Highlights of FDA Activities – 8/1/26 – 8/31/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date of Update
B-Cell-Depleting or Modulating Medications CDC Health Advisory – Risk of Abroviral Disease	The CDC issued a Health Alert Network Health Advisory advising of the risk of severe arboviral neuroinvasive disease among patients who are receiving B cell-depleting or B cell-modulating medications, particularly anti-CD20 monoclonal antibodies. Arboviruses are RNA viruses transmitted by biting arthropods, particularly mosquitoes and ticks. Medications that deplete B cells or modulate B cell function can increase the risk of severe arboviral disease. Anti-CD20 mAbs approved in the US include rituximab, ocrelizumab, ofatumumab, ublituximab, obinutuzumab, and ibritumomab tiuxetan. Case reports have described arboviral neuroinvasive disease in patients on anti-CD20 mAbs, with overall mortality of approximately 40% and long-term neurologic sequelae reported among most survivors. West Nile virus was the most common infecting arbovirus. With the use of anti-CD20 mAbs or other medications affecting B cell function, patients should be advised of the risk and to take measures to prevent mosquito and tick bites and clinicians should be aware that the disease course may be atypical in such patients and require molecular testing for diagnosis in the absence of antibody responses.	8/11/26
Compounders Reminded Not to Use Dietary Supplement Grade Glutathione for Injectables	The FDA reminded compounders to ensure all components used in injectable drugs are appropriate for their intended use. Dietary supplement grade ingredients should not be used when making injectable drugs. Several recent recalls and adverse event reports associated with the use of dietary supplement grade glutathione in injectable products prompted this notification.	8/27/26

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

Product	Description	Date Announced
Medline Convenience Kits Containing Huons Lidocaine Hydrochloride and Bupivacaine Hydrochloride in Dextrose Injection: Recall – Kit Correction due to Inclusion of Recalled Product	Medline issued a letter advising customers to correct certain convenience kits by removing included Lidocaine Hydrochloride and Bupivacaine Hydrochloride in Dextrose Injection that has been recalled by Huons Co Ltd following quality issues detected on an FDA inspection. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/3/26
Intraosseous Vascular Access System Needle Sets, Becton Dickinson and Company (BD): Recall – Difficulty Removing	BD recalled specific lots of BD® Intraosseous Vascular Access System Needle Sets following reports that some users experienced difficulty removing the obturator (stylet) after placement of the needle set. A full list of recalled products can be found on the FDA site.	8/3/26
OPTIRAY Imaging Bulk Package 350, 500 mL in Vial, Liebel-Flarsheim Company LLC: Recall – Particulate Matter	Liebel-Flarsheim Company LLC recalled one lot of OPTIRAY Imaging Bulk Package 350, 500 mL in vial (ioversol injection 74% 350 mg iodine/mL, multiple dose container packaged in cases of 6 vials; NDC 0019-1333-65, Lot 25ZF3670, Expiration May 31, 2027) to the user level due to the presence of particulate matter identified as polyethylene and other plastic materials, stainless steels, and glass.	8/4/26
Morphine Sulfate Injection, USP, in Simplist Prefilled Syringe, Fresenius Kabi: Recall – Mislabeled	Fresenius Kabi recalled one lot of morphine sulfate injection, USP, Simplist® 2mg/1 mL (lot 6402820, expiration date 12/2028) due to potential mislabeling. The MicroVault labeled morphine 2 mg/1 mL may contain a prefilled syringe of Dilaudid (hydromorphone HCl) 0.5 mg/0.5 mL. Affected product was distributed from 1/29/26 though 6/9/26.	8/5/26
VMC Compounded Glutathione 200 mg/mL Multi-Dose Vials, Victory Medical Center: Recall – Elevated Endotoxin Levels	Victory Medical Center recalled 3 lots of compounded glutathione 200 mg/mL multi-dose vials after pharmacy testing identified elevated endotoxin levels. Adverse events including fever, chills, severe headache, nausea, vomiting, tachycardia, changes in blood pressure, body aches, and injection site reactions have been reported. Affected product (lots 1980571, 1981940, 1984345; expiration August 27, 2026) was distributed in Texas, Florida, and New York.	8/5/26

