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PharmNOTES

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

Date: 07/10/2020

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Management
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NEWS

Drug issue	Date	Details
FDA alert about Amneal and Impax Epinephrine Auto-Injector Devices Malfunction	06/01/2020	The FDA published a safety communication for Epinephrine Auto-Injector Devices produced by Amneal Pharmaceuticals and Impax Laboratories, due to possible malfunctions. The FDA is alerting healthcare professionals, patients, and caregivers to immediately inspect certain lots of Amneal and Impax epinephrine auto-injector 0.3 mg to ensure the yellow "stop collar" in the device is present. If the auto-injector is missing the yellow "stop collar" component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient. Read FDA's letter to healthcare professionals for full details, including affected lots, step by step visual inspections instructions, and additional actions to take.
COVID-19 Update: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use	06/15/2020	The FDA is warning about a potential drug interaction between remdesivir and chloroquine phosphate or hydroxychloroquine sulfate, were co-administration may result in the reduced antiviral activity of remdesivir. Remdesivir is an investigational antiviral drug that received an emergency use authorization (EUA) on May 1, 2020, for the treatment of hospitalized COVID-19 patients with severe disease. The safety and efficacy of remdesivir for the treatment of COVID-19 continue to be evaluated. Additional information is available at the FDA's Press Announcements portal and in the fact sheet for health care providers.
COVID-19 Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine	06/15/2020	The has revoked the emergency use authorization (EUA) issued on March 28, 2020 allowing for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile (SNS) to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was not available or feasible. Additional information is available at the Revocation of the EUA Letter and the FAQs on the Revocation of the EUA for Hydroxychloroquine Sulfate and Chloroquine Phosphate for additional information.
FDA advises not to use hand sanitizer products manufactured by Eskbiochem	06/24/2020	The FDA published a safety communication for advising not to use any hand sanitizer manufactured by Eskbiochem SA de CV in Mexico, due to the potential presence of methanol (wood alcohol), a substance that can be toxic when absorbed through the skin or ingested. **Products manufactured by Eskbiochem identified by the FDA** • All-Clean Hand Sanitizer (NDC: 74589-002-01) • Esk Biochem Hand Sanitizer (NDC: 74589-007-01) • CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol (NDC: 74589-008-04) • Lavar 70 Gel Hand Sanitizer (NDC: 74589-006-01) • The Good Gel Antibacterial Gel Hand Sanitizer (NDC: 74589-010-10) • CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol (NDC: 74589-005-03) • CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol (NDC: 74589-009-01) • CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol (NDC: 74589-003-01) • Saniderm Advanced Hand Sanitizer (NDC: 74589-001-01)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Nyvepria™ (pegfilgrastim-apgf) Injection, for subcutaneous use	Pfizer Inc.	06/10/2020

THERAPEUTIC CLASS
Hematopoietic growth factor

FDA-APPROVE INDICATION(S)
Nyvepria™ is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

DOSAGE AND ADMINISTRATION
The recommended dose is 6 mg administered subcutaneously once per chemotherapy cycle. Weight based dosing is recommended for pediatric patients weighing less than 45 kg. See full prescribing information for additional details.

DOSAGE FORMS AND STRENGTHS
Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only.

Orphan status: N/A
Biosimilar to Neulasta™ (pegfilgrastim)

SAFETY PROFILE

CONTRAINDICATIONS
- History of serious allergic reactions to human granulocyte colony-stimulating factors such as pegfilgrastim products or filgrastim products.

WARNINGS AND PRECAUTIONS
- Splenic rupture: Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- Acute respiratory distress syndrome (ARDS): ARDS can occur in patients receiving pegfilgrastim products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue in patients with ARDS.
- Serious allergic reactions: Can occur. Permanently discontinue in patients with serious allergic reactions.
- Sickle cell crises: Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products. Discontinue if sickle cell crisis occurs.
- Glomerulonephritis: Can occur. Evaluate and consider dose-reduction or interruption if causality is likely.

