2023 Novel Drug Approvals

A Presentation for HealthTrust Members

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Objectives

1. Recognize the new molecular entities approved by the Food and Drug Administration (FDA) in 2023

2. Recall the indications and drug classes of the new drugs

3. Identify common adverse events, available dosage forms, and clinical pearls of the new drugs

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Abbreviations

ABC: *Acinetobacter baumannii-calcoaceticus* complex
ACM: All-cause mortality
AE: Adverse event
ARIA-H: Amyloid-related imaging abnormalities - haemosiderin
ARIA-E: Amyloid-related imaging abnormalities - edema
ALT: Alanine transaminase
AST: Aspartate aminotransferase
CBC: Complete blood count
CDC: Centers for Disease Control and Prevention
CDR-SB: Clinical dementia rating-sum of boxes
CGRP: Calcitonin Gene-Related Peptide
CI: Confidence Interval
CNS: Central nervous system
CRBSI: Catheter-related bloodstream infection
CVC: Central venous catheter
DDI: Drug-drug interaction
DSM-IV: Diagnostic and statistical manual of mental disorders-IV
DSN: Duration of severe neutropenia
ECG: Electrocardiogram
ECOG: Eastern Cooperative Oncology Group
eGFR: Estimated glomerular filtration rate
ESA: Erythropoietin stimulating agent

FN: Febrile neutropenia
GABA: Gamma-aminobutyric acid
HAMD-17: Hamilton rating scale for depression
HbA1c: Glycated hemoglobin
HFpEF: Heart failure with preserved ejection fraction
HFrEF: Heart failure with reduced ejection fraction
HIT: Heparin-induced thrombocytopenia
HIF: Hypoxia-inducible factor
IL: Interleukin
IM: Intramuscular
IV: Intravenous
LDL: Low-density lipoprotein
LFT: Liver function test
MACE: Major adverse cardiovascular event
MAOI: Monoamine oxidase inhibitor
MDD: Major depressive disorder
NaCl: Sodium chloride
OAT1: Organic anion transporter 1 inhibitor
PET: Positron-emission tomography
PH: Prolyl hydroxylase

PO: By mouth
PPD: Postpartum depression
RSV: Respiratory syncytial virus
SE: Standard error of the mean
SGLT1: Sodium-glucose co-transporter 1
SGLT2i: Sodium-glucose co-transporter 2
SubQ: Subcutaneous
T2DM: Type 2 Diabetes Mellitus
TA: Taxane and anthracycline
TB: Tuberculosis
tCFS: Total corneal fluorescein staining
TEAE: Treatment emergent adverse event
TNF: Tumor necrosis factor
URTI: Upper respiratory tract infection
UTI: Urinary tract infection
VAS: Visual analogue scale

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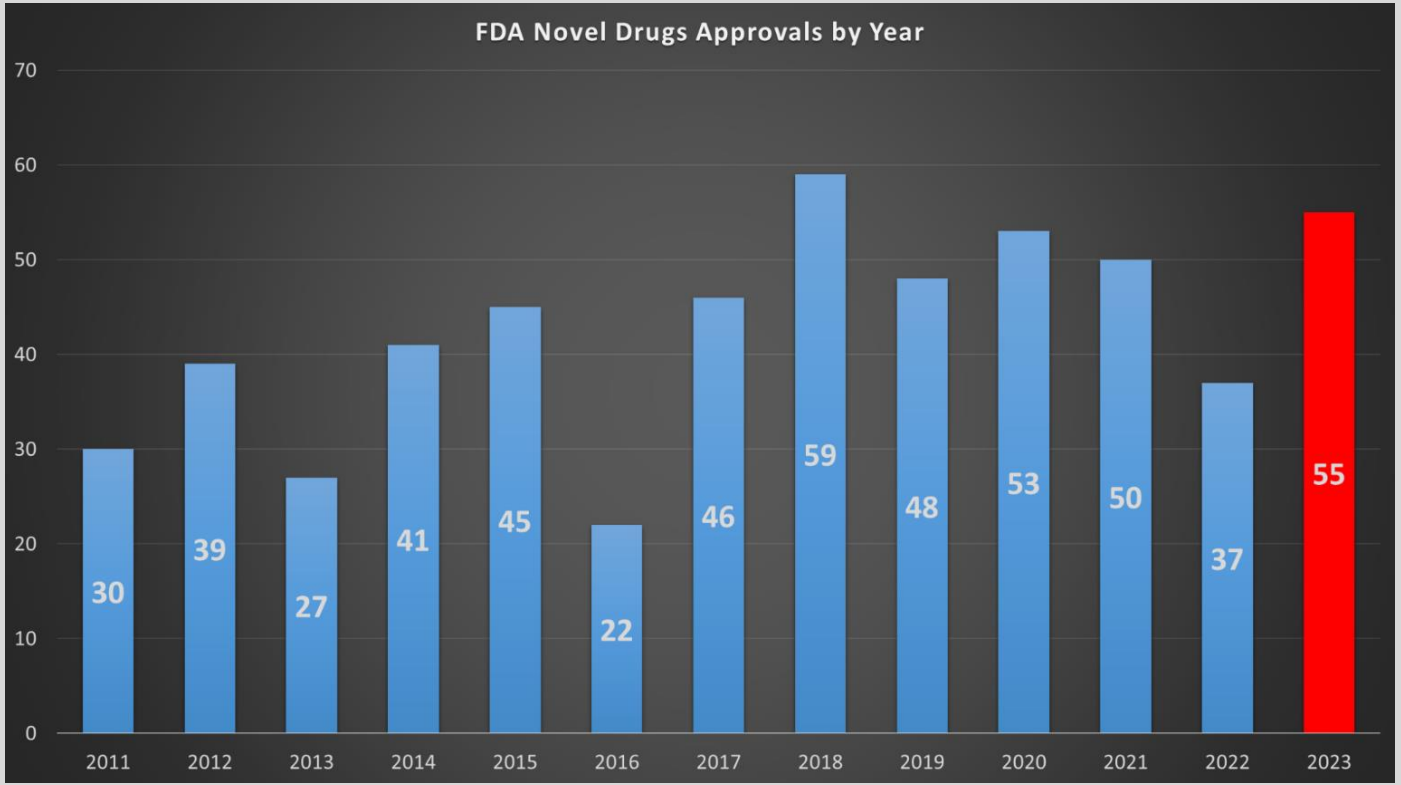
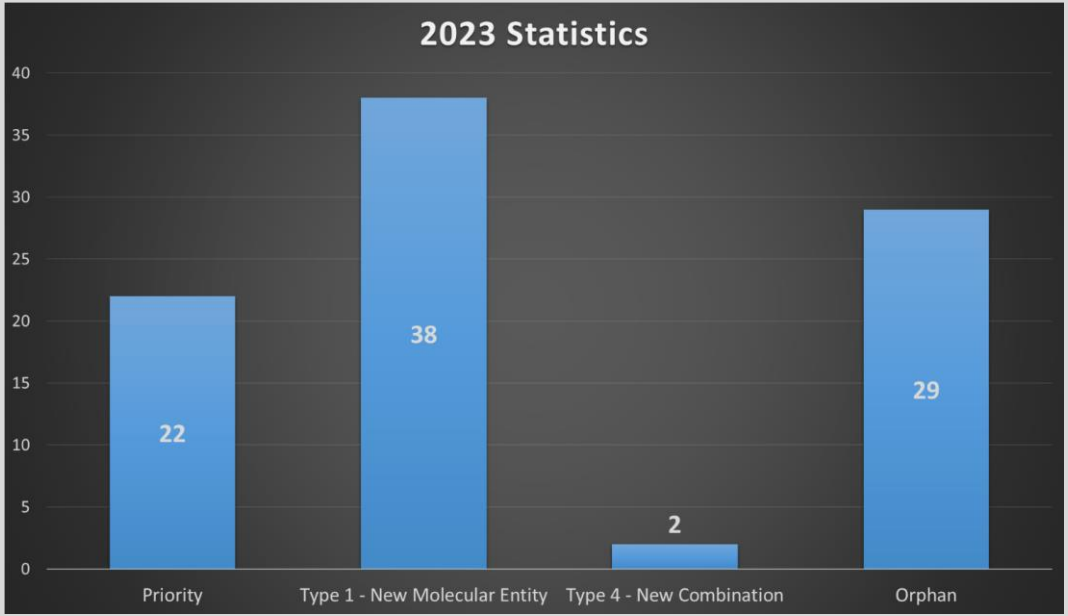
FDA Novel Drug Approvals by Year



