New Drug Update 2023

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Raabe College of Pharmacy, Ohio Northern University

Ohio Pharmacists Association

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Reimagining Pharmacy

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Disclosure Statement

- Karen L. Kier has no relevant financial relationship(s) 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 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.

Zavzpret (zavegepant) Nasal Spray

Pfizer
Migraine

Approval: March 9, 2023

- calcitonin gene-related peptide (CGRP) receptor antagonist for *acute treatment*
- migraines with and without aura
- placebo controlled trials
- nasal spray 10mg (device looks like Narcan)
- 10mg once in 24 hours, do not repeat in that time frame
- Single spray in one nostril
- No more than 8 uses in 30 day period

Zavzpret (zavegepant) Nasal Spray

- 15 minute for early pain relief
- About 24% were pain free at 2 hours
- About 40% reported response to most bothersome symptoms at 2 hours
- dysgeusia and taste disorders (less than 18%)
- Avoid in patients with severe liver or renal dysfunction
- Avoid with intranasal decongestants (if use then at least 1 hour after zavegepant)
- Available near July 2023

Rykindo (risperidone) for Extended-Release Injectable Suspension

Luye Pharma
Schizophrenia, Bipolar Disorder

Approval: January 13, 2023

- long-acting injection for schizophrenia and bipolar I disorder in adults
- extended-release microsphere technology
- IM injection every 2 weeks
- Oral to IM LAI injection conversions
- Shake syringe vigorously
- Deltoid or gluteal injection
- Other LAI for risperidone include Perseris (SC inj) once per month and RisperDAL Consta (IM inj) every 2 weeks

Igalmi (dexmedetomidine) Sublingual Film

BioXcel Therapeutics
Agitation

Approval: April 5, 2022

- sublingual film of alpha2-adrenergic receptor agonist for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults
- Mild to moderate: 120 mcg; if agitation persists, up to 2 additional doses of 60 mcg at least 2 hours apart. Maximum: 240 mcg/day
- Severe: 180 mcg; if agitation persists, up to 2 additional doses of 90 mcg at least 2 hours apart. Maximum: 360 mcg/day
- 120mcg and 180mcg film available

Leqembi (lecanemab-irmb) Injection

Biogen and Eisai
Alzheimer's Disease

Approval: January 6, 2023

- amyloid beta-directed antibody
- treatment of Alzheimer’s disease
- directed against aggregated soluble ("protofibril") and insoluble forms of amyloid beta
- approval is based on Phase 2 data showing reduced accumulation of Aβ plaque in the brain
- just published confirmatory Phase 3 clinical trial, Clarity AD (10mg/kg dosing every 2 weeks) NEJM Jan 5, 2023
- 18-month study
- Early disease either mild cognitive impairment or mild dementia
- Greater reductions in Aβ burden

Leqembi (lecanemab-irmb) Injection

- Significant side effects
- 26.4% had infusion related reactions
- 12.6% had brain edema or effusions ARIA-E (amyloid-related imaging abnormalities)
- ARIA-E events occur within the first 7 doses
- ARIA-hemosiderin deposition (ARIA-H) consistent with microhemorrhage
- 10mg/kg dose is infused over 1 hour
- Injection 200 mg/2 mL
- Injection 500 mg/5 mL contains plysorbate 80 (allergic reactions)

Briumvi (ublituximab-xiiy) Injection

TG Therapeutics
Multiple Sclerosis

Approval: December 28, 2022

- CD20-directed cytolytic antibody for relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults
- ULTIMATE I & II Phase 3
- demonstrated superiority over teriflunomide (Aubagio) in significantly reducing the annualized relapse rate
- Teriflunomide has a different MOA than ublituximab
- Other MS drugs with similar MOA are ocrelizumab (Ocrevus) IV administration and ofatumaumab (Kesimpta) SC administration

Briumvi (ublituximab-xiiy) Injection

- 1st dose infusion of 150mg administered in four hours, day 15 infusion of 450mg administered in one hour, followed by 450mg infusions every 24 weeks administered in one hour
- 150 mg/6 mL
- Significant infusion-related reactions
- Patient need premedicated prior to infusion including methylprednisolone, diphenhydramine, and acetaminophen
- Important to get infusion as soon as possible if a dose is missed
- Screen for hepatitis B and TB
- Increase risk for infections

Relyvrio (sodium phenylbutyrate and taurursodiol) Powder for Oral Suspension

Amylyx Pharmaceuticals
Amyotrophic Lateral Sclerosis

Approval: September 29, 2022

- neuroprotective therapy for amyotrophic lateral sclerosis (ALS)
- reduces neuronal cell death in vitro (in vivo mechanism not well understood)
- Packet of sodium phenylbutyrate 3 g/taurursodiol 1 g
- One packet once daily for 3 weeks, then increase dose to 1 packet twice daily (if tolerated)
- Take before a meal or snack
- High fat meal decrease Cmax by 76% and AUC by 50%

