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PharmNOTES

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

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NEWS……

Drug Issue	Date	News/Event
Serious breathing problems with seizure and nerve pain medicines gabapentin and pregabalin	12/19/2019	The FDA is warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system (CNS), and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk. The FDA is requiring new warnings about the risk of respiratory depression to be added to the prescribing information of the gabapentinoids. Recommendation for healthcare providers: • Start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other CNS depressants. Patients with underlying respiratory disease and elderly patients are also at increased risk and should be managed similarly. • Be aware of the potential additive effects of all CNS depressants and plan accordingly, by starting with low doses, titrating carefully, and informing patients of the potential for CNS and respiratory depression and their symptoms.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Avsola™ (infliximab-axxq) Injection, for intravenous use / Amgen Inc.	Tumor necrosis factor (TNF) blocker
	
	Note: Biosimilar to Remicade™
		Treatment of:
		• Crohn's disease (adult and pediatric)
		• Ulcerative colitis (adult and pediatric)
		• Rheumatoid arthritis
		• Ankylosing spondylitis
		• Psoriatic arthritis
		• Plaque psoriasis
		
		Black box warning
		Serious infections and malignancy.
			12/06/2019	**DOSAGE AND ADMINISTRATION**
				• Crohn's disease:
				  • Adult: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.
				  • Pediatric: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
				• Ulcerative Colitis:
				  • Adult: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
				  • Pediatric: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
				• Rheumatoid arthritis: In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
				• Ankylosing spondylitis: 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks.
				• Psoriatic arthritis and Plaque psoriasis: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
				
				DOSAGE FORMS AND STRENGTHS
				For injection: 100 mg of lyophilized infliximab-axxq in a 20 mL single-dose vial for intravenous infusion.
				