Novel Drug Approvals for 2023. U.S. Food and Drug Administration. Updated January 16, 2024. Accessed January 23, 2024. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023

2023 Statistics

- **Priority:** 22/55
- **Type 1:** New Molecular Entity: 38/55
- **Type 4:** New Combination: 2/55
- **Orphan:** 29/55



Novel Drug Approvals for 2023. U.S. Food and Drug Administration. Updated January 16, 2024. Accessed January 23, 2024. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023

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Approved Medications

- Leqembi®
- Brenzavvy®
- Jaypirca®
- Orserdu®
- Jesduvroq®
- Lamzede®
- Filspari®
- Skyclarys®
- Zavzpret®
- Daybue®
- Zynyz®
- Rezzayo®
- Joenja®
- Qalsody®
- Elfabrio®
- Veozah®
- Miebo®
- Epkinly®
- Xacduro®
- Paxlovid®
- Posluma®
- Inpefa®
- Columvi®
- Litfulo®
- Rystiggo®
- Ngenla®
- Beyfortus®
- Vanflyta®
- Xdemvy®
- Zurzuvae®
- Izervay®
- Talvey®
- Elrexfio®
- Sohonos®
- Veopoz®
- Aphexda®
- Ojjaara®
- Exxua®
- Pombiliti®
- Rivfloza®
- Velsipity®
- Zilbrysq®
- Bimzelx®
- Agamree®
- Omvoh®
- Loqtorzi®
- Fruzaqla®
- Defencath®
- Augtyro®
- Ryzneuta®
- Truqap®
- Ogsiveo®
- Fabhalta®
- Filsuvez®
- Wainua®

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2023 Approved Medications

- Leqembi® (lecanemab)
- Brenzavvy® (bexagliflozin)
- Jesduvroq® (daprodustat)
- Zavzpret® (zavegepant)
- Rezzayo® (rezafungin)
- Veozah® (fezolinetant)
- Miebo® (perfluorhexyloctane)
- Xacduro® (sulbactam and durlobactam)
- Inpefa® (sotagliflozin)
- Beyfortus® (nirsevimab)
- Zurzuvae® (zuranolone)
- Exxua® (gepirone)
- Omvoh® (mirikizumab)
- Defencath® (taurolidine and heparin)
- Ryzneuta® (efbemalenograstim alfa)

Leqembi®

Lecanemab-irmb (lek-AN-e-mab)

Approval Date	1/6/2023
Indication	Alzheimer's disease
Class	Anti-amyloid monoclonal antibody; immune globulin; monoclonal antibody
Mechanism of Action	A humanized monoclonal antibody that reduces amyloid plaques by directing against aggregated both soluble and insoluble amyloid beta forms
Common Adverse Events (>10%)	Infusion-related reaction (20% to 26%), hemosiderosis (ARIA-H, including microhemorrhage and superficial siderosis: 6% to 17%), headache (11% to 14%), brain edema (ARIA-E, including sulcal effusion: 10% to 13%)
Dosage Forms	IV solution
Clinical Pearls	● For those with mild cognitive impairment ● Dosing based on actual body weight; given once every 2 weeks ● Confirm presence of amyloid beta pathology prior to treatment ● Testing for apolipoprotein ε4 is recommended prior to treatment
Cost (WAC)	2 mL of 100 mg/1 mL IV solution, $254.81; 5 mL of 100 mg/1 mL IV solution, $637.02

Lecanemab. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated November 7, 2023. Accessed January 30, 2024. https://online.lexi.com
Leqembi. Package insert. Eisai Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Leqembi®: Clinical Trials

Study	Van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early alzheimer's disease. *NEJM*. 2023;388(1):9-21. doi: 10.1056/NEJMoa2212948		
Study Objective	"To determine the safety and efficacy of lecanemab in participants with early Alzheimer's disease"		
Study Design	Multicenter, double-blind, phase 3 trial		
Study Subjects	Persons 50-90 years of age with early Alzheimer's disease with evidence of amyloid on PET or by cerebrospinal fluid testing		
Intervention	Randomly assigned 1:1 ratio to receive IV lecanemab (10 mg/kg) or placebo every 2 weeks		
Primary Endpoint	Change from baseline to 18 months in on the CDR-SB		
Efficacy Results	Lecanemab (N = 898)	Placebo (N = 897)	Difference (95% CI); p-value
	• Mean baseline CDR-SB score: 3.2 • Mean change from baseline at 18 months: 1.21	• Mean baseline CDR-SB score: 3.2 • Mean change from baseline at 18 months: 1.66	-0.45 (-0.67 to -0.23); p < 0.001
Safety Results	• Serious adverse event (14.0 % vs 11.3 %) • Death (0.7 % vs 0.8 %)	• Infusion-related reaction (26.4 % vs 7.4 %) • ARIA-H (14.0 % vs 7.7 %)	• ARIA-E (12.6 % vs 1.7 %) • Headache (11.1 % vs 8.1 %)
Additional Trials	NCT01767311 active, non-recruiting; NCT03887455 active, non-recruiting; NCT04468659 recruiting; NCT05269394 recruiting		

Leqembi. Package insert. Eisai Inc.; 2023.

Brenzavvy®

bexagliflozin (BEX-a-gli-FLOE-zin)

Approval Date	1/20/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Treatment for T2DM
Class	Antidiabetic agent, SGLT2 inhibitor
Mechanism of Action	Increases urinary glucose excretion by reducing renal reabsorption of filtered glucose and lowering the renal threshold for glucose due to SGLT2 inhibition.
Common Adverse Events (1-10%)	Diuresis (7%; including nocturia, polyuria, urinary frequency, and urinary urgency), urinary tract infection (6%; including urinary tract infection with sepsis), vaginal mycosis (6%; including vulvovaginal candidiasis), vulvovaginal pruritus (3%), increased thirst (3%), increased hemoglobin (3%), hypoglycemia (2%), increased LDL cholesterol (2%), male genital disease (2%; including balanoposthitis, localized fungal infection), tinea cruris (2%), increased hematocrit (1%)
Dosage Forms	Tablet
Clinical Pearls	● If present, correct hypovolemia before treatment initiation ● Administer in the morning without regard to meals ● Not recommended if eGFR < 30 mL/min/1.73m^2 ● Swallow tablet whole; do not crush or chew
Cost (WAC)	30 count of 20 mg tablets, $39.00; 90 count of 20 mg tablets, $117.00

