New Drug Update 2023: What's Hot and What's Not

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Disclosure

- Speaker Bureau
  - Sanofi-Pasteur, Merck, Pfizer – Vaccines
  - AbbVie and Biohaven – Migraines
  - Idorsia – Insomnia
- Consultant
  - Sanofi-Pasteur, Merck, Pfizer, Moderna, and Seqirus – Vaccines
  - GlaxoSmithKline – OA and Pain
  - Bayer – Chronic Kidney Disease
  - Idorsia – Insomnia
  - Shield Therapeutics – Iron Deficiency Anemia
- All relevant financial relationships have been mitigated.

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Objectives

- At the end of this presentation, the participant will be able to:

1. Identify several new medications.
2. Discuss the use, adverse effects, drug-drug interactions, and benefits of each of the medications.
3. Discuss updates related to labeling, indications, and risks associated with various medications.

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Tips

- References
  - Listed throughout and at the end of the presentation
- To facilitate your learning
  - Specific tables/images can be viewed full page at the end of your handout.

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New Drugs

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Center for Drug Evaluation and Research (CDER) 2022 Data

37 new medications approved

Majority: oncology, biologics (asthma, psoriasis), rare/orphan diseases

https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022
Accessed 01-03-2023

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Women's Health

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Ibrexafungerp (Brexafemme®)[1]

Ibrexafungerp

- Class
  - Antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis
    - New indication: reduction of recurrent infections
  - Inhibits glucan synthase, an enzyme involved in the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall
  - Has activity against the following species: *Candida auris, Candida dubliniensis, Candida glabrata, Candida guilliermondii, Candida keyfr, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis*
  - *In vitro* activity against –azole resistant strains

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Ibrexafungerp[1] (continued)

- Dosage
  - Acute treatment: 300 mg twice daily × 1 day (600 mg total)
    - Available in 150 mg tablets
    - Administer 12 hours apart.
    - With or without food
  - Recurrence reduction:
    - 300 mg PO every 12 hours x 1 day
    - Administer on the same day every month

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Ibrexafungerp[1] (continued)

Contraindications

- Pregnancy – Verify pregnancy status is child-bearing age women before administering
- Ibrexafungerp administered orally to pregnant rabbits during organogenesis was associated with fetal malformations including absent forelimb(s), absent hind paw, absent ear pinna, and thoracogastroschisis at dose exposures greater or equal to approximately 5 times the human exposure at the recommended human dose (RHD).
- Advise women to avoid pregnancy for 4 days after the last dose is taken.

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Ibrexafungerp[1] (continued)

- Efficacy
  - 545 women were exposed to drug in two placebo controlled, double blind trials
  - 18–76 years of age
- Drug interactions
  - CYP 3A4 substrate
  - Strong 3A4 inhibitors – Reduce dose to 150 mg two times daily (12 hours apart)
  - Strong-moderate 3A4 inducers – Not studied; avoid

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Ibrexafungerp[1] (continued)

- Adverse events (drug vs. placebo)
  - Diarrhea (16.7% vs. 3.3%)
  - Nausea (11.9% vs. 4.0%)
  - Abdominal pain (11.4% vs. 5.1%)
  - Dizziness (3.3% vs. 2.5%)
  - Vomiting (2.0% vs. 0.7%)
- Good RX pricing:
  - 4 tablets: 1 carton: $494.00

- Warnings and precautions
  - No evidence of QT prolongation
- Efficacy (drug vs. placebo)
  - Trial one – Complete clinical response
    - **50% vs. 28% (p 0.001)**
  - Trial two – Complete clinical response
    - **63.5% vs. 44.9% (p 0.009)**

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Neurology

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Most Controversial Approval

Figure 2

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Aducanumab-avwa (Aduhelm™)[2]

- Class
  - An amyloid beta-directed antibody which in clinical trials demonstrated a reduction in amyloid beta plaques
  - Recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta
- Indication
  - Initiated in the mild dementia stage of Alzheimer's

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Aducanumab-avwa (Aduhelm™)[2] (continued)