Relyvrio (sodium phenylbutyrate and taurursodiol) Powder for Oral Suspension

- High fat meal decrease Cmax by 76% and AUC by 50%
- ADRs: diarrhea, abdominal pain, URI, nausea, fatigue, dizziness, excessive saliva flow (sialorrhea)
- Significant drug-drug interactions including CYP3A4
- CENTAUR, a multicenter Phase 2 clinical trial in 137 participants
- significantly slowed loss of physical function over six months
- Long-term studies are continuing

Radicava ORS (edaravone) Oral Suspension

Mitsubishi Tanabe Pharma
Amyotrophic Lateral Sclerosis

Approval: May 12, 2022

- Free radical scavenger for amyotrophic lateral sclerosis
- Oral equivalent to the IV formulation
- Clinically slows loss of physical function
- Does not need to be refrigerated
- Does not need to be reconstituted
- Phase 3 clinical trial (MCI186-19)
- 1/3 patients showed reduction in progression over 24 weeks

Radicava ORS (edaravone) Oral Suspension

- First cycle 105 mg (5 mL suspension) once daily for 14 days, followed by a 14-day drug-free period
- Next cycles: 105 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period
- Switching IV to oral: 60 mg IV switched to 105 mg orally at the same dosing frequency
- Take in morning on an empty stomach after overnight fasting (8 hours for high-fat meal; 4 hours for a low-fat meal, or 2 hours for caloric supplement (e.g. protein drink)
- Do not consume food (except water) for 1 hour after administration
- Invert bottle upside down and shake vigorously for at least 30 seconds prior to opening
- Administer using the provided calibrated measuring device
- Do not use a household teaspoon or tablespoon
- Can be placed in an NG tube

Sezaby (phenobarbital sodium) Powder for Injection

Sun Pharmaceutical
Neonatal Seizures

Approval: November 17, 2022

- barbiturate for neonatal seizures in term and preterm infants
- first and only product approved for treating seizures in neonatal patients
- granted orphan drug status by FDA
- 100mg vial, reconstitute 10ml NS for conc 10mg/ml
- Highly alkaline formulation
- benzyl alcohol-free and propylene glycol-free formulation
- NEOLEV2 phase 2 study evaluated levetiracetam to phenobarbital
- 73% (pb) vs 23% (leve) seizure free in 24 hours

Zonisade (zonisamide) Oral Suspension

Azurity Pharmaceuticals Approval: July 15, 2022
Seizures

- oral suspension formulation indicated as adjunctive therapy for partial-onset seizures in adults and pediatrics 16 years of age and older
- 100 mg/5 mL contains sodium benzoate
- 150 mL bottle, strawberry flavor
- Food may delay peak blood level
- withdraw gradually to minimize the potential of increased seizure frequency
- Medication Guide

Xelstrym (dextroamphetamine) Transdermal System

Noven Pharmaceuticals Approval: March 22, 2022
ADHD

- CNS stimulant for ADHD in adults and children 6 years and older
- Pediatric patients (6 to 17 years): Recommended starting dose is 4.5 mg/9 hours. Titrate dosage in weekly increments of 4.5 mg up to a maximum recommended dose of 18 mg/9 hours
- Adults: Recommended starting dose is 9 mg/9 hours. Maximum recommended dose is 18 mg/9 hours
- Apply one XELSTRYM transdermal system 2 hours before an effect is needed and remove within 9 hours
- Apply XELSTRYM to one of the following sites: hip, upper arm, chest, upper back or flank
- Change site with new patch
- Strengths available include 4.5 mg/9 hours, 9 mg/9 hours, 13.5 mg/9 hours, 18 mg/9 hours

Aponvie (aprepitant) Injection

Heron Therapeutics Approval: September 16, 2022
Nausea/Vomiting, Postoperative

- IV formulation of the aprepitant for the prevention of postoperative nausea and vomiting (PONV)
- only IV formulation of substance P/neurokinin-1 (NK_1) receptor *for PONV*, not first in the class for other indications primarily chemotherapy N&V
- single 30-second IV injection, 32 mg prior to anesthesia induction, flush line with saline