Bexagliflozin. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated December 19, 2023. Accessed January 30, 2024. https://online.lexi.com
Brenzavvy. Package insert. TheracosBio, LLC; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Brenzavvy®: Clinical Trials

Study	NCT02715258		
Study Objective	“Evaluate the efficacy and safety of Brenzavvy monotherapy”		
Study Design	Randomized, double-blind, multi-center, placebo-controlled trial		
Study Subjects	Adults with T2DM inadequately controlled (HbA1c 7-10.5 %)		
Intervention	Randomized 2:1 to Brenzavvy 20 mg PO once daily or placebo		
Primary Endpoint	Reduction in HbA1c		
Efficacy Results	Brenzavvy (N = 138)	Placebo (N = 69)	Difference (95% CI)
	• Mean baseline HbA1c: 8.1 • Change from baseline at 24 weeks: -0.5	• Mean baseline HbA1c: 7.9 • Change from baseline at 24 weeks: (-0.1)	-0.4 (-0.6 to -0.1)
Safety Results	None reported		
Additional Trials	NCT03259789; NCT02769481; NCT03115112; NCT02836873; NCT02558296; NCT05612594 (not yet recruiting, sleep apnea)		

Brenzavvy. Package insert. TheracosBio, LLC; 2023.
Adipose Dysfunction, Imaging, Physiology, and Outcomes with Sodium Glucose Cotransporter 2 Inhibitor (SGLT2i) for Sleep Apnea: The ADIPOSA Study (ADIPOSA). ClinicalTrials.gov identifier: NCT05612594. Updated February 5, 2024. Accessed February 6, 2024. https://clinicaltrials.gov/study/NCT05612594

Jesduvroq®

daprodustat (DAP-roe-DOO-stat)

Approval Date	2/1/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Anemia due to chronic kidney disease
Class	Hypoxia-inducible factor prolyl hydroxylase inhibitor
Mechanism of Action	Causes stabilization and nuclear accumulation of HIF-1a and HIF-2a transcription factors by increasing the transcription of HIF responsive genes through reversible inhibition of HIF-PH1, PH2, and PH3
Common Adverse Events (>10%)	Exacerbation of hypertension (24%; serious 3%), abdominal pain (11%)
Dosage Forms	Tablet
Clinical Pearls	● Ensure patient has adequate iron stores before initiating and during therapy ● Administer without regard to meals ● Swallow tablet whole; do not cut, chew, or crush
Cost (WAC)	30 count of 1 mg tablets, $117.30; 30 count of 2 mg tablets, $234.60; 30 count of 4 mg tablets, $469.20; 30 count of 6 mg tablets, $703.80; 30 count of 8 mg tablets, $938.40

Daprodustat. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 29, 2024. Accessed January 30, 2024. https://online.lexi.com
Jesduvroq. Package insert. GlaxoSmithKline LLC; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Jesduvroq®: Clinical Trials

Study	Singh AK, Carroll K, Perkovic V, et al. Daprodustat for the treatment of anemia in patients undergoing dialysis. *N Engl J Med*. 2021;385(25):2325-2335. doi:10.1056/NEJMoa2113379
Study Objective	“evaluate the safety and efficacy of daprodustat”
Study Design	Phase 3, randomized, open-label, noninferiority, multi-center, parallel-group, active-controlled study
Study Subjects	Adults with chronic kidney disease who have been treated with dialysis for at least 90 days and have had been treated with an ESA for at least 6 weeks with a hemoglobin level of 8.0 to 12.0 g/dL
Intervention	Randomized 1:1 to oral daprodustat or an injectable ESA
Primary Endpoint	Co-primary endpoints of mean change in hemoglobin level from baseline to average (weeks 28 to 52) and first occurrence of MACE

Jesduvroq. Package insert. GlaxoSmithKline LLC; 2023.
Singh AK, Carroll K, Perkovic V, et al. Daprodustat for the treatment of anemia in patients undergoing dialysis. *N Engl J Med*. 2021;385(25):2325-2335. doi:10.1056/NEJMoa2113379
Anemia studies in chronic kidney disease: erythropoiesis via a novel prolyl hydroxylase inhibitor daprodustat-dialysis (ASCEND-D). ClinicalTrials.gov identifier: NCT02879305. Updated December 3, 2021. Accessed February 9, 2024. https://clinicaltrials.gov/study/NCT02879305

Jesduvroq®: Clinical Trials

Efficacy Results	Daprodustat (N=1487)	ESA (N=1477)	Difference (95% CI) Hazard Ratio
	• Change in hemoglobin level from baseline to average (weeks 28 to 52): 0.28±0.02 • MACE: 374 (25.2%)	• Change in hemoglobin level from baseline to average (weeks 28 to 52): 0.10±0.02 • MACE: 394 (26.7%)	• 0.18 (0.12 to 0.24) • 0.93 (0.81 to 1.07)
Safety Results	• MACE (25.2% vs 26.7%) • Non-fatal stroke (2.0% vs 2.4%)	• Death any cause (16.4% vs 15.8%)	• Non-fatal myocardial infarction (6.8% vs 8.5%)
Additional Trials	NCT05682326 (recruiting), NCT05951192 (Active), 31 other completed trials, 3 terminated trials		

Jesduvroq. Package insert. GlaxoSmithKline LLC; 2023.
Singh AK, Carroll K, Perkovic V, et al. Daprodustat for the treatment of anemia in patients undergoing dialysis. *N Engl J Med*. 2021;385(25):2325-2335. doi:10.1056/NEJMoa2113379
Anemia studies in chronic kidney disease: erythropoiesis via a novel prolyl hydroxylase inhibitor daprodustat-dialysis (ASCEND-D). ClinicalTrials.gov identifier: NCT02879305. Updated December 3, 2021. Accessed February 9, 2024. https://clinicaltrials.gov/study/NCT02879305

Zavzpret®

zavegepant (za-VE-je-pant)

Approval Date	3/9/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Acute treatment for moderate to severe migraines
Class	Antimigraine agent; CGRP receptor antagonist
Mechanism of Action	Calcitonin gene related peptide receptor antagonist
Common Adverse Events (>10%)	Taste disorder (18%)
Dosage Forms	Intranasal spray
Clinical Pearls	● NOT for preventative migraine treatment ● Administer at the first sign of migraine attack ● Administer intranasal decongestants ≥1 hour after zavegepant
Cost (WAC)	6x (10 mg/1 spray) of nasal spray, $1,100.00

Zavegepant. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated December 1, 2023. Accessed January 30, 2024. https://online.lexi.com
Zavzpret. Package insert. Pfizer Laboratories Div Pfizer Inc; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Zavzpret®: Clinical Trials

Study	Lipton RB, Croop R, Stock DA, et al. Safety, tolerability, and efficacy of zavegepant 10 mg nasal spray for the acute treatment of migraine in the USA: a phase 3, double-blind, randomised, placebo-controlled multicentre trial. *Lancet Neurol*. 2023;22(3):209-217. doi:10.1016/S1474-4422(22)00517-8
Study Objective	"Test the safety and efficacy of zavegepant"
Study Design	Phase 3, double-blind, randomised, multicentre trial
Study Subjects	Adults who have had a history of migraine with/without aura for at least 1 year.
Intervention	Randomized 1:1 to zavegepant 10 mg nasal spray or placebo nasal spray
Primary Endpoint	Coprimary endpoints of pain freedom and freedom from the most bothersome symptom associated with migraine at 2 hours after first dose

