pharmpiX
POWERED BY ONEARK

PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: AUGUST 2020

Date: 09/07/2020

urac
ACCREDITED
Pharmacy
Benefit
Management
Expires 12/01/2022

Table of Contents

NEWS

Drug issue	Date	Details
Boxed Warning about Risk of Leg and Foot Amputations Removed for Invokana, Invokamet, Invokamet XR (canagliflozin)	08/26/2020	The boxed warning about amputation risk was removed from canagliflozin (Invokana, Invokamet, Invokamet XR) prescribing information, based on FDA's review of new data suggesting that the risk of amputation, while still increased with canagliflozin, is lower than previously described, particularly when appropriately monitored. Recommendations for healthcare professionals: • Continue to recognize the importance of preventative foot care and monitor for new pain, tenderness, sores, ulcers, and infections in the legs and feet. Consider risk factors that may predispose patients to the need for amputation when choosing antidiabetic medicines. • Report adverse events or side effects involving naloxone, opioids, or other medicines at MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program and FDA's Drug Safety and Availability portal.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Blenrep™ (belantamab mafodotin-blmf) Injection, for intravenous use	GlaxoSmithKline	08/05/2020

THERAPEUTIC CLASS
Antineoplastic agent; B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate

FDA-APPROVE INDICATION(S)
Blenrep™ is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

DOSAGE AND ADMINISTRATION
The recommended dose is 2.5 mg/kg as an intravenous infusion over approximately 30 minutes once every 3 weeks.

DOSAGE FORMS AND STRENGTHS
For injection: 100 mg as a lyophilized powder in a single-dose vial for reconstitution and further dilution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Thrombocytopenia
- Infusion-related reactions
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: keratopathy (corneal epithelium change on eye exam), decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise women of reproductive potential and males with female partners of reproductive potential to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Renal impairment: No dose adjustment recommended for mild or moderate renal impairment. Recommended dose has not been established in patients with severe renal impairment or end-stage renal disease (ESRD).
- Hepatic impairment: No dose adjustment recommended for mild hepatic impairment. Recommended dose has not been established in patients with moderate or severe hepatic impairment.

pharmpix POWERED BY ONEARK

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Lampit™ (nifurtimox) Tablets, for oral use	Bayer HealthCare Pharmaceuticals Inc.	08/06/2020

THERAPEUTIC CLASS
Anti-infective agent; Nitrofuran antiprotozoal

FDA-APPROVE INDICATION(S)
Lampit™ is indicated for the treatment of Chagas disease (American Trypanosomiasis), caused by Trypanosoma cruzi, in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg).

DOSAGE AND ADMINISTRATION
The recommended dose is based on patient's weight (kg):
- ≥40 kg: 8 to 10 mg/kg/day
- <40 kg: 10 to 20 mg/kg/day

Administered orally three times a day with food, for 60 days.

DOSAGE FORMS AND STRENGTHS
Tablets:
- 30 mg (functionally scored)
- 120 mg (functionally scored)

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to nifurtimox or to any of the excipients.
- Alcohol consumption during treatment.

WARNINGS AND PRECAUTIONS
- Potential for genotoxicity and carcinogenicity
- Embryo-fetal toxicity
- Worsening neurological and psychiatric conditions
- Hypersensitivity
- Decreased appetite and weight loss
  - Weight must be checked every 14 days as dosage may need to be adjusted.
- Porphyria

ADVERSE REACTIONS
Most common adverse reactions: vomiting, abdominal pain, headache, decreased appetite, nausea, pyrexia, and rash.

DRUG INTERACTIONS
- Alcohol: Concomitant use may increase the incidence and severity of undesirable effects.

