WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 1/1/23 – 1/31/23

FDA Drug Safety Communications & Drug Information Updates:

Guidance to Increase Ibuprofen Oral Suspension Supply in Hospitals and Health Systems. 1/20/23
The FDA issued a guidance describing the FDA's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for use in hospitals and health systems. This includes minimum steps that outsourcing facilities should take to reduce the risk associated with the compounded products, such as ingredient purity.

Evusheld (tixagevimab co-packaged with cilgavimab) NOT Currently Authorized for Emergency Use 1/26/23
The FDA has revised the EUA for Evusheld to limit its use to when the combined frequency of non-susceptible SARS-CoV-2 variants nationally is less than or equal to 90%. Based on this revision, Evusheld is not currently authorized for use in the U.S. until further notice by the Agency. This action was to prevent exposing patients to possible side effects of Evusheld, which can be potentially serious, at a time when fewer than 10% of circulating variants in the U.S. causing infection are susceptible to the product. Evusheld supplies should be retained in the event that susceptible strains become more prevalent in the U.S. in the future.

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

Epinephrine (L-Adrenaline) USP, Spectrum Laboratory Products, Inc.: Recall - Discoloration 1/10/23
Spectrum Laboratory Products recalled lots 1K0865, 2KL0353, and 2KF0151 of Epinephrine, USP bulk active pharmaceutical ingredient (API) used to manufacture or compound prescription products due to customer complaints of product discoloration.

Emergent RSDL Kits, by Emergent: Recall – Leaking 1/26/23
Emergent recalled Emergent RSDL (Reactive Skin Decontamination Lotion) Kits (batch 23005060) distributed in October 2022 due to the potential for leaks which may impact product performance and cause unintentional prolonged exposure to the product. The recall was issued to organizations that distribute RSDL kits to their personnel (military) and personnel who carry RSDL kits in case of exposure to chemical warfare agents or T-2 toxin.

New Product Shortages	***Date Initially Posted***
Sucralfate Tablets	1/4/23
Somatropin injection	1/6/23
Quinapril Hydrochloride Tablets	1/19/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Abacavir sulfate tablets (Ziagen, ViiV): 300 mg tablet 60 count (NDC 49702-221-18); abacavir generics will remain available.	1/3/23
Abacavir sulfate; lamivudine tablets (Epzicom, ViiV): 600 mg; 300 mg tablets 30 count (NDC 49702-206-13); generics will remain available	1/3/23
Abacavir sulfate; lamivudine; zidovudine tablets (Trizivir, ViiV): 300 mg; 150 mg; 300 mg tablets 60 count (NDC 49702-217-18); generics will remain available	1/3/23
Dolutegravir sodium tablets (Tivicay, ViiV): 25 mg tablet 30 count (NDC 49702-227-13); Tivicay 50 mg tablets (NDC 49702-228-13) and Tivicay 5 mg (NDC 49702-255-37) will still be available.	1/3/23

Discontinuations/Withdrawals continued…

Fosamprenavir calcium oral suspension (Lexiva, ViiV): 50 mg/mL Oral Solution 225 mL bottle (NDC 49702-208-53); generic tablets will remain available.	1/3/23
Fosamprenavir calcium tablets (Lexiva, ViiV): 700 mg tablet 60 count (NDC 49702-207-18); generics will remain available.	1/3/23
Glyburide tablets (Glynase, Pfizer): 1.5 mg tablet bottle of 100 (NDC 0009-0341-01), 3 mg tablet bottle of 100 (NDC 0009-0352-01), 6 mg tablet bottle of 100 (NDC 0009-3449-01), 6 mg tablet bottle of 100 (NDC 0009-3449-03); generics will remain available.	1/3/23
Maraviroc tablets (Selzentry, ViiV): 25 mg tablet 120 count (NDC 49702-233-08) and 75 mg tablet 120 count (NDC 49702-235-08); Selzentry 150 mg (49702-223-18), 300 mg (49702-224-18), and generics will remain available.	1/3/23
Moxetumomab pasudotox-tdfk Injection (Lumoxiti, AstraZeneca): 1 mg vial (NDC 0310-4700-01); planned permanent discontinuation from U.S market is 8/31/23. New treatment with moxetumomab should not be initiated; alternatives include vemurafenib with or without rituximab and ibrutinib.	1/10/23
Somatropin Injection (Saizen, EMD Sereno, Inc.): 5 mg vial (NDC 44087-1005-2), 8.8 mg vial (44087-1088-1), and reconstitution kit containing one 8.8 mg vial, diluent, and Saizenprep Reconstitution Device (44087-0016-1); alternative somatropin products remain available,	1/6/23
Somatropin Injection (Humatrope, Eli Lilly): 12 mg kit (0002-8148-01) and 24 mg kit (NDC 002-8149-01); alternative somatropin products remains available.	1/6/23
Testosterone Transdermal System (Androderm, AbbVie): 2 mg/day (NDC 0023-5990-60) and 4 mg/day (NDC 0023-5992-30); alternatives available from other manufacturers.	1/10/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Lecanemab-irmb / Leqembi / Eisai Inc.	Amyloid beta-directed antibody approved under accelerated approval for the treatment of Alzheimer's disease with mild cognitive impairment or mild dementia	1/6/23
Bexagliflozin / Brenzavvy / TheracosBio, LLC	SGLT2 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	1/20/23
Elacestrant / Orserdu / Stemline Therapeutics, Inc.	Estrogen receptor antagonist indicated for postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	1/27/23
Pirtobrutinib / Jaypirca / Eli Lilly and Co.	Bruton's tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a prior BTK inhibitor	1/27/23

