WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 10/1/22 – 10/31/22

FDA Drug Safety Communications & Drug Information Updates:

Increased Risk of COVID-19 Due to Variants Not Neutralized by Evusheld 10/3/22
FDA added important information to the authorized Fact Sheets for Evusheld (tixagevimab co-packaged with cilgavimab) to inform health care providers and individuals receiving Evusheld of the increased risk for developing COVID-19 when exposed to variants of SARS-CoV-2 that are not neutralized by Evusheld.

Boostrix Vaccine Approved for Use During Pregnancy to Prevent Whooping Cough in Infants 10/7/22
FDA approved Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed [Tdap]) for immunization during the third trimester of pregnancy to prevent pertussis (whooping cough) in infants younger than two months of age.

Bivalent COVID-19 Vaccines Authorized for Use as a Booster Dose in Younger Age Groups 10/12/22
FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 vaccine, bivalent and the Pfizer-BioNTech COVID-19 vaccine, bivalent for use as a single booster dose at least two months following completion of primary or booster vaccination in children 6 years of age and up (Moderna) and children 5 years of age and up (Pfizer-BioNTech).

Baxter Issues Urgent Medical Device Correction Regarding Potential Radio Frequency Interference with Other Devices Near Beds Installed with WatchCare System 10/26/22
Baxter International Inc. issued an Urgent Medical Device Correction for the WatchCare Incontinence Management System due to potential for radio frequency (RF) interference with other medical devices. This RF interference could result in erroneous readings or additional malfunctions of these other devices and could therefore result in inappropriate medical intervention. Interference has been reported with insulin pump/blood glucose sensors, fetal monitors, telemetry devices, bladder scanners, and infusion pumps.

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

COVID-19 Ag Rapid Test Devices, Jiangsu Well Biotech Co., Ltd.: Recall - Not FDA Approved 10/13/22
Jiangsu Well Biotech Co., Ltd. recalled COVID-19 Ag Rapid Test Devices because they were distributed to U.S. customers without authorization, clearance, or approval from the FDA. There is no adequate validation data to show that the test's performance is accurate.

Sodium Bicarbonate Injection - USP, 8.4%, Exela Pharma Sciences: Recall - Vial Breakage 10/14/22
Exela Pharma Sciences, LLC recalled 49 lots of Sodium Bicarbonate Injection, USP, 8.4%, 50 mEq/50 mL vial, 20-count carton, because the product poses a potential safety concern with vial breakage and flying glass when pressurized while preparing the product for administration. The vials are labeled with Exela brand (Carton NDC: 51754-5001-5; Vial NDC: 51754-5001-1) and Civica brand (Carton NDC: 72572-740-20; Vial NDC: 72572-740-1). Product was distributed nationwide to wholesalers, distributors, and other customers between December 16, 2021 and August 10, 2022. A complete list of recalled lots can be found on the FDA website.

Ready-to-Feed Liquid Products, Abbott: Recall – Bottles May Not be Sealed 10/18/22
Abbott recalled certain lots of 2 fluid ounce/59 milliliter bottles of Ready-to-Feed liquid products for infants and children, including the brands Similac Pro-Total Comfort, Similac 360 Total Care, Similac 360 Total Care Sensitive, Similac Special Care 24, Similac Stage 1, Similac NeoSure, Similac Water (Sterilized), and Pedialyte Electrolyte Solution manufactured at the Columbus, Ohio, manufacturing facility. A small percentage of bottles (less than 1%) in the recalled lots have bottle caps that may not have sealed completely, which could result in spoilage. A complete list of recalled lot numbers can be found on the company's website.

Quinapril and Hydrochlorothiazide Tablets, USP 20mg/12.5mg, Aurobindo Pharma USA: Recall - Detection of N-Nitroso Quinapril Impurity 10/25/22

Aurobindo Pharma USA recalled 2 lots of Quinapril and Hydrochlorothiazide Tablets, USP 20 mg /12.5 mg due to the presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril. The manufacturer began shipping lots QE2021005-A and QE2021010-A to customers nationwide in May 2021.

