New Drug Update 2026: CNS, Behavioral Health, Musculoskeletal, Immunology, Oncology, & Ocular/Derm

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Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

OPA Annual Conference & Trade Show April 9-11, 2026

OHIO PHARMACISTS ASSOCIATION

Disclosure Statement

- Karen L. Kier has no relevant financial relationships with ineligible companies to disclose.

  and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. review the pharmacology and therapeutics of selected prescription medications released to the market within the past year;
2. state the indications and clinical applications of the medications presented, and how they compare to current therapies;
3. list the most common adverse effects, toxicities, and significant drug-drug and drug-food interactions reported; and
4. explain important patient/caregiver counseling information for these medications.

CNS

Dihydroergotamine mesylate (Atzumi) Nasal Powder

Migraine

April 30, 2025 Satsuma Pharmaceuticals

- Nasal powder formulation of the ergotamine derivative dihydroergotamine mesylate for the acute treatment of migraine with and without aura
- Unique nasal delivery device
- Do **not** use within 24 hours of triptans or another ergotamine product
- Screen for CV disease prior to use
- Single-dose nasal device contains 5.2 mg of dihydroergotamine (equivalent to 6.0 mg dihydroergotamine mesylate).
- Nasal powder designed to be administered into one nostril using a, prefilled, *non-priming* device
- Recommended dose is 5.2 mg with a second 5.2 mg dose taken if needed, at least 1 hour after the first dose
- Maximum dose
- No more than 4 doses within a 7 days or 12 doses within 30 days
- Better absorption with high peaks, more reliable levels
- ADRs: nasal congestion, dysgeusia, nasal discomfort

Dihydroergotamine mesylate (Brekiya) Injection

Migraine, Cluster Headaches

May 14, 2025 Amneal Pharmaceuticals

- Ready-to-use autoinjector of dihydroergotamine mesylate for acute treatment of migraine and the acute treatment of cluster headaches
- Does *NOT* require refrigeration, assembly, or priming of device
- DDI: Serious or potentially life-threatening reductions in blood flow to the brain or extremities due to interactions between dihydroergotamine with strong CYP3A4 inhibitors (protease inhibitors and macrolide antibiotics) have been reported rarely
- Avoid in pregnancy, can induce labor
- Evaluate for pre-existing CV disease

Dihydroergotamine mesylate (Brekiya) Injection

- First dose in HC provider setting
- Each autoinjector contains 1mg (one dose)
- If headache returns after the first complete dose, a 2nd dose and 3rd dose can be given
- Wait at least one hour between doses.
- **Do not** inject more than 3 doses (3 mg) in a 24-hour period or 6 doses (6 mg) in 7-day period.
- Can cause a flare of Raynaud's
- Increases risk of stroke in those with CV disease
- Can cause medication overuse headache if taken too often
- Store at room temperature, do not refrigerate or freeze

Ketamine hydrochloride (KETARx) Injection

Pain

August 7, 2025

PharmaTher Holdings

- General anesthetic for surgical pain management
- Racemic mixture
- 3rd attempt for FDA approval
- Class III controlled substance
- IV or IM
- 10mg/mL, 50mg/mL, 100mg/mL (needs diluted)

Lidocaine (Bondlido) Topical System

Postherpetic Neuralgia

September 25, 2025 MEDRx Co

- Amide local anesthetic topical system in adults for relief of pain associated with post-herpetic neuralgia
- 10% Rx patch with Ionic Liquid Transdermal System technology
- Ionic liquid is a salt with a melting point of not more than 100ºC and is called a room temperature molten salt
- Properties include a low melting point, high ion conductivity, high polarity, non-volatility and noncombustibility
- Stronger film adhesion with less skin irritation
- Do not apply to broken or damaged skin
- Apply on **dry skin** 12 hours of 24 hour period, maximum of 2 patches at one time
- Remove before getting wet including showering and swimming
- Released first half of 2026

Nipocalimab-aahu (Imaavy) Injection

Myasthenia Gravis

April 29, 2025 Johnson & Johnson

- Neonatal Fc receptor (FcRn) blocker for treatment of generalized myasthenia gravis
- Novel mechanism of action
- Adults and pediatric patients 12 years of age and older who are anti-acetylcholine receptor or anti-muscle-specific kinase antibody positive (about 90% of MG patients)
- Evaluate vaccination history prior to administration with no live vaccines once therapy has started
- 30 mg/kg IV single dose then 15 mg/kg IV every 2 weeks, starting 2 weeks after initial dose
- Initial dose infused over 30 minutes and maintenance dose over 15 minutes