Auvelity (dextromethorphan and bupropion) Extended-Release Tablets

Axsome Therapeutics
Major Depressive Disorder

Approval: August 18, 2022

- *N*-methyl *D*-aspartate (NMDA) receptor antagonist for MDD in adults
- rapid-acting oral treatment, starting in 1 week
- Starting dose of dextromethorphan 45 mg/bupropion 105 mg once daily in the morning, then after 3 days, increase to dextromethorphan 45 mg/bupropion 105 mg twice daily, administered at least 8 hours apart
- Maximum daily dose: dextromethorphan 90 mg/bupropion 210 mg
- *CYP2D6 poor metabolizers:* Dextromethorphan 45 mg/bupropion 105 mg once daily in the morning
- Reduce dose if CrCl is less than 60 mL/min
- Extended release tablet -- Dextromethorphan hydrobromide 45 mg and bupropion hydrochloride 105 mg

Auvelity (dextromethorphan and bupropion) Extended-Release Tablets

- Do not abruptly stop drug, withdraw symptoms from bupropion
- Cross titration when switching antidepressants
- 14 day discontinuation if switching to or away from MOAI
- FDA-approved Medication Guide
- ADR: dizziness, precipitate mania, suicidal ideation, seizures, psychosis
- Significant drug-drug interactions, CYP2D6 and CYP2B6
- GEMINI placebo-controlled study
- ASCEND study comparing combination product to bupropion sustained-release tablets
- Measured speed of onset and overall response

Iheezo (chloroprocaine hydrochloride) Ophthalmic Gel

Harrow
Ocular Surface Anesthesia

Approval: September 27, 2022

- ester anesthetic for ocular surface anesthesia
- First new topical ophthalmic anesthetic in 14 years
- 3% gel, 3 drops to surface of eye, may repeat if necessary
- Onset is 1 to ½ minutes, with 22 minute duration
- no preservatives
- randomized, prospective, multi-center, active-controlled, observer-masked study evaluated in patients undergoing cataract surgery
- Patent protected until 2038

Iyuzeh (latanoprost) Ophthalmic Solution

Thea Pharma Approval: December 13, 2022
Intraocular Hypertension, Glaucoma, Open Angle

- prostaglandin F2α analogue for reduction of elevated intraocular pressure with open-angle glaucoma or ocular hypertension
- 0.005%
- first and only preservative-free formulation
- Similar side effects, pigmentation and eye lash changes
- clinical trials lowered IOP by 3 – 8 mmHg versus 4 – 8 mmHg by XALATAN®
- XALATAN contains benzalkonium chloride
- one drop in the affected eye(s) once daily in the evening

Omlonti (omidenepag isopropyl) Ophthalmic Solution

Santen
Glaucoma/Intraocular Hypertension

Approval: September 22, 2022

- relatively selective prostaglandin E2 (EP2) receptor agonist for reduction of elevated intraocular pressure (IOP) with open-angle glaucoma or ocular hypertension
- First in class MOA
- increases aqueous humor drainage through the conventional (or trabecular) and uveoscleral outflow pathways
- 0.002% eye drops
- One drop in affected eye(s) once daily in evening
- Refrigerate product until opened, then room temperature for 31 days
- ADR: change of pigmentation of the iris

Syfovre (pegcetacoplan) Injection

Apellis Pharmaceuticals Approval: February 17, 2023
Macular Degeneration

- Complement C3 inhibitor for geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
- First and only FDA approved tx for GA
- 15 mg/0.1 mL intravitreal injection
- every 25 to 60 days
- Phase 3 OAKS and DERBY studies at 24 months
- 36% reduction in lesion growth with monthly treatment

Syfovre (pegcetacoplan) Injection

- In clinical trials, the drug was dosed 15mg monthly for 1/3 of patients and 15mg every other month for 1/3 patients, other third placebo
- Patient must have normal IOP
- ADRs: ocular discomfort, neovascular AMD, vitreous floaters, and conjunctival hemorrhage
- Temporarily impairs vision, do not drive immediately after injection
- Drug is absorped across the eye and systemic blood levels occur between 7-14 days after injection

Cimerli (ranibizumab-eqrn) Intravitreal Injection

Coherus BioSciences Approval: August 2, 2022
Macular Degeneration, Macular Edema, Diabetic Macular Edema, Diabetic Retinopathy, Myopic Choroidal Neovascularization

- 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)
- dosage strengths of 0.3 mg, 0.5 mg, same formulation and excipients, and same amino acid sequence
- Will received 12 month exclusivity for interchangeable designation as a biosimilar

Jesduvroq (daprodustat) Tablets

GlaxoSmithKline
Anemia Associated with Chronic Renal Failure

Approval: February 1, 2023

- oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI)
- once-a-day treatment of anemia due to CKD in adults
- receiving dialysis for at least four months
- increases erythropoietin levels
- Oral option and different mechanism than erythropoietin stimulating agents such epoetin alfa (Epogen, Procrit)
- ASCEND-D trial—NEJM publication in dialysis patients
- ASCENT—Phase III study in CKD patients (note indication is dialysis patients)
- boxed warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access
- Use the lowest dose of daprodustat sufficient to reduce the need for RBC transfusions