				CONTRAINDICATIONS
				• Doses >5 mg/kg in moderate to severe heart failure.
				• Previous severe hypersensitivity reaction to infliximab products or known hypersensitivity to inactive components of Avsola™ or to any murine proteins.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Avsola™ (infliximab-axxq) Injection, for intravenous use / Amgen Inc. (continuation)	Tumor necrosis factor (TNF) blocker Note: Biosimilar to Remicade™	Treatment of: • Crohn's disease (adult and pediatric) • Ulcerative colitis (adult and pediatric) • Rheumatoid arthritis • Ankylosing spondylitis • Psoriatic arthritis • Plaque psoriasis **Black box warning** Serious infections and malignancy.	12/06/2019	**WARNINGS AND PRECAUTIONS** • **Serious infections:** Patients treated with infliximab products are at increased risk for developing serious infections. Do not give Avsola™ during an active infection. If an infection develops, monitor carefully and stop if infection becomes serious. • **Malignancies:** Malignancies, some fatal, have been reported. The risk/benefit must be carefully assessed. • **Hepatitis B virus reactivation:** Test for HBV infection must be performed before treatment initiation. HBV carriers must be monitored during and several months after therapy. If reactivation occurs, stop Avsola™ and begin anti-viral therapy. • **Hepatotoxicity:** Severe hepatic reactions, some fatal or necessitating liver transplantation, have been reported. Treatment must be stop in cases of jaundice and/or marked liver enzyme elevations. • **Heart failure (HF):** New onset or worsening symptoms may occur. • **Hematologic reactions:** Cytopenias have been reported. Patients should be advised to seek immediate medical attention if signs and symptoms develop, and consider stopping treatment. • **Hypersensitivity:** Serious infusion reactions including anaphylaxis or serum sickness-like reactions may occur. • **Cardiovascular and cerebrovascular reactions:** Cerebrovascular accidents, myocardial infarctions (some fatal), and arrhythmias have been reported during and within 24 hours of initiation of infliximab product infusion. Patients must be monitored during infusion and if serious reaction occurs, discontinue infusion.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Avsola™ (infliximab-axxq) Injection, for intravenous use / Amgen Inc. (continuation)	Tumor necrosis factor (TNF) blocker Note: Biosimilar to Remicade™	Treatment of: • Crohn's disease (adult and pediatric) • Ulcerative colitis (adult and pediatric) • Rheumatoid arthritis • Ankylosing spondylitis • Psoriatic arthritis • Plaque psoriasis **Black box warning** Serious infections and malignancy.	12/06/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Demyelinating disease:** Exacerbation or new onset may occur. • **Lupus-like syndrome:** Treatment must be stop if syndrome develops. **ADVERSE REACTIONS** Most common adverse reactions: infections (e.g., upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain. **DRUG INTERACTIONS** • **Anakinra or abatacept:** Concomitant use increased risk of serious infections. • **Live vaccines or therapeutic infectious agents:** Should not be given with Avsola™. Bring pediatric patients up to date with all vaccinations prior to initiating. At least a six-month waiting period following birth is recommended before the administration of live vaccines to infants exposed in utero to infliximab products. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Infliximab products have not been studied in children with Crohn's disease or Ulcerative colitis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyondys 53™ (golodirsen) Injection, for intravenous use / Sarepta Therapeutics	Musculoskeletal agent; Antisense oligonucleotide Note: Orphan	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping, including pediatric patients	12/12/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 30 mg/kg once weekly, administered as an intravenous infusion over 35 to 60 minutes. Dilution required prior to administration and glomerular filtration rate must be measured prior to initiation. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/2 mL (50 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hypersensitivity reactions:** Hypersensitivity reactions have occurred. If a hypersensitivity reaction occurs, appropriate medical treatment must be instituted and consider slowing the infusion or interrupting therapy. • **Renal toxicity:** Based on animal data, may cause renal toxicity. Renal function should be monitored; creatinine may not be a reliable measure of renal function in DMD patients. **ADVERSE REACTIONS** Most common adverse reactions: headache, pyrexia, fall, abdominal pain, nasopharyngitis, cough, vomiting, and nausea. **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** DMD is largely a disease of children and young adults; therefore, there is no geriatric experience with Vyondys 53™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Padcev™ (enfortumab vedotin-ejfv) for Injection, for intravenous use/ Astellas and Seattle Genetics	Antineoplastic agent; Nectin-4 targeted antibody-drug conjugate (ADC)	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	12/18/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 1.25 mg/kg (up to a maximum dose of 125 mg) given as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity. Dose modifications are recommended if the patient presents certain adverse reactions. **DOSAGE FORMS AND STRENGTHS** For injection: 20 mg and 30 mg of enfortumab vedotin-ejfv as a lyophilized powder in a single-dose vial for reconstitution. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hyperglycemia:** Hyperglycemia, including death, and diabetic ketoacidosis (DKA) have been reported in patients with and without pre-existing diabetes mellitus (DM). Blood glucose levels must be closely monitor in patients with, or at risk for, DM or hyperglycemia. Withhold if blood glucose >250 mg/dL. • **Peripheral neuropathy:** Peripheral neuropathy have been reported. Patients must be monitored for new or worsening peripheral neuropathy and consider dose interruption, dose reduction or discontinuation. • **Ocular disorders:** Ocular disorders, including vision changes, may occur. Patients must be monitor for signs or symptoms. Prophylactic artificial tears may be considered for dry eyes and treatment with ophthalmic topical steroids after an ophthalmic exam. Dose interruption or dose reduction may also be considered when symptomatic ocular disorders occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Padcev™ (enfortumab vedotin-ejfv) for Injection, for intravenous use/ Astellas and Seattle Genetics (continuation)	Antineoplastic agent; Nectin-4 targeted antibody-drug conjugate (ADC)	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	12/18/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Skin reactions:** Skin reactions have been reported. If severe, withhold until improvement or resolution. • **Infusion site extravasation:** Skin and soft tissue reactions secondary to extravasation have been observed. Ensure adequate venous access prior to administration. Monitor the infusion site during administration and stop the infusion immediately for suspected extravasation. • Embryo-fetal toxicity: PADCEV. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, peripheral neuropathy, decreased appetite, rash, alopecia, nausea, dysgeusia, diarrhea, dry eye, pruritus and dry skin. **DRUG INTERACTIONS** • Concomitant use of strong inhibitors of CYP3A4 with PADCEV may increase the exposure to monomethyl auristatin E (MMAE). **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating treatment. • **Females and males of reproductive potential:** Advise of the potential risk to a fetus and to use effective contraception. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and efficacy have not been established. • **Geriatric use:** No overall differences in safety or efficacy were observed between these patients and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Padcev™ (enfortumab vedotin-ejfv) for Injection, for intravenous use/ Astellas and Seattle Genetics (continuation)	Antineoplastic agent; Nectin-4 targeted antibody-drug conjugate (ADC)	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	12/18/2019	**USE IN SPECIFIC POPULATIONS** (continuation) • **Hepatic impairment:** Avoid the in patients with moderate or severe hepatic impairment. No adjustment in the starting dose is required when administering to patients with mild hepatic impairment. • **Renal impairment:** No dose adjustment is required in patients with mild, moderate, or severe renal impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ervebo™ (ebola zaire vaccine, live) Injection, for intramuscular use / Merck	Vaccine	Prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older	12/19/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is to administer a single 1 mL dose intramuscularly. **DOSAGE FORMS AND STRENGTHS** 1 mL suspension for injection supplied as a single-dose vial. **CONTRAINDICATIONS** • Severe allergic reaction (e.g., anaphylaxis) to any component. **WARNINGS AND PRECAUTIONS** • Anaphylaxis has been observed following administration. Appropriate medical treatment and supervision must be available in case of anaphylaxis following the administration. • Vaccinated individuals should continue to adhere to infection control practices to prevent virus infection and transmission. • Vaccine virus RNA has been detected in blood, saliva, urine, and fluid from skin vesicles of vaccinated adults; transmission of vaccine virus is a theoretical possibility. **ADVERSE REACTIONS** Most common adverse reactions: injection-site reactions were injection-site pain (70%), swelling (17%), and redness **DRUG INTERACTIONS** • Interference with laboratory tests: Following vaccination, individuals may test positive for anti-Ebola glycoprotein (GP) antibody and/or Ebola GP nucleic acid or antigens. GP-based testing may have limited diagnostic value during the period of vaccine viremia, in the presence of vaccine-derived Ebola GP, and following antibody response to the vaccine