Nipocalimab-aahu (Imaavy) Injection

- ADRs: infusion-related (polysorbate 80), increase risk of infections (43%), muscle spasms, peripheral edema, increased LDL, decreased HDL, neutralizing antibody formation
- DDI: Strong CYP3A4 inducers
- Drug crosses placenta, pregnancy data unknown, company has pregnancy registry
- Vivacity-MG3 study showed superior disease control throughout 24 weeks when compared to placebo plus standard of care, as measured by improvement in the MG-ADLb score
- Improvements continued through 20 months with open-label extension study
- Similar results were since in Vibrance Phase 2/3 pediatric study

Tradipitant (Nereus) Capsules

Motion Sickness
December 30, 2025

Vanda Pharmaceuticals

- Substance P/neurokinin-1 (NK-1) receptor antagonist for **prevention** of motion sickness in adults
- interrupts nausea signal to the brain
- First new drug for motion sickness in 40 years
- 25-30% of population has motion sickness
- MOA for prescription drugs used for N&V of chemotherapy and PONV
- Real world studies—put people with hx of motion sickness on boats off the US coast!
- Tradipitant vomiting rates 10-20% vs placebo 40-50%

Tradipitant (Nereus) Capsules

- CYP3A4 substrate--strong CYP3A4 inhibitors may increase tradipitant
- Must be given 1 hour before travel on an empty stomach
- 85mg and 170mg doses (take 2 capsules as one dose to achieve 170)
- Only 85mg available later in 2026
- It is a preventative and not treatment
- Should not be combined with other motion sickness medications (OTC or Rx)
- Avoid alcohol
- Not studied in peds, renal or hepatic impairment
- No data on pregnancy or lactation
- Low rate of ADRs but fatigue and drowsiness did occur (6-8%)

Acellular nerve allograft-arwx (Avance) for Surgical Implantation

Nerve Discontinuities

December 3, 2025 Axogen

- Acellular nerve scaffold indicated for the treatment of sensory, mixed, and motor peripheral nerve discontinuities
- Adult and pediatric patients aged 1 month or older
- Indications for sensory nerve discontinuities >25mm and for mixed and motor nerve discontinuities were approved under FDA's Accelerated Approval pathway

Sepiapterin (Sephience) Oral Powder

Phenylketonuria

July 28, 2025 PTC Therapeutics

- Phenylalanine hydroxylase activator for treatment of patients with phenylketonuria
- Adult and pediatric patients 1 month of age and older with sepiapterin-responsive PKU
- Used in conjunction with a phenylalanine-restricted diet
- 60 mg/kg once daily, rounded to the nearest 250 mg (max 60 mg/kg/day)
- If blood phenylalanine levels do not decrease after 2 weeks, discontinue
- May adjust dose within the range of 7.5 to 60 mg/kg/day if needed to maintain adequate control of blood Phe levels

Sepiapterin (Sephience) Oral Powder

- Oral packets 250 mg or 1000 mg
- Must be given with food
- Must take or give more food after the dose as well
- For doses less than 1,000 mg daily
  - mix oral powder with water or apple juice before giving or taking.
- For doses 1,000 mg or greater
  - oral powder can be mixed with water, apple juice, strawberry jam, or applesauce before taking or giving
- Studies showed rapid reduction in 6 weeks

Sepiapterin (Sephience) Oral Powder

- ADRs: diarrhea, headache, abdominal pain, feces discoloration (yellow or orange)
- Warning: Increase risk of bleeding
- DDI: levodopa, drugs inhibiting folate synthesis dihydrofolate reductase (methotrexate, trimethoprim), PDE-5 inhibitors lower blood pressure
- Monitor Phe levels (blood levels can get too low)
- Avoid in pregnancy and breastfeeding
- Phase 3 APHENITY trial of treatment effect 63% blood level Phe reduction in treatment group compared to 1% in placebo group
- APHENITY long-term extension study showed 97% maintained lower levels

Lamotrigine (Subvenite) Oral Suspension

Epilepsy, Bipolar Disorder

September 16, 2025 OWP Pharmaceuticals

- Oral suspension formulation for treatment of epilepsy and bipolar disorder
- Allows for dose titration and flexibility
- Adjunctive therapy in 2 years and older for epilepsy including partial-onset seizures, primary generalized tonic-clonic, generalized seizures of Lennox-Gastaut syndrome
- Monotherapy 16 years and older in epilepsy
- Bipolar I disorder
- 10 mg/mL (240 mL), cherry flavor, contains saccharin

Behavioral Health

Aripiprazole (Mezofy) Oral Film

Schizophrenia

April 15, 2025

CMG Pharmaceutical Co

- Oral film formulation indicated for schizophrenia in adult and pediatric patients ages 13 years and older
- No water needed to dissolve (water can be used), with or without food
- Place on top of the tongue, allow to adhere to tongue and dissolve
- Only one film at a time, a second film can be used immediately after 1st
- Film comes as 5mg, 10mg, and 15mg

