Imjudo (BLA)
(tremelimumab-actl; AstraZeneca Pharmaceuticals LP)
Class/route: Cytotoxic T-lymphocyte–associated antigen 4–blocking antibody
Indication: Indicated in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma; in combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non–small cell lung cancer with no sensitizing epidermal growth factor receptor mutation or anaplastic lymphoma kinase genomic tumor aberrations
Approval date: October 21, 2022

Tecvayli (BLA)
(teclistamab-cqyv; Janssen Biotech, Inc.)
Class/route: Bispecific B-cell maturation antigen–directed CD3 T-cell engager
Indication: Treatment of adult patients with relapsed or refractory multiple myeloma who have received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
Approval considerations: Accelerated approval
Approval date: October 25, 2022

Elahere (BLA)
(mirvetuximab soravtansine-gynx; Immunogen, Inc.)
Class/route: Folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate
Indication: Indicated for the treatment of adult patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1-3 prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.
Approval considerations: Accelerated approval
Approval date: November 14, 2022

Tzield (BLA)
(teplizumab-mzwv; Provention Bio, Inc.)
Class/route: CD3-directed antibody
Indication: Indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged ≥8 years with stage 2 type 1 diabetes
Approval date: November 18, 2022

Rezlidhia (NDA)
(olutasidenib; Rigel Pharmaceuticals, Inc.)
Class/route: Isocitrate dehydrogenase-1 inhibitor (IDH1)
Indication: Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible *IDH1* mutation, as detected by an FDA-approved test
Approval date: December 1, 2022

Krazati (NDA)
(adagrasib; Mirati Therapeutics, Inc.)
Class/route: Inhibitor of the RAS GTPase family
Indication: Treatment of adult patients with *KRAS* G12C–mutated locally advanced or metastatic non–small cell lung cancer, as determined by an FDA-approved test, who have received ≥1 prior systemic therapy
Approval considerations: Accelerated approval, orphan status
Approval date: December 12, 2022

Sunlenca (NDA)
(lenacapavir; Gilead Sciences, Inc.)
Class/route: A human immunodeficiency virus type 1 (HIV-1) capsid inhibitor
Indication: Treatment of HIV-1 infection in combination with other antiretroviral(s) in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection who respond inadequately to their current antiretroviral regimen due to resistance, intolerance, or safety considerations
Approval considerations: Priority review
Approval date: December 22, 2022

Lunsumio (BLA)
(mosunetuzumab-axgb; Genentech, Inc.)
Class/route: Bispecific CD20-directed CD3 T-cell engager
Indication: Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after ≥2 lines of systemic therapy
Approval considerations: Accelerated approval, orphan status
Approval date: December 22, 2022

Xenoview (NME)
(xenon XE 129 hyperpolarized; Polarean, Inc.)
Class/route: A hyperpolarized contrast agent prepared from the Xenon Xe 129 gas blend
Indication: Indicated for use with magnetic resonance imaging for evaluation of lung ventilation in adults and pediatric patients aged ≥12 years
Approval date: December 23, 2022

Briumvi (BLA)
(ublituximab-xiiy; TG Therapeutics, Inc.)
Class/route: CD20-directed cytolytic antibody
Indication: Treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Approval date: December 28, 2022

NexoBrid (BLA)
(anacaulase-bcdb; Vericel Corporation)
Class/route: Contains proteolytic enzymes
Indication: Indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns
Approval considerations: Orphan status
Approval date: December 28, 2022

Leqembi (BLA)
(lecanemab-irmb; Esai, Inc.)
Class/route: Amyloid beta–directed antibody
Indication: Treatment of Alzheimer disease in patients with mild cognitive impairment or mild dementia stage of disease
Approval considerations: Accelerated
Approval date: January 6, 2023

Brenzavvy (NME)
(bexagliflozin; TheracosBio, LLC)
Class/route: Sodium-glucose co-transporter 2 inhibitor
Indication: Treatment of adults with type 2 diabetes mellitus to improve glycemic control, as an adjunct to diet and exercise
Approval date: January 20, 2023

