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Novel Drug Approvals for 2021-2022 – Year in Review

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ABSTRACT

This article provides an abbreviated overview of the newly Federal Drug Administration (FDA)approved novel drugs of 2021-2022 with their respective approved indication(s). The FDA serves as the governing body that regularly evaluates and approves medications that will eventually be introduced to the market for routine use. These medications include both drugs that are the same or related to previously approved products (e.g., Extended indications of priorly approved medications) and novel drugs. By definition, a novel drug is an innovative product which serves to improve quality care in patient populations with unmet or advanced medical needs to overall advance patient care and public health. This article was employed to highlight medications that may be seen in practice and to heighten overall awareness of these new drugs. From January 1, 2021, through June 13, 2022, the FDA approved 66 drugs characterized as novel (*Table 1*). The four drugs highlighted in this article were selected based on potential inpatient and outpatient utility, disease-state prevalence, and overall innovative medication-based treatment approaches. The four highlighted drugs are included in *Table 2*.

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INCLISIRAN (LEQVIO)

Hepatocytes are responsible for the removal of circulating low-density lipoprotein (LDL) from the plasma through LDL receptor-mediated endocytosis.[1] Hepatocytes produce proprotein convertase subtilisin-kexin type 9 (PCSK9), a serine protease, which binds to LDL-receptors. This binding results in lysosomal degradation and ultimately a reduction in LDL receptors and an elevation in circulating plasma LDL-C.[2] Hypercholesterolemia, a chronic disease-state marked by an elevated LDL-C, remains a significant risk factor in the development of cardiovascular disease. Therefore, clinically significant reductions in LDL-C can reduce the risk of cardiovascular disease and improve cardiovascular outcomes.[2,3]

Inclisiran is an oligonucleotide that is conjugated to triantennary N-acetylgalactosamine carbohydrates which facilitates the drug's binding to asialoglycoprotein receptors expressed on hepatocytes of the liver. Upon uptake of inclisiran into the hepatocyte, inclisiran binds to RNA-induced silencing complex (RISC), which is a ribonucleoprotein complex that primarily functions in gene silencing and regulation. Single strand RNA serves as a template for RISC to determine appropriate messenger RNA complements. RISC can also activate ribonuclease (RNase) and can cleave target mRNA.[2] Incorporation of inclisiran to RISC disrupts PCSK9 translation through targeted cleavage of PCSK9 specific mRNA. This cleavage results in the decreased hepatic production of PCSK9 which consequently allows for increased LDL-receptor

recycling and concentration thereby decreasing circulating LDL-C.[3] It is recommended to administer inclisiran in combination with maximally tolerated statin therapy. Due to the established CV morbidity and mortality benefits of statin therapy, inclisiran use is reserved as an alternative augmentation therapy.

The ORION-9, -10 and -11 clinical trials examined the use of Inclisiran as an adjunct to diet and maximal statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Across all three trials, Inclisiran use resulted in statically significant percentage change in LDL-C from baseline to day 510 when compared to placebo, suggesting its clinical prevalence and utility in outpatient management of ASCVD and HeFH. The ORION-10 and -11 trials examined inclisiran-use in the setting of ASCVD and found that inclisiran-use was correlated to a significant reduction in LDL-C when compared to placebo. Similar results were also produced in the ORION-9 trial, which focused primarily on inclisiran verses placebo in the setting of HeFH. The effect of inclisiran on CV morbidity and mortality has not been determined. Common adverse reactions occurring greater than or equal to 3% of inclisiran patients as compared to placebo included antibody development, injection site reaction, arthralgia, urinary tract infections, diarrhea, bronchitis, pain in extremities and dyspnea.

The recommended dose of Inclisiran is 284mg as a single subcutaneous injection once initially with additional doses administered at 3 months and then every 6 months thereafter. In terms of efficacy monitoring, it is recommended to monitor LFTs (fasting or non-fasting) before initiation of treatment and then reassess fasting lipid profile 4-12 weeks after starting therapy and then every 3-12 months thereafter. Toxicity monitoring consists of antibody development, injection site reaction, arthralgia, urinary tract infections, diarrhea, bronchitis, pain in the extremities and dyspnea.[4,5]

VERICIGUAT (VERQUVO)

More than 6 million Americans are living with heart failure. Over 900,000 new cases are diagnosed each year.6 Approximately 50% of heart failure patients have heart failure with a reduced ejection fraction of 40%.7 Heart failure with reduced ejection fraction (HFrEF) is also known as systolic failure. The left ventricle loses its ability to contract normally, rendering the heart unable to maintain adequate perfusion.