Jesduvroq (daprodustat) Tablets

- Use the lowest dose of daprodustat sufficient to reduce the need for RBC transfusions
- hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events
- Also seen with erythropoietin stimulating agents (ESAs)
- Significant drug-drug interactions CYP2C8 (major), CYP3A4 (minor)
- ADRs: Hypertension (24%), abdominal pain (11%)
- Has not been shown to improve quality of life, fatigue, or patient well-being
- Monitor liver function
- Tablet strengths 1, 2, 4, 6, 8 mg
- Hemoglobin less than 9 g/dL, start at 4 mg
- Hemoglobin levels between 9 and 10, start at 2 mg
- Hemoglobin levels > 10, start at 1mg

Brenzavvy (bexagliflozin) Tablets

TheracosBio
Diabetes, Type 2

Approval: January 20, 2023

- sodium-glucose co-transporter 2 (SGLT2) inhibitor
- adjunct to diet and exercise in adults type 2 DM
- 20mg tablet, taking in AM with or without food
- 23 clinical trials involving > 5000 patients
- Trials included monotherapy, combinations with metformin, DDP4, insulin, sulfonylureas
- Renal CrCL > 30 ml/min, no ESRD or dialysis
- ADRs: similar to other SGLT2
- No CV or renal data yet, ?class effect

Mounjaro (tirzepatide) Injection

Eli Lilly
Diabetes, Type 2

Approval: May 13, 2022

- glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist adjunct to diet and exercise to improve glycemic control in adults with type 2 DM
- Dual mechanism compared to GLP-1 (first approved by FDA)
- Once-weekly
- 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg
- Autoinjector with pre-attached hidden needle from patients
- Inject into the abdomen, thigh, or upper arm any time of day on the same day each week
- Allow ≥72 hours between 2 doses if changing day of administration
- Rotate injection sites
- Do not mix with other injectable products
- Avoid adjacent injections if administering other agents in the same area of the body
- Solution should be clear and colorless to slightly yellow
- Single-dose device –do not prime before injection

Mounjaro (tirzepatide) Injection

- Phase 3 SURPASS compared to semaglutide 1 mg, insulin glargine and insulin degludec
- 5 mg, 10 mg and 15 mg tirzepatide was used alone or in combination with diabetes meds, including metformin, SGLT2 inhibitors, sulfonylureas and insulin glargine
- 5mg tirzepatide reduced HgA1c by 1.8% and 2.1%
- 10 and 15mg tirzepatide reduced HgA1c by 1.7% and 2.4%
- Study participants lost an average of 12 lb on lower dose and 25 lb on 15mg
- Long-term studies SURPASS 4 and SURPASS 5
- Weight loss is off label use, being evaluated by FDA, may see indication in April or May of 2023
- Similar contraindications and warnings to GLP-1 including thyroid disease/cancer
- ADRs: nausea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain

Tzield (teplizumab-mzwv) Injection

Provention Bio Approval: November 17, 2022
Delaying the Onset of Stage 3 Type 1 Diabetes

- CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatrics aged 8 years and older with Stage 2 T1D
- Stage 1 is defined as the presence of β-cell autoimmunity as evidenced by the presence of two or more islet autoantibodies with normoglycemia and is presymptomatic
- Stage 2 as the presence of β-cell autoimmunity with dysglycemia and is presymptomatic
- Stage 3 as onset of symptomatic disease
- Stage 3 T1D eventually requires insulin injections for life

Tzield (teplizumab-mzwv) Injection

- Clinical study showed delay of the median onset of Stage 3 T1D by 25 months compared to placebo
- IV infusion
- Premedicate with NSAIDs or acetaminophen, an antihistamine, and/or an antiemetic for the first 5 days of teplizumab infusions to mitigate risk of cytokine release syndrome
- Once daily for 14 consecutive days using BSA
- High rate of ADRs including reduced WBC, rash and headache
- No live vaccines during treatment

Airsupra (albuterol and budesonide) Inhalation Aerosol

AstraZeneca
Asthma

Approval: January 10, 2023

- beta2-adrenergic agonist and corticosteroid fixed-dose combination rescue inhaler
- reduce the risk of asthma exacerbations
- albuterol/budesonide 90 mcg/80 mcg MDI for oral inhalation as needed or for prevention
- Do not take more than 12 inhalations in a 24 hours
- Prime inhaler prior to first use
- To prime, release 4 sprays into the air away from face, shaking well before each spray
- Re-prime when inhaler has not been used for more than 7 days, is dropped, or after cleaning
- Discard when the dose counter displays 0