Jaypirca (NME)
(pirtobrutinib; Loxo Oncology, Inc.)
Class/route: Noncovalent Bruton tyrosine kinase (BTK) inhibitor
Indication: Treatment of adult patients with relapsed or refractory mantle cell lymphoma after ≥2 lines of systemic therapy, including a BTK inhibitor
Approval considerations: Accelerated, orphan status
Approval date: January 27, 2023

Orserdu (NME)
(elacestrant; Stemline Therapeutics, Inc.)
Class/route: 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 ≥1 line of endocrine therapy
Approval considerations: Fast track
Approval date: January 27, 2023

Jesduvroq (NME)
(daprodustat; GlaxoSmithKline)
Class/route: Hypoxia-inducible factor prolyl hydroxylase inhibitor
Indication: Treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for ≥4 months
Approval date: February 1, 2023

Lamzede (BLA)
(velmanase alfa-tycv; Chiesi Farmaceutici S.p.A.)
Class/route: Recombinant human lysosomal alpha-mannosidase
Indication: Treatment of non–central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients
Approval considerations: Fast track, orphan status
Approval date: February 16, 2023

Filspari (NME)
(sparsentan; Travere Therapeutics, Inc.)
Class/route: Endothelin and angiotensin II receptor antagonist
Indication: To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for rapid disease progression, generally a urine protein-to-creatinine ratio ≥1.5 g/g
Approval considerations: Accelerated, orphan status
Approval date: February 17, 2023

Skyclarys (NME)
(omaveloxolone; Reata Pharmaceuticals, Inc.)
Class/route: Precise mechanism is unknown
Indication: Treatment of Friedreich ataxia in adults and adolescents aged ≥16 years
Approval considerations: Fast track, orphan status
Approval date: February 28, 2023

Zavzpret (NME)
(zavegepant; Pfizer)
Class/route: Calcitonin gene-related peptide receptor antagonist
Indication: Acute treatment of migraine with or without aura in adults
Approval date: March 9, 2023

Daybue (NME)
(Trofinetide; Acadia Pharmaceuticals Inc.)
Class/route: Precise mechanism is unknown
Indication: Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older
Approval considerations: Fast track, orphan status
Approval date: March 10, 2023

Zynyz (BLA)
(retifanlimab-dlwr; Incyte Corporation)
Class/route: Programmed death receptor-1–blocking antibody
Indication: Treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma
Approval considerations: Accelerated, orphan status
Approval date: March 22, 2023

Rezzayo (NME)
(rezafungin for injection; Melinta Therapeutics)
Class/route: Echinocandin antifungal
Indication: Indicated in patients ≥18 years of age who have limited or no alternative options for the treatment of candidemia and invasive candidiasis
Approval considerations: Fast track, orphan status
Approval date: March 22, 2023

Joenja (NME)
(leniolisib; Pharming Technologies B.V.)
Class/route: Phosphoinositide 3-kinases-delta (PI3K-delta) inhibitor
Indication: Treatment of activated PI3K-delta syndrome in adult and pediatric patients ≥12 years of age
Approval considerations: Priority, orphan status
Approval date: March 24, 2023

Qalsody (NME)
(tofersen; Biogen MA Inc.)
Class/route: Antisense oligonucleotide
Indication: Treatment of amyotrophic lateral sclerosis in adults who have a mutation in the *SOD1* gene
Approval considerations: Accelerated, orphan status
Approval date: April 25, 2023

Elfabrio (BLA)
(pegunigalsidase alfa-iwxj; Chiesi Farmaceutici S.p.A.)
Class/route: Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme
Indication: Treatment of adults with confirmed Fabry disease
Approval date: May 9, 2023

Veozah (NME)
(fezolinetant; Astellas Pharma US, Inc.)
Class/route: Neurokinin 3 receptor antagonist
Indication: Treatment of moderate to severe vasomotor symptoms due to menopause
Approval considerations: Priority status
Approval date: May 12, 2023

Miebo (NME)
(perfluorohexyloctane ophthalmic solution; Bausch & Lomb Inc.)
Class/route: Semifluorinated alkane
Indication: Treatment of the signs and symptoms of dry eye disease
Approval date: May 18, 2023