Vericiguat (Verquvo) is the first oral soluble guanylate cyclase (sGC) stimulator developed and approved for the treatment of heart failure (HF). Specifically, it is indicated to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics in adults with symptomatic chronic HF and an ejection fraction less than 45%.[8] Vericiguat is a stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide signaling pathway. When nitric oxide binds to the enzyme sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling.[8] cGMP is activated independent of nitric oxide involvement. Vericiguat also works by sensitizing sGC to nitric oxide by stabilizing nitric oxide binding to the binding site. Ultimately, vericiguat replenishes the cGMP in the presence of oxidative stress and low nitric oxide.[9,10] Heart failure is associated with impaired synthesis of nitric oxide and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. Through the direct, independent, and synergistic stimulation of sGC with nitric oxide, vericiguat augments levels of intracellular cGMP, which leads to smooth muscle relaxation and vasodilation.[8]

The VICTORIA trial was conducted to assess the effect of vericiguat (Verquvo) in patients with heart failure with reduced ejection fraction (HFrEF) who had recently been hospitalized or had received IV diuretic therapy. The primary endpoint of the trial was a composite of time of first cardiovascular death or hospitalization for heart failure. The secondary endpoints identified were cardiovascular death and heart failure hospitalization.[9,10] The primary composite endpoint of vericiguat was superior to placebo at 33.6 events/100 patient-yr vs 37.8 events/100 patient-yr respectively. Vericiguat significantly lowered cardiovascular death and hospitalization (16.4% vs 17.5%; CI 0.90 (0.82-0.98) and 27.4% vs 29.6% CI 0.90 (0.81-1), respectively.[9,10] To prevent a primary-outcome event with vericiguat, the number needed to treat (NNT) is 24 patients per 1 year. Though the number needed to harm (NNH/0.9 years) for the clinical endpoints of symptomatic hypotension and syncope are not statistically significant, the NNH/0.9 years for anemia is 53 patients.[11]

Within the VICTORIA clinical trial, the most observed adverse events with vericiguat were hypotension 9.1% vs 7.9% P=0.12, syncope 4% vs 3.5%; P=0.3, and anemia 7.6% vs 5.7%; P<0.001.[9,10] With concern for potential hypotension and syncope, con-

Table 1.– FDA-approved medications in 2021-2022

Brand Name	Generic Name	Approval Date	FDA-approved indication(s)
Quviviq	Daridorexant	1/7/2022	Insomnia
Cibinqo	Abrocitinib	1/14/2022	Refractory, moderate-to-severe atopic dermatitis
Kimmtrak	Tebentafusp-tebn	1/25/2022	Unresectable or metastatic uveal melanoma
Vabysmo	Faricimab-svoa	1/28/2022	Neovascular (wet) aged-related macular degeneration and diabetic macular edema
Enjaymo	Sutimlimab-jome	2/4/2022	To decrease the need for RBC transfusion due to hemolysis in cold agglutinin disease
Pyrukynd	Mitapivat	2/17/2022	Hemolytic anemia in pyruvate kinase deficiency
Vonjo	Pacritinib	2/28/2022	Intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets
Opdualag	Nivolumab and Relatlimab-rmbw	3/18/2022	Unresectable or metastatic melanoma
Ztalmy	Ganaxolone	3/18/2022	Seizures in cyclin-dependent kinase-like 5 deficiency disorder
Pluvicto	Lutetium (177Lu) vipivotide tetraxetan	3/23/2022	Prostate-specific membrane antigen-positive metastatic castration-related prostate cancer following other therapies
Vivjoa	Oteseconazole	4/26/2022	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential
Camzyos	Mavacamten	4/28/2022	To treat certain classes of obstructive hypertrophic cardiomyopathy
Voquezna	Vonoprazan, amoxicillin, and clarithromycin	5/3/2022	Helicobacter Pylori infection
Mounjaro	Tirzepatide	5/13/2022	To improve blood sugar control in diabetes, in addition to diet and exercise
Vtama	Tapinarof	5/23/2022	Plaque psoriasis
Amvuttra	Vutrisiran	6/13/2022	Polyneuropathy of hereditary transthyretin-mediated amyloidosis
Leqvio	Inclisiran	12/22/2021	To treat heterozygous familial hypercholesterolemia or clinical ASCVD as add-on therapy
Tezspire	Tezepelumab-ekko	12/17/2021	To treat severe asthma as an add-on maintenance therapy
Qulipta	Atogepant	9/28/2021	To prevent episodic migraines
Aduhelm	Aducanumab-avwa	6/7/2021	To treat Alzheimer's disease
Brexafemme	Ibrexafungerp	6/1/2021	To treat vulvovaginal candidiasis
Nextstellis	Drospirenone and Estetrol	4/15/2021	To prevent pregnancy
Qelbree	Viloxazine	4/2/2021	To treat ADHD
Zegalogue	Dasiglucagon	3/22/2021	To treat severe hypoglycemia
Cosela	Trilacicilib	2/12/2021	To mitigate chemotherapy-induced myelosuppression small cell lung cancer
Evkeeza	Evinacumab-dgnb	2/11/2021	To treat homozygous familial hypercholesterolemia
Tepmetko	Tepotinib	2/3/2021	To treat non-small cell lung cancer
Cabenuva	Cabotegravir and rilpivirine	1/21/2021	To treat HIV
Verquvo	Vericiguat	1/19/2021	To mitigate the risk of CV death and hospitalization for chronic heart failure

