College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 12/1/19 – 12/31/19

FDA Drug Safety Communications & Drug Information Updates:

Ranitidine and Nizatidine Updates: Detection of N-nitrosodimethylamine (NDMA) 12/4/19
The FDA maintains a site with updates and press announcements on NDMA testing in ranitidine products and ranitidine recalls. They are requiring manufacturers test all lots of ranitidine and nizatidine prior to release.

FDA Launches CURE ID App for Health Care Professionals 12/5/19
The FDA launched an internet repository for health care professionals to report their experience treating difficult-to-treat infectious diseases with novel uses of existing FDA-approved drugs. The CURE ID repository, accessible through a website, a smartphone or other medical device, is designed to enable crowdsourcing of medical information that may guide use of life-saving interventions and facilitate development of new drugs. The application may be accessed at https://cure.ncats.io or by downloading "CURE ID" from the App or Play Store.

NDMA Impurities Found in Metformin Outside the U.S.: Drug Information Update 12/6/19
The FDA is aware that low levels of NDMA have been detected in some metformin products available in other countries. The levels reported have been within the range naturally occurring in some foods and water. Currently no metformin product has been recalled in the U.S.; the FDA is working with manufacturers to test samples and will recall products if the levels are found to contain NDMA at levels above the acceptable daily intake limit of 96 ng.

Public Safety Alert Due to Marketing of Unapproved Exosome Products 12/6/19
The FDA notified patients and healthcare practitioners of serious adverse effects experienced by patients who were treated with unapproved products marketed as containing exosomes, and issued a reminder that there are currently no FDA-approved exosome products and any such use should be through a clinical trial with a product with an Investigational New Drug Application.

Naltrexone Extended-Release Injection (Vivitrol, Alkermes) – Warning Letter – Misbranded 12/11/19
The FDA issued a warning letter to Alkermes, Inc for misbranding Vivitrol by omitting warnings about serious risks associated with the drug (primarily vulnerability to opioid overdose) from promotional materials. The manufacturer must cease use of the printed advertising materials and develop a plan to disseminate corrective information to those who received the promotional materials.

Consensus Report for Framing Opioid Prescribing Guidelines for Acute Pain: Drug Information Update 12/19/19
The FDA released a statement on the National Academics of Sciences, Engineering, and Medicine consensus study report. The purpose of the study was to provide framework to evaluate current and future opioid prescribing to support clinical practice guidelines and identify gaps in the evidence for future research. Recommendations included in the report will be considered as the FDA moves forward to implement the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

Gabapentin and Pregabalin: Drug Safety Communication – Serious Breathing Problems 12/19/19
The FDA issued a warning that gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) may cause serious breathing difficulties in patients who have respiratory risk factors. The prescribing information for gabapentin and pregabalin will require new warnings about the risk of respiratory depression.

FDA Announces Compounding Quality Center of Excellence Initiative 12/19/19
The FDA announced the development of an initiative, Compounding Quality Center of Excellence, to enhance collaboration among and provide educational programs for outsourcing facilities that improves the overall quality of compounded products. Information for in-person training programs or web-based training courses can be found at the FDA site.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Drugs, Dietary Supplements, & Medical Devices from Basic Reset and Biogenyx: Recall – Unapproved 12/10/19
The FDA alerted consumers of a recall of 25 drug, drug supplement, and medical device products distributed by Basic Reset and Biogenyx. These products are not FDA-approved, do not meet FDA standards, and have the potential to be unsafe or ineffective for their promoted uses. A complete list of products can be found at the FDA link.

SynchroMed II Implantable Drug Infusion Pump by Medtronic: Recall – Pump Motor Stall Potential 12/16/19
Medtronic recalled the SynchroMed II Implantable Drug Infusion Pump due to the potential presence of foreign particles within the pump motor that may cause the pump motor to stall. The manufacturer has received 5 reports of motor stall due to the presence of foreign particles which resulted in drug withdrawal, surgery to replace the pump, and delay of care. Patients with these pumps implanted should be advised to be attentive to all alarms and seeks immediate medical attention if they notice signs or symptoms of drug withdrawal or of their underlying condition.