Octreotide Acetate Injection, 500 mcg/mL, Mylan Institutional: Recall - Glass Particulates 10/25/22

Mylan Institutional LLC recalled lot AJ21002, exp 3/2024, of Octreotide Acetate Injection, 500 mcg/mL, packaged in a carton of ten 1 mL syringes due to a product complaint of the presence of glass particles in a syringe. This lot was manufactured by Italfarmaco SpA, Italy and was distributed by Mylan Institutional LLC in the US between January 11 and June 21, 2022.

New Product Shortages	***Date Initially Posted***
Etomidate Injection	10/5/22
Amphetamine mixed salts (immediate release)	10/12/22
Verteporfin (Visudyne) Injection	10/18/22
Alprostadil (Muse) suppository	10/18/22
Albuterol sulfate inhalational solution 0.5%	10/25/22
Amoxicillin oral powder for suspension	10/28/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Tremelimumab-actl / Imjudo / AstraZeneca Pharmaceuticals	Cytotoxic T-lymphocyte-associated antigen 4 blocking antibody for the treatment of adult patients with unresectable hepatocellular carcinoma in combination with durvalumab.	10/21/22
Teclistamab-cqyv / Tecvayli / Janssen Biotech, Inc.	Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteosome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody	10/25/22

New Indications:	***Description***	***Date Approved***
Lumasiran / Oxlumo / Alnylam Pharmaceuticals, Inc.	Lowering of plasma oxalate levels in adult and pediatric patients with primary hyperoxaluria type 1 (PH1)	10/6/22
Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, adsorbed (Tdap) / Boostrix / GSK Biologicals	Immunization during the third trimester of pregnancy to prevent pertussis (whooping cough) in infants younger than two months of age	10/7/22
Insulin lispro-aabc / Lyumjev / Eli Lilly Co.	Indication expanded to pediatric patients with diabetes mellitus and addition of continuous subcutaneous insulin infusion	10/14/22
Tenofovir alafenamide / Vemlidy / Gilead Sciences, Inc.	Treatment of chronic hepatitis B virus infection in pediatric patients 12 years and older	10/17/22
Durvalumab / Imfinzi / AstraZeneca Pharmaceuticals	Treatment of adult patients with unresectable hepatocellular carcinoma in combination with tremelimumab-actl	10/21/22
Upadacitinib / Rinvoq / Abbvie Inc	Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy	10/21/22
Cobimetinib fumarate / Cotellic / Genentech, Inc	Treatment of adult patients with histiocytic neoplasms	10/28/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Furosemide / Furoscix / scPharmaceuticals	Injection: 80 mg/10 mL in a single-dose prefilled cartridge co-packaged with a single-use on-body infusor; for treatment of congestion due to fluid overload in adults with NYHA class II/III chronic heart failure. The pump is pre-programmed to deliver 30 mg of furosemide subcutaneously over the first hour then 12.5 mg per hour for the subsequent 4 hours. It is not for use in emergency situations or in patients with acute pulmonary edema. It is not intended for chronic use and should be replaced with oral diuretics.	10/7/22
Bictegravir, emtricitabine, tenofovir alafenamide / Biktarvy / Gilead	Low-Dose Tablet (B/F/TAF 30/120/15 mg): expanded indication including HIV-1 infected pediatric patients weighing at least 14 kg	10/7/22
Pexidartinib / Turalio / Daiichi Sankyo, Inc.	Introduction of 125 mg capsule, removal of 200 mg capsule; modifications to REMS	10/14/22

Compiled by:

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Tremelimumab-actl / Imjudo / AstraZeneca Pharmaceuticals	
Generic Name / Brand Name / Company	Tremelimumab-actl / Imjudo / AstraZeneca Pharmaceuticals
Date of approval	10/21/22
Drug Class (Mechanism of Action if novel agent)	Blocks the activity of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4)
Indication	Treatment of adult patients with unresectable hepatocellular carcinoma in combination with durvalumab
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Solution for injection 25 mg/1.25 mL (20 mg/mL) and 300 mg/15 mL (20 mg/mL) in single-dose vials
Common Dose/sig	Single dose of 300 mg as an intravenous infusion over 60 minutes with first dose of durvalumab in patients 30 kg or more. Single dose of 4 mg/kg as an intravenous infusion over 60 minutes with first dose of durvalumab in patients less than 30 kg.
DEA Schedule	N/A
Date of market availability	Early November 2022
Similar Medication Names	Tralokinumab, Imdur
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Rash, diarrhea, fatigue, pruritus, musculoskeletal pain, and abdominal pain; laboratory abnormalities ≥40%: AST increased, ALT increased, hemoglobin decreased, sodium decreased, bilirubin increased, alkaline phosphatase increased, lymphocytes decreased
Severe Adverse Effects	Hemorrhage (6%), diarrhea (4%), sepsis (2.1%), pneumonia (2.1%), rash (1.5%), vomiting (1.3%), acute kidney injury (1.3%), and anemia (1.3%)

Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver enzymes, creatinine, adrenocorticotropic hormone level and thyroid function at baseline and before each dose (currently approved regimen is a single dose followed by durvalumab)
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No recommended dosage adjustments; pharmacokinetics were not affected in mild to moderate renal or hepatic impairment. The effect of severe renal or hepatic impairment has not been assessed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - None Warnings and Precautions - Immune-mediated adverse reactions - Infusion-related reactions - Embryo-Fetal toxicity - Durvalumab associated toxicities
Special administration technique or considerations	Tremelimumab-actl should be administered as an intravenous infusion over 60 minutes using a 0.2- or 0.22-micron filter. The patient should be observed for 60 minutes following completion of infusion. Durvalumab must be administered as a separate intravenous infusion over 60 minutes on the same day. Durvalumab as a single agent should be administered every 4 weeks thereafter.
Prepared by	Brittney Kessel
Source	Tremelimumab-actl (Imjudo) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2022.

Teclistamab-cqyv / Tecvayli / Janssen Biotech, Inc.	
Generic Name / Brand Name / Company	Teclistamab-cqyv / Tecvayli / Janssen Biotech, Inc.
Date of approval	10/25/22
Drug Class (Mechanism of Action if novel agent)	Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
Indication	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteosome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Solution for subcutaneous injection 30 mg/3 mL (10 mg/mL) and 153 mg/1.7 mL (90 mg/mL) in single-dose vials
Common Dose/sig	Dose of 0.06 mg/kg on Day 1, followed by 0.3 mg/kg on Day 4, and 1.5 mg/kg on Day 7 and then once weekly until disease progression or unacceptable toxicity
DEA Schedule	N/A
Date of market availability	Available through Tecvayli REMS program
Similar Medication Names	Tivicay, daclizumab
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Pyrexia, cytokine release syndrome, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. Grade 3 or 4 laboratory abnormalities ≥ 20%: decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Severe Adverse Effects	Pneumonia (15%), cytokine release syndrome (8%), sepsis (6%), general physical health deterioration (6%), COVID-19 (6%), acute kidney injury (4.8%), pyrexia (4.8%), musculoskeletal pain (2.4%), and encephalopathy (2.4%)
Severe Drug-Drug Interactions	The activity of P450 CYP enzymes may be suppressed
Severe Drug-Food Interactions	None identified
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC, immunoglobulin levels, liver enzymes, bilirubin at baseline and periodically or as clinically indicated; due to risk of cytokine release syndrome and neurologic toxicity patients should be hospitalized for 48 hours after administration of all doses within the step-up schedule (first 3 doses) and closely monitored. Verify pregnancy status of females of reproductive potential prior to initiating.
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No recommended dosage adjustments; pharmacokinetics were not affected in mild to moderate renal or mild hepatic impairment. The effects of severe renal or moderate to severe hepatic impairment has not been assessed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - None Warnings and Precautions - Cytokine release syndrome - Neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome - Hepatotoxicity - Infections - Neutropenia - Hypersensitivity and Injection-site reactions - Embryo-Fetal Toxicity
Special administration technique or considerations	For subcutaneous injection only into the abdomen (preferred site). Pretreatment medications should be administered 1-3 hours before each dose of the step-up dosing and first treatment dose. - Dexamethasone 16 mg or equivalent - Diphenhydramine 50 mg or equivalent - Acetaminophen 650-1000 mg or equivalent Consider initiation of prophylaxis for Herpes zoster reactivation. Consult prescribing information for dosage delays recommended for management of adverse effects.
Prepared by	Brittney Kessel
Source	Teclistamab-cqyv (Tecvayli) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; October 2022.