporfin / Mallinckrodt plc	01/04/2018	Treatment of neonates at risk for developing severe hyperbilirubinemia, or severe jaundice	Stannsoporfin is a heme oxygenase inhibitor. If approved, the drug is expected to become the first and only pharmacologic option in the US indicated for treatment of neonates at risk for developing severe hyperbilirubinemia, or severe jaundice.	Moderate
Inveltys (loteprednol etabonate) / Kala Pharmaceuticals, Inc.	01/05/2018	For the treatment of post-operative ocular inflammation and pain	Inveltys (loteprednol etabonate) is a nanoparticle ocular corticosteroid formulation. FDA has accepted for review the NDA for Inveltys.	Moderate
Doravirine / Merck	01/08/2018	For the treatment of HIV-1 infection in adults	Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). FDA has accepted for review the NDA for Doravirine.	Moderate

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Inotersen / Ionis Pharmaceuticals, Inc.	01/08/2018	For the treatment of of patients with hereditary TTR amyloidosis (hATTR)	Inotersen is an antisense oligonucleotide inhibitor of the transthyretin (TTR) protein. FDA has accepted for review the NDA for Inotersen.	High
Revefenacin / Theravance Biopharma, Inc.	01/29/2018	For the treatment of chronic obstructive pulmonary disease (COPD)	Revefenacin is a long-acting muscarinic antagonist (LAMA). FDA has accepted for review the NDA for Revefenacin.	Moderate
ALKS 5461 (buprenorphine and samidorphan) / Alkermes plc	01/31/2018	To rebalance brain function in patients with treatment-resistant depression	ALKS 5461 (buprenorphine and samidorphan) is a novel opioid modulator, combining a partial opioid agonist with an opioid antagonist. The NDA submission is based on a comprehensive clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD. Throughout the clinical development program, ALKS 5461 demonstrated a consistent profile of antidepressant activity, safety and tolerability in the adjunctive treatment of MDD.	Moderate

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

References:

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