Lisdexamfetamine dimesylate (Arynta) Oral Solution

ADHD, Binge Eating Disorder

June 16, 2025

C-II

Azurity Pharmaceuticals

- Oral solution formulation lisdexamfetamine for treatment of ADHD and moderate to severe binge eating disorder in those 6 years and older
- 10 mg/mL clear colorless oral solution with oral syringe and bottle adaptor with product
- Keep adaptor in bottle consistently, throw away any unused in 30 days
- Once daily in the morning, with or without food
- 14 hour therapeutic response

Musculoskeletal

Meloxicam (Xifyrm) Injection

Pain

June 5, 2025 Azurity Pharmaceuticals

- Non-steroidal anti-inflammatory drug (NSAID) for management of moderate-to-severe pain
- 30mg/mL single-dose vial for IV bolus injection over 15 seconds
- Delayed analgesic effect, not used for rapid pain relief
- Time to meaningful analgesic effect is 2-3 hours (variation is wide, some did not get relief in first 24 hours)
- Clear, pale yellow to yellow color solution

Cyclobenzaprine hydrochloride (Tonmya)

Fibromyalgia

August 15, 2025 Tonix Pharmaceuticals

- Sublingual formulation indicated for fibromyalgia in adults
- Bedtime dose
- 2.8 mg once daily at bedtime for 2 weeks, then increase to 5.6 mg once daily at bedtime
- Max dose: of 5.6 mg daily
- ADRs: mouth numbness and tingling, taste change, canker sores
- 2 RCT, Phase 3 trials of nearly 1,000 pts at bedtime showed significantly reduced daily pain scores compared to placebo at 14 weeks
- Greater percentage experienced a clinically meaningful (≥30%) improvement in their pain after 3 months compared to placebo

Elamipretide hydrochloride (Forzinity) Injection

Barth Syndrome

September 19, 2025 Stealth BioTherapeutics

- Mitochondrial cardiolipin binder for treatment of Barth syndrome
- Rare X-linked genetic disease, primarily in males
- Barth syndrome is a life-limiting pediatric mitochondrial cardioskeletal disease affecting approximately 150 individuals in US
- Approval is for children and adults > 30 kg
- SQ 40 mg once daily

Doxecitine and Doxribtimine (Kygevvi) Powder for Oral Solution

Thymidine Kinase 2 Deficiency

November 3, 2025 UCB

- Combination of two pyrimidine nucleosides for treatment of thymidine kinase 2 deficiency in adults and pediatric patients with an age of symptom onset on or before 12 years
- Ultra-rare, life-threatening, genetic mitochondrial disease characterized by progressive and severe muscle weakness
- First and only approved treatment
- Phase 2 clinical study, two retrospective chart review studies, and an expanded access use program
- Survival time from treatment start was improved; treatment reduced the overall risk of death from treatment start by approximately 86%

Doxecitine and Doxribtimine (Kygevvi)

- 1:1 ratio so 260mg would be 130mg of each, supplied as 2 gm doxecitine and 2 gm doxribtimine
- Mix with room temperature water in provided mixing bottles following directions closely (40ml of water per packet)
- Initial: 260 mg/kg/day in 3 equally divided doses (rounded to the nearest 500 mg) administered 6 hours apart (± 2 hrs)
- If initial dose is tolerated for at least 2 weeks, increase daily dosage to 520 mg/kg/day in 3 equally divided doses administered 6 hours apart
- If intermediate dose is tolerated for at least 2 weeks, increase daily dosage to 800 mg/kg/day in 3 equally divided doses (rounded to the nearest 500 mg) administered 6 hours apart
- Patients with GI ADRs (diarrhea, vomiting): Reduce dosage or interrupt until symptoms improve or return to baseline
- If treatment is interrupted, consider resuming at the previously tolerated dose and increase as tolerated
- Permanent discontinuation if symptoms return or persist
- Baseline and monitor liver function

Copper histidinate (Zycubo) Injection

Menkes Disease

January 12, 2026 Sentynl Therapeutics, Inc.