Product	Description	Date Announced
Tyenne (tocilizumab-aazq) Injection 400 mg/20 mL Vials, Fresenius Kabi: Recall – Glass Particals	Fresenius Kabi recalled one lot (16UI07, expiration date 08/2028) of Tyenne (tocilizumab-aazq) injection 400 mg/20 mL vials due the present of glass particles. Recalled product was distributed nationwide from 3/3/26 through 3/25/26.	8/11/26
Medline Convenience Kits Containing ICU Medical Pain Management Components affected by the Huons Recall: Recall – Kit Correction due to Inclusion of Recalled Product	Medline issued a letter advising customers to correct certain convenience kits for use in knee or hip procedures containing ICU Medical, Inc pain management kits by removing included Bupivacaine Hydrochloride in Dextrose Injection that has been recalled by Huons Co Ltd following quality issues detected on an FDA inspection. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/12/26
Medline Convenience Kits Containing BD Chloraprep Applicators Affected by the BD Chloraprep Recall: Recall – Kit Correction due to Inclusion of Recalled Product	Medline issued a letter advising customers to correct certain convenience by removing BD ChloraPrep applicators affected by the BD ChloraPrep recall due to a potential breach of sterility. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/12/26
Immune globulin Intravenous (IGIV) and Immune Globulin Subcutaneous (IGSC), Multiple Manufacturers: Recall – Allergic/Hypersensitivity Reactions	Select lots of IGIV and IGSC products from ADMA Biologics, Biotest AG, GC Biopharma, Grifols, Grifols for Kedrion, and Octapharma have been recalled due to higher rates of allergic/hypersensitivity type reactions. Recalls were initiated in January 2025 and the most recent recall occurred in August 2026. A full list of products and recalled lots can be found on the FDA site.	8/14/26
Becton Dickinson Convenience Kits Containing Sodium Chloride Ampules Affected by the Huons Co Ltd Recall: Recall – Kit Correction due to Inclusion of Recalled Products	Becton Dickinson issued a letter advising customers to correct certain convenience by removing sodium chloride ampules manufactured by Huons Co Ltd and recalled by Elevaris Medical Devices due to a potential breach of sterility. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/18/26

Product	Description	Date Announced
Excel Lactated Ringers Injection, 1000 mL, B. Braun Medical: Recall – Particulate Matter	B. Braun Medical recalled one lot (J4H077, expiration 30NOV2026) of Excel® Container Lactated Ringers Injection, 1000 mL (catalog number L7500, NDC 0264-7750-00) due to the presence of particulate matter identified as cellulose cotton fibers with individual particles also identified as cellulose wood fiber and polystyrene.	8/19/26
Compounded Glutathione 200 mg/mL Multi-Dose Vials, Optimal Balance Pharmacy: Recall – Elevated Endotoxin Levels	Optimal Balance Pharmacy recalled one lot of compounded glutathione 200 mg/mL multi-dose vials after pharmacy testing identified elevated endotoxin levels. Adverse events including fever, chills, severe headache, nausea, vomiting, pain, and symptoms consistent with an allergic reaction have been reported. Affected product (lot LG342009076; expiration October 4, 2026) was distributed in Arizona, Colorado, Florida, Illinois, Louisiana, Michigan, New York, Nevada, Oklahoma, Pennsylvania, Texas, Utah, Vermont, and Washington.	8/20/26
Medline Convenience Kits Containing B. Braun Bupivacaine Hydrochloride: Recall – Kit Correction due to Inclusion of Recalled Product	Medline issued a letter advising customers to correct certain convenience kits by removing included B. Braun Bupivacaine Hydrochloride in Dextrose Injection that has been recalled by Huons Co Ltd following quality issues detected on an FDA inspection. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/20/26
Medical Action Industries Epidural Kits Containing Sodium Chloride Ampules Affected by the Huons Co Ltd Recall: Recall – Kit Correction due to Inclusion of Recalled Products	Medical Action Industries issued a letter advising customers to correct certain epidural kits by removing sodium chloride ampules manufactured by Huons Co Ltd and recalled by Spectra Medical Devices due to a potential breach of sterility. A full list of kits requiring correction can be found on the FDA site. Over-labels should be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. The remaining kit components may be used.	8/21/26