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and male patients with female partners of reproductive potential to use effective contraception.
- Pediatric use: Safety and effectiveness established in pediatric patients from birth to less than 18 years of age weighing at least 2.5 kg. Safety and effectiveness has not been established in pediatric patients weighing less than 2.5 kg.
- Renal impairment: Administer under close medical supervision.
- Hepatic impairment: Administer under close medical supervision.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Olinvyk™ (oliceridine) Injection, for intravenous use	Trevena, Inc.	08/07/2020

THERAPEUTIC CLASS
Analgesic; Opioid agonist

FDA-APPROVE INDICATION(S)
Olinvyk™ is indicated for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

DOSAGE AND ADMINISTRATION
The dose is individualized based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse. The cumulative total daily dose should not exceed 27mg.

DOSAGE FORMS AND STRENGTHS
Injection:
- 1 mg/mL and 2 mg/2 ml (1 mg/mL) in single-dose vials
- 30 mg/30 mL (1 mg/mL) in single-patient-use vial, For PCA Use Only

Orphan status: N/A
Controlled substance: Schedule pending

SAFETY PROFILE

CONTRAINDICATIONS
- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to oliceridine.

WARNINGS AND PRECAUTIONS
- Boxed warning: Addiction, abuse and misuse; Life-threatening respiratory depression neonatal opioid withdrawal syndrome; and Risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants.
- Potential for QT prolongation with daily doses exceeding 27 mg
- Life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients
- Adrenal insufficiency
- Severe hypotension
- Risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness

ADVERSE REACTIONS
Most common adverse reactions: nausea, vomiting, dizziness, headache, constipation, pruritus, and hypoxia.

DRUG INTERACTIONS
Oliceridine has clinically significant drug interactions with the following drug
- Moderate to strong inhibitors of CYP2D6 and CYP3A4
- Inducers of CYP3A4
- Benzodiazepines and other CNS depressants
- Serotonergic drugs
- Mixed agonist/antagonist and partial agonist opioid analgesics
- Muscle relaxants
- Diuretics
- Anticholinergic drug

Caution should be used. If concomitant use is necessary, dose adjustment and/or closely monitoring may be required. See full prescribing information for additional important details.

pharmpix POWERED BY ONEARK

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Olinvyk™ (oliceridine) Injection, for intravenous use	Trevena, Inc.	08/07/2020

THERAPEUTIC CLASS
Analgesic; Opioid agonist

FDA-APPROVE INDICATION(S)
Olinvyk™ is indicated for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

DOSAGE AND ADMINISTRATION
The dose is individualized based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse. The cumulative total daily dose should not exceed 27mg.

DOSAGE FORMS AND STRENGTHS
Injection:
- 1 mg/mL and 2 mg/2 ml (1 mg/mL) in single-dose vials
- 30 mg/30 mL (1 mg/mL) in single-patient-use vial, For PCA Use Only

Orphan status: N/A
Controlled substance: Schedule pending

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Prolonged use of opioid analgesics during pregnancy may result in neonatal opioid withdrawal syndrome.
- Pediatric use: Safety and effectiveness has not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, caution must be used when selecting a dosage for an elderly patient, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.
- Renal impairment: No dose adjustment required.
- Hepatic impairment: No adjustment of the initial dose needed for mild or moderate hepatic impairment; however, less frequent dosing may be required. For severe hepatic impairment, consider reducing the initial dose, and administer subsequent doses only after a careful review of the patient's severity of pain and overall clinical status.

USE IN SPECIFIC POPULATIONS (continuation)
- Poor metabolizers of CYP2D6 substrates: Patients known or suspected to be poor CYP2D6 metabolizers may require less frequent dosing. Monitor closely and administer subsequent doses based on severity of pain and patient response.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Evrysdi™ (risdiplam) for Oral Solution	Genentech, Inc.	08/07/2020

THERAPEUTIC CLASS
Musculoskeletal agent

FDA-APPROVE INDICATION(S)
Evrysdi™ is indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.

DOSAGE AND ADMINISTRATION
The recommended dose is based on patient's age and weight (kg):

- 2 months to less than 2 years of age: 0.2 mg/kg/day
- 2 years of age and older weighing less than 20 kg: 0.25 mg/kg/day
- 2 years of age and older weighing 20 kg or more: 5 mg/day

Administered orally once daily. Must be constituted by a pharmacist prior to dispensing.

