New Drug Update 2024: CV, Respiratory, GI, ID, Renal

Karen L. Kier, PhD, MSc, RPh, BCPS, BCACP, CTTS, FASHP, FCCP
Professor of Pharmacy Practice, Director of Drug and Health Information
Raabe College of Pharmacy, Ohio Northern University
k-kier@onu.edu

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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 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.

CARDIOVASCULAR

semaglutide (Wegovy)

March 8, 2024 Novo Nordisk

- The FDA approved an expanded label for semaglutide 2.4 mg once weekly for prevention of CV events in patients with overweight/obesity and prior CVD
- Based on positive results of the SELECT trial
- 17,604 people in study
- 6.5% of the semaglutide compared with 8% placebo ($p < 0.001$)

sotagliflozin (Inpefa) Tablets

May 26, 2023 Lexicon Pharmaceuticals
Heart Failure

- sodium-glucose cotransporter 2 (SGLT2) inhibitor used for heart failure
- both mechanisms of sodium-glucose co-transporter type 2 (SGLT2) and type 1 (SGLT1)
- heart failure patients including preserved and reduced left ventricular ejection fraction (LVEF) and for patients with or without diabetes
- Phase 3 cardiovascular outcomes studies in patients: SOLOIST-WHF (Worsening Heart Failure) and SCORED enrolled almost 12,000 patients
- CV benefits in patients with type 2 DM and CKD along with other cardiovascular risk factors
- 200 mg once daily not more than 1 hour before first meal of the day, increase to 400 mg once daily after ≥2 weeks
- may decrease to 200 mg once based on tolerability
- similar ADR profile to other SGLT2
- Beers list in those over 65 years old
- temporarily discontinue ≥3 days prior to surgery
- available as 200mg and 400mg tablets

colchicine (Lodoco) Tablets

June 16, 2023 AGEPHA
Pharma USA
Cardiovascular Risk Reduction

- alkaloid to reduce the risk of MI, stroke, coronary revascularization, and CV death in adults with established atherosclerotic disease or with multiple risk factors for CVD
- Colcrys (treatment and prophylaxis gout flares and the treatment of Familial Mediterranean fever)
- Mitigare and Gloperba for the prophylaxis of gout flares
- theory: suppress local cardiac production of inflammatory cytokines IL-1β, IL18, and IL-6 in patients with coronary artery disease
- 0.5 mg once daily, renal dosing adjustments (only commercially available)
- counsel on adequate fluid intake
- hold colchicine and call if diarrhea, stomach pain, upset stomach, and throwing up
- avoid in severe liver dysfunction
- clinical trials with over 5,500 patients, showed a hazard ratio of 0.65 (0.57-0.83)

sildenafil citrate (Liqrev) Oral Suspension

April 28, 2023
Pulmonary Arterial Hypertension

CMP Pharma

- ready-made oral liquid formulation of the PDE-5 inhibitor sildenafil for pulmonary arterial hypertension
- improve exercise ability and delay clinical worsening
- 20 mg orally three times a day
- strawberry flavor
- 122 mL bottle (10mg/mL)
- 24-month shelf life
- shake well before using for at least 10 seconds
- calibrated measuring device is recommended for use

aprocitentan (Tryvio) Tablets

March 19, 2024 Idorsia
High Blood Pressure

- endothelin receptor antagonist (ERA) for the combination treatment of hypertension not adequately controlled
- Novel mechanism of action, first-in-class
- endothelin receptor antagonist that inhibits the binding of endothelin (ET)-1 to ET_A and ET_B receptors
- ET-1 is a major driver of aldosterone production
- 12.5 mg orally once daily with or without food
- Phase 2 trials were with monotherapy
- Phase 3 trial (PRECISION) was combination therapy in resistant hypertension
- adults with SBP ≥140 mmHg who were prescribed at least three antihypertensives
- superior to placebo in lowering blood pressure at week 4, with a sustained effect at week 40 (pressure lowering seen at week 2)