WARNINGS AND PRECAUTIONS
- Leukocytosis: Can occur. Monitor CBC.
- Capillary leak syndrome: Can occur. Monitor closely.
- Potential for tumor growth stimulatory effects on malignant cells
- Aortitis

ADVERSE REACTIONS
Most common adverse reactions: bone pain and pain in extremity

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New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Uplizna™ (inebilizumab-cdon) Injection, for intravenous use	Viela Bio	06/11/2020

THERAPEUTIC CLASS
Immunological agent; CD19-directed cytolytic antibody

FDA-APPROVE INDICATION(S)
Uplizna™ is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

DOSAGE AND ADMINISTRATION
The recommended initial dose is 300 mg intravenous (IV) infusion followed 2 weeks later by a second 300 mg intravenous infusion. For subsequent doses (starting 6 months from the first infusion): single 300 mg IV infusion every 6 months.

Specific assessments and premedication are required prior to first dose and before every infusion. See full prescribing information for details.

DOSAGE FORMS AND STRENGTHS
Injection: 100 mg/10 mL (10 mg/mL) solution in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- Previous life-threatening reaction to infusion of Uplizna™.
- Active hepatitis B infection.
- Active or untreated latent tuberculosis.

WARNINGS AND PRECAUTIONS
- Infusion reactions: Can cause infusion reactions. Administer pre-medications prior to infusion. Management recommendations for infusion reactions depend on the type and severity of the reaction. Permanently discontinue if a life-threatening or disabling infusion reaction occurs.
- Infections: An increased risk of infections has been observed with other B-cell-depleting therapies. Delay administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

WARNINGS AND PRECAUTIONS (continuation)
- Immunoglobulin levels: There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued Uplizna™ treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment until B-cell repletion. Consider discontinuing if a patient develops a serious opportunistic infection or recurrent infections if immunoglobulin levels indicate immune compromise.
- Fetal risk: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and after stopping.

ADVERSE REACTIONS
Most common adverse reactions: urinary tract infection and arthralgia.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Uplizna™ (inebilizumab-cdon) Injection, for intravenous use	Viela Bio	06/11/2020

THERAPEUTIC CLASS
Immunological agent; CD19-directed cytolytic antibody

FDA-APPROVE INDICATION(S)
Uplizna™ is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

DOSAGE AND ADMINISTRATION
The recommended initial dose is 300 mg intravenous (IV) infusion followed 2 weeks later by a second 300 mg intravenous infusion. For subsequent doses (starting 6 months from the first infusion): single 300 mg IV infusion every 6 months.

Specific assessments and premedication are required prior to first dose and before every infusion. See full prescribing information for details.

DOSAGE FORMS AND STRENGTHS
Injection: 100 mg/10 mL (10 mg/mL) solution in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE (continuation)

DRUG INTERACTIONS

- Immunosuppressive or Immune-Modulating Therapies: Concomitant use of Uplizna™ with immunosuppressant drugs, including systemic corticosteroids, may increase the risk of infection. Consider the risk of additive immune system effects when co-administering immunosuppressive therapies with Uplizna™.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: There are no data on the presence of ineblizumab-cdon in human milk, the effects on a breastfed infant, or the effects on milk production. Human IgG is excreted in human milk, and the potential for absorption of Uplizna™ to lead to B-cell depletion in the breastfed infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Uplizna™ and any potential adverse effects on the breastfed infant from Uplizna™ or from the underlying maternal condition.
- Pediatric use: Safety and effectiveness have not been established.

USE IN SPECIFIC POPULATIONS

- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.
- Females of reproductive potential: Advise to use contraception while receiving treatment and for 6 months after the last infusion .

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Zepzelca™ (lurbinectedin) Injection, for intravenous use	PharmaMar and Jazz Pharmaceuticals pl	06/15/2020

THERAPEUTIC CLASS
Antineoplastic agent; Selective oncogenic transcription inhibitor

FDA-APPROVE INDICATION(S)
Zepzelca™ is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dose is 3.2 mg/m2 administered by intravenous (IV) infusion every 21 days until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
For injection: 4 mg lyophilized powder in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Myelosuppression: Can cause myelosuppression. Blood counts must be monitored prior to each administration. Initiate treatment only if baseline neutrophil count is ≥ 1,500 cells/mm3 and platelet count is ≥ 100,000/mm3 . Withhold, reduce the dose, or permanently discontinue based on severity.
- Hepatotoxicity: Can cause hepatotoxicity. Monitor liver function tests prior to initiating, periodically during treatment and as clinically indicated. Withhold, reduce the dose, or permanently discontinue based on severity.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: leukopenia, lymphopenia, fatigue, anemia, neutropenia, increased creatinine, increased alanine aminotransferase, increased glucose, thrombocytopenia, nausea, decreased appetite, musculoskeletal pain, decreased albumin, constipation, dyspnea, decreased sodium, increased aspartate aminotransferase, vomiting, cough, decreased magnesium and diarrhea.