- Dosing
  - Titration schedule
  - Dosages must be separated by 21 days
  - IV infusion (every 4 weeks)
    - **Infusion 1 and 2: 1 mg/kg over 1-hour**
    - **Infusion 3 and 4: 3 mg/kg over 1-hour**
    - **Infusion 5 and 6: 6 mg/kg over 1-hour**
    - **Infusion 7 and beyond: 10 mg/kg over 1-hour**
    - **10 mg/kg: Once monthly indefinitely**

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Aducanumab-avwa (Aduhelm™)[2] (continued)

- Monitoring
  - MRI within 1-year of starting the medication
  - Obtain repeat MRI after the 6th and before the 7th infusion.
  - Obtain repeat prior to the 12th infusion.
    - 6th infusion of the maximum dose of 10 mg/kg
  - There are specific criteria which warrant discontinuation of the infusions. (See next slide.)

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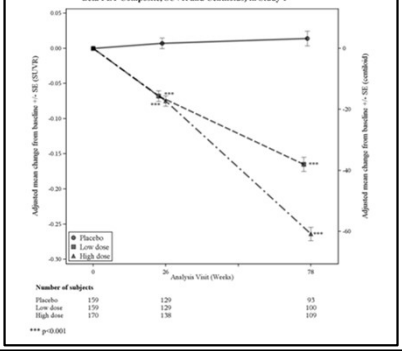
Aducanumab

Figure 1: Reduction in Brain Amyloid Beta Plaque (Change from Baseline in Amyloid Beta PET Composite, SUVR and Centiloids) in Study 1



Number of subjects

Placebo	159	129	93
Low dose	159	129	100
High dose	170	138	109

*** p<0.001

Figure 3

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Aducanumab (cont.)

Table 5: Clinical Results of ADUHELM in Study 1

Clinical Endpoint at Week 78	ADUHELM High dose (N=547)	Placebo (N=548)
CDR-SB		
Mean baseline	2.51	2.47
Change from baseline	1.35	1.74
Difference from placebo (%)	-0.39 (-22%) p=0.0120	
MMSE		
Mean baseline	26.3	26.4
Change from baseline	-2.7	-3.3
Difference from placebo (%)	0.6 (-18%) p=0.0493	
ADAS-Cog 13		
Mean baseline	22.246	21.867
Change from baseline	3.763	5.162
Difference from placebo (%)	-1.400 (-27%) p=0.0097	
ADCS-ADL-MCI		
Mean baseline	42.5	42.6
Change from baseline	-2.5	-4.3
Difference from placebo (%)	1.7 (-40%) p=0.0006	
NPI-10[1]		
Mean baseline	4.5	4.3
Change from baseline	0.2	1.5
Difference from placebo (%)	-1.3 (-87%) p=0.0215	

[1]P-value was not statistically controlled for multiple comparisons.

Figure 4

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Aducanumab-avwa (Aduhelm™)[2] (continued)

- Adverse events
  - Amyloid imaging related abnormalities-edema (ARIA-E) which are seen on MRI as brain edema
  - Amyloid imaging related abnormalities-hemosiderin deposition (ARIA-H) which are seen as microhemorrhage and superficial siderosis
  - These were seen in 41% of individuals treated with the 10 mg/kg dosage vs. 10% of placebo.

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Aducanumab-avwa (Aduhelm™)[2] (continued)

- Adverse events (drug vs. placebo)
  - ARIA-E: 35% vs. 3%
  - Headache: 21% vs. 16%
  - ARIA-H microhemorrhage: 19% vs. 7%
  - ARIA-H superficial siderosis: 15% vs. 2%
  - Fall: (15% vs.12%)
  - Diarrhea: (9% vs. 7%)
  - Confusion/altered mental status: 8% vs. 4%

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Aducanumab-avwa (Aduhelm™)[2] (continued)

- Cost:
  - 100 mg/mL (1 vial, 1.7 mL): $981.00
  - 100 mg/mL (1 vial, 3 mL): $1,723.00
  - Initial estimated cost – About $56,000 per year
  - Cost cut by 50% to spur use

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Now What…

- Medicare coverage of aducanumab is now limited to beneficiaries enrolled in approved clinical trials.

- "There is the potential for promise with this treatment; however, there is not currently enough evidence of demonstrating improved health outcomes to say that it is reasonable and necessary for people with Medicare."