aprocitentan (Tryvio) Tablets

- ADRs: edema/fluid retention, anemia, allergic dermatitis
- risk of birth defects
- only available through a restricted program
- TRYVIO Risk Evaluation and Mitigation Strategy
- estimated to be available in 2nd half of 2024
- FDA approved dose is 12.5 mg daily, the 25mg dose was also studied but not approved
- 25mg dose did not provide additional BP lowering effects compared to the 12.5mg dose
- 63% of patients in the PRECISION study were taking 4 meds or more

pegunigalsidase alfa-iwxj (Elfabrio) Injection

May 9, 2023
Fabry Disease

Protalix BioTherapeutics

- hydrolytic lysosomal neutral glycosphingolipid-specific enzyme for adults with Fabry disease
- Fabry disease is a rare X-linked lysosomal disorder resulting in excessive deposition of lipids in the tissues
- young patients usually present with stroke, skin lesions, heart attack, or renal failure
- recombinant human α–Galactosidase–A enzyme expressed in plant-cell culture designed to provide a long half-life
- initial half-life of 78.9 ± 10.3 hours
- IV infusion: 1 mg/kg every 2 weeks, specific infusion rates based on patient's weight
- 20 mg/10 mL vial

prothrombin complex concentrate, human-lans (Balfaxar) Lyophilized Powder for Injection

July 21, 2023 Octapharma USA
Warfarin Reversal in Urgent Surgery & Invasive Procedures

- blood coagulation factor replacement product for urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adults with need for an urgent surgery/invasive procedure
- contains vitamin K-dependent factors: Factor II (prothrombin), Factor VII, Factor IX and Factor X, and antithrombotic Proteins C and S
- clinical trial LEX-209 compared the efficacy and safety head-to-head with 4F-PCC (Kcentra)
- effective hemostasis in 94.6% of pts versus 93.5% with Kcentra
- 2,000 units once (Factor IX units), given IV push at 0.12 mL/kg/minute
- reconstituted solution should be administered immediately, but may be stored for up to 8 hours at 68°F to 77°F

ENDOCRINOLOGY

norgestrel (Opill) Tablets

July 13, 2023
Birth Control

Perrigo

- progestin-only birth control pill for the prevention of pregnancy
- over-the-counter
- all ages, not just adults
- take at the same time each day
- when one pack is done, start a new pack the next day
- do not skip days between starting a new pack
- if severe diarrhea or vomiting occur within 4 hours after taking a tablet, use a condom or other barrier method of contraception for the next 2 days (48 hours)
- If >3 hours late taking dose or if missed dose completely then take 1 tablet immediately, then continue taking 1 tablet once daily at the usual time
- use a condom or other barrier method of contraception for the first 2 days (48 hours) after the missed dose
- CDC US MEC US SPR app for phone or computer is very helpful

fezolinetant (Veozah) Tablets

May 12, 2023
Menopausal Disorders, Hot Flashes

Astellas Pharma

- selective neurokinin 3 (NK3) receptor antagonist for moderate to severe vasomotor symptoms (VMS) associated with menopause
- nonhormonal treatment, root cause
- balance between estrogens (ovaries) and neurokinin B (NKB) in the brain
- balance regulates the brain's temperature control center
- BRIGHT SKY™ program includes three Phase 3 clinical trials and Phase 4 (SKYLIGHT 4)
- measure LFTs before prescribing
- patients should not receive this drug if there LFTs are greater than or equal to 2x normal

fezolinetant (Veozah) Tablets

- 45 mg once daily
- administer same time each day with liquids
- can be taken with or without food
- swallow tablet whole--do not cut, crush, or chew
- missed dose as soon as remembered, if less than 12 hours to next dose, skip dose and wait for next scheduled dose
- counsel patients on signs and symptoms of liver damage such as dark urine, decreased appetite, upset stomach, light-colored stools, or yellow skin or eyes
- drug interaction potential with CYP1A2 (major)—includes caffeine