Airsupra (albuterol and budesonide) Inhalation Aerosol

- MANDALA and DENALI Phase III trials
- MANDALA compared to albuterol monotherapy in moderate to severe asthma
- Dose in study (FDA approved dosing) 180mcg albuterol/160mcg budesonide (2 actuations)
- DENALI evaluated mild to moderate asthma and compared to each individual ingredient
- ADR: similar to individual components, also paradoxical bronchospasm must DC inhaler

Sunlenca (lenacapavir) Injection and Tablets

Gilead Sciences
HIV Infection

Approval: December 22, 2022

- long-acting HIV-1 capsid inhibitor in combination with antiretrovirals for multi-drug resistant HIV-1 infection
- first capsid inhibitor-based HIV treatment
- twice-yearly treatment
- 2 dosing strategy, 2 day initiation versus 15 day initiation both include oral with SC injection
- SC injection: 927 mg every 6 months (26 weeks) from the date of last injection ±2 weeks
- Two 1.5 mL injections are required for a complete dose
- Administer each injection at separate sites in abdomen (≥2 inches from the navel)
- Significant CYP3A4 drug-drug interactions

Priorix (measles, mumps, and rubella virus vaccine, live) Injection

GSK Approval: June 3, 2022
Measles Prophylaxis, Mumps Prophylaxis, Rubella Prophylaxis

- live attenuated vaccine for immunization against MMR
- 12 months and older
- Another supplier/source of vaccine
- Six clinical studies with 12,151 participants
- Can be given as second dose of MMR if another brand has been given for first dose
- Tip caps of prefilled syringes contain natural rubber latex

Rebyota (fecal microbiota, live-jslm) Suspension for Rectal Use - formerly RBX2660

Ferring Pharmaceuticals Approval: November 30, 2022
Prevention of Recurrent Clostridioides difficile Infection

- novel first-in-class
- microbiota-based live biotherapeutic for the prevention of recurrence of Clostridioides difficile infection (CDI) in adults following antibiotics for recurrent CDI
- five clinical trials with more than 1,000 participants
- Phase 3 PUNCH CD3 trial, single dose
- pre-packaged, single-dose 150 mL microbiota suspension for rectal administration
- Screened donors and screened for transmissible diseases
- Stored ultracold freezer
- Administered by hc professionals

Voquezna Triple and Double Pak (amoxicillin, clarithromycin, and vonoprazan) Co-Packaged Capsules and Tablets

Phathom Pharmaceuticals
Helicobacter Pylori Infection

Approval: May 3, 2022

- Amoxicillin, clarithromycin, and vonoprazan (potassium-competitive acid blocker) for Helicobacter pylori infection in adults in triple pack
- Amoxicillin and vonoprazan in double pack
- Triple Pak: Vonoprazan 20 mg, amoxicillin 1 g, clarithromycin 500 mg administered together twice daily for 14 days
- Double Pak: Vonoprazan 20 mg twice daily plus amoxicillin 1 g three times daily for 14 days

Voquezna Triple and Double Pak (amoxicillin, clarithromycin, and vonoprazan) Co-Packaged Capsules and Tablets

- Vonoprazan is innovative acid suppressant, first in class
- New choice to treat with out PPI therapy or failure on PPI therapy
- Phase 3 PHALCON-HP, over 1000 participants, compared to triple therapy with lansoprazole, noninferior results
- Similar side effect profile as lansoprazole triple therapy

Vivjoa (oteseconazole) Capsules

Mycovia Pharmaceuticals
Vaginal Yeast Infection

Approval: April 26, 2022

- oral azole antifungal to reduce the incidence of recurrent vulvovaginal candidiasis with a history of RVVC who are NOT of reproductive potential
- chronic yeast infection
- Monotherapy Day 1: 600 mg as a single dose, Day 2: 450 mg as a single dose, starting day 14: 150 mg once weekly for 11 weeks
- Combination with fluconazole: Days 1 to 7: Fluconazole 150 mg as a single dose on days 1, 4, and 7, Days 14 to 20: Oteseconazole 150 mg once daily, starting day 28: Oteseconazole 150 mg once weekly for 11 weeks
- 150 mg capsules in 18 count therapy pack

Vivjoa (oteseconazole) Capsules

- three Phase 3 trials – two global, pivotal VIOLET studies and one U.S.-focused ultraVIOLET study, including 875 patients at 232 sites across 11 countries
- two global VIOLET studies, 93.3% and 96.1% of women with RVVC did not have a recurrence for the 48-week maintenance period compared to 57.2% and 60.6% of placebo

Idacio (adalimumab-aacf) Injection

Fresenius Kabi Approval: December 13, 2022
Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis

- tumor necrosis factor (TNF) blocker biosimilar to Humira
- citrate-free formulation
- July 1, 2023