Zavzpret. Package insert. Pfizer Laboratories Div Pfizer Inc; 2023.
Lipton RB, Croop R, Stock DA, et al. Safety, tolerability, and efficacy of zavegepant 10 mg nasal spray for the acute treatment of migraine in the USA: a phase 3, double-blind, randomised, placebo-controlled multicentre trial. *Lancet Neurol*. 2023;22(3):209-217. doi:10.1016/S1474-4422(22)00517-8
Randomized trial in adult participants with acute migraines. ClinicalTrials.gov identifier: NCT04571060. Updated April 24, 2023. Accessed February 9, 2024. https://clinicaltrials.gov/study/NCT04571060?term=NCT04571060&rank=1

Zavzpret®: Clinical Trials

Efficacy Results	Zavegepant 10 mg (N=623)	Placebo (N=646)	Difference from placebo
	• Pain free at 2 hours: 24% • Most bothersome symptom free at 2 hours: 40%	• Pain free at 2 hours: 15% • Most bothersome symptom free at 2 hours: 31%	• 8.8% (4.5 to 13.1);p<0.001 • 8.7% (3.4 to 13.9);p<0.001
Safety Results	• Reported AE (30% vs. 16%)	• Local irritation (23% vs. 7%)	• Dysgeusia (21% vs. 5%)
Additional Trials	NCT05989048 (Recruiting), NCT04804033 (Active), NCT06103734 (Not yet recruiting), 2 (Terminated), 6 (Completed)		

Zavzpret. Package insert. Pfizer Laboratories Div Pfizer Inc; 2023.
Lipton RB, Croop R, Stock DA, et al. Safety, tolerability, and efficacy of zavegepant 10 mg nasal spray for the acute treatment of migraine in the USA: a phase 3, double-blind, randomised, placebo-controlled multicentre trial. *Lancet Neurol*. 2023;22(3):209-217. doi:10.1016/S1474-4422(22)00517-8
Randomized trial in adult participants with acute migraines. ClinicalTrials.gov identifier: NCT04571060. Updated April 24, 2023. Accessed February 9, 2024. https://clinicaltrials.gov/study/NCT04571060?term=NCT04571060&rank=1

Rezzayo®

rezafungin (RE-za-FUN-jin)

Approval Date	3/22/2023 Type 1 - New Molecular Entity, PRIORITY; Orphan
Indication	Treatment of Candidemia and invasive candidiasis in adults
Class	Antifungal agent; echinocandin
Mechanism of Action	Causes osmotic instability and cellular lysis of the fungal cell walls of the *candida* species by decreasing glucagon content through the reduced formation of 1,3-beta-D-glucan due to rezafungins concentration-dependant inhibition of 1,3-beta-D-glucan synthase.
Common Adverse Events (>10%)	Hypokalemia (15%), fever (12%), diarrhea (11%)
Dosage Forms	IV solution
Clinical Pearls	● Missed dose instructions vary from ≤3 days, >3 days, and ≥2 weeks missed ● Infuse over 1 hour ● You can reduce infusion rate if an infusion reaction occurs
Cost (WAC)	200 mg IV solution, $1,950.00

Rezafungin. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated December 29, 2023. Accessed January 30, 2024. https://online.lexi.com
Rezzayo. Package insert. Melinta Therapeutics, LLC; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Rezzayo®: Clinical Trials

Study	Thompson GR 3rd, Soriano A, Cornely OA, et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial. *Lancet*. 2023;401(10370):49-59. doi:10.1016/S0140-6736(22)02324-8
Study Objective	Determine the efficacy and safety of intravenous rezafungin in the treatment of invasive candadiasis and/or candidemia when compared to caspofingin
Study Design	Randomized, double-blind, prospective, mulitcenter, double-dummy, non-inferiority phase 3 study
Study Subjects	Adults with signs of systemic candidaemia or invasive candidiasis
Intervention	Randomized 1:1 to IV rezafungin or IV caspofungin (followed by oral step down therapy)**
Primary Endpoint	Co-primary endpoints: global cure at the day 14 visit and 30 day all-cause mortality

Rezzayo. Package insert. Melinta Therapeutics, LLC; 2023.
Thompson GR 3rd, Soriano A, Cornely OA, et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial. *Lancet*. 2023;401(10370):49-59. doi:10.1016/S0140-6736(22)02324-8
Study of rezafungin compared to caspofungin in subjects with candidemia and/or invasive candidiasis (ReSTORE). ClinicalTrials.gov identifier: NCT03667690. Updated January 6, 2023. Accessed February 12, 2024. https://clinicaltrials.gov/study/NCT03667690?term=NCT03667690&rank=1

Rezzayo®: Clinical Trials

Efficacy Results	Rezafungin (N=93)	Caspofungin (N=94)	Difference (95% CI)
	• 30 day all-cause mortality: 23.7% • Global cure at day 14: 59.1%	• 30 day all-cause mortality: 21.3% • Global cure at day 14: 60.6%	• 2.4 (-9.7, 14.4) • -1.5 (-15.4, 12.5)
Safety Results	• 30 day all-cause mortality: 23.7% vs. 21.3% • Hypokalemia: 13% vs. 9%	• Patients with ≥ 1 adverse event: 91% vs. 85% • Pneumonia: 10% vs. 3%	• Pyrexia: 14% vs. 5% • Septic shock: 10% vs. 9%
Additional Trials	NCT05534529, NCT04368559 (recruiting), NCT05835479 (not yet recruiting), NCT04117607 (terminated), 5 completed		

Rezzayo. Package insert. Melinta Therapeutics, LLC; 2023.
Thompson GR 3rd, Soriano A, Cornely OA, et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial. *Lancet*. 2023;401(10370):49-59. doi:10.1016/S0140-6736(22)02324-8
Study of rezafungin compared to caspofungin in subjects with candidemia and/or invasive candidiasis (ReSTORE). ClinicalTrials.gov identifier: NCT03667690. Updated January 6, 2023. Accessed February 12, 2024. https://clinicaltrials.gov/study/NCT03667690?term=NCT03667690&rank=1

Assessment Question #1

Which novel drug did the FDA approve in 2023?

A. NexoBrid®
B. Cibinqo®
C. Sotyktu®
D. Leqembi®

Assessment Question #1: Correct Response

Which novel drug did the FDA approve in 2023?

A. NexoBrid®
B. Cibinqo®
C. Sotyktu®
D. Leqembi®

Veozah®

fezolinetant (FEZ-oh-LIN-e-tant)

Approval Date	5/12/2023 Type 1 - New Molecular Entity, PRIORITY
Indication	Vasomotor symptoms associated with menopause
Class	Neurokinin 3 receptor antagonist
Mechanism of Action	Modulates neuronal activity in the thermoregulatory center through neurokinin 3 receptor antagonist blocking neurokinin B binding on the kisspeptin/neurokinin B/dynorphin neuron
Common Adverse Events (1-10%)	Abdominal pain (4%), diarrhea (4%), insomnia (4%), hot flash (3%), back pain (3%), increased serum transaminases (2%)
Dosage Forms	Tablet
Clinical Pearls	● Administer close to the same time each day with liquids ● Test LFTs prior to starting treatment ● DO NOT begin treatment if patients ALT, AST, an/or total bilirubin is greater than or equal to 2x the upper normal limit
Cost (WAC)	30 count of 45 mg tablets, $550.00

Fezolinetant. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated December 5, 2023. Accessed January 30, 2024. https://online.lexi.com
Veozah. Package insert. Astellas Pharma US, Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

BELMONT UNIVERSITY
CHRISTY HOUSTON FOUNDATION DRUG INFORMATION CENTER

Veozah®: Clinical Trials

Study	Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. *Lancet*. 2023;401(10382):1091-1102. doi:10.1016/S0140-6736(23)00085-5
Study Objective	"Evaluate the efficacy of fezolinetant versus placebo on the frequency and severity of moderate-to-severe vasomotor symptoms."
Study Design	Randomised, double-blind, placebo-controlled, phase 3 trial
Study Subjects	Women 40-65 years of age experiencing an average of ≥ 7 moderate to severe hot flashes a day
Intervention	Randomized 1:1:1 to fezolinetant 30 mg orally once daily, fezolinetant 45 mg orally once daily, or matching placebo
Primary Endpoint	Coprimary endpoints: mean change in frequency of moderate-to-severe vasomotor symptoms from baseline to weeks 4 and 12, mean change in severity of moderate-to-severe vasomotor symptoms from baseline to weeks 4 and 12.