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ervebo™ (ebola zaire vaccine, live) Injection, for intramuscular use / Merck (continuation)	Vaccine	Prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older	12/19/2019	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy have not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Genosyl™ (nitric oxide), for inhalation use / Vero Biotech	Vasodilator Note: Orphan	To improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents	12/20/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 20 ppm, maintained for up to 14 days or until the underlying oxygen desaturation has resolved. Doses greater than 20 ppm are not recommended. **DOSAGE FORMS AND STRENGTHS** Gas, available at concentrations up to 800 ppm. **CONTRAINDICATIONS** • Neonates dependent on right-to-left shunting of blood. **WARNINGS AND PRECAUTIONS** • **Rebound pulmonary hypertension:** Abrupt discontinuation may lead to worsening oxygenation and increasing pulmonary artery pressure. • **Methemoglobinemia:** Methemoglobin increases with the dose of nitric oxide; following discontinuation or reduction of nitric oxide, methemoglobin levels return to baseline over a period of hours. • **Elevated NO2 levels:** NO2 levels must be monitor. • **Heart failure:** In patients with pre-existing left ventricular dysfunction, Genosyl™ may increase pulmonary capillary wedge pressure leading to pulmonary edema. **ADVERSE REACTIONS** Most common adverse reactions: hypotension. **DRUG INTERACTIONS** • Nitric oxide donor compounds may increase the risk of developing methemoglobinemia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Dayvigo™ (lemborexant) Tablets, for oral use / Eisai Inc.	Central nervous system (CNS) agent; Orexin receptor antagonist Note: Controlled substance [schedule pending]	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	12/20/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. Dosage may be increased to 10 mg based on clinical response and tolerability. The maximum recommended dose is 10 mg once daily. **DOSAGE FORMS AND STRENGTHS** Tablets: 5 mg, 10 mg. **CONTRAINDICATIONS** • Patients with narcolepsy. **WARNINGS AND PRECAUTIONS** • **CNS depressant effects and daytime impairment:** Impairs alertness and motor coordination including morning impairment. Risk increases with dose and use with other CNS depressants. For patients taking 10 mg, caution against next-day driving and other activities requiring complete mental alertness. • **Sleep paralysis, hypnogogic/hypnopompic hallucinations, and cataplexy-like symptoms:** May occur. • **Complex sleep behaviors:** Behaviors including sleep-walking, sleep-driving, and engaging in other activities while not fully awake may occur. Discontinue immediately if a complex sleep behavior occurs. • **Compromised Respiratory Function:** Effect on respiratory function should be considered. • **Worsening of depression/suicidal ideation:** Worsening of depression or suicidal thinking may occur. Prescribe the lowest number of tablets feasible to avoid intentional over dosage.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Dayvigo™ (lemborexant) Tablets, for oral use / Eisai Inc. (continuation)	Central nervous system (CNS) agent; Orexin receptor antagonist Note: Controlled substance [schedule pending]	Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	12/20/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Need to evaluate for co-morbid diagnoses:** Reevaluate if insomnia persists after 7 to 10 days of treatment. **ADVERSE REACTIONS** Most common adverse reactions: somnolence. **DRUG INTERACTIONS** • **Strong or moderate CYP3A inhibitors:** Avoid concomitant use. • **Weak CYP3A inhibitors:** The maximum recommended dose is 5 mg. • **Strong or moderate CYP3A inducers:** Avoid concomitant use. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to Dayvigo™ during pregnancy. Healthcare providers are encouraged to register patients. • **Pediatric use:** Safety and efficacy have not been established. • **Renal impairment:** No dose adjustment is required in patients with mild, moderate, or severe renal impairment. • **Hepatic impairment:** Has not been studied in patients with severe hepatic impairment. Use in this population is not recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Enhertu™ (fam-trastuzumab deruxtecan-nxki) Injection, for intravenous use / AstraZeneca and Daiichi Sankyo Company, Limited	Antineoplastic agent; HER2-directed antibody and topoisomerase inhibitor conjugate	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting **Black box warning** Interstitial lung disease (ILD) and embryo-fetal toxicity	12/20/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. Management of adverse reactions (ILD, neutropenia, or left ventricular dysfunction) may require temporary interruption, dose reduction, or discontinuation. Do not substitute Enhertu™ for or with trastuzumab or adotrastuzumab emtansine. **DOSAGE FORMS AND STRENGTHS** For injection: 100 mg lyophilized powder in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **ILD/pneumonitis:** Can occur. Patients must be advised to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Patients must be monitor for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic ILD, consider corticosteroid treatment. Withhold until recovery. In cases of symptomatic ILD, promptly initiate corticosteroid treatment. Upon improvement, follow by gradual taper. Permanently discontinue in patients who are diagnosed with any symptomatic ILD.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Enhertu™ (fam-trastuzumab deruxtecan-nxki) Injection, for intravenous use / AstraZeneca and Daiichi Sankyo Company, Limited (continuation)	Antineoplastic agent; HER2-directed antibody and topoisomerase inhibitor conjugate	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting **Black box warning** Interstitial lung disease (ILD) and embryo-fetal toxicity	12/20/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Neutropenia:** Severe neutropenia, including febrile neutropenia, can occur. Monitor CBC prior to initiation and prior to each dose, and as clinically indicated. Manage through treatment interruption or dose reduction. • **Left ventricular dysfunction:** Assess LVEF prior to initiation and at regular intervals during treatment as clinically indicated. Manage through treatment interruption or discontinuation. Permanently discontinue in patients with symptomatic congestive heart failure (CHF). **ADVERSE REACTIONS** Most common adverse reactions: nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough, and thrombocytopenia. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Verify pregnancy status of females prior to initiation. • **Females and males of reproductive potential:** Advise to use effective contraception. • **Lactation:**. Advise not to breastfeed. • **Pediatric use:** Safety and efficacy have not been established. • **Renal impairment:** No dose adjustment is required in patients with mild or moderate renal impairment. No data are available in patients with severe renal impairment. • **Hepatic impairment:** No dose adjustment is required in patients with mild or moderate hepatic impairment. In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor. No data are available in patients with severe hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Caplyta™ (lumateperone) Capsules, for oral use / Intra-Cellular Therapies, Inc.	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	12/20/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 42 mg once daily. **DOSAGE FORMS AND STRENGTHS** Capsules: 42 mg. **CONTRAINDICATIONS** • Known hypersensitivity to lumateperone or any components of Caplyta™. **WARNINGS AND PRECAUTIONS** • **Increased mortality in elderly patients with dementia-related psychosis:** Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. • **Cerebrovascular adverse reactions in elderly patients with dementia related psychosis:** Increased incidence of cerebrovascular adverse reactions (e.g., stroke and transient ischemic attack). • **Neuroleptic Malignant Syndrome (NMS):** NMS has been reported in association with administration of antipsychotic drugs. Manage with immediate discontinuation and close monitoring. • **Tardive dyskinesia:** May develop in patients treated with antipsychotic drugs. Discontinue treatment if clinically appropriate. • **Metabolic changes:** Antipsychotic drugs have caused metabolic changes. Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Caplyta™ (lumateperone) Capsules, for oral use / Intra-Cellular Therapies, Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	12/20/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Leukopenia, neutropenia, and agranulocytosis:** Have been reported during treatment with antipsychotics. Perform CBC in patients with pre-existing low WBC count or history of leukopenia or neutropenia. Consider discontinuing if clinically significant decline in WBC occurs in absence of other causative factors. • **Orthostatic hypotension and syncope:** Atypical antipsychotics cause orthostatic hypotension and syncope. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope. • **Falls:** Antipsychotics may cause somnolence, postural hypotension, and motor and sensory instability, which may lead to falls and, consequently, fractures and other injuries. For patients with diseases, conditions or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and periodically during long-term treatment. • **Seizures:** Antipsychotics may cause seizures. Use cautiously in patients with a history of seizure or with conditions that lower seizure threshold. • **Potential for cognitive and motor impairment:** Antipsychotics may cause somnolence and has the potential to impair judgment, thinking, and motor skills. Caution must be used when operating machinery. • **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotics use. Antipsychotics should be used cautiously in patients at risk for aspiration.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Caplyta™ (lumateperone) Capsules, for oral use / Intra-Cellular Therapies, Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	12/20/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Body temperature dysregulation:** Atypical antipsychotics may disrupt the body's ability to reduce core body temperature. Strenuous exercise, exposure to extreme heat, dehydration, and anticholinergic medications may contribute to an elevation in core body temperature. Use with caution in patients who may experience these conditions. **ADVERSE REACTIONS** Most common adverse reactions: somnolence/sedation and dry mouth **DRUG INTERACTIONS** • **CYP3A4 inducers:** Concomitant use decreases the exposure of lumateperone. Avoid concomitant use. • **Moderate or strong CYP3A4 inhibitors:** Concomitant use increases lumateperone exposure, which may increase the risk of adverse reactions. Avoid concomitant use. • **UGT inhibitors:** Concomitant use may increase the exposure of lumateperone and/or its metabolites. Avoid concomitant use. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics. Healthcare providers are encouraged to register patients. • **Lactation:** Breastfeeding not recommended. • **Pediatric use:** Safety and efficacy have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Caplyta™ (lumateperone) Capsules, for oral use / Intra-Cellular Therapies, Inc. (continuation)	Atypical antipsychotic	Treatment of schizophrenia in adults **Black box warning** Increased mortality in elderly patients with dementia-related psychosis	12/20/2019	**USE IN SPECIFIC POPULATIONS** (continuation) • **Geriatric use:** Clinical studies did not include any patients aged 65 or older to determine whether or not they respond differently from younger patients. • **Hepatic impairment:** Use is not recommended for patients with moderate to severe hepatic impairment. Patients with moderate and severe hepatic impairment experienced higher exposure to lumateperone. No dosage adjustment is recommended for patients with mild hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
TissueBlue™ (Brilliant Blue G Ophthalmic Solution) 0.025%, for intraocular ophthalmic use / Dutch Ophthalmic Research	Disclosing Agent	To selectively stain the internal limiting membrane (ILM)	10/20/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is to inject TissueBlue 0.025% directly in a Balanced Salt Solution (BSS)-filled vitreous cavity. Excess TissueBlue should be removed from the vitreous cavity. **DOSAGE FORMS AND STRENGTHS** TissueBlue (Brilliant Blue G Ophthalmic Solution) 0.025% is supplied in 2.25 mL syringes filled to a volume of 0.5 mL. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Excessive staining:** Excess TissueBlue 0.025% should be removed from the eye immediately after staining. • **Use of the syringe:** Make sure the plunger moves smoothly before injecting the solution. **ADVERSE REACTIONS** Adverse reactions that have been reported in procedures that included the use of TissueBlue 0.025% have often been associated with the surgical procedure. The complications include retinal break, tear, hemorrhage, and detachment and cataracts.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ubrelvy™ (ubrogepant) Tablets, for oral use / Allergan plc	Antimigraine; Calcitonin gene-related peptide (CGRP) receptor antagonist	Acute treatment of migraine with or without aura in adults	12/23/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg. The safety of treating more than 8 migraines in a 30-day period has not been established. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg and 100 mg. **CONTRAINDICATIONS** • Concomitant use with strong CYP3A4 inhibitors. **ADVERSE REACTIONS** Most common adverse reactions: nausea and somnolence. **DRUG INTERACTIONS** • **CYP3A4 Inhibitors:** Ubrelvy™ should not be used with strong CYP3A4 inhibitors due to significant increase in exposure of ubrogepant. Dose adjustment is recommended with concomitant use of Ubrelvy™ and moderate CYP3A4 inhibitors. • **CYP3A4 inducers:** Concomitant use with strong CYP3A4 inducers should be avoided because loss of ubrogepant efficacy is expected. Dose adjustment is recommended with concomitant use of Ubrelvy™ and moderate or weak CYP3A4 inducers.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ubrelvy™ (ubrogepant) Tablets, for oral use / Allergan plc (continuation)	Antimigraine; Calcitonin gene-related peptide (CGRP) receptor antagonist	Acute treatment of migraine with or without aura in adults	12/23/2019	**DRUG INTERACTIONS** (continuation) • **BCRP and/or P-gp only inhibitors:** Ubrogepant is a substrate of BCRP and P-gp efflux transporters. Use of BCRP and/or P-gp only may increase the exposure of ubrogepant. Dose adjustment is recommended with BCRP and/or P-gp only inhibitors. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Pediatric use:** Safety and efficacy have not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. • **Hepatic impairment:** No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Dose adjustment is recommended for patients with severe hepatic impairment. • **Renal Impairment:** No dose adjustment is recommended for patients with mild or moderate renal impairment. Dose adjustment is recommended for patients with severe renal impairment. Avoid use in patients with end-stage renal disease.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tecentriq™ (atezolizumab) Injection / Genentech, Inc.	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	**Previous indication(s):** Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), and small cell lung cancer (SCLC) **New indication:** In combination with chemotherapy (Abraxane™ [paclitaxel protein-bound; nab-paclitaxel] and carboplatin) for the initial (first-line) treatment of adults with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations	12/03/2019	This approval was based on results from a study that showed Tecentriq™ in combination with chemotherapy helped people live significantly longer compared to chemotherapy alone (median overall survival [OS]: 18.6 versus 13.9 months; HR: 0.80; 95% CI: 0.64–0.99; p-value = 0.0384). The Tecentriq™-based combination also significantly reduced the risk of disease worsening or death compared with chemotherapy alone (median progression free survival: 7.2 versus 6.5 months; HR: 0.75; 95% CI: 0.63–0.91; p-value = 0.0024). In terms of safety, the profile for the Tecentriq™ plus chemotherapy combination appeared consistent with the known safety profiles of the individual medicines, and no new safety signals were identified with the combination.
Xeljanz XR™ (tofacitinib) Tablets / Pfizer Inc.	Janus kinase (JAK) inhibitor	**Previous indication(s):** Treatment of adult patients with moderately to severely active rheumatoid arthritis, and active psoriatic arthritis **New indication:** treatment of adult patients with moderately to severely active ulcerative colitis (UC), after an inadequate response or intolerance to TNF blockers	12/12/2019	Xeljanz™ was already approved for the treatment of UC and this indication have now been expanded to the extended release (XR) formulation.