Furoscix (furosemide) Injection

scPharmaceuticals
Heart Failure

Approval: October 7, 2022

- loop diuretic for the at-home treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure
- Not for emergency management
- Delivers an 80mg/10ml dose over 5 hours
- SC On-Body Infusor attached to abdomen with a button activation device
- Clinical studies compared to IV furosemide with a 99.6% bioavailability and 8-hour urine output of 2.7 L for SC injection

Camzyos (mavacamten) Capsules

Bristol Myers Squibb
Hypertrophic Cardiomyopathy

Approval: April 28, 2022

- first-in-class cardiac myosin inhibitor for adults with symptomatic NYHA class II-III obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms
- 2.5 mg, 5 mg, 10 mg, 15 mg capsules
- Starting therapy at 5 mg once daily, titrate from this dose up or down
- **Boxed WARNING** for the risk of heart failure
- Reduces LVEF and can cause heart failure due to systolic dysfunction
- Echocardiogram assessments of LVEF are required prior to and during treatment
- Initiation in patients with LVEF <55% is not recommended

Camzyos (mavacamten) Capsules

- Phase 3 EXPLORER-HCM trial, majority patients NYHA II
- Composite functional endpoint compared to placebo
- ADRs: Dizziness, syncope
- REMS program
- Concomitant use with certain cytochrome P450 inhibitors or discontinuation of certain cytochrome P450 inducers may increase the risk of heart failure due to systolic dysfunction
- Significant with CYP2C19 and CYP3A4

Terlivaz (terlipressin) Lyophilized Powder for Injection

Mallinckrodt

Approval: September 14, 2022

Hepatorenal Syndrome

- vasopressin receptor agonist to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function
- Phase 3 CONFIRM trial, improve renal function and avoid dialysis
- may cause serious or fatal respiratory failure, fluid overload

Epsolay (benzoyl peroxide) Cream

Sol-Gel Technologies
Rosacea

Approval: April 22, 2022

- topical oxidizing agent for inflammatory lesions of rosacea in adults
- encapsulated within silica-based patented microcapsules
- Allows for slow release
- 5%, 3 gm and 30 gm tubes
- contains cetyl alcohol and edetate disodium
- Phase 3 randomized, double-blind, multicenter, 12-week, clinical trials with 733 participants

NexoBrid (anacaulase-bcdb) for Topical Gel

MediWound

Approval: December 28, 2022

Thermal Burn

- concentrate of proteolytic enzymes indicated for removal of eschar in adults with deep partial- and full-thickness thermal burns
- innovative, non-surgical alternative
- approved for use in 43 countries
- pivotal Phase 3 U.S. clinical study (DETECT)
- evaluated the efficacy and safety of in adults with deep partial-thickness and full-thickness thermal burns of 3%-30% of total body surface area

NexoBrid (anacaulase-bcdb) for Topical Gel

- applied in up to two applications of four hours each
- Prepare surface with a 2 hour application of antibacterial solution prior to applying topical gel
- Once gel is mixed, must be applied within 15 minutes (8.8% strength after mixing)
- Moisten the wound with normal saline before gel application
- 3 mm thick layer of topical gel applied
- first applied to an area of up to 15% body surface area
- second applied 24 hours later
- total treated area for both applications of up to 20% TBSA
- Only applied by a healthcare professional
- Systemic absorption occurs

Sotyktu (deucravacitinib) Tablets

Bristol Myers Squibb
Plaque Psoriasis

Approval: September 9, 2022

- first-in-class, oral, selective
- tyrosine kinase 2 (TYK2) inhibitor for treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- inhibits tyrosine kinase 2, a member of the Janus kinase (JAK) family
- Phase 3 POETYK PSO trials demonstrated superior efficacy of once-daily deucravacitinib over placebo and twice-daily apremilast (Otezla®) in improving skin clearance

Sotyktu (deucravacitinib) Tablets

- 6 mg tablet once daily, swallow whole, with or without food
- Avoid live vaccines
- ADR: increase risk of infection
- FDA-approved medication guide required
- Concerns with other JAK inhibitors such as cardiac, thrombosis, and hepatic enzyme elevations—no black box warning to date

Zoryve (roflumilast) Cream

Arcutis Biotherapeutics
Plaque Psoriasis

Approval: July 29, 2022

- topical phosphodiesterase 4 (PDE4) inhibitor for plaque psoriasis
- Approved for 12 years and older
- 0.3% applied once daily to affected areas
- HydroARQ Technology™, drug delivery formulation creates a non-greasy moisturizing cream that spreads easily and absorbs quickly
- 60 gram tube
- Product contains cetostearyl alcohol, methylparaben, propylparaben