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Atogepant (Qulipta™)[3]

- Class
  - Calcitonin gene-related peptide receptor antagonist
- Indication
  - Indicated for the prevention of episodic migraine in adults
- Dosage
  - 10 mg, 30 mg, or 60 mg taken once daily; with or without food

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Atogepant (Qulipta™)[3] (continued)

- Dosing modifications
  - Strong CYP 3A4 inhibitors – 10 mg once daily
    - Itraconazole, clarithromycin, ketoconazole
  - Strong/moderate CYP 3A4 inducers
    - 30–60 mg once daily
    - Rifampin, carbamazepine, hypericum
  - OATP inhibitors
    - 10 mg or 30 mg once daily
    - Rifampin
  - Severe renal impairment
    - Creatinine clearance <30 mL/min – 10 mg once daily

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Atogepant (Qulipta™)[3] (continued)

- Efficacy
  - 1958 patients in clinical trials
  - Two double blind, placebo-controlled trials
  - Trials conducted for 6 and 12 months
  - Allowed to use all “acute treatment medications except other CGRP antagonists
  - Multiple measures assessed

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Atogepant (Qulipta™)[3] (continued)

Monthly Migraine Days 12 weeks	10 mg	30 mg	60 mg	Placebo
Baseline	7.5	7.9	7.8	7.5
Mean change	-3.7	-3.9	-4.2	-2.5
P value	<0.001	<0.001	<0.001	

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Atogepant (Qulipta™)[3] (continued)

- Warnings and precautions
  - Avoid use in pregnancy and lactation.
  - Avoid use in severe liver disease.

- Adverse events (placebo vs. 10/30/60 mg)
  - Nausea
    - 3% vs. 5% vs. 6% vs. 9%
  - Constipation
    - 1% vs. 6% vs. 6% vs. 6%
  - Fatigue/somnolence
    - 3% vs. 4% vs. 4% vs. 6%
  - Decreased appetite
    - <1% vs. 2% vs. 1% vs. 2%

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Atogepant (Qulipta™)[3] (continued)

- Contraindications
  - None

- Cost
  - $1,000 for 30 pills

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Daridorexant (Quviviq™)[4]

- Class
  - Orexin antagonist
  - "Turns off the wakefulness center"
- Indication
  - Treatment of individuals with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance
- Dosage
  - 25 mg and 50 mg
  - Approved and now available

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Daridorexant (Quviviq™)[4] (continued)

- 50 mg dose
  - Reduced time to fall asleep by 30 minutes
  - Reduced time await during night by 60 minutes
  - Improved scores on daytime sleepiness
  - Improved over 1-month and continued to improve for 1-year
- Adverse events
  - Headache
    - 6%, 7% vs. 5% placebo
  - Fatigue
    - 2%, 3% vs. 1% placebo
  - Nausea
    - 0, 3% vs. 1% placebo
  - Dizziness
    - 2%, 3%, vs. 2%
- To prescribe
  - RX needs to be sent to Vita Care Pharmacy in Boca Raton, Florida
  - Starting to become available in local pharmacies

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Cardiology/Nephrology

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Finerenone (Kerendia®)[5]

- Class
  - Non-steroidal mineralocorticoid receptor antagonist (MRA)
  - Finerenone blocks MR mediated sodium reabsorption and MR overactivation in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, and blood vessels) tissues.
  - It has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.
- Indication

  Reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

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Finerenone (Kerendia®)[5] (continued)

- Dosage
  - 10–20 mg starting dose based upon eGFR and potassium dosed once daily
    - **eGFR: ≥60 mL/min/1.73 m^2 – 20 mg once daily**
    - **eGFR: ≥25 to <60 mL/min/1.73 m^2 – 10 mg once daily**
    - **eGFR: <25 mL/min/1.73 m^2 – Not recommended**
  - Increase dose to 20 mg once daily at 4 weeks based upon eGFR and serum potassium
  - May be dosed with or without food; may be crushed and mixed with water or soft foods

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Finerenone (Kerendia®)[5] (continued)

	10 mg Once Daily	20 mg Once Daily
Potassium: ≤4.8 mEq/L	Increase dose to 20 mg daily.	Maintain dose of 20 mg daily.
Potassium: >4.8–5.5 mEq/L	Maintain 10 mg once daily.	Maintain dose of 20 mg once daily.
Potassium: >5.5 mEq/L	Withhold finerenone Consider restarting at 10 mg once daily when potassium ≤5.0 mEq/L.	Withhold finerenone Restart at 10 mg once daily when potassium ≤5.0 mEq/L.