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Vascepa™ (icosapent ethyl) Capsules / Amarin Corporation plc	Anti-hyperlipidemic and Cardiovascular agent	**Previous indication(s):** As an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia **New indication:** As an adjunct to statin therapy to reduce the risk of cardiovascular events	12/13/2019	The global REDUCE-IT cardiovascular outcomes study, showed that approximately 28% of patients treated with statins and other contemporary therapy, but not treated with Vascepa™, experienced a major adverse cardiovascular event (MACE). This MACE occurrence supports that there is a group of patients who, despite controlling their cholesterol on statin therapy, continue to need additional preventative cardiovascular care. For those adult patients in this group who have elevated triglycerides (TG) ≥150 mg/dL and established cardiovascular disease or diabetes and two or more additional risk factors for cardiovascular disease, Vascepa comes to be the first drug approved to help reduce this persistent cardiovascular risk. In a published exploratory analysis of the REDUCE-IT study, examining total (first and subsequent) cardiovascular events over a period of approximately five years, patients taking Vascepa™ on average experienced one fewer MACE per six patients studied, representing a 30% risk reduction in total MACE compared to placebo
Xtandi™ (enzalutamide) Capsules / Astellas Pharma US, Inc.	Antineoplastic agent; Androgen receptor inhibitor	**Previous indication(s):** Treatment of castration-resistant prostate cancer (CRPC) **New indication:** Treatment of metastatic castration-sensitive prostate cancer	12/16/2019	This approval was based on data from the ARCHES trial, which demonstrated that treatment with Xtandi™ plus androgen deprivation therapy (ADT) significantly reduced the risk of radiographic progression or death by 61% compared to placebo plus ADT (n=1,150; HR: 0.39; 95% CI: 0.30-0.50]; p-value <0.0001). Overall survival data were not mature at the time of final analysis. In terms of safety, the profile was generally consistent with the safety profile of Xtandi™ in previous clinical trials in CRPC.
Fiasp™ (insulin aspart) Injection / Novo Nordisk	Antidiabetic; Rapid-acting human insulin analog	**Previous indication(s):** To improve glycemic control in patients with diabetes mellitus **Patient population altered:** To include children with diabetes.	12/19/2019	-