Veozah. Package insert. Astellas Pharma US, Inc.; 2023.
Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. *Lancet*. 2023;401(10382):1091-1102. doi:10.1016/S0140-6736(23)00085-5
A study to find out if fezolinetant helps reduce moderate to severe hot flashes in women going through menopause (Skylight 1). ClinicalTrials.gov identifier: NCT04003155. Updated September 6, 2023. Accessed February 12, 2024. https://clinicaltrials.gov/study/NCT04003155?term=NCT04003155&rank=1

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Veozah®: Clinical Trials

Efficacy Results	Fezolinetant 45 mg (N=174)	Placebo (N=175)	
	• Baseline Mean: 10.4 • Mean frequency change from baseline to week 4: -5.4 • Difference vs Placebo (95% CI): -2.1 (-2.9, -1.3) • P value vs placebo:<0.001 • Baseline Mean: 10.4 • Mean frequency change from baseline to week 12: -6.4 • Difference vs Placebo (95% CI): -2.6 (-3.4, -1.7) • P value vs placebo: <0.001 • Baseline Mean: 2.4 • Mean severity change from baseline to week 4: -0.5 • Difference vs Placebo (95% CI): -0.2 (-0.3, -0.1) • P value vs placebo: 0.002 • Baseline Mean: 2.4 • Mean severity change from baseline to week 12: -0.6 • Difference vs Placebo (95% CI): -0.2 (-0.4, -0.1) • P value vs placebo: 0.007	• Baseline Mean: 10.5 • Mean frequency change from baseline to week 4: -3.3 • Baseline Mean: 10.5 • Mean frequency change from baseline to week 12: -3.9 • Baseline Mean: 2.4 • Mean severity change from baseline to week 4: -0.3 • Baseline Mean: 2.4 • Mean severity change from baseline to week 12: -0.4	
Safety Results	• Headache: 6% vs. 7% • Depression : 2% vs. 1%	• Blood glucose increase: 3% vs. 0% • Any TEAE: 43% vs 45%	• Liver test elevations: 4% vs. 3%
Additional Trials	NCT06049797 (recruiting), NCT06206408 and NCT06206421 (not yet recruiting), 15 (completed)		

Veozah. Package insert. Astellas Pharma US, Inc.; 2023.
Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. *Lancet*. 2023;401(10382):1091-1102. doi:10.1016/S0140-6736(23)00085-5
A study to find out if fezolinetant helps reduce moderate to severe hot flashes in women going through menopause (Skylight 1). ClinicalTrials.gov identifier: NCT04003155. Updated September 6, 2023. Accessed February 12, 2024. https://clinicaltrials.gov/study/NCT04003155?term=NCT04003155&rank=1

Miebo®

perfluorhexyloctane (per-FLOOR-oh-HEX-il-OK-tane)

Approval Date	5/18/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Dry eye disease
Class	Ophthalmic agent; ophthalmic semifluorinated alkane
Mechanism of Action	Reduces evaporation by forming a monolayer at the air-liquid interface of the tear film
Common Adverse Events (1-10%)	Blurred vision (1-3%), conjunctival erythema (1-3%)
Dosage Forms	Ophthalmic solution
Clinical Pearls	● Remove contact lenses before administration and wait at least 30 minutes before putting them back in.
Cost (WAC)	3 mL of the solution, $771.00

Perfluorhexyloctane. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated May 18, 2023. Accessed January 30, 2024. https://online.lexi.com
Miebo. Package insert. Bausch & Lomb Incorporated; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Miebo®: Clinical Trials

Study	Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for dry eye disease associated with meibomian gland dysfunction: results of the randomized phase 3 GOBI study. *Ophthalmology*. 2023;130(5):516-524. doi:10.1016/j.ophtha.2022.12.021		
Study Objective	"To evaluate the efficacy and safety of perfluorhexyloctane"		
Study Design	Randomized, multicenter, double-masked, phase 3 trial		
Study Subjects	Adults with a self reported history of dry eye disease in both eyes for 6 months or more		
Intervention	Randomized 1:1 to NOVO3 or hypotonic saline solution instill 1 drop to eye 4 times a day for 8 weeks		
Primary Endpoint	Coprimary endpoints of change from baseline at week 8 in total corneal fluorescein staining score and VAS eye dryness score		
Efficacy Results	Perfluorhexyloctane (N=286)	Saline solution (N=279)	Difference (95% CI) P-value
	• Change from baseline to week 8 in tCFS score: -2.0 • Change from baseline to week 8 in VAS dryness score: -27.4	• Change from baseline to week 8 in tCFS score: -1.0 • Change from baseline to week 8 in VAS dryness score: -19.7	• tCFS score difference: -7.6 (-11.8, -3.4) ○ P <0.001 • VAS dryness difference: -0.97 (-1.40, -0.55) ○ P <0.001
Safety Results	• ≥ 1 ocular AE: 9.6% vs. 7.5% • Conjunctival hemorrhage: 0.3% vs. 1.4%	• Blurred vision: 3.0% vs. 0.3% • Eye discharge: 1.0% vs. 0%	• Instillation site pain: 1.0% vs. 1.0%
Additional Trials	NCT06176651 (recruiting),NCT05723770 (not yet recruiting), 7 completed		

Miebo. Package insert. Bausch & Lomb Incorporated; 2023.
Tauber J, Berdy GJ, Wirta DL, Krösser S, Vittitow JL; GOBI Study Group. NOV03 for dry eye disease associated with meibomian gland dysfunction: results of the randomized phase 3 GOBI study. *Ophthalmology*. 2023;130(5):516-524. doi:10.1016/j.ophtha.2022.12.021
Perfluorohexyloctane (NOV03) for the treatment of signs and symptoms of dry eye disease associated with meibomian gland dysfunction (gobi study). ClinicalTrials.gov identifier: NCT04139798. Updated March 16, 2022. Accessed February 12, 2024. https://clinicaltrials.gov/study/NCT04139798?term=NCT04139798&rank=1

Xacduro®

sulbactam and durlobactam

Approval Date	5/23/2023 Type 1 - New Molecular Entity and Type 4 - New Combination, PRIORITY
Indication	Hospital acquired or ventilator associated pneumonia
Class	Antibiotic, beta-lactam; beta-lactamase inhibitor
Mechanism of Action	The sulbactam binds to penicillin binding proteins 1 and 3 which inhibit bacterial cell wall synthesis and the durlobactam protects sulbactam from degrading by serine beta lactamases.
Common Adverse Events (>10%)	Abnormal hepatic function tests (19%), diarrhea (17%), anemia (13%), hypokalemia (12%)
Dosage Forms	IV solution
Clinical Pearls	• Only indicated for *Acinetobacter baumannii-calcoaceticus* • Reconstituted prior to administration; compatible with 0.9% NaCl • Stored refrigerated • Administered every 6 hours; infused over 3 hours; 7-14 days of therapy • For altered renal function, dosage adjustments (frequency) begin at ≤44 mL/minute • Sound-alike/look-alike issues with ampicillin and sulbactam • DDI with OAT1 inhibitors
Cost (WAC)	3 x (500 mg durlobactam; 1 gm sulbactam) vials of IV solution, $475.00