Zoryve (roflumilast) Cream

Arcutis Biotherapeutics
Plaque Psoriasis

Approval: July 29, 2022

- DERMIS-1 and DERMIS-2 clinical trials compared to placebo vehicle, response rates 65-80% in itch and plaque clearance
- Did involve sensitive areas and face
- Avoid eyes, vaginal area
- Rub in completely and wash hands after use, unless treating hands

Vtama (tapinarof) Cream

Dermavant Sciences
Plaque Psoriasis

Approval: May 23, 2022

- topical aryl hydrocarbon receptor (AhR) modulating agent (agonist) for plaque psoriasis in adults
- mild, moderate and severe plaque psoriasis
- 1% cream, 60 gram tube
- Contains benzoic acid, edetate disodium, polysorbate 80, propylene glycol
- Can be used on sensitive areas including face
- Avoid eyes and vaginal area
- Apply thin layer, wash hands unless hands are being treated
- Apply once daily for up to a maximum of 12 weeks

Vtama (tapinarof) Cream

- Clinical studies, PSOARING 1 and PSOARING 2
- Compared to placebo, greater than 75% of patients saw significant improvement
- Improvements still seen 4 months after discontinuing therapy
- ADRs: skin reactions, contact dermatitis
- Patients should be warned of rare and severe skin reactions, need immediate medical attention
- Hypersensitivity has been reported with difficulty breathing and swallowing

Spevigo (spesolimab-sbzo) Injection

Boehringer Ingelheim
Generalized Pustular Psoriasis

Approval: September 1, 2022

- interleukin-36 receptor antagonist for generalized pustular psoriasis flares in adults
- Novel, first approved treatment option
- rare and potentially life-threatening neutrophilic skin disease
- Screen for TB and other infections
- 900 mg once; if flare persists, another 900 mg may be administered one week later
- Infusion-related reactions

Konvomep (omeprazole and sodium bicarbonate) Powder for Oral Suspension

Azurity Pharmaceuticals
Stomach Ulcer, Gastrointestinal Hemorrhage

Approval: August 30, 2022

- PPI omeprazole and sodium bicarbonate combination for active benign gastric ulcer, and reduction of risk of upper GI bleeding in critically ill patients
- Kit: 2 mg omeprazole and 84 mg sodium bicarbonate per mL
- Kit omeprazole (as a powder) and a strawberry-flavored diluent containing sodium bicarbonate
- Supplied as 90 mL, 150 mL, or 300 mL bottles
- Dose to omeprazole, 20 mg = 10 mL, 40 mg = 20 mL
- Compare to OTC Zegrid capsule = omeprazole 20 mg and sodium bicarbonate 1100 mg
- Compare to Zegrid suspension = omeprazole 20 mg or 40 mg and sodium bicarbonate 1680 mg per packet
- Sodium content consideration in critically ill patients

Kyzatrex (testosterone undecanoate) Capsules

Marius Pharmaceuticals
Hypogonadism, Male

Approval: July 27, 2022
C-III

- androgen for testosterone replacement in adult males for conditions associated with a deficiency or absence of endogenous testosterone
- 40% of men older than 45 years of age and 30-50% of men with obesity or type 2 diabetes have hypogonadism
- 100mg, 150mg, and 200mg
- 100 mg daily or 100 to 400 mg twice daily AM and PM(max 800 mg/day) with food
- oral softgel capsule absorbed primarily via the lymphatic system, avoiding liver toxicity

Kyzatrex (testosterone undecanoate) Capsules

- Advantage over other formulations is the reduction in risk for hepatotoxicity
- phase 3 six-month study in 155 hypogonadal males between 18 and 65 years of age
- 88% in the study achieved normal range testosterone levels within 24 hours
- Hypertension was seen in 2.6% of patients (3-5 mmHg increase in systolic and no change in diastolic)
- REMS with Medication Guide (testosterone products)
- Monitoring: measure testosterone 3 to 5 hours after morning dose beginning 7 days after initiating therapy or after dosage adjustments and then periodically

Tlando (testosterone) Capsules

Antares Pharma
Hypogonadism, Male

Approval: March 28, 2022
C-III

- testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone
- REMS
- Oral therapy
- Strength available is 112.5 mg capsule
- 225 mg twice daily (2 capsules twice daily)
- Increases in blood pressure
- Similar ADRs to other products including liver enzyme elevations

References

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

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

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Table of Drugs for Rare Disease States