New Indications:	***Description***	***Date Approved***
Tetanus toxoid, reduced diptheria toxoid, and acellular pertussis / Adacel / Sanofi Pasteur Ltd.	For immunization during the third trimester of pregnancy to prevent pertussis in infants younger than two months of age	1/9/23
Zanubrutinib / Brukinsa / BeiGene USA, Inc.	Treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).	1/19/23
Tucatinib / Tukysa / Seagen, Inc.	In combination with trastuzumab for the treatment of adult patients with RAS wild-type HER 2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy	1/19/23

New Indications continued…

Pembrolizumab / Keytruda / Merck & Co	For single agent, adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer due to its activity as a programmed death receptor-1 (PD-1)-blocking antibody.%	1/26/23
Sildenafil citrate / Revatio / Viatris	Treatment of pulmonary arterial hypertension (WHO Group 1) in pediatric patients (1 to 17 years old) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise	1/31/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Albuterol and budesonide / Airsupra / AstraZeneca	Pressurized metered-dose inhaler: 90/80 mcg; For the as-needed treatment or for prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age or older	1/11/23

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Lecanemab-irmb / Leqembi / Eisai, Inc.	
Generic Name / Brand Name / Company	Lecanemab-irmb / Leqembi / Eisai, Inc.
Date of approval	1/6/2023
Drug Class (Mechanism of Action if novel agent)	Anti-amyloid monoclonal antibody; reduction of amyloid beta plaques in Alzheimer's disease
Indication	Treatment of Alzheimer's disease; treatment should be initiated in patients with mild cognitive impairment or mild dementia stage of disease
Comparative agent – Therapeutic interchange?	Aducanumab
Dosage forms/strengths.	Injection: 100 mg/mL single-dose vial
Common Dose/sig	Administer 10 mg/kg as an intravenous infusion over one hour, once every two weeks
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Lectopam, Lecalpin, Lequin
Clinical Use Evaluation	
Common Adverse Effects	≥10%: infusion-related reactions, headache, ARIA-edema
Severe Adverse Effects	ARIA with edema, ARIA with hemosiderin deposition
Severe Drug-Drug Interactions	Antiplatelet and thrombolytic agents, anticoagulants, efgartigimod alfa
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Confirm amyloid beta pathology prior to initiation. Obtain MRI within one year prior to initiation. Obtain MRI prior to the 5th, 7th, and 14th infusions.
Used in Pediatric Areas	The safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No adjustments recommended in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings and Precautions - Monitoring for Amyloid Related Imaging Abnormalities (ARIA) - Infusion-related reactions
Special administration technique or considerations	Reduce infusion rate or consider pre-medication with antihistamines, NSAIDs, or corticosteroids if infusion-related reactions develop. Dosing interruption recommended in ARIA-E or ARIA-H depending upon severity (see prescribing information).
Prepared by	Kiana Lee
Source	*Leqembi* (lecanemab) [prescribing information]. Nutley, NJ: Eisai, Inc.; January 2023.

Bexagliflozin / Brenzavvy / TheracosBio, LLC	
Generic Name / Brand Name / Company	Bexagliflozin / Brenzavvy / TheracosBio, LLC
Date of approval	1/20/2023
Drug Class (Mechanism of Action if novel agent)	SGLT2 inhibitor
Indication	Adjunct therapy to diet and exercise in adults with type 2 diabetes mellitus for glycemic control
Comparative agent – Therapeutic interchange?	Canagliflozin, dapagliflozin, empagliflozin, ertugliflozin
Dosage forms/strengths.	Tablets: 20 mg
Common Dose/sig	One tablet (20 mg) orally once daily in the morning
DEA Schedule	N/A
Date of market availability	Unknown
Similar Medication Names	Bexsero, Bextra, bexarotene
Clinical Use Evaluation	
Common Adverse Effects	>5%: female genital mycotic infection, UTI, increased urination
Severe Adverse Effects	Ketoacidosis, lower limb amputation, urosepsis/pyelonephritis, Fournier's Gangrene, hypoglycemia, dehydration
Severe Drug-Drug Interactions	Sulfonylureas, insulin and insulin secretagogues, UGT inducers, lithium
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess renal function before initiating. Monitor HgbA1c as clinically indicated. Assess and correct volume status in patients with impaired renal function or low blood pressure, elderly patients, or patients on diuretics.
Used in Pediatric Areas	The safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Not recommended in patients with severe hepatic impairment. Contraindicated in dialysis, not recommended if eGFR <30 mL/min/1.73 m^2.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - Hypersensitivity - Dialysis Warnings and Precautions - Ketoacidosis - Lower limb amputation - Volume depletion - Urosepsis and pyelonephritis - Hypoglycemia with concomitant insulin or insulin secretagogue use - Fournier's Gangrene - Genital mycotic infection
Special administration technique or considerations	Can be administered with or without food. Swallow tablets whole. Take at the same time each day.
Prepared by	Kiana Lee
Source	*Brenzavvy* (bexagliflozin) [prescribing information]. Marlborough, MA: TheracosBio, LLC; January 2023.