Product	Description	Date Announced
AVID Medical IV Start Kit Non-Sterile Convenience Kit Containing BD ChloraPrep Applicators Affected by the BD Chloraprep Recall: Recall – Potential Contamination	AVID Medical issued a letter advising customers of an update to a 7/14/26 action to correct certain convenience by removing BD ChloraPrep applicators affected by the BD ChloraPrep recall due to a potential breach of sterility. Over-labels were to be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. Subsequently AVID advises that instructions have changed for one product in the original notification. IV Start Kit Non-Sterile (model KRIV26-02, lot 1658437) should be quarantined and destroyed.	8/24/26
Medline Convenience Kits Containing BD ChloraPrep Applicators Affected by the BD Chloraprep Recall: Recall – Potential Contamination	Medline issued a letter advising customers of an update to a 6/12/26 action to correct certain convenience by removing BD ChloraPrep applicators affected by the BD ChloraPrep recall due to a potential breach of sterility. Over-labels were to be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. Subsequently Medline advises that instructions have changed for products containing ChloraPrep 1 mL single sterile applicators (item #930480, lot 4032183) or FREPP Clear 1.5 mL applicators with paper lidding (item #930299, lot 4073005); these entire kits should be quarantined and destroyed. A complete list of affected products can be found on the FDA site.	8/24/26
Thyroid Tablets, USP 30 mg, Vitruvias Therapeutics: Recall – Potential Super Potency	VItruvias Therapeutics Inc recalled one lot (504950) of thyroid tablets, USP 30 mg to the consumer level after testing confirmed the potential for superpotency. Product was distributed nationwide to Vitruvias Therapeutics' direct accounts from 1/31/25 to 9/30/25.	8/24/26
70% Dextrose Injection, Baxter: Recall – Particulate Matter	Baxter International recalled one lot (Y495066, expiration 31-Jul-2027) of 70% dextrose injection, USP in 2000 mL Viaflex plastic container, pharmacy bulk package, due to the presence of stainless steel particulate in the solution.	8/25/26
Anticoagulant Sodium Citrate Solution, Baxter: Recall – Particulate Matter	Baxter International recalled one lot (Y493475, expiration 31-Dec-2027) of anticoagulant sodium citrate solution USP, 250 mL Viaflex plastic container due to the presence of fiberglass particulate in the solution.	8/25/26
0.9% Sodium Chloride Injection, Baxter: Recall – Particulate Matter	Baxter International recalled two lots (Y495523 and Y495523A, expiration 31-Oct-2027) of 0.9% sodium chloride injection USP, 500 mL in Viaflex plastic containers due to the presence of fiberglass particulate in the solution.	8/26/26

Product	Description	Date Announced
0.9% Sodium Chloride Injection, B. Braun: Recall – Particulate Matter	B. Braun recalled three lots (J6B435, J6B444, J6B457, expiration 30APR2027) of 0.9% sodium chloride injection USP, 100 mL in a 150 mL PAB® container due to the presence of iron oxide particulate in the solution. Product was distributed nationwide from 2/27/26 to 8/3/26.	8/28/26
IV Start Kit from Avid Medical Containing BD ChloraPrep Applicators Affected by the BD ChloraPrep Recall: Recall – Potential Contamination	Avid Medical issued a letter advising customers of an update to a 7/22/26 action to correct certain convenience by removing BD ChloraPrep applicators affected by the BD ChloraPrep recall due to a potential breach of sterility. Over-labels were to be applied to affected products instructing staff to remove and discard the affected components prior to using the kit. Subsequently Avid Medical advises that instructions have changed for products containing ChloraPrep 1 mL single sterile applicators (lot 4032183); these entire kits should be quarantined and destroyed.	8/28/26

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
Anaconda Premium 500K	Sexual enhancement	Tadalafil
B. Magi	Weight loss	Phenolphthalein[1], neriifolin[2], thevetin B[2]
DMagic Plus	Weight loss	Diclofenac, neriifolin[2], thevetin B[2]
Esbelta Chupapanza Flat Belly	Weight loss	Phenolphthalein[1]
Esbelta Intense Loss	Weight loss	Sibutramine[3], desmethylsibutramine, benzyl sibutramine, sildenafil
Lipofit Extreme Fat Burner 2.0*	Weight loss	Fluoxetine, 2,4-dinitrophenol[4]
Qu Feng Huo Lou Dan	Pain relief	Dexamethasone
Premium OrgaZEN 10000	Sexual enhancement	Sildenafil

**recalled*

[1]Phenolphthalein was an over-the-counter laxative that is no longer marketed in the US due to carcinogenicity concerns

[2]Neriifolin and thevetin B are found in the yellow oleander plant and can cause neurologic, gastrointestinal, and cardiovascular adverse effects that may be severe or fatal

[3]Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010[FDA]; N-desmethylsibutramine is an active metabolite of sibutramine

[4]2,4-dinitrophenol is a toxic substance used as a pesticide, dye, wood preservative, and herbacide

New Product Shortages (per FDA or ASHP)

Product	Date Initially Posted
Terbutaline sulfate injection	8/3/26
Sufentanil injection	8/3/26
Pentostatin injection	8/10/26, 8/27/26-FDA
Tuberculin intradermal injection	8/10/26
Iopamidol injection	8/25/26

