

Table Upcoming FDA Actions, October Through December 2023

Drug name	PDUFA date	Application type	Target indication	Route of administration	Therapeutic category	Refs
ONPATTRO (patisiran)	10/8/2023	sNDA	Transthyretin amyloid cardiomyopathy	Intravenous injection	RNA interference therapeutic	1-4
OPDIVO (nivolumab)	10/13/2023	sBLA	Completely resected stage IIB or IIC melanoma	Intravenous injection	Programmed death-1 immune checkpoint inhibitor	1,5,6
KEYTRUDA (pembrolizumab)	10/16/2023	sBLA	Resectable stage II, IIIA, or IIIB non-small cell lung cancer	Intravenous injection	Programmed death-1 immune checkpoint inhibitor	1,7,8
VOXZOGO (vosoritide)	10/21/2023	sNDA	Children <5 years of age with achondroplasia	Subcutaneous injection	C-type natriuretic peptide analog	1,9,10
DUPIXENT (dupilumab)	10/22/2023	sBLA	Chronic spontaneous urticaria	Subcutaneous injection	Human monoclonal antibody	1,11-13
ZYNRELEF (bupivacaine and meloxicam)	10/23/2023	sNDA	Expanded use in soft tissue and orthopedic surgical procedures	Local anesthetic applied with a needle-free syringe to surgical site prior to suturing	Local anesthetic	1,14,15
Vamorolone	10/26/2023	NDA	Duchenne muscular dystrophy	Oral	Anti-inflammatory	1,16,17
EXPAREL (bupivacaine liposome injectable suspension)	11/13/2023	sNDA	Regional anesthesia (sciatic nerve block in the popliteal fossa and femoral nerve block in the adductor canal)	Injectable suspension (nerve block)	Regional anesthetic	1,18,19
DefenCath (taurolidine/citrate/heparin)	11/15/2023	NDA	Reduction of catheter-related bloodstream infections in patients with kidney failure	Injection, catheter lock solution	Antimicrobial	1,20,21
Vonoprazan	11/17/2023	NDA	Erosive esophagitis/gastroesophageal reflux disease	Oral tablet	Potassium-competitive acid blocker	1,22,23
Reproxalap	11/23/2023	NDA	Dry eye disease	Topical ocular solution	Small-molecule modulator of reactive aldehyde species, anti-inflammatory	1,24
Lifileucel	11/25/2023	BLA	Advanced melanoma	Infusion	Polyclonal tumor infiltrating lymphocyte therapy	1,25,26
Repotrectinib	11/27/2023	NDA	ROS1-positive locally advanced or metastatic non-small cell lung cancer	Oral	Tyrosine kinase inhibitor	1,27-29
Nirogacestat	11/27/2023	NDA	Desmoid tumors	Oral	Small-molecule gamma secretase inhibitor	1,30
Fruquintinib	11/30/2023	NDA	Previously treated metastatic colorectal cancer	Oral	Vascular endothelial growth factor receptor inhibitor	1,31
NurOwn	12/8/2023	BLA	Amyotrophic lateral sclerosis	Injection, spinal canal	Mesenchymal stem cell therapy	1,32,33
Exagamglogene autotemcel (exa-cel)	12/8/2023	BLA	Severe sickle cell disease and transfusion-dependent beta thalassemia	CRISPR/Cas9 gene editing with stem cell transplant	Autologous, ex vivo CRISPR/Cas9 gene-edited cell therapy	1,34-36
LIVMARLI (maralixibat)	12/13/2023	sNDA	Cholestatic pruritus in patients with Alagille syndrome who are ≥3 months of age	Oral	Ileal bile acid transporter inhibitor	1,37,38
Roflumilast foam 0.3%	12/16/2023	NDA	Seborrheic dermatitis in individuals ≥9 years of age	Topical	Selective phosphodiesterase type 4 inhibitor	1,39
ABECMA (idecabtagene vicleucel)	12/16/2023	sBLA	Adult patients with relapsed and refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody	Infusion	Antineoplastic; B-cell maturation antigen-directed chimeric antigen receptor T-cell immunotherapy	1,40-42
KEYTRUDA (pembrolizumab)	12/16/2023	sBLA	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma	Intravenous injection	Programmed death-1 immune checkpoint inhibitor	1,43
XHANCE (fluticasone propionate)	12/16/2023	sNDA	Chronic rhinosinusitis	Nasal spray	Anti-inflammatory	1,44
Lovotibeglogene autotemcel (lovo-cel)	12/20/2023	BLA	Patients with sickle cell disease aged ≥12 years who have a history of vaso-occlusive events	Gene therapy	Gene therapy	1,45
iDose TR (travoprost intraocular implant)	12/22/2023	NDA	Open-angle glaucoma or ocular hypertension	Intraocular implant	Prostaglandin analog	1,46
Eplontersen	12/22/2023	NDA	Hereditary transthyretin-mediated amyloid polyneuropathy	Subcutaneous injection	Ligand-conjugated antisense therapy	1,47,48
LUMAKRAS (sotorasib)	12/24/2023	sNDA	Adults with previously treated locally advanced or metastatic KRAS G12C-mutated non-small cell lung cancer	Oral	RAS GTPase inhibitor	1,49,50
Gefapixant	12/27/2023	NDA	Chronic cough	Oral	Selective P2X3 receptor antagonist	1,51-53

BLA, Biologics License Application; NDA, New Drug Application; PDUFA, Prescription Drug User Fee Act; sBLA, supplemental Biologics License Application; sNDA, supplemental New Drug Application.

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