Ranitidine Tablets by Glenmark Pharmaceutical Inc: Recall –Potential Presence of NDMA 12/18/19
Glenmark recalled all lots of ranitidine tablets 150 mg and 300 mg to the consumer level due to the potential presence of NDMA above FDA accepted limits. The full list of lots can be found on the FDA site.

Levetiracetam Oral Solution by Lannett Company, Inc.: Recall – Microbial Contamination 12/18/19
Lannett recalled 2 lots (2190A and 2191A) of levetiracetam oral solution 100 mg/mL to the consumer level due to contamination with *Bacillus subtilis*. Lannett is notifying distributors and customers via email and via Lannett website and arranging for the return of all recalled products.

Medfusion 4000 Syringe Pumps by Smiths Medical ASD: Recall – Malfunctioning Alarms 12/19/19
Smiths Medical recalled the Medfusion 4000 Syringe Pumps with Firmware Version 1.7.0 due to a software issue that may cause the low battery alarms to not function, potentially resulting in interruption of therapy.

All Products Manufacturered by Mavidon: Recall – Burkholderia cepacia Contamination 12/26/19
Mavidon recalled all of their manufactured products (LemonPrep, PediaPrep, Wave Prep, Cardio Prep and Collodions, Collodion Remover, and Medical Adhesive Remover) due to contamination with Burkholderia cepacia. One report of an adverse event in a neonate has been related to a product in this recall.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Detox Plus	Digestive health	Tadalafil[1], paynantheine[2], mitragynine[2]
PremierZEN Gold 7000	Sexual enhancement	Sildenafil[1], tadalafil[1]
SUPER Platinum 30000 BULL*	Sexual enhancement	Tadalafil[1]
SUPER Platinum 30000 PANTHER*	Sexual enhancement	Tadalafil[1]
SUPER Platinum 30000 RHINO 7*	Sexual enhancement	Tadalafil[1]
SUPER Platinum 30000 STALLION*	Sexual enhancement	Sildenafil[1], tadalafil[1], dapoxetine[3]
U-Dream Full Night	Sleep Aid	Substance similar to eszopiclone and zopiclone[4]
U-Dream Lite	Sleep aid	Substance similar to eszopiclone and zopiclone[4]

*recalled

[1]Sildenafil and tadalafil may interact with nitrates to lower blood pressure to dangerous levels

[2]Paynantheine and mitragynine are alkaloids found in kratom

[3]Dapoxetine is a selective serotonin reuptake inhibitor that is not FDA approved

[4]Eszopiclone and zopiclone are Schedule IV nonbenzodiazepine hypnotics

New Product Shortages	***Date Initially Posted***
Hydroxyzine pamoate oral capsules	12/5/19
Leuprolide acetate injection	12/10/19

Product Discontinuations/Withdrawals	***Date Posted***
Tranexamic acid 650 mg tablets (Apotex); remains available from other manufacturers	12/4/19
Methylprednisolone 4 mg tablets (Teva); remains available from other manufacturers	12/5/19
Sumatriptan succinate injection (Teva); remains available from other manufacturers	12/5/19
Risedronate 5 mg Tablets (Allergan Sales LLC); remains available from other manufacturers	12/9/19
Metoprolol tartrate 50 mg and 100 mg tablets (Teva); remains available from other manufacturers	12/16/19
Methotrexate Sodium Injection 250 mg in 10 mL (25 mg/mL) (Mylan); remains available in other volumes and from other manufacturers	12/16/19
Gemcitabine Hydrochloride Injection 1 gram (Mylan); remains available from other manufacturers	12/16/19
Flumazenil Injection 1 mg/10 mL and 0.5 mg/5 mL (Mylan); remains available from other manufacturers	12/16/19
Promethazine Hydrochloride Injection solution (Teva); remains available from other manufacturers	12/19/19