ASHP Drug Shortages List contains up-to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Dianeal PD-2 with Dextrose, Intraperitoneal Injection Solution (Vantive US Healthcare); alternative formulations are available but no generic equivalent	8/3/26
Dianeal Low Calcium with Dextrose, Intraperitoneal Injection Solution (Vantive US Healthcare); alternative formulations are available but no generic equivalent	8/3/26
Glyburide tablet (Diabeta, Sanofi-Aventis); a generic remains available	8/10/26
Disopyramide phosphate capsule (Norpace CR, Pfizer); generic prompt release remains available	8/24/26
Liraglutide injection (Saxenda, Novo Nordisk); generics remain available	8/25/26
Medroxyprogesterone acetate tablet (Provera, Pfizer); a generic remains available	8/31/26

Removed/Restricted Indications

Product	Description	Date Announced
Lurbinectedin/Zepzelca/Jazz Pharmaceuticals	Removal of indication for second-line therapy of small cell lung cancer; will remain available for use as first line maintenance therapy in combination with atezolizumab for patients with extensive-stage small cell lung cancer	8/4/26 by manufacturer

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Oveporexton/Orzeyful/Takeda Pharmaceuticals America	Orexin receptor 2 agonist for the treatment of narcolepsy type 1 in adults	8/5/26
Influenza vaccine, mRNA/mFlusiva/ Moderna	mRNA influenza vaccine for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine in patients 50 years of age and older	8/5/26
Vusolimogene oderparepvec-wtpg/Tudriqev/Replimune Inc	Genetically modified oncolytic viral therapy for use in combination with nivolumab for treatment of adults with unresectable advanced cutaneous melanoma that has progressed after a PD-1-blocking antibody-based regimen	8/6/26
Florquinitau F-18/Tauklarify/Cerveau Technologies	Radioactive diagnostic drug indicated for positron emission tomography of the brain in adults with cognitive impairment who are being evaluated for Alzheimer's disease to identify patients with tau neurofibrillary tangle pathology	8/13/26
Iberdomide/Zenbexus/Bristol Myers Squibb	Cereblon-modulating protein degrader for use with daratumumab and hyaluronidase-fihj and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulator	8/13/26
Garetosmab-grts/Pasatru/Regeneron Pharmaceuticals Inc	Activin signaling inhibitor to reduce new heterotopic ossification and clinician-assessed disease flare-ups in adults with fibrodysplasia ossificans progressiva	8/19/26
Pariglasgene brecaparvovec-opnr/ Genglycos/Ultragenyx Pharmaceutical Inc	As an adjunct to nutritional management in patients 8 years and older with glycogen storage disease type 1a	8/19/26
Daraxonrasib/Rasonque/Revolution Medicines	Inhibitor of the RAS GTPase family for the treatment of adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or are not candidates for multiagent systemic therapy	8/26/26
Brepocitinib/Lisraya/Roivant	Janus kinase and tyrosine kinase 2 inhibitor for the treatment of dermatomyositis in adults	8/27/26
Rusfertide/Mimrylo/Takeda Pharmaceuticals America	Hepcidin mimetic for the treatment of erythrocytosis in adults with polycythemia vera	8/28/26

New Indications

Product	Description	Date Approved
Nipocalimab-aahu/Imaavy/Janssen Biotech	Treatment of warm autoimmune hemolytic anemia in adult and pediatric patients 12 years and older currently or previously treated with corticosteroids	8/24/26
Dolutegravir sodium/Tivicay PD/ViiV	Dolutegravir tablets for oral suspension indication for treatment of HIV expanded to include infants weighing at least 2 kg from birth up to age 4 weeks, adding to previous approval in adults and infants aged at least 4 weeks and weighing 3 kg or more	8/25/26
Zanidatamab-hrii/Ziihera/Jazz Pharmaceuticals	In combination with fluoropyrimidine- and platinum-containing chemotherapy, with or without tislelizumab-jsgr, in previously untreated, HER2-positive advanced unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma	8/25/26
Ustekinumab/Stelara/Janssen Biotech	Treatment of moderately to severely active ulcerative colitis in pediatric patients aged 2 years and older	828/26
Ropeginterferon alfa-2b-njft/Besremi/ Pharmaessentia	Treatment of adults with essential thrombocytopenia	8/28/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Leuprolide acetate/Vobrig/Sun Pharmaceutical Industries	Injection: 28 mg/2.8 mL (10 mg/mL) in single-patient use prefilled pen; for the treatment of central precocious puberty in pediatric patients	8/26/26
Bictegravir and lenacapavir/ Bixlenvo/Gilead	Tablets: bictegravir 75 mg and lenacapavir 50 mg; indicated in adults with HIV-1 RNA levels less than 50 copies per mL who are switching from a stable antiretroviral regimen and have no resistance to the two drugs	8/27/26

Compiled by:

Terri Levien, Pharm.D.
Hayden Wesley, Pharm.D.