DRUG INTERACTIONS
- Strong or moderate CYP3A inhibitors: Co-administration increases lurbinectedin systemic exposure, which may increase the incidence and severity of adverse reactions to Zepzelca™. Avoid co-administration. If the co-administration cannot be avoided, consider dose reduction of Zepzelca™, if clinically indicated.
- Strong or moderate CYP3A inducers: Co-administration decreases lurbinectedin systemic exposure, which may reduce Zepzelca™ efficacy. Avoid co-administration.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females and males of reproductive potential of the potential risk to a fetus and to use an effective method of contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Zepzelca™ (lurbinectedin) Injection, for intravenous use	PharmaMar and Jazz Pharmaceuticals pl	06/15/2020

THERAPEUTIC CLASS
Antineoplastic agent; Selective oncogenic transcription inhibitor

FDA-APPROVE INDICATION(S)
Zepzelca™ is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dose is 3.2 mg/m2 administered by intravenous (IV) infusion every 21 days until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
For injection: 4 mg lyophilized powder in a single-dose vial.

Orphan status: Orphan

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Geriatric use: No overall difference in effectiveness was observed between patients aged 65 and older and younger patients. There was a higher incidence of serious adverse reactions in patients ≥ 65 years of age than in younger patients.
- Hepatic impairment: No adjustment recommended for mild hepatic impairment. The effect of moderate or severe hepatic impairment has not been studied.

(continuation) – IF APPLY

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Fintepla™ (fenfluramine) Oral Solution	Zogenix, Inc.	06/25/2020

THERAPEUTIC CLASS
Anticonvulsant

FDA-APPROVE INDICATION(S)
Fintepla™ is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended starting and maintenance dose is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability.

For patients not on concomitant stiripentol, the max. daily maintenance dose is 0.35 mg/kg twice daily (max. of 26 mg). For patients taking concomitant stiripentol plus clobazam, the max. daily maintenance dose for patients taking these medications is 0.2 mg/kg twice daily (max. of 17 mg).

DOSAGE FORMS AND STRENGTHS
Oral solution: 2.2 mg/mL fenfluramine

Orphan status: Orphan
Controlled substance: CIV

SAFETY PROFILE

CONTRAINDICATIONS

- Hypersensitivity to fenfluramine or any of the excipients.
- Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome.

WARNINGS AND PRECAUTIONS

- Boxed warning: **Valvular heart disease and pulmonary arterial hypertension** - There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine, and valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment. Fintepla™ is available only through a restricted program called the FINTEPLA REMS.
- Decreased appetite and decreased weight: Advise patients that Fintepla™ can cause decreased appetite and decreased weight.
- Somnolence, sedation, and lethargy: Can cause somnolence, sedation, and lethargy. Monitor for somnolence and sedation. Advise patients not to drive or operate machinery until they have gained sufficient experience on treatment.

WARNINGS AND PRECAUTIONS (continuation)

- Suicidal behavior and ideation: Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.
- Withdrawal of AEDs: As with most AEDs, Fintepla™ should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus.
- Serotonin syndrome: Advise patients that serotonin syndrome is a potentially life-threatening condition and may occur, particularly with concomitant administration with other serotonergic drugs.
- Increase in blood pressure: Can cause an increase in blood pressure. Monitor blood pressure during treatment.
- Glaucoma: Discontinue therapy in patients with acute decrease in visual acuity or ocular pain.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Fintepla™ (fenfluramine) Oral Solution	Zogenix, Inc.	06/25/2020

THERAPEUTIC CLASS
Anticonvulsant

FDA-APPROVE INDICATION(S)
Fintepla™ is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended starting and maintenance dose is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability.

For patients not on concomitant stiripentol, the max. daily maintenance dose is 0.35 mg/kg twice daily (max. of 26 mg). For patients taking concomitant stiripentol plus clobazam, the max. daily maintenance dose for patients taking these medications is 0.2 mg/kg twice daily (max. of 17 mg).