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Golodirsen / Vyondys 53 / Sarepta Therapeutics	Treatment for patients with Duchenne muscular dystrophy who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping	12/12/19
Enfortumab vedotin-ejfv / Padcev / Astellas Pharma US Inc	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	12/18/19
Ebola virus vaccine / Ervebo / Merck & Co., Inc.	Vaccine for the prevention of Ebola virus disease caused by Zaire ebolavirus in individuals 18 years and older	12/19/19
Levamlodipine / Conjupri / CSPC Ouyi Pharmaceutical	Active, anti-hypertensive isomer of amlodipine for the treatment of hypertension	12/19/19
Brilliant Blue G Ophthalmic Solution 0.025% / TissueBlue	Disclosing agent indicated to selectively stain the internal limiting membrane when injected directly in a Balanced Salt Solution-filled vitreous cavity	12/20/19
Fam-trastuzumab deruxtecan-nxki / Enhhertu / Daiichi Sankyo	Treatment of adults with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	12/20/19
Lemborexant / Dayvigo / Eisai	Orexin antagonist for the treatment of insomnia	12/20/19
Lumateperone / Caplyta / Intra-Cellular Therapies	Antipsychotic for the treatment of schizophrenia in adults	12/20/19
Ubrogepant / Ubrelvy / Allergan	CGRP agonist for the acute treatment of migraine in adults	12/23/19

New Indications:	***Description***	***Date Approved***
Atezolizumab / Tecentriq / Genentech, Inc	Use in combination with paclitaxel protein-bound and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.	12/4/19
Tofacitinib extended-release / Xeljanz XR / Pfizer, Inc.	Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or who are intolerant to TNF blockers	12/12/19
Icosapent ethyl / Vascepa / Amarin Pharma Inc.	Adjunctive therapy to reduce the risk of cardiovascular events in adults with triglyceride levels of 150 mg/dL or higher and either established cardiovascular disease or diabetes or two or more additional risk factors for cardiovascular disease.	12/13/19
Enzalutamide / Xtandi / Astellas Pharma	Treatment of patients with metastatic castration-sensitive prostate cancer	12/16/19
Olaparib / Lynparza / AstraZeneca	Maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.	12/27/19

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Cysteine hydrochloride / Nouress / Avadel Pharmaceuticals	Injection, 500 mg/10 mL (50 mg/mL), USP: as additive to amino acid solutions to meet the nutritional needs of neonates requiring total parenteral nutrition	12/13/19
Tazarotene / Arazlo / Bausch Health	Lotion, 0.045%: to treat acne vulgaris in individuals aged 9 years and older	12/18/19

Compiled by:

Terri Levien, Pharm.D.
Brittany Craft, Pharm.D., PGY1 Drug Information Resident
Li-Wei Chen, Doctor of Pharmacy Candidate 2021
Racheal Slater, Doctor of Pharmacy Candidate 2020
Estera Pruteanu, Doctor of Pharmacy Candidate 2020

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Golodirsen / Vyondys 53 / Sarepta Therapeutics	
Generic Name / Brand Name / Company	Golodirsen / Vyondys 53 / Sarepta Therapeutics
Date of approval	12/12/2019
Drug Class (Mechanism of Action if novel agent)	Antisense oligonucleotide
Indication	Treatment of Duchenne muscular dystrophy in patients with confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 100 mg/2 mL (50 mg/mL) solution in a single-dose vial
Common Dose/sig	Administer 30mg/kg once weekly via intravenous infusion over 35 to 60 minutes.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Eteplirsen, Exondys 51
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Headache, fever, fall, abdominal pain, nasopharyngitis, cough, vomiting, and nausea.
Severe Adverse Effects	Hypersensitivity reactions
Severe Drug-Drug Interactions	None reported
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Measurement of glomerular filtration rate by 24-hour urine collection prior to initiation; monthly monitoring for proteinuria by dipstick urinalysis and monitoring of serum cystatin C every 3 months.
Used in Pediatric Areas	The indication includes pediatric patients; clinical trials enrolled males 6 to 13 years of age.
Renal or Hepatic Dosing	Renal: No specific dosage adjustment can be recommended for DMD patients with renal impairment based on estimate glomerular filtration rate; monitor patients with known renal impairment closely. Hepatic: Not studied in patients with hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings: - Hypersensitivity reactions: Hypersensitivity reactions including rash, pyrexia, pruritis, urticaria, dermatitis, and skin exfoliation have occurred. If hypersensitivity reaction occurs, initiate appropriate medical treatment 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.
Special administration technique or considerations	Administer via intravenous infusion over 35 to 60 minutes following dilution in 0.9% Sodium Chloride Injection, USP (total volume of 100 to 150 mL). Flush the IV access line with Sodium Chloride Injection, USP, prior to and after infusion. Complete infusion should be within 4 hours of dilution. Consider applying topical anesthetic cream to the infusion site prior to administration.
Prepared by	Brittany Craft, PharmD
Source	Vyondys 53 (golodirsen) [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; December 2019.