Dr Danial Baker Drug Information and Telehealth 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

New Drug Approvals: Drug Summaries

Oveporexton / Orzeyful / Takeda Pharmaceuticals America

Date of approval	8/5/26
Drug Class/Mechanism of Action	Orexin receptor 2 agonist
Indication	Treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adults
Comparative agent	None
Dosage forms/strengths	Tablets: 0.5 mg, 1 mg, 2 mg
Common Dose/sig	1 mg orally upon awakening and then 1 mg 3-5 hours later OR 2 mg orally upon awakening and then 2 mg 3-5 hours later
DEA Schedule	Pending
Date of market availability	Upon completion of DEA scheduling process
Similar Medication Names	Orserdu

Clinical Use Evaluation

Common Adverse Effects	Insomnia (55-60%), pollakiuria (53-58%), micturition urgency (15-16%), salivary hypersecretion (7-8%)
Severe Adverse Effects	Urinary frequency, incontinence
Severe Drug-Drug Interactions	CYP3A inhibitors or inducers: contraindicated with strong CYP3A inhibitors, reduce dose with moderate CYP3A inhibitors; avoid use with strong or moderate CYP3A inducers
Severe Drug-Food Interactions	None known
Important Lab Monitoring	None required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Avoid use in severe hepatic impairment or severe renal impairment on dialysis; no dosage adjustments in mild to moderate hepatic impairment or mild to severe renal impairment not requiring dialysis
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: patients taking strong CYP3A inhibitors Warnings: Insomnia Urinary frequency and urgency Creatine phosphokinase elevations
Special administration technique or considerations	Administer at approximately the same time each day. Swallow tablets whole with water. May be taken with or without food.
Source	Orzeyful (oveporexton) [prescribing information]. Cambridge, MA: Takeda Pharmaceuticals America Inc; August 2026.

Influenza vaccine, mRNA / mFlusiva / Moderna

Date of approval	8/5/26
Drug Class/Mechanism of Action	mRNA influenza vaccine encoding A/Missouri/11/2025 (H1N1) pdm09-like virus, A/Michigan/105/2025, an A/Darwin/1415/2025-like virus, and B/Pennsylvania/19/2025, a B/Pennsylvania/14/2025-like virus
Indication	Active immunization for prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine in patients 50 years of age and older
Comparative agent	Influenza vaccine, inactivated or recombinant
Dosage forms/strengths	Injectable suspension: 0.38 mL in pre-filled syringes
Common Dose/sig	Administer 0.38 mL as a single dose intramuscularly
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Influenza vaccine, inactivated or recombinant

Clinical Use Evaluation

Common Adverse Effects	Patients 50-64 years: injection site pain (69%), fatigue (48%), headache (42%), myalgia (41%), arthralgia (32%), chills (28%), underarm swelling or tenderness (20%); patients 65 years and older: injection site pain (63%), fatigue (42%), headache 34%), myalgia (30%), arthralgia (24%), chills (18%), underarm swelling or tenderness (14%)
Severe Adverse Effects	Injection site pain, underarm swelling or tenderness, swelling, erythema, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, fever
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments necessary
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: severe allergic reactions to the vaccine or components Warnings: Appropriate treatment to manage potential anaphylactic reactions Guillain-Barre syndrome (GBS): if GBS has occurred within 6 weeks following previous influenza vaccination, carefully consider potential benefits and risks Syncope Altered immunocompetence
Special administration technique or considerations	Do not shake.
Source	mFlusiva (influenza vaccine, mRNA) [prescribing information]. Princeton, NJ: Moderna; August 2026.

Vusolimogene oderparepvec-wtpg / Tudriqev / Replimune Inc

Date of approval	8/6/26
Drug Class/Mechanism of Action	Antineoplastic agent, genetically modified herpes simplex virus type 1 oncolytic viral therapy
Indication	In combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with a PD-1 blocking antibody-based regimen
Comparative agent	Talimogene laherparepvec
Dosage forms/strengths	Injection: 10^6 plaque-forming units (PFU)/mL, 10^7 PFU/mL single-dose vials
Common Dose/sig	Intratumor injections of 1 mL/cm of largest dimension tumor (up to 10 mL across all lesions) every 2 weeks for 8 consecutive doses, starting at 10^6 PFU/mL at week 1 and 10^7 PFU/mL for subsequent weeks
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Tudorza