Epkinly (BLA)
(epcoritamab-bysp; Genmab US, Inc.)
Class/route: Bispecific CD20-directed CD3 T-cell engager
Indication: Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after ≥2 lines of systemic therapy
Approval considerations: Accelerated status
Approval date: May 19, 2023

Xacduro (NME and Type 4, New Combination)
(sulbactam for injection, durlobactam for injection; Entasis Therapeutics Ltd.)
Class/route: Sulbactam is a beta-lactam antibacterial and beta lactamase inhibitor; durlobactam is a beta lactamase inhibitor
Indication: Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex in patients ≥18 years of age
Approval considerations: Fast track
Approval date: May 23, 2023

Paxlovid (NME)
(nirmatrelvir tablets, ritonavir tablets; Pfizer)
Class/route: Nirmatrelvir is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) main protease inhibitor; ritonavir is an HIV-1 protease inhibitor and CYP3A inhibitor
Indication: Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death
Approval considerations: Fast track
Approval date: May 25, 2023

Posluma (NME)
(flotufolastat F 18; Blue Earth Diagnostics)
Class/route: Radioactive diagnostic agent
Indication: Indicated for positron emission tomography of prostate-specific membrane antigen–positive lesions in men with prostate cancer
Approval date: May 25, 2023

Inpefa (NME)
(sotagliflozin; Lexicon Pharmaceuticals, Inc.)
Class/route: Sodium-glucose cotransporter 2 inhibitor
Indication: Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with
- Heart failure or
- Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

Approval date: May 26, 2023

Columvi (BLA)
(glofitamab-gxbm; Genentech, Inc.)
Class/route: Bispecific CD20-directed CD3 T-cell engager
Indication: Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after ≥2 lines of systemic therapy
Approval considerations: Accelerated, orphan status
Approval date: June 15, 2023

Litfulo (NME)
(ritlecitinib; Pfizer)
Class/route: Janus kinase 3 inhibitor
Indication: Treatment of severe alopecia areata in adults and adolescents ≥12 years of age
Approval date: June 23, 2023

Rystiggo (BLA)
(rozanolixizumab-noli; UCB, Inc.)
Class/route: Neonatal Fc receptor blocker
Indication: Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti–muscle-specific tyrosine kinase antibody positive
Approval considerations: Orphan status
Approval date: June 26, 2023

Ngenla (BLA)
(somatrogon-ghla; Pfizer Labs)
Class/route: Human growth hormone analog
Indication: Treatment of pediatric patients aged ≥3 years who have growth failure due to inadequate secretion of endogenous growth hormone
Approval considerations: Orphan status
Approval date: June 27, 2023

Beyfortus (BLA)
(nirsevimab-alip; AstraZeneca, Inc.)
Class/route: Respiratory syncytial virus (RSV) F protein–directed fusion inhibitor
Indication: Indicated for the prevention of RSV lower respiratory tract disease in:
- Neonates and infants born during or entering their first RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

Approval date: July 17, 2023

Vanflyta (NME)
(quizartinib; Daiichi Sankyo)
Class/route: fms-related receptor tyrosine kinase 3
Indication: Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is *FLT3* internal tandem duplication–positive as detected by an FDA-approved test
Approval considerations: Priority, orphan status
Approval date: July 20, 2023

Xdemvy (NME)
(lotilaner ophthalmic solution; Tarsus Pharmaceuticals, Inc.)
Class/route: Ectoparasiticide (antiparasitic)
Indication: Treatment of Demodex blepharitis
Approval date: July 25, 2023

Zurzuvae (NME)
(zuranolone; Sage Therapeutics, Inc.)
Class/route: Neuroactive steroid gamma-aminobutyric acid A receptor–positive modulator
Indication: Treatment of postpartum depression in adults
Approval considerations: Priority status
Approval date: August 4, 2023

Izervay (NME)
(avacincaptad pegol intravitreal solution; IVERIC bio, Inc.)
Class/route: Complement inhibitor
Indication: Treatment of geographic atrophy secondary to age-related macular degeneration
Approval considerations: Priority status
Approval date: August 4, 2023