- Menkes Disease is a rare, severe genetic disorder caused by mutations in the ATP7A gene on the X-chromosome, leading to copper deficiency in the brain and other tissues, despite copper buildup in the gut
- Recessive trait, seen in males
- Life expectancy is 2-3 years, no cure
- Affects muscle/connective tissue and neurodevelopment
- Copper replacement therapy for Menkes disease in pediatric patients
- Median overall survival was 177.1 months compared to 17.6 months for the untreated cohort

Immunology

Prademagene zamikeracel (Zevaskyn) Gene-Modified Cellular Sheets

Epidermolysis Bullosa

April 28, 2025 Abeona Therapeutics

- Autologous, cell sheet-based gene therapy for the treatment of recessive dystrophic epidermolysis bullosa
- Rare, inherited genetic disorders causing extreme skin fragility, where minor friction or trauma leads to painful, recurrent blistering and open wounds, often called "butterfly skin“
- Phase 3 VIITAL™ study across 43 large and chronic wounds treated with a single application, 81% showed 50% or more healing ($P<0.0001$) at 6 months, compared to 16% in 43 matched control with standard of care

Ustekinumab-hmny (Starjemza) Injection

Plaque Psoriasis, Psoriatic Arthritis, Crohn's Disease, Ulcerative Colitis

May 22, 2025 Bio-Thera Solutions

- Human interleukin-12 and -23 antagonist interchangeable biosimilar to Stelara used for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
- 8th biosimilar on the market

Garadacimab-gxii (Andembry) Injection

Hereditary Angioedema

June 16, 2025 CSL

- Activated Factor XII (FXIIa) inhibitor (monoclonal antibody) for prophylaxis to prevent attacks of hereditary angioedema in adult and pediatric patients aged 12 years and older
- Unique MOA compared to other therapies, preventative therapy
- Once-monthly dosing, 400mg loading dose then 200mg monthly
- SQ self-injection delivered in 15 seconds via autoinjector
- Allow to come to room temperature for 30 minutes, do not shake
- Administer in upper arm (caregiver only), abdomen, or thigh
- Administer the 400 mg loading dose as 2 injections of 200 mg, one after another
- Rotate injection site with each injection
- Do not inject into moles, scars, bruises, or into areas where the skin is red, hard, or injured
- Citrate-free formula
- ADRs: prolonged bleeding time, nasopharyngitis

Donidalorsen (Dawnzera) Injection

Hereditary Angioedema

August 21, 2025 Ionis Pharmaceuticals

- Prekallikrein-directed antisense oligonucleotide indicated for *prophylaxis* to prevent attacks of hereditary angioedema in adult and pediatric patients 12 years of age and older
- First and only RNA-targeted drug approved for HAE, designed to target plasma prekallikrein (PKK), a key protein activating inflammatory mediators associated with acute attacks of HAE
- SQ 80 mg once every 4 weeks or 8 weeks autoinjector
- 80 mg/0.8 mL autoinjector, preservative free
- Abdomen, upper thigh, or upper arm
- Remove from refrigerator and allow at room temperature for 30 minutes
- Solution should be clear and colorless to yellow

Donidalorsen (Dawnzera) Injection

- Monitor liver functions
- ADRs: injection site, neutralizing antibodies, GI, UTI, URI
- No data for pregnancy or breastfeedings
- OASIS-HAE study met its primary endpoint, with Q4W significantly reducing monthly HAE attack rate by 81% compared to placebo over 24 weeks
- OASISplus showed improve response when pts were switched from other HAE drugs
- Patient assistance with Ionis Every Step program

Sebetralstat (Ekterly) Tablets

Hereditary Angioedema

July 3, 2025 KalVista Pharmaceuticals

- Oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema attacks in adults and pediatric patients aged 12 years and older
- First oral, on-demand treatment of an acute attack
- 600 mg once at the earliest sign of acute attack. May repeat 1 additional 600 mg dose ≥3 hours after the first dose if attack persists, worsens, or recurs
- Max dose: 1,200 mg per 24 hours
- 300mg tablets

Sebetralstat (Ekterly) Tablets

- ADRs: headache
- DDI: significant CYP3A4 strong inducers
- Phase 3 KONFIDENT trial, showing sebetralstat achieved significantly faster symptom relief, reduction in attack severity, and attack resolution than placebo, and was well-tolerated with a safety profile similar to placebo
- Real-world KONFIDENT-S open-label extension trial, enabled patients to treat attacks in a median of 10 minutes following onset
- KONFIDENT-S shows symptom relief occurring in a median of 1.3 hours among attacks involving the larynx, the abdomen, and for breakthrough attacks among patients receiving long-term prophylaxis

Oncology/Hematology

Telisotuzumab vedotin-tllv (Emrelis) Lyophilized Powder for Injection - formerly Teliso-V

Non-Small Cell Lung Cancer

May 14, 2025 AbbVie

- First-in-class, c-Met protein directed antibody-drug conjugate for treatment of non-squamous non-small cell lung cancer with high c-Met protein overexpression
- High c-Met protein overexpression is defined as ≥ 50% of tumor cells with strong (3+) staining as determined by an FDA-approved test
- Infusion reaction premedication necessary
- Clinical trials still evaluating efficacy and safety more long term

Taletrectinib (Ibtrozi) Capsules

Non-Small Cell Lung Cancer

June 11, 2025 Nuvation Bio

- Kinase inhibitor for treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer
- 600 mg once daily, continue until disease progression or unacceptable toxicity
- 200mg capsules
- Moderate to high emetogenic potential
- Increase risk of fracture warning and liver toxicity