DOSAGE FORMS AND STRENGTHS
Oral solution: 2.2 mg/mL fenfluramine

Orphan status: Orphan
Controlled substance: CIV

SAFETY PROFILE (continuation)

ADVERSE REACTIONS
Most common adverse reactions: decreased appetite; somnolence, sedation, lethargy; diarrhea; constipation; abnormal echocardiogram; fatigue, malaise, asthenia; ataxia, balance disorder, gait disturbance; blood pressure increased; drooling, salivary hypersecretion; pyrexia; upper respiratory tract infection; vomiting; decreased weight; fall; status epilepticus.

DRUG INTERACTIONS
- **Stiripentol Plus Clobazam:** Co-administration of Fintepla™ with stiripentol plus clobazam, with or without valproate, increases fenfluramine plasma concentrations and decreases its metabolite, norfenfluramine, because of the inhibition of the metabolism of fenfluramine. Dose adjustment is required for patients taking stiripentol plus clobazam.
- **Strong CYP1A2 and CYP2B6 inducers:** Co-administration with rifampin or a strong CYP1A2 and CYP2B6 inducer will decrease fenfluramine plasma concentrations, which may lower the efficacy of Fintepla™. Consider an increase in Fintepla™ dosage when co-administered with rifampin or a strong CYP1A2 and CYP2B6 inducer.

DRUG INTERACTIONS (continuation)
- Serotonin receptor antagonists: Cyproheptadine and potent 5-HT1A, 5-HT1D, 5-HT2A, and 5-HT2C serotonin receptor antagonists may decrease the efficacy of Fintepla™. If cyproheptadine or potent 5-HT1A, 5-HT1D, 5-HT2A, or 5-HT2C serotonin receptor antagonists are co-administered, patients should be monitored appropriately.
- Serotonergic drugs: Concomitant administration of Fintepla™ and drugs (e.g. SSRIs, SNRIs, TCAs, MAO
- inhibitors, trazodone, etc.), over-the-counter medications (e.g. dextromethorphan), or herbal supplements (e.g. St. John's Wort) that increase serotonin may increase the risk of serotonin syndrome. Concomitant use with MAOIs is contraindicated. Use caution in patients taking other medications that increase serotonin.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AEDs.
- Pediatric use: Safety and effectiveness in patients less than 2 years of age have not been established.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Fintepla™ (fenfluramine) Oral Solution	Zogenix, Inc.	06/25/2020

THERAPEUTIC CLASS
Anticonvulsant

FDA-APPROVE INDICATION(S)
Fintepla™ is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended starting and maintenance dose is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability.

For patients not on concomitant stiripentol, the max. daily maintenance dose is 0.35 mg/kg twice daily (max. of 26 mg). For patients taking concomitant stiripentol plus clobazam, the max. daily maintenance dose for patients taking these medications is 0.2 mg/kg twice daily (max. of 17 mg).

DOSAGE FORMS AND STRENGTHS
Oral solution: 2.2 mg/mL fenfluramine

Orphan status: Orphan
Controlled substance: CIV

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Geriatric use: Clinical studies for the treatment of Dravet syndrome did not include patients 65 years of age and over to determine whether they respond differently from younger patients.
- Renal impairment: Administration to patients with moderate or severe renal impairment is not recommended.
- Hepatic impairment: Administration to patients with hepatic impairment is not recommended.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Dojolvi™ (triheptanoin) Oral Liquid	Ultragenyx Pharmaceutical Inc.	06/30/2020

THERAPEUTIC CLASS
Nutritive agent; Medium-chain triglyceride

FDA-APPROVE INDICATION(S)
Dojolvi™ is indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

DOSAGE AND ADMINISTRATION
The recommended target daily dosage is up to 35% of the patient's total prescribed DCI divided into at least four doses and administered orally diluted with foods, liquids, or formula via a silicone or polyurethane feeding tube.

DOSAGE FORMS AND STRENGTHS
Oral Liquid, 100% w/w of triheptanoin

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
- Feeding tube dysfunction: Feeding tube performance and functionality can degrade over time depending on usage and environmental conditions. Regularly monitor the tube to ensure proper functioning and integrity.
- Intestinal malabsorption in patients with pancreatic insufficiency: Pancreatic enzymes hydrolyze triheptanoin and release heptanoate as medium-chain fatty acids in the small intestine. Low or absent pancreatic enzymes may reduce absorption of Dojolvi™. Avoid administration in patients with pancreatic insufficiency.