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Lynparza™ (olaparib) Tablets / AstraZeneca	Antineoplastic agent; Poly ADP ribose polymerase (PARP) inhibitor	**Previous indication(s):** Treatment of ovarian cancer, and breast cancer **New indication:** Treatment of pancreatic cancer	12/272019	This approval was based on results from the pivotal Phase III POLO trial. Results showed a statistically significant and clinically meaningful improvement in progression-free survival, where Lynparza™ nearly doubled the time patients with gBRCAm metastatic pancreatic cancer lived without disease progression or death to a median of 7.4 months vs. 3.8 months on placebo (HR: 0.53; 95% CI: 0.35-0.81, p-value = 0.0035). The safety and tolerability profile of Lynparza™ in the POLO trial was in line with that observed in prior clinical trials.

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Nouress™ (cysteine hydrochloride) Injection / Avadel Pharmaceuticals plc	Sulfur-containing amino acid	As an additive to amino acids solutions to meet nutritional requirements of neonates requiring total parenteral nutrition	12/13/2019	Nouress™ is a sulfur-containing amino acid indicated for use as an additive to amino acids solutions to meet nutritional requirements of neonates requiring total parenteral nutrition.
Arazlo™ (tazarotene) Lotion / Bausch Health Companies Inc.	Retinoid	Topical treatment of acne vulgaris in patients 9 years of age and older	12/18/2019	Arazlo™ is the first tazarotene acne treatment available in a lotion formation. Tazarotene is currently available generically as a topical cream and brand topical foam (Fabior™), topical gel (Tazorac™), and cream (Avage™). Tazarotene is also available as a lotion in combination with halobetasol (Duobrii™). • The generic topical cream and gel are approved for plaque psoriasis and acne vulgaris. • The topical foam is approved for acne vulgaris. • Avage™ is approved as an adjunctive agent for use in the mitigation of facial fine wrinkling, facial mottled hyper- and hypopigmentation, and benign facial lentigines in patients who use comprehensive skin care and sunlight avoidance programs. • Duobrii™ is approved for the treatment of plaque psoriasis.
Conjupri™ (levamlodipine maleate) Tablets, for oral use / CSPC Pharmaceutical Group Limited	Antihypertensive; Calcium Channel Blocker	Treatment of hypertension, to lower blood pressure	12/19/2019	Levoamlodipine is the purified (S)-amlodipine, the pharmacologically active enantiomer in amlodipine (a racemic mixture of (R)- and (S)-amlodipine).