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Finerenone (Kerendia®)[5] (continued)

- Monitoring
  - Check potassium prior to initiating this medication.
  - Do not initiate if potassium is >5.0 mEq/L.
  - Check potassium periodically and prior to increasing dosage.

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Finerenone (Kerendia®)[5] (continued)

- Efficacy
  - Reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of ≥40%, kidney failure, or renal death.
  - The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and reduced progression to kidney failure.
  - Reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure

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Finerenone (Kerendia®)[5] (continued)

- Contraindications
  - Concomitant use of strong CYP 3A4 inhibitors
    - **Increased finerenone AUC by >400%**
  - Patients with adrenal insufficiency

- Warnings and precautions
  - Hyperkalemia
    - Monitor potassium levels and adjust dosage as needed.
  - Avoid grapefruit and grapefruit juice.
  - Avoid strong or moderate CYP 3A4 inducers.
  - Not studied in pregnancy or lactation

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Finerenone (Kerendia®)[5] (continued)

- Adverse events (drug vs. placebo)
  - Hyperkalemia (18.3% vs. 9.0%)
  - Hypotension (4.8% vs. 3.4%)
  - Hyponatremia (1.4% vs. 0.7%)
- Cost
  - $600 per month

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Endocrinology

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Tirzepatide (Mounjaro)

- Class: GIP/GLP-1 agonist
  - Works by increasing insulin secretion, decreasing glucagon secretion, increasing insulin sensitivity and delaying gastric emptying
  - Indications:
    - Type 2 diabetes (adults only); it is not indicated for Type 1 diabetes
  - Dosing:
    - 2.5 mg sc once weekly x 4 weeks; then 5 mg once weekly x 4 weeks; then 7.5 mg once weekly x 4 weeks; then 10 mg once weekly x 4 weeks; then 12.5 mg once weekly x 4 weeks
    - Maximum: 15 mg once weekly

https://uspl.lilly.com/mounjaro/mounjaro.html#pi accessed 01-05-2023

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Tirzepatide

- Clinical trials/efficacy
  - 1539 (30.1%) were 65 years of age or older, and 212 (4.1%) were 75 years of age or older
  - 5 clinical trials to assess efficacy: SURPASS 1-5
    - 40-week monotherapy trial:
      - A1C baseline: (8.1, 8.0, 7.9, 7.9)
      - A1C 40 weeks (placebo, 5 mg, 10 mg, and 15 mg)
        - -0.1, -1.8, -1.7, -1.7
      - Weight baseline
        - -1.0kg, -6.3kg, -7.0kg, -7.8kg

https://uspl.lilly.com/mounjaro/mounjaro.html#pi accessed 01-05-2023

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Tirzepatide

- Precautions/warnings:
  - No hepatic and renal dosing adjustments
  - Caution: history of gastroparesis or pancreatitis
  - Caution when adding to medications with narrow therapeutic index
  - Do not use in pregnancy; no data on impact in lactation
- Contraindications:
  - Patients with medullary thyroid carcinoma or family history of such
  - Patients with multiple endocrine neoplasia syndrome

https://uspl.lilly.com/mounjaro/mounjaro.html#pi accessed 01-05-2023

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Tirzepatide

- Adverse reactions (placebo, 5 mg, 10 mg, and 15 mg)
  - Nausea: (4%, 12%, 15%, 18%)
  - Diarrhea: (9%, 12%, 13%, 17%)
  - Decreased appetite: (1%, 5%, 10%, 11%)
  - Vomiting: (2%, 5%, 5%, 9%)
  - Constipation: (1%, 6%, 6%, 7%)
- Cost: approximately 1000.00 for 4 weeks
  - Numerous copay cards are available online

https://uspl.lilly.com/mounjaro/mounjaro.html#pi accessed 01-05-2023

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Teplizumab-mzwv (Tzield)