ADVERSE REACTIONS
Most common adverse reactions: abdominal pain, diarrhea, vomiting, and nausea.

DRUG INTERACTIONS
- Pancreatic lipase inhibitors: Co-administration of triheptanoin with a pancreatic lipase inhibitor (e.g. orlistat) may reduce exposure to the triheptanoin metabolite, heptanoate, and reduce the clinical effect of triheptanoin. Avoid co-administration due to potential for reduced clinical effect of Dojolvi™.

USE IN SPECIFIC POPULATIONS
- Pediatric use: The safety and effectiveness have been established in pediatric patients aged birth and older
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

(continuation) – IF APPLY

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Semglee™ (insulin glargine) Injection / **Mylan N.V. and Biocon Ltd.**	Antidiabetic; Long-acting human insulin analog	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	06/11/2020	Semglee™ is a new formulation of insulin glargine, which has an identical amino acid sequence to Lantus™ (insulin glargine) and is approved for the same indications. Orphan status: N/A
Tivicay PD™ (dolutegravir) Tablets for Oral Suspension / **ViiV Healthcare**	Antiviral; Integrase strand transfer inhibitor (INSTI)	In combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged at least 4 weeks and weighing at least 3 kg	06/12/2020	Tivicay PD™ is a new formulation of dolutegravir in tables for oral suspension for use in pediatric patients. Dolutegravir was already available as a tablet formulation, branded Tivicay™. However, this formulation should not be used in pediatric patients weighing 3 to 14 kg. Orphan status: N/A
Dupixent™ (dupilumab) Injection / **Sanofi and Regeneron Pharmaceuticals, Inc.**	Interleukin-4 receptor alpha antagonist	• For the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable • As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma • As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)	06/18/2020	The FDA approved a new dosage form of Dupixent™ in pre-filled pen, which is expected to provide a more convenient option of administration. Dupixent™ was already available in the market as a pre-filled syringe, and this dosage form will continue to be available for use in a clinic or at home by self-administration. Of important note, this pre-filled pen is only approved for use in adults and adolescents aged 12 years and older and both methods of administration (by syringe and by pen) require training by a healthcare professional. Orphan status: N/A

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Lyumjev™ (insulin lispro-aabc) Injection / **Eli Lilly and Company**	Antidiabetic; Rapid-acting human insulin analog	To improve glycemic control in adults with diabetes mellitus	06/15/2020	Lyumjev™ is a novel formulation of insulin lispro, developed to speed the absorption of insulin into the blood stream. Insulin lispro was already available in the market as brand Humalog™ and Admelog™ as well as an authorized brand alternative (ABA) to Humalog™. • Humalog™ and the ABA are indicated to improve glycemic control in adults and children with diabetes mellitus. • Admelog™ is indicated to improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. Orphan status: N/A
Gimoti™ (metoclopramide) Nasal Spray / **Evoke Pharma, Inc.**	Dopamine-2 (D2) antagonist	For the relief of symptoms of acute and recurrent diabetic gastroparesis in adults	06/19/2020	Gimoti™ is the first intranasal formulation of metoclopramide. Oral metoclopramide is available generically as an orally disintegrating tablet (ODT), solution, and tablet. • The ODT, solution, and tablet formulations are approved for symptomatic gastroesophageal reflux disease, and diabetic gastroparesis. Orphan status: N/A
Mycapssa™ (octreotide) Delayed-Release Capsules / **Chiasma, Inc.**	Endocrine and metabolic agent; Somatostatin analog	Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide	06/26/2020	Mycapssa™ is a new oral formulation of the approved somatostatin analog octreotide. Mycapssa™ is the first oral somatostatin analog approved by the FDA and the first product approved by the FDA utilizing Chiasma's Transient Permeability Enhancer (TPE®) technology. Orphan status: Orphan

