



Highlights of FDA Activities – 9/1/20 – 9/30/20

FDA Drug Safety Communications & Drug Information Updates:

Efficacy & Safety Concerns for Atezolizumab in Combination with Paclitaxel

9/8/20

The FDA alerted health care professionals and patients that a clinical trial evaluating atezolizumab plus paclitaxel in patients with previously untreated inoperable locally advanced or metastatic triple negative breast cancer that the drug combination was not effective. The combination of atezolizumab with another paclitaxel formulation, paclitaxel protein-bound, is currently approved for use in adult patients with metastatic triple negative breast cancer, but this continued approval may be contingent on the results of additional studies. Paclitaxel should NOT be used as a replacement for paclitaxel protein bound in clinical practice.

Electronic Expanded Access Requests

9/23/20

The FDA announced that the Reagan-Udall Foundation has launched [Expanded Access eRequest](#), a tool to submit expanded access requests for individual patient expanded access for drugs and biologics in non-emergency settings. The tool allows auto population of forms, uploading of relevant documents, links to resources for physicians, patients, and caregivers, and secure application submission to the FDA.

Benzodiazepine Drug Class: Drug Safety Communication - Boxed Warning Update

9/23/20

The FDA is requiring the Boxed Warning be updated for all benzodiazepines to address serious risks of abuse, addiction, physical dependence, and withdrawal across the medication class. Changes are also being incorporated in the Medication Guides, and other sections of the prescribing information including the Warnings and Precautions, Drug Abuse and Dependence, and Patient Counseling Information sections.

Diphenhydramine (Benadryl): Serious Problems with High Doses

9/24/20

The FDA issued a warning that taking higher than recommended doses of the common OTC allergy medication diphenhydramine (Benadryl) can lead to serious heart problems, seizures, coma, or even death. The warning was prompted by reports of teenagers ending up in emergency rooms or dying after participating in a new trend called “Benadryl Challenge” encouraged in videos posted on the social media site Tik Tok.

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

Leafree Instant Hand Sanitizer Aloe Vera, CorgioMed LLC: Recall - Labeled as EDIBLE ALCOHOL

9/3/20

CorgioMed recalled all lots of Leafree Instant Hand Sanitizer-Aloe Vera to the consumer level. The recall comes after products were labeled “EDIBLE ALCOHOL.” The product is packaged in 100 mL (UPC #6970495860325), 300 mL (UPC #69705860318), and 500 mL (UPC #6970495860301) bottles and was distributed nationwide via the CorgioMed website.

Nature-Throid and WP Thyroid, RLC Labs, Inc.: Recall - Sub Potency

9/3/20

RLC Labs, Inc. recalled 483 lots of WP Thyroid and Nature-Throid in all strengths to the consumer level after testing from 6 lots by the FDA determined samples to be sub-potent. Testing revealed that the products may have as low as 87% of the labeled amounts of liothyronine or levothyroxine.

bio aaa Advance Hand Sanitizer, AJR Trading LLC: Recall – Possible Methanol Presence

9/3/20

AJR Trading recalled 2,004 units of lot 20DF8307 of bio aaa Advance Hand Sanitizer to the consumer level due to a possible methanol contamination. The hand sanitizer was packaged in 480 mL plastic bottles with UPC 7502272121085 and was distributed in Miami beginning in April 2020.

Recalls Continued...**M Hand Sanitizer, Medek, LLC: Recall - Potential Presence of Methanol and Subpotent Ethanol** 9/10/20

Medek LLC recalled all lots of M Hand Sanitizer Alcohol Antiseptic 80% 128 oz/3785 mL to the consumer level after analysis by the FDA found that the product contained methanol and sub-potent levels of ethanol. The recalled hand sanitizer was distributed directly to walk-in customers in Alamo, TX between 4/17/20 and 5/22/20.

Alaris System PC Unit and PC Unit Front Case Keypad Replacement Kits, Becton Dickinson: Recall - Risk of Stuck or Unresponsive Keys 9/14/20

Becton, Dickinson and Company recalled the Alaris PC Unit Model 8015 infusion pump and PC Unit Front Case Keypad Replacement Kits (TC10008389, TC10010217, TC10012515, TC10013702, TC10013664) due to the keypads having one or more keys that become stuck or unresponsive. The affected devices were distributed between 4/12/17 and 6/25/20.