- Class: Anti-CD3 Antibodies
- Indication:
  - Diabetes mellitus type 1, Stage 2
    - 8 years of age and older
  - Exact MOA is unknown: binds to CD3, may produce deactivation of pancreatic beta cell autoreactive T cells
- Dosing:
  - IV titration schedule from day 1 – day 14 (30 minute minimum)
  - Premedicate with antipyretic, antihistamine, and/or antiemetic prior to 1st 5 doses, then as needed

https://static1.squarespace.com/static/5f4574ed93f3456c76f3a95d/t/638f76b5ec1e430049cf4cd9/1670346457470/tzield-full-prescribing-information.pdf accessed 01-05-2023

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Teplizumab-mzwv

- Prior to initiation, must confirm Type 1 diabetes stage 2
  - Confirm Stage 2 T1D by documenting at least two positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method if appropriate and OGTT is not available
  - CBC and hepatic panel are required
  - Make sure all vaccinations are up to date (at least 8 weeks before treatment initiation)

https://static1.squarespace.com/static/5f4574ed93f3456c76f3a95d/t/638f76b5ec1e430049cf4cd9/1670346457470/tzield-full-prescribing-information.pdf **accessed 01-05-2023**

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Teplizumab-mzwv

- Monitoring:
  - Discontinue if AST or ALT is 5x or more upper limits of normal
  - CBC: monitor white count and discontinue if severe lymphopenia occurs
  - Monitor for serious infections; may need to d/c or place on hold if it occurs
  - Acute hypersensitivity reactions

https://static1.squarespace.com/static/5f4574ed93f3456c76f3a95d/t/638f76b5ec1e430049cf4cd9/1670346457470/tzield-full-prescribing-information.pdf **accessed 01-05-2023**

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Teplizumab-mzwv

- Clinical trial efficacy:
  - In Study TN-10, Stage 3 type 1 diabetes was diagnosed in 20 (45%) of the teplizumab patients and in 23 (72%) of the placebo-treated patients
  - Median time from randomization to Stage 3 type 1 diabetes diagnosis was 50 months in the teplizumab group and 25 months in the placebo group

https://static1.squarespace.com/static/5f4574ed93f3456c76f3a95d/t/638f76b5ec1e430049cf4cd9/1670346457470/tzield-full-prescribing-information.pdf accessed 01-05-2023

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Infectious Disease

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COVID-19 Treatments EUA Approvals

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Ritonavir-boosted nirmatrelvir (Paxlovid®)

EUA approval only

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Ritonavir-boosted nirmatrelvir[7] (continued)

- EUA approval
  - The treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

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Ritonavir-boosted nirmatrelvir[7] (continued)

- Class
  - Nirmatrelvir is a SARS-CoV-2 main protease (Mpro) inhibitor.
    - **Inhibits viral replication**
  - Ritonavir is an HIV-1 protease inhibitor.

- Study
  - Phase 2/3, randomized, double-blind, placebo-controlled study in nonhospitalized symptomatic adult subjects with a laboratory confirmed diagnosis of SARS-CoV-2 infection

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Covid-related Death or Hospitalization within 28 Days

- Efficacy

Placebo (n=1046)	Drug (n=1039)
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Ritonavir-boosted nirmatrelvir[7] (continued)

- Dosing
  - Initiate as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset.
  - Dosed with or without food
  - 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days
  - If the patient misses a dose within 8 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule.

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Ritonavir-boosted nirmatrelvir[7] (continued)

- Warnings and precautions
  - Dose reduction for moderate renal impairment (eGFR ≥30 to 60 mL/min/1.73m^2)
    - **150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days**
  - Not recommended for patients with eGFR <30 mL/min/1.73 m^2
  - Not recommended for those with severe liver disease

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Numerous Drug Interactions[7]

Avoid with the following medications (CY3A cleared)

- Alpha1-adrenoreceptor antagonist – Alfuzosin
- Analgesics – Pethidine, piroxicam, propoxyphene
- Antianginal – Ranolazine
- Antiarrhythmic – Amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout – Colchicine
- Antipsychotics – Lurasidone, pimozide, clozapine
- Ergot derivatives – Dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors – Lovastatin, simvastatin
- PDE5 inhibitor – Sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH)
- Sedative/hypnotics – Triazolam, oral midazolam

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CYP 3A Inducers[7]

- Will result in decrease in levels and can result in reduced efficacy and drug failure
  - Anticancer drugs – Apalutamide
  - Anticonvulsant – Carbamazepine, phenobarbital, phenytoin
  - Antimycobacterials – Rifampin
  - Herbal products – St. John's Wort (hypericum perforatum)