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Sucralfate Oral Suspension 1gm/10mL / Amneal Pharmaceuticals LLC	Antiulcer	12/02/2019	Generic for: Carafate Oral Suspension
Fingolimod Hydrochloride Capsules 0.5mg (base) / Biocon Pharma Inc.; HEC Pharm USA Inc.; Sun Pharmaceutical Industries, Inc.	Multiple sclerosis agent; Sphingosine 1-Phosphate Receptor Modulator	12/04/2019	Generic for: Gilenya
Everolimus Tablets 2.5 mg, 5 mg, 7.5 mg, and 10 mg / Teva Pharmaceuticals USA, Inc.; Par Pharmaceutical Inc. (excl. 10 mg)	Antineoplastic agent	12/09/2019	Generic for: Afinitor
Sodium Tetradecyl Sulfate Injection 60 mg/2mL / Custopharm, Inc.	Cardiovascular agent	12/09/2019	Generic for: Sotradecol
Etonogestrel and Ethinyl Estradiol Vaginal Ring (EluRyng) 0.120 mg/0.015 mg per day / Amneal Pharmaceuticals LLC	Contraceptive	12/12/2019	Generic for: NuvaRing
Alvimopan Capsules 12 mg / Watson Laboratories Inc.	Gastrointestinal Agent; Opioid Antagonist	12/19/2019	Generic for: Entereg
Diazoxide Oral Suspension 50 mg/mL / E5 Pharma Inc.	Cardiovascular agent; Endocrine and metabolic agent	12/20/2019	Generic for: Proglycem Oral Suspension
Apixaban Tablets 2.5 mg and 5 mg / Mylan Pharmaceuticals Inc.; Micro Labs Limited	Anticoagulant	12/23//2019	Generic for: Eliquis
Ziprasidone Mesylate Injection 20 mg (base) /mL / Gland Pharma Limited	Antipsychotic	12/26/2019	Generic for: Geodon Injection
Mirabegron Extended Release Tablets 25 mg / Sawai USA Inc.	Genitourinary agent	12/27/2019	Generic for: Myrbetriq