Enfortumab vedotin-ejfv / Padcev / Astellas Pharma and Seattle Genetics	
Generic Name / Brand Name / Company	Enfortumab vedotin-ejfv / Padcev / Astellas Pharma & Seattle Genetics
Date of approval	12/18/2019
Drug Class (Mechanism of Action if novel agent)	Nectin-4-directed antibody and microtubule inhibitor conjugate
Indication	Locally advanced or metastatic urothelial cancer in patients previously treated with a programmed death receptor-1 (PD-1) or programmed
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	For intravenous infusion: 20 mg and 30 mg as a lyophilized power in a single-dose vial
Common Dose/sig	Administer 1.25 mg/kg (up to a maximum of 125 mg for patients ≥ 100 kg) as an IV infusion over 30 minutes on Days 1, 8, and 15 of a 28-day cycle
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Exforge, efalizumab
Clinical Use Evaluation	
Common Adverse Effects	≥ 20%: fatigue, peripheral neuropathy, decreased appetite, rash, alopecia, nausea, dysgeusia, diarrhea, dry eye, pruritis, and dry skin
Severe Adverse Effects	Urinary tract infection, cellulitis, febrile neutropenia, diarrhea, sepsis, acute kidney injury, dyspnea, rash, decreased hemoglobin
Severe Drug-Drug Interactions	Strong CYP3A4 inhibitors – may increase exposure to monomethyl auristatin E (MMAE)
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established.
Renal or Hepatic Dosing	Renal: No dose adjustments in patients with mild, moderate, or severe renal impairment. Hepatic: Avoid use in moderate to severe hepatic impairment. No dose adjustments with mild impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings: - Diabetic ketoacidosis may occur in patients with or without pre-existing diabetes mellitus. Closely monitor; withhold if blood glucose > 250 mg/dL. - Peripheral neuropathy: monitor for new or worsening peripheral neuropathy and consider dose reduction, interruption, or discontinuation. - Ocular disorders, including vision changes may occur. Monitor for ocular disorders; consider using prophylactic artificial tears and steroid treatment if indicated. If symptoms occur, consider dose reduction or interruption. - Skin reactions: if severe, withhold until improvement or resolution. - Infusion Site Extravasation: Ensure adequate venous access prior to administration. Monitor the site and stop immediately for suspected extravasation. - Embryo-fetal toxicity: drug can cause fetal harm; advise of the potential risk and recommend effective contraception. Dose adjustments are recommended for Grade 3 and 4 toxicities.
Special administration technique or considerations	Administer via IV infusion over 30 minutes. Follow special handling and disposal procedures for cytotoxic drugs.
Prepared by	Brittany Craft, PharmD
Source	Enfortumab vedotin-ejfv (Padcev) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; December 2019.