Sunvozertinib (Zegfrovy) Tablets

Non-Small Cell Lung Cancer

July 2, 2025 Dizal

- Oral, irreversible, epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) for locally advanced or metastatic non-small cell lung cancer patients with EGFR exon 20 insertion (exon20ins) mutations
- Received Priority Review and Breakthrough Therapy Designation
- First-in-class oral therapy
- 200 mg once daily, continue until disease progression or unacceptable toxicity
- Administer at the same time each day with food to reduce GI adverse reactions
- Swallow whole, do not split, crush, chew, or dissolve tablets
- Moderate to high emetogenic potential
- 150 mg and 300 mg tablets

Zongertinib (Hernexeos) Tablets

Non-Small Cell Lung Cancer

August 8, 2025 Boehringer Ingelheim

- Kinase inhibitor for treatment of non-squamous NSCLC with HER2 (ERBB2) tyrosine kinase domain activating mutations
- Accelerated approval based on objective response rate and duration of response
- 60 mg tablets
- Minimal to low emetogenic potential
- Phase Ib Beamion-LUNG 1 trial, demonstrating an objective response rate of 75%, 6% of patients had a complete response and 69% of patients had a partial response and a duration of response of ≥6 months in 58% of patients

Sevabertinib (Hyrnuo) Tablets

Non-Small Cell Lung Cancer (NSCLC)

November 19, 2025 Bayer

- Reversible tyrosine kinase inhibitor (TKI) for HER2-mutant non-small cell lung cancer
- Granted accelerated approval for adults with locally advanced or metastatic NSCLC whose tumors have human epidermal growth factor receptor 2 (*HER2*) tyrosine kinase domain activating mutations, and who have received a prior systemic therapy
- Mutations detected by an FDA-approved test
- Studies looking at this for first-line therapy
- 20 mg twice daily and continue until disease progression or unacceptable toxicity
- Dose can be reduced to 10mg once or twice daily depending on response and side effects

Amivantamab and hyaluronidase-lpuj (Rybrevant Faspro) Injection

Non-Small Cell Lung Cancer

December 17, 2025 Johnson & Johnson Innovative Medicine

- Combination of amivantamab, a bispecific EGF receptor-directed and MET receptor-directed antibody, and hyaluronidase, an endoglycosidase for treatment of epidermal growth factor receptor-mutated non-small cell lung cancer
- SQ injection versus IV formulation of amivantamab
- Reduces administration from several hours to 5 minutes
- Reduced side effect profile including VTE
- Phase 3 PALOMA-3 study showed similar PKIN between SQ and IV

Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex) Injection

Melanoma, Non Small Cell Lung Cancer, Malignant Pleural Mesothelioma, Head and Neck Cancer, Urothelial Carcinoma, Solid Tumors, Colorectal Cancer, Gastric Cancer, Esophageal Carcinoma, Cervical Cancer, Hepatocellular Carcinoma, Biliary Tract Surgery, Merkel Cell Carcinoma, Renal Cell Carcinoma, Endometrial Cancer, Squamous Cell Carcinoma, Breast Cancer, Ovarian Cancer, Fallopian Tube Cancer, Peritoneal Cancer

September 19, 2025 Merck & Co

- Programmed death receptor-1 (PD-1)-blocking antibody and endoglycosidase subcutaneous injection formulation for use in multiple types of cancer
- SQ pembrolizumab 395 mg and berahyaluronidase alfa-pmph 4800 units per 2.4 mL and pembrolizumab 790 mg and berahyaluronidase alfa-pmph 9600 units per 4.8 mL
- Administered by a health care provider
- 38 indications

Mitomycin (Zusduri) for Intravesical Solution - formerly UGN-102

Bladder Cancer

June 12, 2025 UroGen Pharma

- Sustained release, hydrogel-based formulation of mitomycin for intravesical treatment of low-grade intermediate-risk non-muscle invasive bladder cancer
- 75 mg instilled once weekly into the bladder (via urinary catheter) for 6 weeks

Gemcitabine (Inlexzo) intravesical system

Bladder Cancer

September 9, 2025 Johnson & Johnson

- Intravesical system for treating certain patients with BCG-unresponsive non-muscle invasive bladder cancer
- Patients seeking bladder preservation and is the first and only intravesical drug releasing system (iDRS) to provide extended local delivery of a cancer medication into the bladder
- Remains in the bladder for three weeks per treatment cycle for up to 14 cycles