somatrogon-ghla (Ngenla) Injection

June 27, 2023 Pfizer
Pediatric Growth Hormone Deficiency

- long-acting human growth hormone analog for pediatric growth hormone deficiency
- growth failure due to inadequate secretion of endogenous growth hormone
- 3 years and up
- Phase 3 evaluated the safety and efficacy when administered once-weekly compared to once-daily somatropin
- study met its primary endpoint of non-inferiority as measured by annual height velocity at 12 months
- SC: 0.66 mg/kg/dose once weekly, stop if evidence of growth plate closure
- pen with dosage adjustments
- conversion charts available to switch from other GH products
- same day each week, at any time of the day
- abdomen, thighs, buttocks, or upper arms with weekly rotation of injection site
- Prefilled pens in 24mg/1.2mL (20mg/mL) and 60mg/1.2mL (50mg/mL)

donislecel-jujn (Lantidra) Cellular Suspension for Infusion

June 28, 2023
Diabetes, Type 1

CellTrans

- allogeneic pancreatic islet cellular therapy for type 1 diabetes mellitus in adults whose symptoms are not well controlled
- repeated episodes of severe hypoglycemia despite intensive diabetes management and education
- secretion of insulin by the infused allogeneic islet beta cells
- 2 non-randomized, single-arm studies with 30 pts with type 1 diabetes and hypoglycemic unawareness
- at least one infusion and a maximum of three infusions
- infusing into the hepatic portal vein
- use of immunosuppressive medications needed to maintain the islet cell viability
- 21 did not need to take insulin for a year or more
- 11 not needing insulin for one to five years
- 10 not needing insulin for more than five years
- 5 did not achieve any days of insulin independence
- ADRs: nausea, fatigue, anemia, diarrhea and abdominal pain

sitagliptin (Zituvio) Tablets

October 18, 2023
Diabetes, Type 2

Zydus Pharmaceuticals

- dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM
- 25 mg, 50 mg, and 100 mg tablets
- renal dosing with eGFR less than 30 mL/min
- branded equivalent to Januvia

metformin hydrochloride and sitagliptin (Zituvimet) Tablets

November 3, 2023 Zydus Pharmaceuticals
Diabetes, Type 2

- biguanide and dipeptidyl peptidase-4 (DPP-4) inhibitor combination as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM
- branded equivalent to Janumet
- available as 50 mg/500 mg and 50 mg/1000 mg
- twice daily, not extended-release

tirzepatide (Zepbound) Injection

November 8, 2023 Eli Lilly
Anti-obesity Medications for Weight Loss (Obesity/Overweight)

- glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist used for chronic weight management in adults
- adults with obesity (BMI of 30 kg/m^2 or greater) or those who are overweight (BMI of 27 kg/m^2 or greater) and have weight-related medical problems such as hypertension, dyslipidemia, type 2DM, obstructive sleep apnea or CV disease
- FDA has been evaluating reports of suicidal thoughts or actions in patients treated with GLP-1 RAs. A preliminary evaluation has not found evidence that the use of these medicines causes suicidal thoughts or actions, but the FDA is continuing to investigate this issue
- SC Initial: 2.5 mg once weekly for 4 weeks, then increase to 5 mg once weekly, may further increase dose in 2.5 mg/week increments every 4 weeks, if needed
- max 15 mg/week
- increase the risk of regurgitation and pulmonary aspiration of gastric contents during sedation or general anesthesia

Hummm! Not much to say! New COLD/COPD guidelines!