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Phesgo™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf) Injection / **Genentech, Inc.**	Antineoplastic agent	Use in combination with chemotherapy as: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence Use in combination with docetaxel for treatment of patients with HER2 positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease	06/29/2020	Phesgo™ is a combination of two HER2/neu receptor antagonists, pertuzumab and trastuzumab, and the endoglycosidase hyaluronidase. Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Recarbrio™ (imipenem, cilastatin, and relebactam) for Injection / Merck	Anti-infective agent; Antibacterial	Treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI)	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)	06/04/2020
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced 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	Treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy	06/10/2020
Gardasil 9™ (human papillomavirus 9-valent vaccine, recombinant) Injection / Merck	Vaccine	In females 9 through 45 years of age: For the prevention of cervical, vulvar, vaginal, and anal caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11 In males 9 through 45 years of age: For the prevention of anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11	For the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58	06/12/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, and endometrial carcinoma	• As monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options • As monotherapy for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation • As monotherapy for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer	06/16/2020; 06/24/2020; 06/29/2020
Cosentyx™ (secukinumab) Injection / Novartis Pharmaceuticals Corporation	Dermatological agents; Antipsoriatic; Selective interleukin-17A (IL-17A) inhibitor	Treatment of plaque psoriasis, ankylosing spondylitis, and psoriatic arthritis	Treatment of non-radiographic axial spondyloarthritis	06/16/2020

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Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Tazverik™ (tazemetostat) Tablets / Epizyme, Inc.	Antineoplastic agent; Methyltransferase inhibitor	Treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection	Treatment of: • Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies • Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options	06/18/2020
Crysvita™ (burosumab-twza) Injection / Ultragenyx Pharmaceutical Inc.	Endocrine and metabolic agent; Fibroblast growth factor 23 (FGF23) blocking antibody	Treatment of X-linked hypophosphatemia (XLH)	Treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adults and pediatric patients 2 years of age and older	06/18/2020
Xpovio™ (selinexor) Tablets / Karyopharm Therapeutics Inc.	Antineoplastic agent; Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist	Treatment of patients adult patients with multiple myeloma (RRMM)	Treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy	06/22/2020
Bavencio™ (avelumab) Injection /EMD Serono, Inc.	Antineoplastic agent; programmed death ligand-1 (PD-L1) blocking antibody	Treatment of patients with metastatic Merkel cell carcinoma (MCC); patients with advanced or metastatic urothelial carcinoma; and in combination with axitinib for patients with advanced renal cell carcinoma	Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy	06/30/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Date	Generic for:
Halobetasol Propionate Topical Lotion 0.05% / Ultravate Lotion	Corticosteroid	06/03/2020	Ultravate Lotion
Betamethasone Dipropionate Topical Spray 0.05% / Taro Pharmaceuticals Inc.	Corticosteroid	06/17/2020	Sernivo
Methylphenidate Hydrochloride Extended-Release Orally Disintegrating Tablets 8.6 mg, 17.3 mg and 25.9 mg / Actavis Elizabeth LLC	Central nervous system stimulant; Amphetamine	06/19/2020	Cotempla XR-ODT
Pantoprazole Sodium for Delayed-Release Oral Suspension 40 mg (base) / Sun Pharmaceutical Industries Ltd.	Proton pump inhibitor	06/30/2020	Protonix for Delayed-Release Oral Suspension

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
E4/DRSP (estetrol and drospirenone) / Mayne Pharma Group Limited	06/24/2020	Treatment for: Contraception	E4/DRSP (estetrol and drospirenone) is a novel combined hormonal oral contraceptive pill in development for the prevention of pregnancy. FDA accepted NDA for E4/DRSP.	Moderate
Casimersen / Sarepta Therapeutics, Inc.	06/26/2020	Treatment for: Duchenne Muscular Dystrophy	Casimersen is a phosphorodiamidate morpholino oligomer in development for the treatment of patients with Duchenne muscular dystrophy (DMD) who have genetic mutations that are amenable to skipping exon 45 of the Duchenne gene. Sarepta Therapeutics completes submission of MDA for casimersen.	High
Udenafil / Mezzion Pharma Co. Ltd.	06/30/2020	Treatment for: Single Ventricle Heart Disease	Udenafil is a long acting, highly selective phosphodiesterase-5 inhibitor in development for the treatment of patients who have undergone the Fontan operation for single ventricle heart disease. Mezzion submits NDA for its orphan drug udenafil.	High High

References

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