Ebola Zaire Vaccine, Live / Ervebo / Merck & Co, Inc.	
Generic Name / Brand Name / Company	Ebola Zaire Vaccine, Live / Ervebo / Merck & Co, Inc.
Date of approval	12/19/2019
Drug Class (Mechanism of Action if novel agent)	Immunization results in an immune response and protection from disease caused by *Zaire ebolavirus*.
Indication	Prevention of Ebola virus disease, caused by Zaire ebolavirus in individuals 18 years and older.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 1 mL suspension in a single-dose vial.
Common Dose/sig	Administer 1 mL dose intramuscularly
DEA Schedule	None
Date of market availability	Third quarter of 2020
Similar Medication Names	Marqibo
Clinical Use Evaluation	
Common Adverse Effects	Injection site reactions: injection site pain (70%), swelling (17%), and redness (12%). Systemic reactions: headache (37%), feverishness (34%), muscle pain (33%), fatigue (19%), joint pain (18%), nausea (8%), arthritis (5%), rash (4%), and abnormal sweating (3%).
Severe Adverse Effects	Allergic reactions (e.g., anaphylaxis), arthralgia
Severe Drug-Drug Interactions	May interfere with Ebola glycoprotein (GP) based testing – resulting in false positive result for anti-Ebola GP antibody and/or Ebola GP nucleic acid or antigens following vaccination.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy in pediatric patients have not been evaluated.
Renal or Hepatic Dosing	No dose adjustments recommended in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including rice protein. Warnings/Precautions: - Anaphylaxis has been observed following administration. Appropriate treatment and supervision must be available. - Vaccinated individuals should follow infection control practices to prevent the infection and transmission of *Zaire ebolavirus.* - Safety and efficacy have not been assessed in immunocompromised individuals; caution live virus vaccine. - Transmission of vaccine virus is a theoretical possibility as vaccine virus RNA has been detected in blood, saliva, urine, and fluid from skin vesicles of vaccinated adults.
Special administration technique or considerations	Thaw one vial at room temperature (not in the refrigerator) until ice is no longer present. Administer the vaccine immediately after thawing. Administer intramuscularly (preferably in the deltoid area of the non-dominant arm).
Prepared by	Brittany Craft, PharmD
Source	Ebola Zaire Vaccine (Ervebo) [prescribing information]. Whitehouse, NJ: Merck & Co., Inc.; December 2019.

Levamlodipine maleate / Conjupri / CSPC Ouyi Pharmaceutical	
Generic Name / Brand Name / Company	Levamlodipine maleate / Conjupri / CSPC Ouyi Pharmaceutical
Date of approval	12/19/2019
Drug Class (Mechanism of Action if novel agent)	Calcium channel blocker; active, anti-hypertensive isomer of amlodipine
Indication	Treatment of hypertension in adults and pediatric patients 6 years and older.
Comparative agent – Therapeutic interchange?	Amlodipine
Dosage forms/strengths	Tablets: 1.25 mg, 2.5 mg (scored), and 5 mg (scored)
Common Dose/sig	Initial: 2.5 mg once daily up to a maximum dose of 5 mg once daily. Small, fragile, elderly, or patients with hepatic insufficiency: may start on 1.25 mg once daily. Children 6-17 years: 1.25 mg to 2.5 mg once daily; doses above 2.5 mg daily have not been studied.
DEA Schedule	None
Date of market availability	Announcement of availability is pending
Similar Medication Names	Amlodipine
Clinical Use Evaluation	
Common Adverse Effects	>1%: edema (dose-related), fatigue, nausea, abdominal pain, and somnolence.
Severe Adverse Effects	Hypotension, increased angina or myocardial infarction,
Severe Drug-Drug Interactions	Moderate and strong CYP3A inhibitors, CYP3A inducers (monitor if co-administered), sildenafil, simvastatin, and immunosuppressants (e.g., cyclosporine and tacrolimus).
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function tests prior to initiation if possible hepatic impairment.
Used in Pediatric Areas	Effective in pediatric patients 6 to 17 years of age; effect on blood pressure in patients younger than 6 years has not been studied.
Renal or Hepatic Dosing	Renal: No dose adjustments noted Hepatic: may initiate 1.25 mg once daily and titrate slowly to achieve blood pressure goals.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Known sensitivity to amlodipine or product ingredients. Warnings/Precautions: - Symptomatic hypotension, particularly in patients with severe aortic stenosis; however, acute hypotension is unlikely. -Worsening of angina and acute myocardial infarction can develop after initiating or titrating the dose, particularly in patients with severe obstructive coronary artery disease. - Slow titration in patients with severe hepatic impairment.
Special administration technique or considerations	Administer with or without food. Tablets can be split.
Prepared by	Brittany Craft, PharmD
Source	Levamlodipine (Conjupri) [prescribing information]. Princeton, NJ: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