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Ritonavir-boosted nirmatrelvir[7] (continued)

- Adverse events (drug vs. placebo)
  - Dysgeusia (6% vs. <1%)
  - Diarrhea (3% vs. 2%)
  - Hypertension (1% vs. <1%)
  - Myalgias (1% vs. <1%)
  - 2% in the treatment group discontinued due to an adverse event; 4% in the placebo arm

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Molnupiravir[8] (MK-4482)

EUA only; NOT FDA approved

- Indication
  - Treatment of mild-moderate coronavirus 19 in adults with a positive test and who are at increased risk for progressing to moderate-severe disease
  - Outpatient treatment; not indicated for hospitalized patients
- Class – Nucleoside analogue
  - Works by inhibiting viral replication of SARS-CoV-2
  - Results in an accumulation of errors in the viral genome leading to inhibition of replication

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Molnupiravir[8] (continued)

Efficacy

- 1433 patients studied in clinical trials
- Double-blinded, placebo-controlled trial
- Similar efficacy across Alpha, Beta, Gamma, and Delta variants
- MOVe-OUT Trial

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Molnupiravir[8] (continued)

Molnupiravir	Placebo
All-cause hospitalization ≥24 hours for acute care or death through day 29	All-cause hospitalization ≥24 hours for acute care or death through day 29
48 (6.8%)	68 (9.7%)
All cause mortality through day 29	All cause mortality through day 29
1 (0.1%)	9 (1.3%)

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Molnupiravir[8] (continued)

- Dosage
  - 800 mg every 12 hours × 5 days (available in 200 mg capsules)
  - May be dosed with or without food
  - No dosing adjustments for individuals 65 years of age and older
- Patient instructions
  - Begin as soon as possible after the onset of symptoms; ideally within 5 days
  - If they miss a dose of molnupiravir and it is within 10 hours of the time it is usually taken, the patient should take it as soon as possible and resume the normal dosing schedule. If >10 hours, take next dose at regularly scheduled time.

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Molnupiravir[8] (continued)

Contraindications
- None at present
- Not recommended for use in pregnancy or breastfeeding (use contraception for 4 days after the last dose)
  - **Oral administration of molnupiravir to pregnant rats during the period of organogenesis resulted in embryofetal lethality and teratogenicity at 8 times the human NHC (N4-hydroxycytidine) exposures at the recommended human dose (RHD)**
- Not approved for children aged <18 years

- Adverse reactions (drug vs. placebo)
  - Diarrhea (2% vs. 2%)
  - Dizziness (1% vs. 1%)
  - Nausea (1% vs. 1%)

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Molnupiravir[8] (continued)

Precautions and warnings
- Has not been studied in those with eGFR <30 mL/min/1.73 m^2
- Has not been studied in those with moderate-severe liver disease

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PANORAMIC RCT

- 26,411 high risk adults previously vaccinated against SARS-CoV-2
  - Receiving molnupiravir did not reduce rates of hospitalizations or deaths
  - Molnupiravir was linked with shortened recovery time, less primary care services, and decreased viral load

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Quick Updates and Additional Approvals

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New indications

- Semaglutide (Wegovy)
  - Approved 2.4 mg once weekly dosage for use in adolescents 12 years of age and older with obesity
  - Defined as:
    - BMI at or above the 95th percentile for age and sex
- Phentermine/topiramate (Qsymia)
  - Approved for 12 years of age and older with obesity

https://www.medscape.com/for-you?src=WNL_recnlnew1_broad_US_perso_artid986403.0&uac=45241HZ230105&impID=5061962 accessed 01-05-2023

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New

- Secnidazole[9] (Solosec®)
  - Approved for the treatment of trichomoniasis
  - 2 grams as a single dose
  - ALSO, NEW APPROVAL
    - 12 years of age and older for BV and trichomoniasis
- Azelastine hydrochloride nasal spray, 0.15% approved for OTC sales; individuals ages 6 years and older

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Updates

- Montelukast (Singulair®)
  - FDA strengthened warnings re: serious behavior changes and mood changes
- Hydrochlorothiazide
  - Labeling changed to reflect small but increased risk of nonmelanoma skin cancers