Clinical Use Evaluation

Common Adverse Effects	Fatigue (59%), pyrexia (39%), infections (34%), chills (32%), musculoskeletal pain (32%), nausea (29%), diarrhea (29%), injection site reaction (26%), headache (19%), cough (18%), influenza like illness (18%), rash (18%), vomiting (17%), pruritus (17%), arthralgia (16%), constipation (16%), decreased appetite (13%), dizziness (15%), dyspnea (11%), hemorrhage (11%), edema (10%), abdominal pain (10%)
Severe Adverse Effects	Gastrointestinal reactions, fatigue, edema, infections, musculoskeletal pain, anemia, decreased lymphocyte count, increased lipase
Severe Drug-Drug Interactions	Antivirals may reduce efficacy – delay use for 72 hours after antivirals
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Verify pregnancy status prior to initiating
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: no labeled contraindications Warnings: Accidental exposure - healthcare providers, caregivers, close contacts, pregnant women, newborns and patients should avoid contact with injected tumors, dressings, or bodily fluids of patients. Herpetic infection or reactivation Injection procedure complications – monitor for symptoms of injury Immune-mediated events associated with nivolumab therapy Effective contraception should be used during and for 90 days after last dose by females of reproductive potential and males with female partners of reproductive potential

Special administration technique or considerations	Assess size of each injectable lesion on each treatment day to determine the required volume. Prioritize most rapidly growing and largest lesions. May treat injection site with topical or local anesthetic; inject anesthetic around periphery of lesion. Administer nivolumab as IV injection starting at week 3. After initial course, can retreat with 10^7 PFU/mL every 2 weeks if no disease progression.
Source	Tudriqev (vusolimogene oderparepvec-wtpg) [prescribing information]. Woburn, MA: Replimune Inc; August 2026.

Iberdomide / Zenbexus / Bristol Myers Squibb

Date of approval	8/13/26
Drug Class/Mechanism of Action	Cereblon-modulating protein degrader (CELMod) of the broader thalidomide class
Indication	For use with daratumumab and hyaluronidase-fihj and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulator
Comparative agent	Lenalidomide (Revlimid), pomalidomide (Pomalyst)
Dosage forms/strengths	Oral capsule: 0.75 mg and 1 mg
Common Dose/sig	1 mg orally once daily on days 1 to 21 of a 28-day cycle
DEA Schedule	None
Date of market availability	Available through a REMS program
Similar Medication Names	ivermectin

Clinical Use Evaluation

Common Adverse Effects	Upper respiratory tract infection (54%), fatigue (36%), muscle pain (35%), pneumonia (34%), diarrhea (33%), motor dysfunction (26%), rash (26%), sleep disorder (25%), hypogammaglobulinemia (24%), COVID-19 (23%), and constipation (20%).
Severe Adverse Effects	Overall incidence rate of >58.3%; pneumonia (26%), upper respiratory tract infection (6%), second primary malignancy (6%), death (5%), neutropenia (5%), febrile neutropenia (4%), COVID-19 (4%), sepsis (3%)
Severe Drug-Drug Interactions	Strong or moderate CYP3A4 inhibitors or inducers: avoid concomitant use. If use of strong or moderate CYP3A4 inhibitors cannot be avoided while taking iberdomide, reduce the dose of iberdomide.
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Pregnancy tests, complete blood count at baseline and throughout therapy
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.

Renal or Hepatic Dosing	Reduce dose in patients with eGFR less than 30 mL/min/1.73 m2 not receiving dialysis; no dosage adjustment if eGFR greater than 30 mL/min/1.73 m2 or if receiving intermittent hemodialysis or in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Pregnancy Black Box Warning: Embryo-fetal toxicity, serious venous and arterial thromboembolism Warnings: Embryo-fetal toxicity: females of reproductive potential should use 2 forms of birth control or continuous abstinence from heterosexual intercourse, during and for at least 4 weeks following therapy and males should use effective contraception and not donate sperm during or for 4 weeks following therapy. Advise all patients not to donate blood during or for 4 weeks following therapy. Serious venous and arterial thromboembolism: anti-thrombotic prophylaxis advised Neutropenia: monitor Infections: monitor Second primary malignancies: monitor
Special administration technique or considerations	Swallow capsules whole with water; wash hands if come into contact with capsule contents. Store capsules in original container. Follow applicable special handling and disposal procedures for hazardous drugs.
Source	Zenbexus (iberdomide) [prescribing information]. Princeton, NJ: Bristol Meyers Squibb; August 2026.