Alaris System Infusion Pumps, Becton Dickinson: Recalls – Damaged Hardware 9/14/20

Becton, Dickinson and Company recalled 8 models of the Alaris System Infusion Pumps due to damaged, loose, or missing parts including inter-unit interface connectors, hinge and frame parts, batteries, and LED displays. The affected devices were distributed between 7/1/04 and 4/30/20. A complete list of recalled models can be found on the FDA [site](#).

Alaris Syringe and Alaris PCA Modules, Becton Dickinson: Recall - Potential Incorrect Display of Syringe Types and/or Sizes 9/16/20

Becton, Dickinson and Company recalled Alaris Syringe Module 8110, Alaris PCA Module 8120, and Alaris Syringe/PCA Sizer Sensor Replacement Kit P/N 122786 due to potential incorrect displays of syringe types and/or sizes. The affected devices were distributed between 3/1/10 and 3/12/20.

NP Thyroid, Acella Pharmaceuticals, LLC: Recall - Sub Potency 9/17/20

Acella Pharmaceuticals LLC recalled two lots of NP Thyroid, one lot of 15 mg tablets (NDC# 42192-0327-01, lot M327E19-1, expiration date of October 2020) and one lot of 120 mg tablets (NDC# 42192-0328-01, lot M328F19-3, expiration date of November 2020), to the consumer level due to sub potency. Testing revealed potency potentially as low as 87% of the labeled amount of levothyroxine.

Albuterol Inhaler, Perrigo Pharmaceutical: Recall - Clogging of Inhaler 9/22/20

Perrigo Pharmaceutical Company recalled to the retail level all unexpired albuterol sulfate inhalation aerosol manufactured by Catalent Pharma Solutions for Perrigo due to possible clogging of the inhaler. Perrigo informed the FDA it has received several thousand complaints of clogging and failure to dispense medication, and they have stopped production and are investigating the malfunction. Patients should be instructed to continue use of inhalers they have on hand but seek immediate emergency care if needed and have extra inhalers or alternative treatment available in case of malfunction.

Riomet ER (Metformin HCl ER Oral Suspension), Sun Pharmaceutical: Recall - NDMA Content 9/23/20

Sun Pharmaceutical recalled Riomet ER (metformin HCl extended-release oral suspension) 500 mg/500 mL (NDC #10631-019-17, lot #AB06381, expiration date 10/2021) due to the level of N-Nitrodimethylamine (NDMA) which has been found to be above the allowable acceptable daily intake limit established by the FDA.

Cleaner Hand Sanitizer, DMM VISSION, S.A. DE C.V.: Recall - Undeclared Methanol 9/30/20

DMM VISSION, S.A. de C.V. recalled one lot of 500 mL bottles of Cleaner Hand Sanitizer (lot number LC2020408) and four lots of 1,200 mL bottles of Cleaner Hand Sanitizer (lot numbers LC2020407, LC2020502, LC2020504, and LC2020507) currently in the US distribution to the consumer level due to the detection of methanol. Products were distributed between 4/27/20 and 6/9/20.

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.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Red-E Male Enhancement Tablet* *recalled	Sexual Enhancement	Sildenafil

New Product Shortages

	<u>Date Initially Posted</u>
Hydralazine HCl Injection, USP	9/8/20
Nefazodone Hydrochloride Tablets	9/18/20

Sole Source or Branded Product Discontinuations/Withdrawals

	<u>Date Posted</u>
Indinavir 200 mg capsules (Crixivan, Merck); all indinavir strengths have now been discontinued	9/21/20
Guanidine Hydrochloride 125 mg tablets (Merck)	9/28/20

New Drug Approvals:

<u>Description</u>	<u>Date Approved</u>
Copper Cu 64 Dotatate / Detectnet / Radiomedix Inc	9/3/20
Radioactive diagnostic for use with positron emission tomography for localization of somatostatin receptor positive neuro-endocrine tumors in adults	
Pralsetinib / Gavreto / Blueprint Medicines	9/4/20
Kinase inhibitor indicated for the treatment of metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (see attached drug summary)	

New Indications:

<u>Description</u>	<u>Date Approved</u>
Fluticasone furoate, umecclidinium, vilanterol / Trelegy Ellipta / GlaxoSmithKline	9/9/20
Maintenance treatment of asthma in adults	
Mepolizumab / Nucala / GlaxoSmithKline	9/25/20
Treatment of patients age 12 years and older with hypereosinophilic syndrome for six months or longer without another identifiable non-blood related cause	
Cefiderocol / Fetroja / Shionogi Inc.	9/25/20
Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of the following gram-negative microorganisms (<i>Acinetobacter baumannii</i> complex, <i>Escherichia coli</i> , <i>Enterobacter cloacae</i> complex, <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , and <i>Serratia marcescens</i>)	
Coagulation factor IX recombinant / Aptevo BioTherapeutics	9/25/20
Routine prophylaxis to reduce the frequency of bleeding episodes in patients 12 years of age and older with hemophilia B	
Golimumab / Simponi Aria / Janssen Pharmaceutical	9/29/20
Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older	

<u>New Dosage Forms or Formulation:</u>	<u>Description</u>	<u>Date Approved</u>
Azacitidine / Onureg / Celgene Corp	Oral tablet: 200 mg and 300 mg; for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and are not able to complete intensive curative therapy	9/1/20
Tramadol hydrochloride / Qdolo / Athena Bioscience, LLC	Oral solution: 5mg/mL; for management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate	9/1/20
Tofacitinib citrate / Xeljanz / Pfizer	Oral solution: 1 mg/mL; for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older	9/25/20
Hydrocortisone / Alkindi Sprinkle / Eton Pharmaceuticals	Oral granules: 0.5 mg, 1 mg, 2 mg, 5 mg contained in capsules; replacement therapy in pediatric patients with adrenocortical insufficiency	9/29/20

Compiled by:

Terri Levien, Pharm.D.
 Brittany Craft, Pharm.D., PGY2 Drug Information Resident
 Matthew Cavaletto, Doctor of Pharmacy Candidate 2021
 Andrew Stephens, Doctor of Pharmacy Candidate 2021
 Erica Chan, Doctor of Pharmacy Candidate 2021
 Marissa Yocham, Doctor of Pharmacy Candidate 2021

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

Pralsetinib / Gavreto / Blueprint Medicines	
Generic Name / Brand Name / Company	Pralsetinib / Gavreto / Blueprint Medicines
Date of approval	9/4/20
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	Metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer in adults
Comparative agent – Therapeutic interchange?	Selpercatinib
Dosage forms/strengths	Capsules: 100 mg
Common Dose/sig	400 mg once daily orally on an empty stomach
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Gaviscon, Gabitril, Gabarone, Prasugrel
Clinical Use Evaluation	
Common Adverse Effects	≥25%: fatigue, constipation, musculoskeletal pain, hypertension
Severe Adverse Effects	Hepatotoxicity, interstitial lung disease, hemorrhagic events, impaired wound healing, hypertension, diarrhea, pneumonia, decreased lymphocytes, decreased neutrophils
Severe Drug-Drug Interactions	Strong CYP3A inhibitors: avoid coadministration Combined P-gp/strong CYP3A inhibitors: avoid coadministration, or reduce pralsetinib dose Strong CYP3A inducer: avoid coadministration, or increase pralsetinib dose
Severe Drug-Food Interactions	Exposure significantly increased when administered with a high-fat meal
Important Labs Values to assess prior to order entry or at point of clinical follow up.	ALT and AST prior to initiation, every 2 weeks for 3 months, then monthly thereafter; pregnancy testing prior to initiating
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	No dose adjustment required in mild hepatic impairment; has not been studied in moderate or severe hepatic impairment. Mild and moderate renal impairment had no effect on exposure; has not been studied in patients with severe renal impairment (CLcr < 15 mL/min).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings/Precautions: --ILD/pneumonitis; monitor for pulmonary symptoms, withhold dose for any respiratory symptoms indicative of ILD --Hypertension; optimize blood pressure before initiation. Monitor one week after initiation and monthly thereafter --Hepatotoxicity: monitor as described above. Withhold, reduce dose, or discontinue according to severity --Hemorrhagic events; permanently discontinue in patients with severe or life-threatening hemorrhage --Risk of impaired wound healing; withhold for at least 5 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate healing. --Embryo-fetal toxicity; can cause fetal harm. Use non-hormonal contraception
Special administration technique or considerations	Administer on an empty stomach (no food for 2 hours before and at least 1 hour after pralsetinib).
Prepared by	Matthew Cavaletto
Source	Gavreto (pralsetinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; September 2020.