Linvoseltamab-gcpt (Lynozyfic) Injection

Multiple Myeloma

July 2, 2025 Regeneron Pharmaceuticals

- Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager for relapsed or refractory multiple myeloma
- FDA granted accelerated approval
- First FDA-approved BCMAxCD3 bispecific antibody that can be dosed every two weeks starting at week 14, and every four weeks for 24 weeks
- Premedication treatment
- Low emetogenic potentials

Pertuzumab-dpzb (Poherdy) Injection

Breast Cancer

November 13, 2025 Shanghai Henlius Biotech and Organon

- HER2/neu receptor antagonist interchangeable biosimilar to Perjeta for treatment of HER2-positive breast cancer
- 420 mg/14 mL injection for IV use

Imlunestrant (Inluriyo) Tablets

Breast Cancer

September 25, 2025 Eli Lilly and Company

- Estrogen receptor antagonist for treatment of adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2–), ESR1-mutated advanced or metastatic breast cancer (MBC) whose disease progressed after at least one line of endocrine therapy
- 200mg tablets
- EMBER-3 trial patients harboring *ESR1*-mutated MBC (n=256). Patients received Imlunestrant or endocrine therapy as first-line treatment for MBC following recurrence on adjuvant aromatase inhibitor (AI), +/- prior CDK4/6 inhibitor (21%), or as second-line treatment for MBC following progression on AI, +/- prior CDK4/6 inhibitor (79%). Median PFS of 5.5 months vs 3.8 months

Avutometinib and defactinib, co-packaged (Avmapki Fakzynja Co-Pack) Capsules/Tablets

Ovarian Cancer

May 8, 2025 Verastem Oncology

- Kinase inhibitor combination for KRAS-mutated recurrent low-grade serous ovarian cancer
- First therapy specific KRAS-mutated
- Administer topical corticosteroids (to face, scalp, neck, upper chest, and upper back) and systemic oral antibiotics at initiation of treatment; continue for at least the first 2 cycles for prevention of dermatologic toxicities
- Instruct patient to limit unnecessary exposure to sunlight and to apply sunscreen (SPF ≥30) daily during treatment
- Avutometinib potassium 0.8 mg and defactinib hydrochloride 200 mg (66 ea)

Ziftomenib (Komzifti) Capsules

Acute Myeloid Leukemia

November 13, 2025 Kura Oncology and Kyowa Kirin Co

- menin inhibitor for adult patients with relapsed or refractory NPM1-mutated acute myeloid leukemia
- first and only once-daily, oral menin inhibitor approved for R/R *NPM1*-mutated (*NPM1*-m) AML
- *NPM1* mutations are among the most common mutations in AML, approximately 30% of cases
- KOMET-001, which evaluated safety and efficacy in 112 R/R *NPM1*-m AML patients
- Complete remission (CR) plus CR with partial hematologic recovery (CRh) was 21.4% (95% CI: 14.2, 30.2)
- Median duration of CR+CRh was 5.0 months and the median time to first response in patients who achieved a CR or CRh was 2.7 months (range: 0.9 to 15 months)
- 88% of patients who achieved CR or CRh did so within 6 months
- Significant side effects including QT prolongation (monitor electrolytes)
- 600 mg once daily (200mg capsules), dose can be reduced

Penpulimab-kcqx Injection

Nasopharyngeal Carcinoma

April 23, 2025 Akeso

- Programmed death receptor-1 (PD-1)-blocking antibody for treatment of nasopharyngeal carcinoma
- 200 mg once every 3 weeks (in combination with gemcitabine and either cisplatin or carboplatin) for 6 cycles, followed by penpulimab 200 mg once every 3 weeks alone

Dordaviprone (Modeyso) Capsules

Malignant Glioma

August 6, 2025 Jazz Pharmaceuticals

- Protease activator used for diffuse midline glioma
- Adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy
- 625 mg once weekly, continue until disease progression or unacceptable toxicity
- 135mg capsules
- ADRs: QT prolongation, propylene glycol, skin rash, high and low blood sugars

Bevacizumab-nwgd (Jobevne) Injection

Colorectal Cancer, Non Small Cell Lung Cancer, Glioblastoma Multiforme, Renal Cell Carcinoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube Cancer, Peritoneal Cancer

April 9, 2025 Biocon Biologics

- Vascular endothelial growth factor inhibitor biosimilar to Avastin for treatment of colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, and epithelial ovarian, fallopian tube, or primary peritoneal cancer
- 6^{th} biosimilar on the market

Filgrastim-laha (Filkri) Injection

Neutropenia, Neutropenia Associated with Chemotherapy, Neutropenia Associated with Radiation, Bone Marrow Transplantation, Peripheral Progenitor Cell Transplantation, Hematopoietic Syndrome of Acute Radiation Syndrome

January 15, 2026 Accord BioPharma Inc.