Sulbactam and durlobactam. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated October 17, 2023. Accessed January 30, 2024. https://online.lexi.com
Xacduro. Package insert. LaJolla Pharmaceutical Company; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Xacduro®: Clinical Trials

Study	Kaye KS, Shorr AF, Wunderink RG, et al. Efficacy and safety of sulbactam-durlobactam versus colistin for the treatment of patients with serious infections caused by *Acinetobacter baumannii-calcoaceticus* complex: a multicentre, randomised, active-controlled, phase 3, non-inferiority clinical trial (ATTACK). *Lancet Infect Dis*. 2023;23(9):1072-1084. doi: 10.1016/S1473-3099(23)00184-6		
Study Objective	"Evaluate the efficacy and safety of sulbactam-durlobactam compared with colistin, both in combination with imipenem-cilastatin as background therapy, for the treatment of patients with serious infections caused by ABC, including carbapenem-resistant ABC."		
Study Design	Phase 3, multinational, randomised, active-controlled, non-inferiority trial		
Study Subjects	Adults with hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, ventilated pneumonia, or bloodstream infections caused by ABC		
Intervention	Randomised 1:1 to receive sulbactam-durlobactam plus imipenem-cilastatin OR colistin plus imipenem-cilastatin for 7-14 days		
Primary Endpoint	28 day all-cause mortality		
Efficacy Results	Sulbactam-durlobactam (N= 63)	Colistin (N=62)	Difference, % (95% CI)
	• 28-day ACM: 12 (19.0%)	• 28-day ACM: 20 (32.3%)	-13.2% (-30.0 to 3.5)
Safety Results	• Hypersensitivity reaction (16% vs 12%) • Emergent infection (19% vs 29%)	• *C. diff* (1% vs 7%) • AEs leading to discontinuation (11% vs 16%)	
Additional Trials	N/A		

Xacduro. Package insert. LaJolla Pharmaceutical Company; 2023.

Inpefa®

sotagliflozin (SOE-ta-gli-FLOE-zin)

Approval Date	5/26/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Cardiovascular risk reduction and heart failure
Class	SGLT1 inhibitor; SGLT2 inhibitor
Mechanism of Action	While the mechanism for cardiovascular benefits have not been established, the SGLT1 inhibition reduces glucose and sodium intestinal reabsorption and the SGLT2 inhibition reduces glucose and sodium renal reabsorption which may decrease cardiac preload/afterload and downregulate sympathetic activity.
Common Adverse Events (>10%)	UTI (9-12%)
Dosage Forms	Tablet; 200 mg and 400 mg
Clinical Pearls	● If present, hypovolemia should be corrected before initiating therapy ● Administer at least 1 hour before first meal of the day ● On the Beers Criteria, caution in patients ≥65 year old ● DDI with digoxin - monitor digoxin levels
Cost (WAC)	30 count of 400 mg tablets, $598.00; 30 count of 200 mg tablets, $598.00

Sotagliflozin. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated December 5, 2023. Accessed January 30, 2024. https://online.lexi.com
Inpefa. Package insert. Lexicon Pharmaceuticals, Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Inpefa®: Clinical Trials

Study	Bhatt DL, Szarek M, Steg PG, et al. Sotagliflozin in patients with diabetes and recent worsening heart failure. *N Engl J Med*. 2021;384(2): 117-128. doi: 10.1056/NEJMoa2030183		
Study Objective	To determine “whether sotagliflozin would reduce the risks of death from cardiovascular causes, hospitalization for heart failure, and an urgent visit for heart failure among patients with diabetes mellitus and recent worsening of HFpEF or HFrEF when administered soon after a HF episode.”		
Study Design	Phase 3, double-blind, randomized, placebo-controlled trial		
Study Subjects	Adults with T2DM hospitalized with present symptoms of heart failure and received treatment with IV diuretic therapy		
Intervention	Randomized to receive either sotagliflozin 200 mg PO once daily (dose increase to 400 mg if tolerated) or placebo		
Primary Endpoint	Deaths from cardiovascular causes and hospitalizations and urgent visits for heart failure		
Efficacy Results	Sotagliflozin (N = 608)	Placebo (N = 355)	Hazard ratio (95% CI)
	• 245 (51.0%)	• 355 (76.3%)	0.67 (0.52 - 0.85)
Safety Results	• Cardiac failure (18.5% vs 26.4%)	• TEAE leading to discontinuation (4.8% vs 3.8%)	• UTI (4.8% vs 5.1%)
Additional Trials	SCORED Study (NCT03315143)		

Inpefa. Package insert. Lexicon Pharmaceuticals, Inc.; 2023.
Bhatt DL, Szarek M, Steg PG, et al. Sotagliflozin in patients with diabetes and recent worsening heart failure. N Engl J Med. 2021;384(2): 117-128. doi: 10.1056/NEJMoa2030183

Beyfortus®

nirsevimab-alip (nir-SEV-i-mab)

Approval Date	7/17/2023 N/A
Indication	RSV prevention
Class	Immune globulin; monoclonal antibody
Mechanism of Action	RSV F protein directed fusion inhibitor, a human immunoglobulin kappa monoclonal antibody that has anti respiratory syncytial virus activity which provides passive immunization for RSV
Common Adverse Events (<1%)	Skin rash (0.9%), injection-site reaction (0.3%)
Dosage Forms	IM injection solution
Clinical Pearls	● Neonates/infants entering first RSV season; children up to 24 months vulnerable to RSV through second RSV season ● As of October 2023, the CDC warns that Beyfortus® is in a limited supply ● After removal from refrigeration, medication must be used within 8 hours
Cost (WAC)	1 mL of 100 mg/1 mL IM solution, $495.00; 5x (1 mL) syringes of 100 mg/1 mL IM solution, $2,475.00; 5x (0.5 mL) syringes of 50 mg/0.5 mL IM solution, $2,475.00; 0.5 mL of 50 mg/0.5 mL IM solution, $495.00

Nirsevimab. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 2, 2024. Accessed January 30, 2024. https://online.lexi.com
Beyfortus. Package insert. Sanofi Pasteur Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Beyfortus®: Clinical Trials

Study	Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for prevention of RSV in healthy late-preterm and term infants. *N Engl J Med*. 2022;386(9): 837-846. doi: 10.1056/NEJMoa2110275		
Study Objective	"Evaluate the efficacy and safety of nirsevimab in healthy late-preterm and term infants entering their first RSV season"		
Study Design	Phase 3, multicenter, randomized, placebo-controlled trial		
Study Subjects	Healthy infants born at gestational age (35 weeks 0 days), ≤ 1 year of age, entering their first RSV season		
Intervention	Randomized 2:1 to receive either nirsevimab IM once (50 mg <5 kg or 100 mg ≥5 kg) or placebo		
Primary Endpoint	Medically attended RSV-associated lower respiratory tract infection through 150 days after the injection		
Efficacy Results	Nirsevimab (N = 994)	Placebo (N = 496)	Efficacy* (95% CI)
	• 12 (1.2%)	• 25 (5.0%)	74.5 (49.6 to 87.1)
Safety Results	• Pyrexia (12.7% vs 11.0%)	• Nasal Congestion (12.1% vs 13.6%)	
Additional Trials	NCT02878330; NCT03959488		

*Defined as the calculated relative risk reduction

Beyfortus. Package insert. Sanofi Pasteur Inc.; 2023.