RESPIRATORY

GASTROINTESTINAL

budesonide (Eohilia) Oral Suspension

February 9, 2024
Eosinophilic Esophagitis

Takeda Pharmaceutical

- mucoadherent formulation of budesonide for eosinophilic esophagitis
- first and only FDA-approved oral therapy
- 11 years and older
- 2 mg/10 mL convenient, single-dose stick packs
- thixotropic properties – flowing more freely when shaken and returning to a viscous state when swallowed
- 2 mg twice daily for 12 weeks
- two multicenter, randomized, double-blind, parallel-group, placebo-controlled 12-week studies

natalizumab-sztn (Tyruko) Injection

August 24, 2023 Sandoz
Multiple Sclerosis, Crohn's Disease

- integrin receptor antagonist biosimilar to Tysabri, approved for multiple sclerosis and Crohn’s disease
- inducing and maintaining clinical response and remission in adults with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α
- BBW: progressive multifocal leukoencephalopathy
- REMS program
- Jan 2024 was available in Germany, First quarter 2024 for the US

etrasimod (Velsipity) Tablets

October 12, 2023 Pfizer
Ulcerative Colitis

- sphingosine-1-phosphate (S1P) receptor modulator for moderately-to-severely active ulcerative colitis (UC) in adults
- 2 mg once daily
- no live vaccines, give all age-appropriate vaccines before starting
- discontinue therapy if pt develops macular edema or posterior reversible encephalopathy syndrome
- increase risk of infections
- ADRs: ocular effects (monitor and counsel), SOB, infections, skin lesions, increase BP (monitor)
- Contraindications include CV disease including stroke, HF and AV block, pregnancy
- ELEVATE UC Phase 3 had to have failed on biologic or JAK inhibitor

infliximab-dyyb (Zymfentr) Subcutaneous Injection

October 20, 2023 Celltrion USA
Crohn's Disease, Ulcerative Colitis

- tumor necrosis factor (TNF) blocker for the ***maintenance*** of ulcerative colitis and Crohn’s disease in adults
- for pts who have received the IV version first
- LIBERTY-UC and LIBERTY-CD studies were placebo controlled
- 120 mg/mL both as prefilled syringe and auto-injector
- Company announced now available on March 17, 2024

mirikizumab-mrkz (Omvoh) Injection

October 26, 2023
Ulcerative Colitis

Eli Lilly

- interleukin-23 antagonist for moderately to severely active ulcerative colitis in adults
- first and only interleukin-23p19 (IL-23p19) antagonist
- baseline liver function tests, administer age-appropriate vaccinations, and screen for TB
- Induction: IV 300 mg at weeks 0, 4, and 8 (30 minute infusion)
- Maintenance: SC 200 mg (2 consecutive 100 mg injections) at week 12, then every 4 weeks
- IV vial is 300 mg per 15 ml
- SC is auto-injector or prefilled syringe at 100 mg/1 mL (rotate sites)

ustekinumab-auub (Wezlana) Injection

October 31, 2023 Amgen
Plaque Psoriasis, Psoriatic Arthritis, Crohn's Disease, Ulcerative Colitis

- human interleukin-12 and -23 antagonist interchangeable biosimilar to Stelara for plaque psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis
- launch expected in early 2025 with patent expiration of Stelara

vonoprazan (Voquezna) Tablets

November 1, 2023
Erosive Esophagitis

Phathom Pharmaceuticals

- potassium-competitive acid blocker (P-CAB) for erosive esophagitis
- approved in combinations prior to single product
- vonoprazan with amoxicillin (Voquezna Dual Pak)
- vonoprazon/amoxicillin/clarithromycin (Voquezna Triple Pak)
- treatment 20 mg once daily for 8 weeks
- maintenance 10 mg once daily for up to 6 months
- 10 mg and 20 mg tablets available
- clinical studies vonoprazan 20 mg demonstrated non-inferiority to lansoprazole 30 mg in the mean% of 24-hour heartburn free days over the healing period
- maintenance phase, vonoprazan 10 mg was superior to lansoprazole 15 mg in maintaining healing at 6 months

polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride (Suflave) Powder for Oral Solution