- Leukocyte growth factor biosimilar to Neupogen for treatment of neutropenia, neutropenia associated with chemotherapy, neutropenia associated with radiation, bone marrow transplantation, and peripheral progenitor cell transplantation
- 300 mcg/0.5 mL in a single-dose prefilled syringe
- 480 mcg/0.8 mL in a single-dose prefilled syringe

Pegfilgrastim-unne (rmlupeg) Injection

Neutropenia Associated with Chemotherapy, Neutropenia Associated with Radiation

November 28, 2025 Lupin Limited

- PEGylated growth colony-stimulating factor biosimilar to Neulasta to reduce the incidence of febrile neutropenia in patients treated with chemotherapy and to increase survival in patients acutely exposed to myelosuppressive doses of radiation
- Early 2026, there are 7 Neulasta biosimilars on the market

Rilzabrutinib (Wayrilz) Tablets

Immune Thrombocytopenia

August 29, 2025 Sanofi

- Kinase inhibitor for treatment of adult patients with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment
- 400 mg twice daily
- Administer with or without food at same time each day
- Administration with food may improve tolerability in patients who develop gastrointestinal symptoms
- Swallow tablets whole with a glass of water, do not cut, crush, or chew
- Monitor liver function and increase risk of infections

Narsoplimab-wuug (Yartemlea) Injection

Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy

December 23, 2025 Omeros Corporation

- Mannan-binding lectin-associated serine protease 2 (MASP-2) inhibitor indicated for adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy
- Often fatal complication
- Very small studies, but significantly increased survival

Mitapivat (Aqvesme) Tablets

Thalassemia, Beta Thalassemia

December 23, 2025 Agios Pharmaceuticals

- pyruvate kinase activator indicated for anemia in adults with alpha- or beta-thalassemia
- ENERGIZE and ENERGIZE-T Phase 3 trial demonstrated mitapivat can help address anemia, fatigue, and the need for regular transfusions in patients
- REMS program due to liver toxicity/Medication Guide
- If a dose is missed by ≤4 hours, administer as soon as possible. If missed by >4 hours, wait until the next scheduled dose
- ADRs: headache, muscle pain, decreased estradiol levels, increased testosterone
- DI: Major interactions with CYP3A4
- Very different dosing schedules based on diagnosis

Fitusiran (Qfitlia) Injection

Hemophilia A, Hemophilia A with Inhibitors, Hemophilia B, Hemophilia B with Inhibitors

March 28, 2025 Sanofi

- Antithrombin-directed small interfering ribonucleic acid for the prophylactic treatment of people with hemophilia A or B, with or without inhibitors
- SQ 50 mg once every 2 months
- 50 mg/0.5 mL autoinjector, 20 mg/0.2 mL vial
- Measure plasma antithrombin activity at weeks 4, 12, 20, and 24 following initial dose and after any dose modification

Denosumab-bnht (Bomyntra) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

March 25, 2025 Fresenius Kabi USA

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy

Denosumab-nxxp (Bilprevda) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

August 29, 2025 Shanghai Henlius Biotech and Organon

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for the prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy

Denosumab-kyqq (Aukelso) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

September 16, 2025 Biocon Biologics

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for the prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy

Denosumab-qbde (Xtrenbo) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

September 26, 2025

Gedeon Richter and Hikma Pharmaceuticals

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for the prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy

Denosumab-desu (Jubereq) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

October 29, 2025 Accord BioPharma

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy
- This is #5 biosimilar to Xgeva on the market

Denosumab-mobz (Oziltus) Injection

Osteolytic Bone Lesions of Multiple Myeloma, Osteolytic Bone Metastases of Solid Tumors, Giant Cell Tumor of Bone, Hypercalcemia of Malignancy

December 19, 2025 Amneal Pharmaceuticals

- RANK ligand (RANKL) inhibitor biosimilar to Xgeva for prevention of skeletal-related events in patients with multiple myeloma or bone metastases from solid tumors, treatment of giant cell tumor of bone, and treatment of hypercalcemia of malignancy
- Administered by a healthcare professional
- Monitor calcium
- As of December 2025, 6 biosimilars FDA approved

Ocular/Dermatology

Aceclidine (Vizz) Ophthalmic Solution

Presbyopia

July 31, 2025 LENZ Therapeutics

- Cholinergic agonist indicated for presbyopia (age-related blurry near vision) in adults
- Instill 1 drop into each eye, followed by 1 additional drop in each eye 2 minutes later once daily
- Twist off top of vial prior to use
- Remove contact lenses prior to administration, wait 10 minutes before reinserting
- Separate administration of other ophthalmic agents by at least 5 minutes
- Do not touch tip of container to any surface, the eyelids, or the surrounding area
- Single-use vial is used to treat both eyes, discard vial immediately after use
- 1.44% (25 ea)

Brimonidine tartrate and Carbachol (Yuvezzi) Ophthalmic Solution

Presbyopia
January 28, 2026

Tenpoint Therapeutics, Ltd.