Garetosmab-grts / Pasatru / Regeneron Pharmaceuticals Inc

Date of approval	8/19/26
Drug Class/Mechanism of Action	Activin signaling inhibitor reduces formation and progression of new heterotopic bone lesions
Indication	To reduce new heterotopic ossification and clinician-assessed disease flare-ups in adults with fibrodysplasia ossificans progressiva
Comparative agent	Palovarotene (Sohonos)
Dosage forms/strengths	Injection: 300 mg/5 mL (60 mg/mL) solution in a single-use vial
Common Dose/sig	10 mg/kg IV over 60 minutes once every 4 weeks
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	pasireotide

Clinical Use Evaluation

Common Adverse Effects	Abscess (35%), acne (30%), increased hair growth (26%), madarosis (26%), oral ulcers (26%), epistaxis (17%)
Severe Adverse Effects	None reported

Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Pregnancy test
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal or hepatic impairment; safety and efficacy not established in severe renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Pregnancy Warnings: Embryo-fetal toxicity Skin and soft tissue infections Epistaxis
Special administration technique or considerations	If refrigerated, allow to come to room temperature before administering. Infuse diluted solution over 60 minutes using PVC, polyethylene-line PVC, or polyurethane infusion set; an in-line or add-on 0.2- to 5-micron polyethersulfone or polyamide filter is recommended. Infuse using an infusion pump. Flush line with D5W.
Source	Pasatru (garetosmab-grts) [prescribing information]. Tarrytown, NY: Regeneration Pharmaceuticals, Inc.; August 2026.

Pariglasgene brecaparvovec-opnr / Genglycos / Ultragenyx Pharmaceutical Inc

Date of approval	8/19/26
Drug Class/Mechanism of Action	Gene therapy
Indication	To reduce daily cornstarch intake as an adjunct to nutritional management in patients 8 years and older with glycogen storage disease type 1a
Comparative agent	None, first FDA approved treatment
Dosage forms/strengths	Suspension for IV infusion: 3×10^{13} genome copies (gc)/mL in 2 mL vials in a kit containing 3 to 15 vials based on patient body weight
Common Dose/sig	1×10^{13} gc/kg as a single IV infusion
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Increased transaminases (71%), nausea (38%), headache (24%), hypertriglyceridemia (29%, adrenal insufficiency (24%), acne (19%), constipation (19%), hyperglycemia (14%), cushingoid features (14%), anaphylaxis (10%)
Severe Adverse Effects	Anaphylaxis/infusion reaction, adrenal insufficiency, high lactate level, hypoglycemia

Severe Drug-Drug Interactions	Avoid vaccines for 1 month prior to administration
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Baseline testing for pre-existing antibodies to adeno-associated virus (AAV8) and baseline liver function tests, morning serum cortisol and ACTH; monitor transaminases for 6 months or until liver enzymes return to baseline; monitor adrenal function
Used in Pediatric Areas	Safety and efficacy have not been established in patients younger than 8 years
Renal or Hepatic Dosing	No dosage adjustments; contraindicated in hepatic fibrosis or cirrhosis
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known severe hepatic fibrosis or cirrhosis Warnings: Hypersensitivity and infusion reactions Hepatotoxicity Adrenal insufficiency Tumorigenicity risk
Special administration technique or considerations	Premedicate with acetaminophen and non-sedating antihistamines 30 to 60 minutes prior to infusion. Diluted solution should be infused through peripheral venous catheter with a 0.2 micron filter; tubing should be primed with diluted infusion solution up to hub of the catheter. The infusion rate is increased over the course of infusion with the total infusion time taking a minimum of 180 minutes. Flush tubing with 50 mL of 0.9% sodium chloride injection at same infusion rate as last part of infusion. Two weeks after administration, initiate prophylactic corticosteroids for a minimum of 8 weeks.
Source	Genglycos (pariglasgene brecaparvovec-opnr) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; August 2026.

Daraxonrasib / Rasonque / Revolution Medicines

Date of approval	8/26/26
Drug Class/Mechanism of Action	Inhibitor of the RAS GTPase family
Indication	Treatment of adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or are not candidates for multi-agent systemic therapy
Comparative agent	None
Dosage forms/strengths	Tablets: 100 mg, 150 mg
Common Dose/sig	300 mg orally once daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Daratumumab, daridorexant, Rasuvo