Assessment Question #2

What is the available dosage form of Beyfortus (nirsevimab-alip)?

A. Intra Articular Injection solution
B. Intramuscular injection solution
C. Intravenous solution
D. Intranasal spray

Assessment Question #2: Correct Response

What is the available dosage form of Beyfortus (nirsevimab-alip)?

A. Intra Articular Injection solution
B. Intramuscular injection solution
C. Intravenous solution
D. Intranasal spray

Zurzuvae®

zuranolone (zoo-RAN-oh-lone)

Approval Date	8/4/2023 Type 1 - New Molecular Entity, PRIORITY
Indication	Treatment of postpartum depression in adults
Class	Antidepressant; GABA A receptor positive modulator
Mechanism of Action	While the mechanism of action is not completely understood, it is thought to be due to positive allosteric modulation of GABA A receptors
Common Adverse Events (>10%)	Diarrhea (6%), UTI (5%), fatigue (5%;including asthenia), memory impairment (3%), abdominal pain (3%), skin rash (2%), anxiety (2%), temor (2%), muscle twitching (2%), myalgia (2%)
Dosage Forms	Capsule
Clinical Pearls	● May cause impaired driving, advise patients not to drive until atleast 12 hours after administration ● Major psychiatric warning; increased risk of suicidal thinking and behavior ● Medication has abuse potential, as such is a schedule C-IV medication ● Administer with fat-containing food, in the evening for 14 days ● Dose adjusted in hepatic and renal impairment ● DDI with CYP3A4 inhibitors (dose adjust) and inducers (avoid)
Cost (WAC)	14 count of the 20 mg capsules, $7,950.00; 28 count of the 25 mg capsules, $15,900; 14 count of the 30 mg capsules, $15,900

Zuranolone. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 22, 2024. Accessed January 30, 2024. https://online.lexi.com
Zurzuvae. Package insert. Biogen MA Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

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Zurzuvae®: Clinical Trials

Study	Deligiannidia KM, Meltzer-Brody S, Gunduz-Bruce H, et al. Effect of zuranolone vs placebo in postpartum depression: a randomized clinical trial. *JAMA Psychiatry*. 2021;78(9):951-959. doi: 10.1001/jamapsychiatry.2021.1559		
Study Objective	"Compare the efficacy and safety of zuranolone vs placebo in the outpatient treatment of adult women with PPD"		
Study Design	Phase 3, double-blind, randomized, placebo-controlled clinical trial		
Study Subjects	Adult females, 18-45 years old, 6 months or less postpartum with major depressive episode without psychosis		
Intervention	Randomized 1:1 to receive either zuranolone 30 mg PO once in the evening or placebo for 2 weeks		
Primary Endpoint	Change from baseline in HAMD-17 total score (0 to > 24) at day 15		
Efficacy Results	Zuranolone (N=76)	Placebo (N=74)	Difference (95% CI)
	• -17.8 points	• -13.6 points	-4.2 (-6.9 to -1.5)
Safety Results	• Somnolence (15% vs 11%)	• Headache (9% vs 12%)	• Dizziness (8% vs 6%)
Additional Trials	NCT04442503		

Zurzuvae. Package insert. Biogen MA Inc.; 2023.

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Exxua®

gepirone

Approval Date	9/22/2023 Type 1 - New Molecular Entity, STANDARD
Indication	Treatment of unipolar major depressive disorder in adults
Class	Antidepressant, serotonin 5-HT1A receptor agonist
Mechanism of Action	While the mechanism of action is not fully understood, it is thought to be related to major metabolite activity at the alpha-2 receptor and the modulation serotonergic activity in the CNS by the parent drug.
Common Adverse Events (>10%)	Dizziness (49%), nausea (35%), headache (31%), drowsiness (≤15%), fatigue (≤15%), insomnia (14%)
Dosage Forms	Extended-release tablet
Clinical Pearls	• Can prolong the QTc interval; perform an ECG at baseline and during therapy; do not initiate if QTc > 450 msec • Major psychiatric warning; increased risk of suicidal thinking and behavior • High fat meals around 850 calories increase the peak plasma concentration • Titratable depending on response and tolerability • Dose-adjust by 50% when given with a moderate CYP3A4 inhibitor • 14 day washout period with MAOI • Increased risk of serotonin syndrome when administered with other serotonergic agents
Cost (WAC)	Unavailable

Gepirone. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 23, 2024. Accessed January 30, 2024. https://online.lexi.com
Exxua. Package insert. Fabre Kramer Pharmaceuticals, Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

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Exxua®: Clinical Trials

Study	“Study 1” - per Package Insert		
Study Objective	Evaluate the efficacy of gepirone for the treatment of major depressive disorder in adults		
Study Design	Eight-week, randomized, double-blind, placebo-controlled, flexible-dose study		
Study Subjects	Adults who met DSM-IV diagnostic criteria for MDD		
Intervention	Received either 18.2 mg gepirone PO once daily (*titrated) or placebo once daily for 8 weeks		
Primary Endpoint	Change from baseline in the HAMD-17 total score at week 8		
Efficacy Results	Gepirone (N = 101)	Placebo (N = 103)	Difference (95% CI)
	• Mean baseline score: 22.7 • Mean change from baseline (SE): -9.04 (0.78)	• Mean baseline score: 22.8 • Mean change from baseline (SE): -6.75 (0.77)	-2.47 (-4.41 to -0.53)
Safety Results	• Dizziness (49% vs 10%) • Sleepy or tired (15% vs 14%)	• Nausea (35% vs 13%) • Insomnia (14% vs 5%)	• Headache (31% vs 20%)
Additional Trials	“Study 2” - per Package Insert		

*18.2 mg once daily, titrated to 36.3 mg (17%) on day 4, could then be further titrated to 54.5 mg (20%) after day 7, and to 72.6 mg (64%) after an additional 7 days.

Exxua. Package insert. Fabre Kramer Pharmaceuticals, Inc.; 2023.

Omvoh®

mirikizumab-mrkz (MIR-i-KIZ-ue-mab)

Approval Date	10/26/2023 N/A; Orphan
Indication	Treatment of moderate to severe acute ulcerative colitis in adults
Class	IL-23 inhibitor; monoclonal antibody
Mechanism of Action	Inhibits the release of proinflammatory chemokines and cytokines by inhibiting the interaction between the p19 subunit of human IL-23 cytokine
Common Adverse Events (>10%)	Infection (15-24%), URTI (8-14%)
Dosage Forms	IV solution for induction phase; SubQ injection solution for maintenance phase
Clinical Pearls	● Patients with untreated, active infections should not start or continue treatment ● Prior to initiation: evaluate for TB, obtain liver enzyme levels, and receive all up to date immunizations ● Administer over at least 30 minutes ● Induction: 300 mg at weeks 0, 4, and 8 ● Maintenance: 200 mg (2 100 mg infections) at week 12, and every 4 weeks thereafter ● Monitor for hepatotoxicity
Cost (WAC)	15 mL of the 20 mg/1 mL IV solution $9,593.22; 2x (1 mL) syringes of the 100 mg/1 mL SUBQ solution $10,360.67

Mirikizumab. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 23, 2024. Accessed January 30, 2024. https://online.lexi.com
Omvoh. Package insert. Eli Lilly and Company; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

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Omvoh®: Clinical Trials

Study	NCT03518086		
Study Objective	Evaluate the safety and efficacy of Omvoh		
Study Design	Randomized, double-blind, placebo-controlled clinical trial		
Study Subjects	Adults with moderately to severely active ulcerative colitis who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib.		
Intervention	Randomized 3:1 to receive Omvoh 300 mg IV or placebo at week 0, week 4, and week 8		
Primary Endpoint	Clinical remission at week 12 based on the modified Mayo score (0-9)		
Efficacy Results	Omvoh (N = 795)	Placebo (N = 267)	Difference (95% CI)
	● 191 (24%)	● 41 (15%)	10 % (5.0 to 10.0)
Safety Results	● URTI (8% vs 6%)	● Arthralgia (2% vs 1%)	
Additional Trials	NCT03524092 (maintenance phase)		

Omvoh. Package insert. Eli Lilly and Company; 2023.