DOSAGE FORMS AND STRENGTHS
For Oral Solution: 60 mg of risdiplam as a powder for constitution to provide 0.75 mg/mL solution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
None described in prescribing information.

ADVERSE REACTIONS
Most common adverse reactions:

- In later-onset SMA: fever, diarrhea, and rash.
- In infantile-onset SMA: fever, diarrhea, rash, upper respiratory tract infection, pneumonia, constipation, and vomiting.

DRUG INTERACTIONS

- Substrates of multidrug and toxin extrusion (MATE) protein transporters: Risdiplam may increase plasma concentrations of drugs eliminated via MATE1 or MATE2-K (e.g. metformin). Avoid co-administration. If co-administration cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the co-administered drug (based on the labeling of that drug) if needed.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise female patients of reproductive potential to use effective contraception. Male fertility may be compromised. Male patients may consider sperm preservation prior to treatment.
- Pediatric use: Safety and effectiveness have been established in pediatric patients 2 months of age and older. Safety and effectiveness in pediatric patients below the age of 2 months have not been established.
- Geriatric use: Clinical studies did not include patients aged 65 years and over to determine whether they respond differently from younger patients.
- Hepatic impairment: Safety and efficacy in patients with hepatic impairment have not been studied. Because risdiplam is predominantly metabolized in the liver, hepatic impairment may potentially increase the exposures to risdiplam. Avoid use of in patients with impaired hepatic function.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Viltepso™ (viltolarsen) Injection, for intravenous use	NS Pharma, Inc.	08/12/2020

THERAPEUTIC CLASS
Musculoskeletal agent; Muscular dystrophy agent

FDA-APPROVE INDICATION(S)
Viltepso™ is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

DOSAGE AND ADMINISTRATION
The recommended dose is 80mg/kg once weekly, administered as IV infusion.

DOSAGE FORMS AND STRENGTHS
Injection: 250mg/5ml (50mg/mL0 in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Kidney toxicity

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, injection site reaction, cough, and pyrexia.

DRUG INTERACTIONS:
Based on in vitro data, has low potential for drug-drug interactions with major CYP enzymes and drug transporters.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Approved for the treatment of DMD in pediatric population who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
- Geriatric use: No geriatric experience due to the nature of disease.

USE IN SPECIFIC POPULATIONS (continuation)
- Renal impairment: Viltolarsen is mostly excreted unchanged in urine thus renal impairment may increase its exposure. However, it has not been studied in patients with renal impairment. No specific dosage adjustments recommended for patients with renal impairment. Patients with known renal function impairment should be closely monitored during treatment.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Enspryng™ (satralizumab-mwge) Injection, for subcutaneous use	Genentech, Inc.	08/14/2020

THERAPEUTIC CLASS
Immunosuppressive agent

FDA-APPROVE INDICATION(S)
Enspryng ™ is indicated to treat neuromyelitis optica spectrum disorder (NMOSD) in adults patients who are aquaporin-4-antibody (AQP4-IgG) positive.

DOSAGE AND ADMINISTRATION
The recommended loading dose is 120mg subcutaneously at weeks 0, 2, and 4, followed by a maintenance dose of 120mg every 4 weeks.

DOSAGE FORMS AND STRENGTHS
Injection: 120mg/mL in a single-dose prefilled syringes.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Active Hepatitis B infection
- Active or untreated latent tuberculosis
- Known hypersensitivity to satralizumab or any of the inactive ingredients

WARNINGS AND PRECAUTIONS
- Infections
- Elevated liver enzymes
- Decreased neutrophil counts
- Hypersensitivity reactions

ADVERSE REACTIONS
Most common adverse reactions: nasopharyngitis, headache, upper respiratory tract infection, gastritis, rash, arthralgia, extremity pain, fatigue, and nausea.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness has not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently from younger patients. However, caution is advised when dosing elderly population due to the prevalence of hepatic, renal, cardiac function and other concomitant diseases or drug therapies.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Kesimpta™ (ofatumumab) Injection, for subcutaneous use	Novartis Pharmaceuticals Corporation	08/20/2020

THERAPEUTIC CLASS
Multiple sclerosis agent

FDA-APPROVE INDICATION(S)
Kesimpta™ is indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
The recommended initial dose is 20mg at week 0, 1, and 2, followed by 20mg monthly (starting at week 4).
*Hepatitis B and quantitative serum immunoglobulins screening are required prior initiation of treatment.