Clinical Use Evaluation

Common Adverse Effects	Rash (87%), diarrhea (67%), stomatitis (56%), nausea (52%), fatigue (47%), vomiting (42%), abdominal pain (27%), edema (25%), decreased appetite (24%), hemorrhage (22%); plus decrease albumin, calcium, hemoglobin, lymphocytes, platelets, sodium, white blood cells, magnesium, potassium, and increased AST, ALT, alkaline phosphatase, creatinine
Severe Adverse Effects	Rash, stomatitis, diarrhea, fatigue, hemorrhage, decreased sodium, decreased hemoglobin, decreased lymphocyte count
Severe Drug-Drug Interactions	Strong CYP3A inhibitors with P-gp inhibition or cyclosporine: avoid concomitant use; strong CYP3A inhibitors without P-gp inhibition, moderate CYP3A inhibitors with or without P-gp inhibition, or P-gp inhibitors: reduce daraxonrasib dose; strong CYP3A inducers: avoid concomitant use or increase daraxonrasib dose if concomitant use necessary; moderate CYP3A inducers: increase daraxonrasib dose; P-gp substrates: take at least 4 hours apart from daraxonrasib
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Pregnancy test
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal or hepatic impairment; no data in CrCl less than 30 mL/min or severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in prescribing information Warnings: Dermatologic and soft tissue toxicity: limit sun exposure, use sunscreen, and use topical corticosteroid and emollient creams; consider prophylactic oral antibiotics (eg, doxycycline or minocycline) Stomatitis and oral disorders Diarrhea Gastrointestinal perforation: monitor Interstitial lung disease/pneumonitis: monitor for pulmonary symptoms Embryo-fetal toxicity
Special administration technique or considerations	Swallow tablets whole with or without food.
Source	Rasonque (daraxonrasib) [prescribing information]. Redwood City, CA: Revolution Medicines Inc; August 2026.

Brepocitinib / Lisraya / Roivant

Date of approval	8/27/26
Drug Class/Mechanism of Action	Janus kinase and tyrosine kinase 2 inhibitor
Indication	Treatment of dermatomyositis in adults
Comparative agent	Corticosteroids
Dosage forms/strengths	Tablets: 30 mg

Common Dose/sig	30 mg orally once daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Libtayo

Clinical Use Evaluation

Common Adverse Effects	Upper respiratory tract infection (15%), headache (15%), fatigue (12%), urinary tract infection (11%), nausea (11%), bronchitis (10%), arthralgia (10%), diarrhea (9%), back pain (9%), fall (7%), influenza (6%), acne (6%)
Severe Adverse Effects	Infection, liver injury
Severe Drug-Drug Interactions	Avoid use with live vaccines; not recommended in combination with other Janus kinase inhibitors, other tyrosine kinase 2 inhibitors, or biologic DMARDs
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Baseline: tuberculosis screening, viral hepatitis screening, complete blood count, baseline hepatic and renal function tests, pregnancy test; during treatment monitor lymphocyte counts, neutrophil counts, hemoglobin, liver enzymes, lipids
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Avoid use in severe renal or hepatic impairment; no dosage adjustment in mild to moderate renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity Avoid use in patients with active hepatitis B or C, absolute lymphocyte count less than 500 cells/mm^3, absolute neutrophil count less than 1000 cells/mm^3, or hemoglobin level less than 8 g/dL, severe renal or hepatic impairment Boxed warnings: serious infections, mortality, malignancy, major adverse cardiovascular events, thrombosis Warnings: Serious infections Hypersensitivity reactions Gastrointestinal perforation Hypoglycemia in patients with diabetes: monitor blood glucose Laboratory abnormalities Embryofetal toxicity
Special administration technique or considerations	Administer orally with or without food
Source	Lisraya (brepocitinib) [prescribing information]. Durham, NC: Priovant Therapeutics Inc; August 2026.

Rusfertide / Mimrylo / Takeda Pharmaceuticals America

Date of approval	8/28/26
Drug Class/Mechanism of Action	Hepcidin mimetic
Indication	Treatment of erythrocytosis in adults with polycythemia vera
Comparative agent	Hydroxyurea, ruxolitinib
Dosage forms/strengths	Injection: 9.5 mg, 19 mg, 28 mg, 41 mg, 54 mg as lyophilized powder in single-dose vials
Common Dose/sig	Starting dose: 19 mg by subcutaneous injection once a week; adjust dose based on effectiveness and safety to maximum of 108 mg weekly
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Mimvey, Mimyx

Clinical Use Evaluation

Common Adverse Effects	Injection site reactions (56%), anemia (16%)
Severe Adverse Effects	Injection site reactions
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Pregnancy test; complete blood count every 2 to 4 weeks or as clinically indicated upon initiation and during dose modifications
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments in renal impairment or mild to moderate hepatic impairment; no data in severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in prescribing information Warnings: New or worsening thrombocytosis: monitor complete blood count Injection site reactions: use ice, topical corticosteroid creams, antihistamines, or analgesics, as needed, to treat pain and swelling. Embryo-fetal toxicity
Special administration technique or considerations	Injection subcutaneously into abdomen, thigh, or upper arm. Doses above 54 mg will require 2 injections; doses greater than 82 mg should be administered on separate days (day 1 and day 4 or 5).
Source	Mimrylo (rusfertide) [prescribing information]. Cambridge, MA: Takeda Pharmaceuticals America Inc; August 2026.