Defencath®

taurolidine and heparin

Approval Date	11/15/2023 Type 1 - New Molecular Entity and Type 4 - New Combination, PRIORITY
Indication	Prevention of catheter related bloodstream infections (only in patients with kidney failure on chronic hemodialysis with a central venous catheter)
Class	Antibiotic; anticoagulant
Mechanism of Action	Taurolidine acts as the antibiotic and inhibits adherence of microorganisms to biological surfaces by damaging the microbial cell walls. Heparin acts as the anticoagulant and prevents the conversion of fibrinogen to fibrin by inactivating thrombin through the process of potentiating the action of antithrombin III.
Common Adverse Events (1-10%)	Nausea (7%), hemorrhage (7%), vomiting (6%), dizziness (6%), musculoskeletal chest pain (3%), thrombocytopenia (2%)
Dosage Forms	Intracatheter solution
Clinical Pearls	● Instillation into CVCs only ● Not intended for systemic administration ● Contraindicated with a history of HIT
Cost (WAC)	Unavailable

Taurolidine and heparin. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 23, 2024. Accessed January 30, 2024. https://online.lexi.com
Defencath. Package insert. CorMedix Inc.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Defencath®: Clinical Trials

Study	Agarwal AK, Roy-Chaudhury P, Mounts P, Hurlburt E, Pfaffle A, Poggio EC. Taurolidine/heparin lock solution and catheter-related bloodstream infection in hemodialysis: a randomized, double-blind, active-control, phase 3 study. *CJASN*. 18(11);2023:1446-1455. doi: 10.2215/CJN.0000000000000278		
Study Objective	"Evaluate the efficacy and safety of taurolidine/heparin catheter lock solution compared with heparin control for the prevention of CRBSIs in participants with kidney failure receiving hemodialysis via CVC"		
Study Design	Randomized, double-blind, active-control, multicenter, phase 3 study		
Study Subjects	Adults undergoing hemodialysis ≥ 2 times per week with catheters in place for ≥ 14 days		
Intervention	Randomized 1:1 to receive either taurolidine/heparin 13.5 mg/mL/1000 units/mL lock solution or heparin 1000 units/mL lock solution		
Primary Endpoint	Time to CRBSI		
Efficacy Results	Taurolidine/heparin (N = 327)	Heparin (N = 326)	Hazard ratio (95% CI)
	• Participants with CRBSI at interim: 6 (2%)	• Participants with CRBSI at interim: 22 (7%)	0.28 (0.11 to 0.70)
Safety Results	• Hemodialysis catheter malfunction (17% vs 12%)	• Hemorrhage/bleeding (7% vs 9%)	• Nausea (7% vs 11%)
Additional Trials	N/A		

Defencath. Package insert. CorMedix Inc.; 2023.

Ryzneuta®

efbemalenograstim alfa-vuxw

Approval Date	11/16/2023 N/A
Indication	Prevention of chemotherapy induced neutropenia in patients with nonmyeloid malignancies
Class	Colony stimulating factor; hematopoietic agent
Mechanism of Action	A colony stimulating factor that stimulates proliferation, differentiation, commitment, and end cell functional activation by binding to specific receptors on hematopoietic cells.
Common Adverse Events (>10%)	Nausea (51%), anemia (15%), thrombocytopenia (11%-12%)
Dosage Forms	SubQ injection
Clinical Pearls	● Do not use within 14 days before or less than 24 hours after cytotoxic chemotherapy ● May interfere with bone imaging studies ● Monitor CBC and platelets during therapy ● Contraindicated in those with a history of serious allergic reactions to granulocyte stimulating factors
Cost (WAC)	Unavailable

Efbemalenograstim alfa. Lexi-Drugs. Lexicomp. UpToDate, Inc.; 2024. Updated January 18, 2024. Accessed January 30, 2024. https://online.lexi.com
Ryzneuta. Package insert. Evive Biotechnology Singapore PTE. LTD.; 2023.
Drugs@FDA: FDA-approved drugs. US. Food & Drug Administration. Accessed January 30, 2024. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
Merative Micromedex Red Book. Merative Micromedex. Merative; 2024. Accessed January 30, 2024. https://www.micromedexsolutions.com/

Ryzneuta®: Clinical Trials

Study	Glaspy J, Bondarenko I, Burdaeva O, et al. Efbemalenograstim alfa, an Fc fusion protein, long-acting granulocyte-colony stimulating factor for reducing the risk of febrile neutropenia following chemotherapy: results of a phase III trial. *Support Care Cancer*. 2024;32(1): 1-9. doi: 10.1007/s00520-023-08176-6		
Study Objective	"Evaluate the efficacy and safety of a single fixed dose of efbemalenograstim alfa in reducing the risk for FN in breast cancer patients receiving myelosuppressive chemotherapy"		
Study Design	Phase 3, multicenter, randomized, double-clind, placebo-controlled study		
Study Subjects	Females between 18-75 years diagnosed with stage II-IV breast cancer in the adjuvant or metastatic setting with an ECOG performance status ≤ 2 and were scheduled for myelotoxic TA regimen		
Intervention	Randomized 2:1 to receive either a single 20 mg dose of efbemalenograstim alfa or placebo on day 2 of cycle 1		
Primary Endpoint	DSN (number of days in which the subject had an ANC < 0.5 x 10^9/ L in cycle 1)		
Efficacy Results	efbemalenograstim alfa (N = 83)	Placebo (N = 39)	Difference (95% CI)
	• Mean DSN: 1.3 days	• Mean DSN: 3.9 days	2.9 (2.3 to 3.4)
Safety Results	• Neutropenia (65.1% vs 64.1%)	• Nausea (50.6% vs 38.5%)	• Leukopenia (45.8% vs 38.5%)
Additional Trials	NCT03252431		

Ryzneuta. Package insert. Evive Biotechnology Singapore PTE. LTD.; 2023.

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Assessment Question #3

What is the indication of zuranolone?

A. Treatment of postpartum depression in adults
B. Prevention of chemotherapy induced neutropenia in patients with nonmyeloid malignancies
C. Treatment of moderate to severe acute ulcerative colitis in adults
D. Treatment of unipolar major depressive disorder in adults

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Assessment Question #3: Correct Response

What is the indication of zuranolone?

A. Treatment of postpartum depression in adults

B. Prevention of chemotherapy induced neutropenia in patients with nonmyeloid malignancies

C. Treatment of moderate to severe acute ulcerative colitis in adults

D. Treatment of unipolar major depressive disorder in adults

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Thank you!

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