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Additional Indications

- Canaglifozin (Invokana®)
  - Approved to reduce risk of end-stage renal disease, CV death, and risk of hospitalization from CHF
- Dapagliflozin (Farxiga®)
  - Approved to reduce the risk of hospitalization from CHF in adults with type 2 diabetes and cardiovascular disease or multiple cardiovascular risk factors

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Approval

- Fluticasone/umeclidinium/vilanterol (Trelegy™ Ellipta)
  - Approved for asthma maintenance
- Capsaicin 8% patch (Qutenza®)
  - Approved for DPN of the feet
- Levonorgestrel-releasing intrauterine system (Mirena®)
  - Approved for use up to 8 years

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Additional Indications/Approvals or Changes

- Dapagliflozin (Farxiga®)
  - Approved to reduce hospitalizations in patients with congestive heart failure with reduced EF (HFrEF) – With or without diabetes
- Celecoxib (Elyxyb™)
  - Approved for acute migraine
    - 25 mg of celecoxib per every 4.8mL
- Canagliflozin
  - Warning of lower extremity amputation removed by the FDA

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Additional Approval

- Liraglutide (Victoza®)
  - Approved for type 2 diabetes in children ≥10 years of age
- Dupilumab (Dupixent®)
  - Chronic rhinosinusitis in adults with nasal polyposis
    - IL-4 receptor antagonist
    - Already approved for patients with asthma
- Bempedoic acid and ezetimibe (Nexlizet®)
  - Approved for adjunct to statins for ASCVD or heterozygous familial hypercholesterolemia

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Spinosad (Natroba™)

- Topical suspension
- Pediculocide
- Approved for the treatment of scabies in patients 4 years of age and older
- Adverse events
  - 1% application site irritation and dry skin
- Also indicated for head lice in individuals 6 months of age and older.

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Self-injectable Omalizumab[10] (Xolair®)

- Moderate-severe asthma, nasal polyposis, or chronic urticaria
- FDA has approved self-injection.
- Approved for those with no history of anaphylaxis

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Dupilumab

- The Food and Drug Administration (FDA) has approved dupilumab for the treatment of moderate to severe atopic dermatitis in pediatric patients aged 6 months to 5 years whose disease is not adequately controlled with topical therapies or when those therapies are not advisable.

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Immunizations

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PCV 15 and PCV 20

- Age 65 years
  - PCV 15 followed by PPSV23 ***or***
  - PCV 20

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Pneumococcal Recommendations

- Age 18–64 years
  - High or very high-risk condition
    - PCV 15 followed by PPSV 23 ***or*** PCV 20

- Age 65 years and older
  - PCV 15 followed by PPSV23 ***or***
  - PCV 20

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Update[11]

- When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1-year.
- A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak.
- Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1-year after their last PPSV23 dose.
- When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

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RZV

- Recombinant Zoster Vaccine (Shingrix®)
- Approved by FDA for 18 years of age and older; immunocompromised
- Two dose series: day 0 and day 1–2 months
- CDC: Now 19 years – and up; immunocompromised

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New

- Universal hepatitis B vaccination for all unvaccinated adults aged 19 – 59 years
  - Those with risk factors and aged 60 years and older should also be immunized against Hepatitis B.
- PCV 15 may now be substituted in children for PCV 13.
- MCV4 (Menactra®) is being replaced by MenQuadFi®.

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Thank you!

I would be happy to entertain any questions or comments

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End of Presentation!
Thank you for your time, attention.

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Figure 1	U.S. FDA (www.fda.gov) (2022, Jan. 22) Advancing Health through Innovation: New Drug Therapy Approvals 2021. Center for Drug Evaluation and Research. https://www.fda.gov/media/155227/download
Figure 2	Microsoft Stock Image
Figure 3	Salloway S, Chalkias S, Barkhof F, Burkett P, Barakos J, Purcell D, Suhy J, Forrestal F, Tian Y, Umans K, Wang G, Singhal P, Budd Haeberlein S, Smirnakis K. Amyloid-Related Imaging Abnormalities in 2 Phase 3 Studies Evaluating Aducanumab in Patients With Early Alzheimer Disease. JAMA Neurol. 2022 Jan 1;79(1):13-21. doi: 10.1001/jamaneurol.2021.4161.
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