June 15, 2023
Bowel Preparation

Braintree Laboratories

- lemon-lime sports drink flavor
- low volume
- compared in clinical trials to SUPREP® Bowel Prep Kit, (sodium sulfate, potassium sulfate, and magnesium sulfate)
- 79% of patients found the taste neutral to very pleasant compared to SUPREP (54%)
- 87% found Suflave tolerable to very easy to consume
- 80% reported they would ask for Suflave for a subsequent colonoscopy
- low residue breakfast may be consumed on the day before colonoscopy, followed by clear liquids up to 2 hours prior to colonoscopy
- administration of two doses of Suflave are required for a complete preparation for colonoscopy
- each bottle must be reconstituted with water before ingestion
- each bottle and one flavor-enhancing packet are equivalent to one dose
- an additional 16 ounces of water must be consumed after each dose
- stop consumption of all fluids at least 2 hours before the colonoscopy

INFECTIOUS DISEASE

cefepime and enmetazobactam (Exblifep) Injection

February 22, 2024 Allecra Therapeutics
Urinary Tract Infection

- fourth generation cephalosporin and beta lactamase inhibitor combination for complicated urinary tract infections (cUTIs)
- FDA approved for adults
- 5-year patent extension under the Generating Antibiotic Incentives Now Act
- Phase 3 ALLIUM trials comparing to pip/tazo
- effectiveness against antimicrobial resistance in gram-negative bacteria, especially resistance mediated by both ESBL (Extended Spectrum Beta Lactamases) and AmpC
- 2.5 gm (2gm cefepime) every 8 hours by IV infusion over 2 hours
- eGFR between 60-129 mL/min
- Europe has given approval for treatment of pneumonia

sulbactam and durlobactam (Xacduro) Kit for Injection

May 23, 2023 Innoviva
Acinetobacter Pneumonia

- co-packaged product containing the beta-lactam antibacterial sulbactam and the beta lactamase inhibitor durlobactam for serious infections caused by Acinetobacter
- hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex
- 18 years and older
- Phase 3 ATTACK trial evaluating the safety and efficacy versus colistin
- statistical non-inferior for the primary endpoint of 28-day all-cause mortality in patients with carbapenem-resistant *Acinetobacter* infections
- sulbactam 1 g/durlobactam 1 g every 6 hours
- renal dosing interval (not dose) adjustments if eGFR is below 30 mL/min
- ADRs: rare hypersensitivity, C diff
- Monitor liver functions and potassium levels (hypokalemia)

metronidazole (Likmez) Oral Suspension

September 22, 2023 Appili Therapeutics and Saptalis Pharmaceuticals
Bacterial Infection, Trichomoniasis, Amebiasis

- oral liquid suspension of the nitroimidazole antimicrobial metronidazole for trichomoniasis, amebiasis, and anaerobic bacterial infections
- 500 mg/5 mL
- 200 mL bottle
- contains methylparaben, propylparaben
- strawberry peppermint flavor

nirmatrelvir and ritonavir (Paxlovid) Tablets

May 25, 2023 Pfizer Inc.
COVID-19

- nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, a HIV-1 protease inhibitor and CYP3A inhibitor for mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19
- available since December 2021 under EUA
- EPIC (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19) clinical development program with clinical trials
- 86% reduction in risk of COVID-19-related hospitalization or death through day 28 in patients who initiated treatment within 5 days of symptoms onset
- effective for both vaccinated and unvaccinated patients
- 12 to 17 years of age (weighing at least 40 kg) still under the existing EUA