Specific assessments are recommended prior to initiation.

DOSAGE FORMS AND STRENGTHS:
Injection:
- 20mg/0.4mL in a single-dose prefilled Sensoready Pen
- Injection: 20mg/0.4mL solution in single-dose prefilled syringe

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Active Hepatitis B infection

WARNINGS AND PRECAUTIONS
- Infections
- Injection-related reactions
- Reduction of immunoglobulins
- Fetal risk

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, headache, injection-related reactions, and local injection site reactions.

DRUG INTERACTIONS
- Immunosuppressive or immune-modulating therapies: Concomitant use may increase the risk of infections.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm.
- Females of reproductive potential: Should use effective contraception.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of geriatric patients to determine whether they respond differently from younger subjects.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Winlevi™ (clascoterone) Cream, for topical use	Cassiopea, Inc	08/26/2020

THERAPEUTIC CLASS:
Antiacne

FDA-APPROVE INDICATION(S)
Winlevi™ is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended dose is to apply a thin uniform layer of 1% cream topically twice daily to the affected area.

DOSAGE FORMS AND STRENGTHS:
Cream 1%.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Local irritation
- Hypothalamic-pituitary-adrenal (HPA) axis suppression

ADVERSE REACTIONS
Most common adverse reactions: pruritus, scaling or dryness of skin, erythema, edema, burning, and stinging.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established in pediatric population under 12 years.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Sogroya™ (somapacitan-beco) Injection, for subcutaneous use	Novo Nordisk	08/28/2020

THERAPEUTIC CLASS
Growth hormone analog

FDA-APPROVE INDICATION(S)
Sogroya™ is indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

DOSAGE AND ADMINISTRATION
The recommended initial dose for treatment naïve patients and patients switching from daily growth hormone is 1.5 mg administered subcutaneously once weekly. Then, the weekly dose is increased every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response has been achieved. The maximum recommended dose is 8 mg once weekly.

Dose adjustments are recommended for patients aged 65 years or older, patients with hepatic impairment, and women receiving oral estrogen.

DOSAGE FORMS AND STRENGTHS
Injection: 10 mg/1.5 mL (6.7 mg/mL) somapacitan-beco single-patient-use prefilled pen.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Acute critical illness
- Active malignancy
- Hypersensitivity to somapacitan-beco or excipients
- Active proliferative or severe non-proliferative diabetic retinopathy

WARNINGS AND PRECAUTIONS
- Increased mortality in patients with acute critical illness
- Increased risk of neoplasms
- Glucose intolerance and diabetes mellitus
- Intracranial hypertension
- Severe hypersensitivity
- Fluid retention
- Hypoadrenalism
- Hypothyroidism
- Pancreatitis
- Lipohypertrophy/lipoatrophy
- Laboratory tests alterations

ADVERSE REACTIONS
Most common adverse reactions: back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatinine phosphokinase increase, weight increase, anemia .

DRUG INTERACTIONS
- Replacement glucocorticoid treatment: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of somapacitan-beco.
- CYP450-metabolized drugs: Somapacitan-beco may alter the clearance. Monitor carefully if used concomitantly.
- Oral estrogen: Oral estrogens may reduce the serum IGF-1 response to somapacitan-beco. Larger doses of somapacitan-beco may be required.
- Insulin and/or other hypoglycemic agents: Somapacitan-beco may decrease insulin sensitivity, particularly at higher doses. Dose adjustment of insulin or hypoglycemic agent may be required.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Elderly patients may be more sensitive to the action of somapacitan-beco, and therefore may be at increased risk for adverse reactions. Initiate with a dose of 1 mg once weekly and use smaller increments when increasing the dose.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Sogroya™ (somapacitan-beco) Injection, for subcutaneous use	Novo Nordisk	08/28/2020