- Alpha-adrenergic agonist and cholinergic agonist combination indicated for presbyopia in adults
- Carbachol: synthetic direct-acting cholinergic agent that causes miosis by stimulating muscarinic receptors in the eye
- Brimonidine: relatively selective alpha-2 adrenergic agonist blocking contraction of iris dilator muscle and relaxes tonic contraction of the ciliary muscle, enhancing selectivity for the pupil and increasing bioavailability of carbachol in the aqueous humor
- 2.75% carbachol /0.1% brimonidine
- First and only dual-agent eye drop for age-related blurry near vision
- Other FDA approved agents include pilocarpine hydrochloride (Vuity), pilocarpine hydrochloride (Qlosi), and aceclidine (Vizz)
- 2 pivotal Phase 3 studies with more than 800 patients
- BRIO I study demonstrated a superior benefit of the combination over individual ingredients
- BRIO II with vehicle-controlled, combo achieved all primary near vision improvement endpoints with statistically significant 3-lines or greater improvement
- BRIO II longest safety study of 12 months

Brimonidine tartrate and Carbachol (Yuvezzi) Ophthalmic Solution

- ADRs: Headache, Eye Irritation, Hypotension, changes in night vision
- One drop in each eye daily, lasts up to 10 hours
- Preservative free
- Remove contact lenses prior to administration
- Wait 10 minutes before reinserting
- Separate administration of other ophthalmic agents by at least 5 minutes
- Do not touch tip of container to any surface or the eyelids
- One single-dose vial can be used to dose both eyes
- Discard the open single-dose vial and any remaining contents immediately after use
- Available 2026 Q2

Ranibizumab-leyk (Nufymco) Injection

Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy, Myopic Choroidal Neovascularization

December 18, 2025 Formycon AG

- vascular endothelial growth factor (VEGF) inhibitor, interchangeable biosimilar to Lucentis indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), and myopic choroidal neovascularization (mCNV)
- As of 2026, there are 3 FDA approved biosimilars to Lucentis
- Injected into the eye by healthcare professional

Aflibercept-boav (Eydenzelt) Injection

Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy

October 2, 2025 Celltrion USA

- Vascular endothelial growth factor (VEGF) inhibitor biosimilar to Eylea for treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy
- 6th biosimilar approved for Eylea

Acoltremon (Tryptyr) Ophthalmic Solution

Dry Eye Disease

May 28, 2025 Alcon

- First-in-class TRPM8 thermoreceptor agonist for the treatment of the signs and symptoms of dry eye disease
- Stimulates corneal sensory nerves to rapidly increase natural tear production
- Instill 1 drop in each eye twice daily (12 hours apart)
- 0.003% (60 ea) preservative free
- Remove contact lenses, reinsert 15 minutes later
- COMET-2 and COMET-3 about 54% response rate

Riboflavin 5’-phosphate (Epioxa) Ophthalmic Solution and Epioxa HD

Keratoconus

October 17, 2025

Glaukos Corporation

- Next-generation corneal cross-linking therapy for keratoconus
- Progressive eye condition where the cornea thins and gradually bulges outward into a cone shape, rather than dome-shaped
- This deformity disrupts vision, causing significant blurring, distortion, and increased light sensitivity, often starting in teenage years
- Epioxa HD (0.239% riboflavin 5'-phosphate) and Epioxa (0.177% riboflavin 5'-phosphate)
- Apply 2 drops of Epioxa HD on the eye every 60 seconds for 4 minutes followed by 2 drops of Epioxa every 30 seconds for 6 minutes

Remibrutinib (Rhapsido) Tablets

Urticaria

September 30, 2025 Novartis

- Kinase inhibitor indicated for chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamines
- 25 mg twice daily
- Warning: Coughing up blood, dark stools (bleeding)
- Interrupt therapy 3-7 days before procedures or surgery
- ADRs: GI, nasopharyngitis, headache
- DDI: Strong CYP3A4 inducers
- 25mg tablets

Delgocitinib (Anzupgo) Topical Cream

Chronic Hand Eczema July 23, 2025 LEO Pharma

- Topical pan-Janus kinase (JAK) inhibitor for treatment of chronic hand eczema
- Apply a thin layer to affected area(s) on hand(s) and wrists(s) twice daily
- Max dose of 30 g per 2 weeks or 60 g per month
- Watch for increase risk of infections or change in skin growths such as moles
- 20 mg/g (30 g)

References

Notable drug approvals, MPR website, https://www.empr.com/?s=new+drugs&published=12months

FDA access database
FDA safety alerts
Drugs.com
Lexicomp database
Manufacturer websites
PubMed

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