nirmatrelvir and ritonavir (Paxlovid) Tablets

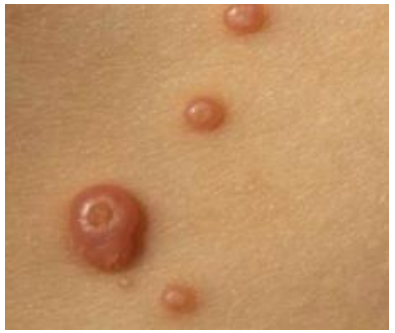
- nirmatrelvir 300 mg with ritonavir 100 mg, administered together, twice daily for 5 days
- If missed dose is less than 8 hours, take dose
- renal dosing: eGFR ≥30 to <60 mL/min--nirmatrelvir 150 mg and ritonavir 100 mg twice daily for 5 days
- Not recommended with eGFR below 30 mL/min
- 2 different dosing packs, one normal renal function and one for renal dosing
- ADRs: Change in taste (dysgeusia), diarrhea, muscle pain
- Rare reactions include hepatotoxicity, SJS, elevated BP with end organ damage
- Significant drug-drug interactions, specific recommendations for certain drugs. Statins should be held, different recommendations for DOAC

berdazimer sodium (Zelsuvmi) Topical Gel

January 5, 2024
Molluscum Contagiosum

Ligand Pharmaceuticals

- What is molluscum contagiosum (MC)?
- fairly common skin infection caused by a virus
- causes round, firm, painless bumps ranging in size from a pinhead to a pencil eraser
- If the bumps are scratched or injured, the infection can spread to nearby skin



berdazimer sodium (Zelsuvmi) Topical Gel

- nitric oxide-releasing agent for the topical treatment of molluscum contagiosum in adults and pediatric patients 1 year of age and older
- Pox virus
- Usually will resolve on its own (6 to 12 months)
- Remove lesions
- New topical gel
- Apply an even, thin layer once daily to each lesion for up to 12 weeks
- supplied as two tubes that must be mixed just prior to administration of each dose using, equal parts mixed together
- Do not mix on the skin, do not premix
- Wash hands after applying, do not bath or remove product for at least 1 hour after application
- Contains alcohol and is flammable
- Stop use and contact provider if skin changes are noted

cantharidin (Ycanth) Topical Solution

July 21, 2023
Molluscum Contagiosum

Verrica Pharmaceuticals

- topical terpenoid for molluscum contagiosum in adult and pediatrics 2 years and older
- unit dosed external solution 0.7% (1s, 6s, 12s)
- single application to cover each lesion
- do not use more than 2 applicators in a single treatment
- remove with soap and water 24 hours after treatment
- may re-treat every 3 weeks as needed
- avoid eyes and mucous membranes
- ADRs: 97% had skin reaction, vesiculation, pruritus, pain, discoloration, and erythema

rezafungin (Rezzayo) Powder for Injection

March 22, 2023
Candidemia, Systemic Candidiasis

Cidara Therapeutics

- echinocandin antifungal for candidemia and invasive candidiasis
- reserved for patients with limited or no alternative options
- not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*
- Qualified Infectious Disease Product (QIDP) designation, priority FDA review
- ReSTORE Phase 3 trial and STRIVE Phase 2 clinical trial
- statistical non-inferiority versus caspofungin
- rezafungin is once weekly dosing versus caspofungin daily
- 400 mg once on day 1, then 200 mg once weekly beginning on day 8 for up to 4 doses
- 200mg vial
- ADRs: hypokalemia, diarrhea, fever, infusion reactions

fecal microbiota spores, live-brpk (Vowst) Capsules

April 26, 2023
Prevention of Recurrent Clostridioides difficile Infection

Seres Therapeutics

- oral microbiome therapeutic to prevent the recurrence of Clostridioides difficile infection (CDI)
- Adults
- 4 capsules once daily for 3 days, beginning 2-4 days after completion of *C. difficile* regimen
- could contain food allergens
- ADRs: GI related, potential transmission of infections
  Interactions: Antibiotics
- Phase 3 studies including ECOSPOR III and ECOSPOR IV (open-label)
- ECOSPOR III in NEJM showed 88% with no recurrence at 8 weeks