THERAPEUTIC CLASS
Growth hormone analog

FDA-APPROVE INDICATION(S)
Sogroya™ is indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

DOSAGE AND ADMINISTRATION
The recommended initial dose for treatment naïve patients and patients switching from daily growth hormone is 1.5 mg administered subcutaneously once weekly. Then, the weekly dose is increased every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response has been achieved. The maximum recommended dose is 8 mg once weekly.

Dose adjustments are recommended for patients aged 65 years or older, patients with hepatic impairment, and women receiving oral estrogen.

DOSAGE FORMS AND STRENGTHS
Injection: 10 mg/1.5 mL (6.7 mg/mL) somapacitan-beco single-patient-use prefilled pen.

Orphan status: N/A

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Hepatic impairment: No adjustment required for mild hepatic impairment. In moderate hepatic impairment, initiate with a dose of 1 mg once weekly and use smaller increments when increasing the dose. The maximum dose should not exceed 4 mg once weekly. Somapacitan-beco not recommended in severe hepatic impairment.

(continuation)

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Xtandi™ (enzalutamide) Tablets / **Astellas Pharma US, Inc.**	Antineoplastic agent	Treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer	08/04/2020	A new tablet dosage form has been approved for enzalutamide (Xtandi™). Previously, enzalutamide was available in capsules. Both dosage forms share the same indications. Orphan status: N/A
Cystadrops™ (cysteamine hydrochloride) Ophthalmic Solution / **Recordati Rare Diseases Inc.**	Ophthalmic agent	Treatment of corneal cystine crystal deposits in adults and children with cystinosis	08/19/2020	Cystadrops™ is a new topical ophthalmic solution formulation of cysteamine 3.8 MG/1 ML. Previously, another topical ophthalmic solution formulation of cysteamine was already available, but with a different strength (4.4 MG/1 ML) and under the brand name Cystaran™. Cystadrops™ and Cystaran™ share the same indication. Orphan status: N/A
Xaracoll™ (bupivacaine HCl) Implant / **Innocoll Pharmaceuticals**	Anesthetic	To produce post-surgical analgesia for up to 24 hours following open inguinal hernia repair	08/28/2020	Xaracoll™ is an new implant dosage form of bupivacaine, for placement into the surgical site by or under the supervision of experienced clinicians who are well versed in the diagnosis and management of dose-related toxicity and other acute emergencies which might arise from bupivacaine exposure. Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Dovato™ (dolutegravir and lamivudine) Tablets / ViiV Healthcare	Anti-infective agent; Antiretroviral	As a complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral (ARV) treatment history and with no known resistance to either dolutegravir (DTG) or lamivudine (3TC)	As a complete regimen for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable ARV regimen with no history of treatment failure and no known resistance to the individual components of Dovato™	08/06/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Indication(s)	Date	Generic for:
Cyprofloxacin and Dexamethasone Otic Suspension Drops (0.3%/0.1%) / Dr. Reddy's Laboratories Ltd.	Anti-infective; Antibacterial/steroid combination	Treatment of acute otitis media and acute otitis externa caused by susceptible microorganism	08/10/2020	Cyprodex

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Remdesivir / Gilead Sciences, Inc.	08/10/2020	Treatment for: COVID-19	Remdesivir is an investigational nucleotide analog antiviral in development as a potential treatment for hospitalized patients with severe COVID-19. Gilead submits NDA.	High
Evinacumab /Regeneron Pharmaceuticals, Inc.	08/12/2020	Treatment for: Homozygous Familial Hypercholesterolemia	Evinacumab is an angiopoietin-like 3 inhibitor used as an adjunctive therapy for patients with homozygous familial hypercholesterolemia, which is considered an ultra-rare inherited disease. FDA accepted the NDA for evinacumab.	High

References

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