Elacestrant / Orserdu / Stemline Therapeutics, Inc.	
Generic Name / Brand Name / Company	Elacestrant / Orserdu / Stemline Therapeutics, Inc.
Date of approval	1/27/23
Drug Class (Mechanism of Action if novel agent)	Estrogen receptor antagonist
Indication	Treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.
Comparative agent – Therapeutic interchange?	Fulvestrant
Dosage forms/strengths.	Tablets: 345 mg and 86 mg
Common Dose/sig	One tablet (345 mg) orally once daily with food
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Arzerra, Elcys, Elestrin, Estrace
Clinical Use Evaluation	
Common Adverse Effects	≥10%: Nausea, increased AST, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flush, and dyspepsia
Severe Adverse Effects	Musculoskeletal pain, increased cholesterol, increased triglycerides
Severe Drug-Drug Interactions	Avoid use of concurrent CYP3A inducers and inhibitors.
Severe Drug-Food Interactions	Grapefruit
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Presence of ESR1 mutation for patient selection; assess lipid profile prior to starting and periodically thereafter
Used in Pediatric Areas	The safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Dose reduction is required in patients with moderate hepatic impairment. Use should be avoided in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings and Precautions - Hypercholesterolemia and hypertriglyceridemia - Embryo-fetal toxicity
Special administration technique or considerations	Take at the same time each day. Take with food to reduce nausea and vomiting. Swallow tablets whole; do not take tablets that are broken, cracked, or look damaged. Dose modifications recommended for adverse reactions.
Prepared by	Brittney Kessel
Source	*Orserdu* (elacestrant) [prescribing information]. New York, NY: Stemline Therapeutics, Inc.; January 2023.

Pirtobrutinib / Jaypirca / Eli Lilly and Co.	
Generic Name / Brand Name / Company	Pirtobrutinib / Jaypirca / Eli Lilly and Co.
Date of approval	1/27/23
Drug Class (Mechanism of Action if novel agent)	Small molecule ATP-competitive inhibitor of Bruton's tyrosine kinase (BTK)
Indication	The treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
Comparative agent – Therapeutic interchange?	No other BTK agents are approved for use after treatment failure with another BTK agent.
Dosage forms/strengths.	Tablets: 50 mg and 100 mg
Common Dose/sig	200 mg orally once daily
DEA Schedule	Not Scheduled
Date of market availability	Available
Similar Medication Names	Ibrutinib
Clinical Use Evaluation	
Common Adverse Effects	≥15%: Fatigue, edema, fever, musculoskeletal pain, arthritis or arthralgia, nausea, vomiting, diarrhea, constipation, dyspnea, cough, bruising, peripheral neuropathy, dizziness, rash
Severe Adverse Effects	Pneumonia, hemorrhage, Upper respiratory tract infections, neutropenia, anemia, thrombocytopenia, atrial fibrillation and flutter, secondary primary malignancies
Severe Drug-Drug Interactions	Strong CYP3A inhibitors, Strong or moderate CYP3A inducers. Sensitive CYP2C8, CYP2C19, CYP3A, P-gp or BCRP substrates
Severe Drug-Food Interactions	Grapefruit
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood counts. Basic metabolic panel. Pregnancy status.
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	Severe renal impairment (eGFR 15-29 mL/min) increases pirtobrutinib exposure, decrease dosing from 200 mg daily to 100 mg, 100 mg to 50 mg or if at 50 mg discontinue the medication. No dosage adjustment required for mild or moderate impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Monitor complete blood counts regularly during treatment. Monitor for signs and symptoms of infection and bleeding. Dosage adjustments, withholding doses or discontinuing the medication may be necessary for toxicity, based on lab results and severity of bleeds or infections. Monitor for symptoms of arrhythmias (atrial fibrillation and atrial flutter) and manage appropriately. Monitor for secondary primary malignancies Embryo-fetal toxicity.
Special administration technique or considerations	Swallow tablets whole with water. Do not cut, crush, or chew tablets. Take at the same time each day without regard for food.
Prepared by	Ryan Anderson
Source	*Jaypirca* (pirtobrutinib) [Prescribing information]. Indianapolis, IN: Eli Lily and Co; January 2023.