Fam-trastuzumab deruxtecan-nxki / Enhertu / Daiichi Sankyo	
Generic Name / Brand Name / Company	Fam-trastuzumab deruxtecan-nxki / Enhertu / Daiichi Sankyo
Date of approval	12/20/2019
Drug Class (Mechanism of Action if novel agent)	Human epidermal growth factor receptor 2 (HER2)-directed antibody and topoisomerase inhibitor conjugate
Indication	Unresectable or metastatic HER2-positive breast cancer in adult patients who have received two or more prior anti-HER2-based regimens
Comparative agent – Therapeutic interchange?	None at this time; administered after ado-trastuzumab emtansine in clinical trial
Dosage forms/strengths	Available as intravenous powder for solution: 100 mg in single dose vial
Common Dose/sig	5.4 mg/kg IV infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Trastuzumab, ado-trastuzumab emtansine
Clinical Use Evaluation	
Common Adverse Effects	≥20%: nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough, thrombocytopenia
Severe Adverse Effects	Interstitial lung disease, neutropenia, left ventricular dysfunction
Severe Drug-Drug Interactions	No known drug interactions at this time. It is a substrate of OATP1B1, OATP1B3, MATE2-K, P-gp, MRP1, BCRP
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC prior to initiation and each dose LVEF prior to initiation and at regular intervals during treatment
Used in Pediatric Areas	No data at this time
Renal or Hepatic Dosing	No dose adjustments in mild or moderate renal impairment. No dose adjustment in mild or moderate hepatic impairment. Monitor closely in moderate hepatic impairment. No data available in patients with severe hepatic or renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications Warnings: - Interstitial lung disease and pneumonia, have been reported. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. - Neutropenia: monitor CBC - Left ventricular dysfunction: assess LVEF prior to initiation and at regular intervals, permanently discontinue in patients with symptomatic congestive heart failure - Embryo-fetal toxicity: drug can cause fetal harm; advise of the potential risk and recommend effective contraception. -Dose adjustments or discontinuation recommended for toxicities.
Special administration technique or considerations	Administer as IV infusion over 90 minutes for first dose and 30 minutes for subsequent infusions if well tolerated. Slow or interrupt infusion if infusion-related symptoms occur. Use infusion set made of polyolefin or polybutadiene and a 0.20 or 0.22 micron in-line polyethersulfone (PES) or polysulfone (PS) filter. Cytotoxic drug, follow special handling and disposal procedures.
Prepared by	Racheal Slater
Source	Enhertu (fam-trastuzumab deruxtecan) [package insert]. Basking Ridge, NJ: Daiichi Sankyo Inc.; December 2019.

Lemborexant / Dayvigo / Eisai	
Generic Name / Brand Name / Company	Lemborexant / Dayvigo / Eisai
Date of approval	12/20/19
Drug Class (Mechanism of Action if novel agent)	Orexin receptor antagonist: blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive.
Indication	Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance
Comparative agent – Therapeutic interchange?	Suvorexant (Belsomra)—not interchangeable
Dosage forms/strengths	Tablets: 5 mg, 10 mg
Common Dose/sig	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. May be increased to 10 mg based on response and tolerability.
DEA Schedule	Controlled Substance schedule pending
Date of market availability	Available after DEA review (within 90 days)
Similar Medication Names	Daypro, suvorexant
Clinical Use Evaluation	
Common Adverse Effects	>5%: somnolence or fatigue (lethargy, sluggishness), headache
Severe Adverse Effects	Sleep paralysis, hypnagogic hallucinations, complex sleep behavior
Severe Drug-Drug Interactions	Avoid use with strong or moderate CYP3A4 inhibitors or inducers; limit dose to 5 mg with weak CYP3A inhibitors. May reduce efficacy of concomitant CYP2B6 substrates. Avoid concomitant CNS depressants.
Severe Drug-Food Interactions	Effect may be delayed if taken with or soon after a meal.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not established in pediatric patients.
Renal or Hepatic Dosing	Renal: No dose adjustment required in with mild, moderate, or severe renal impairment. Patients with severe renal impairment may experience an increased risk of somnolence. Hepatic: Avoid use in severe hepatic impairment. Reduced maximum dose in moderate hepatic impairment. Increased risk of somnolence in mild hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: patients with narcolepsy Warnings: - CNS depressant effects and daytime impairment: impairs alertness and motor coordination including morning impairment. Risk increases with dose and use with other central nervous system depressants. - Sleep paralysis, hypnogogic/hypnopompic hallucinations, and cataplexy-like symptoms may occur with use of lemborexant - 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: not studied in this patient population - Worsening of depression/suicidal ideation
Special administration technique or considerations	Take immediately before going to bed, with at least 7 hours remaining before the planned time of awakening.
Prepared by	Estera Pruteanu
Source	Dayvigo (lemborexant) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; December 2019.