Date	Generic	Brand	Indication	MOA
3/10	Trofinetide oral solution*	Daybue	Rett syndrome	amino-terminal tripeptide of IGF-1
2/28	Omaveloxolone capsules*	Skyclarys	Friedreich's Ataxia	activator of Nrf2 (nuclear factor erythroid 2–related factor 2)
2/22	Antihemophilic Factor VIII* ^	Altuviiio	Hemophilia A	antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein
2/27	Sparsentan tablets	Filspari	IgA nephropathy	endothelin and angiotensin II receptor antagonist
2/16	Velmanase Alfa-tycv inj*	Lamzede	Alpha-mannosidosis	human lysosomal alpha-mannosidase
12/22/22	Sodium phenylbutyrate suspension	Olpruva	Urea Cycle Disorders	nitrogen-binding agent
9/16	Elivaldogene autotemcel inj*	Skysona	Cerebral Adrenoleukodystrophy	gene therapy
8/31	Olipudase alfa injection*	Xenpozyme	Acid Sphingomyelinase deficiency	Hydrolytic lysosomal sphingomyelin-specific enzyme
8/17	Betibeglogene autotemcel* injection	Zynteglo	Beta Thalassemia	gene therapy
6/13	Vutrisiran injection*	Amvuttra	Hereditary Amyloidosis	RNAi therapeutic
4/28	Trientine tetrahydrochloride tablets	Cuvrior	Wilson's Disease	copper chelator
4/5	Alpelisib tablets	Vijoice	PIK3CA-related overgrowth spectrum	kinase inhibitor
3/22	Sirolimus topical gel	Hyftor	Facial Angiofibroma Associated with Tuberous Sclerosis	mTOR inhibitor
3/18	Ganaxolone oral suspension*	Ztalmy	CDKL5 deficiency disorder	neuroactive steroid GABA A receptor positive modulator

*first in class or novel ^once weekly dosing

Table of Oncology Drugs

Date	Generic	Brand	Indication	MOA
1/27	Pirtobrutinib tablets*	Jaypirca	Mantle Cell Lymphoma	Bruton's tyrosine kinase (BTK) inhibitor
1/27	Elacestrant tablets	Orserdu	Breast Cancer	estrogen receptor antagonist
12/22/22	Mosunetuzumab-axgb injection*	Lunsumio	Follicular Lymphoma	bispecific CD20-directed CD3 T-cell engager
12/16	Nadofaragene firadenovec-vncg suspension for intravesical use*	Adstiladrin	Bladder Cancer	non-replicating adenoviral vector-based gene therapy
12/12	Adagrasib tablets	Krazati	Non-Small Cell Lung Cancer	small-molecule inhibitor of KRAS G12C
12/1	Olutasidenib capsules*	Rezlidhia	Acute Myeloid Leukemia	isocitrate dehydrogenase-1 (IDH1) inhibitor
11/14	Mirvetuximab soravtansine-gynx injection*	Elahere	Ovarian Cancer, Fallopian Tube Cancer, Peritoneal Cancer	folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate
10/25	Teclistamab-cqyv injection	Tecvayli	Multiple Myeloma	bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
10/21	Tremelimumab-actl injection	Imjudo	Hepatocellular Carcinoma	cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody
9/30	Futibatinib tablets	Lytgobi	Cholangiocarcinoma	irreversible tyrosine kinase inhibitor of FGFR1, 2, 3 and 4
9/27	Bevacizumab-adcd injection, biosimilar to Avastin	Vegzelma	Colorectal Cancer, Non-Small Cell Lung Cancer, Glioblastoma Multiforme, Renal Cell Carcinoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube Cancer, Peritoneal Cancer	vascular endothelial growth factor (VEGF) inhibitor
9/20	Sodium thiosulfate injection	Pedmark	Prevention of cisplatin-induced ototoxicity	cisplatin neutralizing agent
9/9	Eflapegrastim-xnst injection*	Rolvedon	Neutropenia associated with chemotherapy	leukocyte growth factor

9/1	Pegfilgrastim-fpgk injection biosimilar to Neulasta	Stimufend	Neutropenia associated with chemotherapy	leukocyte growth factor
5/26	Pegfligrastim-pbbk injection biosimilar to Neulasta	Fylnetra	Neutropenia associated with chemotherapy	leukocyte growth factor
4/13	Bevacizumab-maly injection biosimilar to Avastin	Alymsys	Colorectal Cancer, Non-Small Cell Lung Cancer, Glioblastoma Multiforme, Renal Cell Carcinoma, Cervical Cancer, Ovarian Cancer, Fallopian Tube Cancer, Peritoneal Cancer	vascular endothelial growth factor (VEGF) inhibitor
3/23	Lutetium lu 177 vipivotide tetraxetan injection	Pluvicto	Prostate Cancer	Radioligand
3/18	Nivolumab and relatlimab-rmbw inection*	Opdualag	Melanoma	PD-1 blocking antibody and lymphocyte activation gene-3 blocking

***first in class or novel**