taurolidine and heparin (DefenCath) Catheter Lock Solution

- thiadiazinane antimicrobial and anticoagulant combination to reduce catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter
- taurolidine is a thiadiazinane antimicrobial derived from the amino acid taurine
- NOT A FLUSH, not for systemic use
- heparin 1,000 units/mL and taurolidine 13.5 mg/mL (supplied 1000-13.5 unit-mg/mL)
- Instill a sufficient volume of solution into each catheter lumen at the conclusion of each HD session
- prior to initiation of the next HD session, aspirate and discard solution from the catheter
- clinical trial, 403 patients were assigned to the taurolidine/heparin combination and heparin only arms

omidubicel-onlv (Omisirge) Suspension for Infusion

April 17, 2023
Stem Cell Therapy

Gamida Cell

- modified allogeneic hematopoietic progenitor cell therapy for use in patients with hematologic malignancies to reduce risk of infection following stem cell transplantation
- benefit in acute myeloid leukemia, acute lymphoblastic leukemia, chronic myeloid leukemia and myelodysplastic syndromes
- reduce the time to neutrophil recovery and the incidence of infection
- orphan drug designation
- first allogeneic stem cell transplant therapy
- 12 years and older
- Phase 3 clinical study, omidubicel demonstrated a median time to neutrophil recovery of 12 days in the ITT population compared to 22 days for standard cord blood ($p<0.001$)
- patients require premedication prior to infusion of cells (diphenhydramine, hydrocortisone, acetaminophen)
- Avoid methylprednisolone, decreases effectiveness

anthrax vaccine adsorbed, adjuvanted (Cyfendus) Injection

July 20, 2023 Emergent BioSolutions
Anthrax Prophylaxis

- vaccine for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in persons 18 through 65 years when administered in conjunction with recommended antibacterial drugs
- solely on studies in animal models of inhalational anthrax
- Human phase 1 and 2 studies have been done
- Biomedical Advanced Research and Development Authority and support from the Defense Advanced Research Projects Agency and the National Institute of Allergy and Infectious Diseases
- component of the U.S. government's preparedness efforts against anthrax
- 2 doses administered over 14 days elicit protective levels of immune response
- ciprofloxacin or doxycycline

respiratory syncytial virus vaccine, adjuvanted (Arexvy) Suspension for Intramuscular Injection

May 3, 2023 GlaxoSmithKline
Prevention of RSV Infection

- active immunization for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older
- June 21, 2023, ACIP voted to recommend that adults aged ≥60 years may receive a single dose of an RSV vaccine, using shared clinical decision-making
- ACIP: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable
- HOWEVER: Data are lacking on the safety of coadministration with other vaccines that might be recommended for persons in this age group, such as COVID-19 vaccines; pneumococcal vaccines; adult tetanus, diphtheria, and pertussis vaccines; and the recombinant zoster vaccine
- When deciding whether to coadminister other vaccines with an RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences
- ONLY coadministration studies were with flu vaccine, which showed efficacy maintained but increase CNS side effects

respiratory syncytial virus vaccine, adjuvanted (Arexvy)
Suspension for Intramuscular Injection

- Not approved for children or pregnant patients
- 0.5 mL IM injection, one-time dose
- Deltoid injection
- 120 mcg/0.5 mL, contains polysorbate 80
- refrigerated between 36°F and 46°F, protect from light
- good at room temperature for 4 hours
- powder (antigen vial) must be reconstituted (slowly injected) with the liquid (adjuvant vial), gently swirl, do not shake
- liquid should be opalescent, colorless to pale brownish

respiratory syncytial virus vaccine (Abrysvo) Injection

May 31, 2023 Pfizer, Inc.
RSV

- for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)
- individuals 60 years and older and pregnant patients 32 through 36 weeks' gestation (September through January in most of the continental US)
- 0.5 mL IM injection, deltoid
- powder reconstituted with the provided diluent (sterile water), use vial adapter provided, swirl (do not shake), twist to disconnect syringe from adapter
- should be a clear, colorless solution
- give immediately, good for 4 hours out of refrigerator