Generic / Brand / Manufacturer	
Generic Name / Brand Name / Company	Lumateperone / Caplyta / Intra-Cellular Therapies
Date of approval	12/20/19
Drug Class (Mechanism of Action if novel agent)	Atypical antipsychotic
Indication	Indicated for treatment of schizophrenia in adults
Comparative agent – Therapeutic interchange?	Other antipsychotics
Dosage forms/strengths	Capsules: 42 mg
Common Dose/sig	42 mg orally once daily
DEA Schedule	None
Date of market availability	Available late Q1 2020
Similar Medication Names	Cablivi, Luspatercept
Clinical Use Evaluation	
Common Adverse Effects	>5%: somnolence/sedation and dry mouth, nausea, dizziness
Severe Adverse Effects	
Severe Drug-Drug Interactions	Avoid concomitant use with moderate or strong CYP3A4 inhibitors and inducers or with UGT inhibitors.
Severe Drug-Food Interactions	Grapefruit juice - avoid
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose, lipid profile at baseline and periodically. Perform complete blood counts (CBC) frequently during first months of therapy in patients with pre-existing low white blood cell count or history of leukopenia or neutropenia.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	Hepatic: Avoid use in moderate to severe hepatic impairment. No dosage adjustment is recommended in mild hepatic impairment or in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Known hypersensitivity to lumateperone or any product ingredients Warnings: - 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 - Tardive dyskinesia - Metabolic changes: monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain - Leukopenia, neutropenia and agranulocytosis - Orthostatic hypotension and syncope - Falls - Seizures - Body temperature dysregulation - Dysphagia - Potential for cognitive and motor impairment
Special administration technique or considerations	Administer with food, dose titration is not required.
Prepared by	Estera Pruteanu
Source	Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019

Ubrogepant / Ubrelvy / Allergan	
Generic Name / Brand Name / Company	Ubrogepant / Ubrelvy / Allergan
Date of approval	12/23/2019
Drug Class (Mechanism of Action if novel agent)	Small-molecule calcitonin gene-related peptide (CGRP) receptor antagonist.
Indication	For the acute treatment of migraine with or without aura in adults
Comparative agent – Therapeutic interchange?	No other CGRP antagonists for treatment; others indicated for prevention
Dosage forms/strengths	Tablets : 50 mg and 100 mg
Common Dose/sig	50 mg or 100 mg orally as needed; a second dose may be administered at least 2 hours after the initial dose if needed. Maximum dose is 200 mg in a 24-hour period.
DEA Schedule	None
Date of market availability	First quarter of 2020
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	≥2%: nausea, somnolence, dry mouth
Severe Adverse Effects	No results available at this time
Severe Drug-Drug Interactions	Avoid with strong CYP3A4 inducers; dose adjustments with moderate and weak CYP3A4 inhibitors, moderate and weak CYP3A4 inducers, and BCRP and/or P-glycoprotein only inhibitors.
Severe Drug-Food Interactions	Dose adjust with grapefruit juice
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No important labs
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Recommended dose is 50 mg, with a second 50 mg dose if needed, in patients with severe renal or severe hepatic impairment. Avoid use in patients with end-stage renal disease. No adjustments in mild or moderate hepatic impairment or mild or moderate renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in use with strong CYP3A4 inhibitors.
Special administration technique or considerations	Orally with or without food. Safety of treating more than 8 migraines in a 30-day period has not been established.
Prepared by	Racheal Slater
Source	Ubrelvy (ubrogepant) [prescribing information]. Madison, NJ; Allergan; December 2019.