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Pemigatinib / Incyte Corporation and Innovent Biologics, Inc.	12/01/2019	Treatment for: Cholangiocarcinoma	Pemigatinib is a selective fibroblast growth factor receptor (FGFR) inhibitor in development for the treatment of locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements. The FDA accepted the NDA for pemigatinib and granted it orphan drug designation.	High
Libervant (diazepam) Buccal Film / Aquestive Therapeutics, Inc.	12/02/2019	Treatment for: Seizure Clusters	Libervant is a buccal film formulation of the approved benzodiazepine diazepam in development for the management of seizure clusters. NDA was submitted to the FDA.	Moderate
Alkindi (hydrocortisone granules in capsules for opening) / Diurnal Group plc	12/02/2019	Treatment for: Adrenal Insufficiency (AI)	Alkindi Sprinkle is an immediate-release pediatric formulation of the approved glucocorticoid hydrocortisone in development for the treatment of AI in infants, children and adolescents. NDA was submitted to the FDA. Paediatric AI has been identified as an orphan disease in the US and Diurnal will request the confirmation of Orphan drug status for Alkindi.	High
Fostemsavir / ViiV Healthcare	12/05/2019	Treatment for: HIV Infection	Fostemsavir is an investigational, first-in-class attachment inhibitor for the treatment of multidrug-resistant HIV-1 infection. NDA was submitted to the FDA.	High
KTE-X19 / Kite, a Gilead Company	12/11/2019	Treatment for: Mantle Cell Lymphoma	KTE-X19 is an investigational, autologous, anti-CD19 CAR T cell therapy in development for the treatment of mantle cell lymphoma (MCL). BLA was submitted to the FDA.	High

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Berotralstat / BioCryst Pharmaceuticals, Inc.	12/11/019	Treatment for: Hereditary Angioedema	Berotralstat (BCX7353) is an oral inhibitor of plasma kallikrein in development for the prevention and treatment of hereditary angioedema (HAE). NDA was submitted to the FDA.	Moderate
Lonafarnib / Eiger BioPharmaceuticals, Inc.	12/16/2019	Treatment for: Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies	Lonafarnib is an oral farnesyltransferase inhibitor (FTI) in development for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. NDA was submitted to the FDA. The FDA granted orphan drug designation for lonafarnib.	High
Ripretinib / Deciphera Pharmaceuticals, Inc.	12/16/2019	Treatment for: Gastrointestinal Stromal Tumor	Ripretinib is an investigational broad-spectrum KIT and PDGFRα inhibitor in development for the treatment of patients with advanced gastrointestinal stromal tumors (GIST). NDA was submitted to the FDA. The FDA granted orphan drug designation for ripretinib.	High
Lisocabtagene maraleucel / Bristol-Myers Squibb Company	12/18/2019	Treatment for: Large B-Cell Lymphoma	Lisocabtagene maraleucel (liso-cel) is an investigational chimeric antigen receptor (CAR) T-cell therapy in development for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL). BLA was submitted to the FDA.	High
Tazemetostat / Epizyme, Inc.	12/18/2019	Treatment for: Epithelioid Sarcoma; Follicular Lymphoma	Tazemetostat is an oral, first-in-class, EZH2 inhibitor in development for the treatment of patients with metastatic or locally advanced epithelioid sarcoma, and patients with relapsed or refractory follicular lymphoma. NDA was submitted to the FDA.	High

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Filgotinib / Gilead Sciences, Inc.	12/19/2019	Treatment for: Rheumatoid Arthritis	Filgotinib is an oral, selective JAK1 inhibitor in development for the treatment of adults with moderate-to-severe rheumatoid arthritis (RA). NDA was submitted to the FDA.	Moderate
Tucatinib / Seattle Genetics, Inc.	12/23/2019	Treatment for: Breast Cancer	Tucatinib is a potent tyrosine kinase inhibitor in development for the treatment of patients with locally advanced or metastatic HER2-positive breast cancer. NDA was submitted to the FDA.	High
Valoctocogene roxaparvovec / BioMarin Pharmaceutical Inc.	12/23/2019	Treatment for: Hemophilia A	Valoctocogene roxaparvovec is an investigational gene therapy in development for the treatment of hemophilia A. BLA was submitted to the FDA. The FDA granted orphan drug designation for valoctocogene roxaparvovec	High

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

References:

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- IBM Micromedex® (www.micromedexsolutions.com)
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