RSV Vaccine Errors—CDC

Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People

Vaccine administration errors are known to occur and are routinely monitored through the Vaccine Adverse Event Reporting System (VAERS). Since approval of RSV vaccines and the monoclonal antibody nirsevimab, **the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have received reports of the Pfizer (Abrysvo) or GSK (Arexvy) RSV vaccines being administered in error to young children. CDC and FDA have also received reports of the GSK RSV vaccine (Arexvy) being administered in error to pregnant people.** As of January 17, 2024, the number of reports received by VAERS suggests that these types of errors are uncommon in young children less than 2 years of age (25 reports) and pregnant people (128 reports) relative to an estimated 1 million infants protected from RSV either through infant receipt of nirsevimab or through vaccination of pregnant people.

nirsevimab-alip (Beyfortus) Injection

July 17, 2023 AstraZeneca
RSV

- respiratory syncytial virus F protein-directed fusion inhibitor for the prevention of RSV lower respiratory tract disease in neonates and infants
- newborns and infants born during or entering their first RSV season and for children up to 24 months vulnerable to severe RSV through their second RSV season
- first preventive option
- single dose long-acting antibody
- weight-based dosing
- IM in the anterolateral aspect of the thigh
- store vials between 36°F to 46°F in original carton to protect from light
- may be kept at 68°F to 77°F for a maximum of 8 hours
- after removal from the refrigerator, must be used within 8 hours or discarded
- shortages have been an issue

meningococcal groups A, B, C, W, and Y vaccine (Penbraya) Injection

October 20, 2023 Pfizer

Meningococcal Disease Prophylaxis

- active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals 10 through 25 years of age
- first and only pentavalent vaccine
- IM injection 0.5 mL/dose administered as a 2-dose series at 0 and 6 months
- suspension reconstituted
- monitor for hypersensitivity and syncope for 15 minutes following administration

RENAL/HEPATIC

tenapanor (Xphozah) Tablets

October 17, 2023 Ardelyx
Hyperphosphatemia of Renal Failure

- sodium hydrogen exchanger 3 (NHE3) inhibitor to treat hyperphosphatemia in adults with chronic kidney disease
- add-on therapy in pts on dialysis who have an inadequate response to phosphate binders or who are unable to tolerate phosphate binders
- 30 mg twice daily, may decrease dose if needed based on serum phosphate concentration and GI tolerability
- 20 mg, 30 mg tablets
- 5 to 10 minutes before a meal increased the 24-hour stool sodium excretion compared to administration in the fasting state
- ADRs: diarrhea is common (severe in 3-5%),
- Monitor for diarrhea and dehydration, serum phosphorus and potassium
- Ibsrela is the approved form for IBS-C (50 mg tablet)
- BBW: Avoid use in pts 6 to <12 years of age, safety and effectiveness have not been established in pts <18 years of age (serious dehydration)

resmetirom (Rezdiffra) Tablets

March 14, 2024
Metabolic Dysfunction-Associated Steatotic Liver Disease

Madrigal Pharmaceuticals

- thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis
- liver fibrosis stages F2 to F3, not for decompensated liver disease
- adults
- accelerated approval by FDA BUT verification and description of clinical benefit in ongoing confirmatory trials
- Phase 3 MAESTRO-NASH trial, NEJM 100 mg and 80 mg doses of Rezdiffra demonstrated statistically significant improvement compared to placebo, 52 week trial
- <100 kg recommended 80 mg daily
- ≥100 kg recommended 100 mg daily
- Distributed through specialty pharmacy network, available April 2024

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

Need More Information?

Karen L. Kier, PhD, MSc, RPh, BCPS, BCACP, CTTS, FASHP, FCCP
k-kier@onu.edu