Table 2.– Highlighted FDA-approved medications in 2021-2022

Generic	Trade	Dosing	Adverse Effects	Monitoring
Inclisiran	Leqvio	284mg IM x 1, again at 3 months, and then every 6 months thereafter	Antibody development Injection site reaction: Arthralgia, Urinary tract infections, Diarrhea, Bronchitis, Pain in extremities Dyspnea	Lipid profile (fasting or non-fasting) before initiation of treatment. Fasting lipid profile should be reassessed 4-12 weeks after starting therapy and then every 3-12 months thereafter
Vericiguat	Verquvo	Recommended starting dose is 2.5 mg orally once daily with food Double the dose of vericiguat approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient	Most reported ≥5% are hypotension and anemia	Monitor blood pressure, heart rate, and hemoglobin
Cabotegravir/ Rilpivirine	Cabenuva	Monthly: 600 mg cabotegravir and 900 mg rilpivirine at month 1, then 400 mg cabotegravir and 600 mg rilpivirine monthly Every 2 months: 600 mg cabotegravir and 900 mg rilpivirine at month 1, month 2, then every 2 months thereafter	Injection site reactions: Pyrexia Fatigue Headache Musculoskeletal pain Nausea	Hepatotoxicity, signs and symptoms of hypersensitivity and/or skin reactions, injection-related reactions, mood changes
Vonoprazan/ Amoxicillin/ Clarithromycin	Vocqquenza	TriplePak: Vonoprazan 20 mg Q12H, amoxicillin 1000 mg Q12H, clarithromycin 500 mg Q12H with or without food for 14 days Dual Pak: Vonoprazan 20 mg Q12H and amoxicillin 1000 mg Q8H with or without food for 15 days	Dysgeusia, Diarrhea, Vulvovaginal candidiasis, Headache, Abdominal pain, Hypertension	Hepatotoxicity, anaphylaxis, c.diff, QT prolongation, Myasthenia gravis

comitant use of vericiguat with PDE-5 inhibitors, soluble guanylate cyclase (sGC) inhibitors, and long-acting nitrates are contraindicated.[9,10]
When initiating vericiguat, the recommended starting dose is 2.5 mg orally once daily with food. The dose is to then be doubled every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient.[8] Vericiguat has a black box warning of embryo-fetal toxicity and is therefore contraindicated in pregnancy.[8] Women of reproductive potential must utilize effective forms of contraception during therapy and for one month after treatment discontinuation.

CABENUVA (CABOTEGRAVIR/RILPIVIRINE)

Cabenuva is an intramuscularly injected combination therapy indicated for the treatment of HIV-1 infections in adult patients and pediatric patients over 12 years old weighing more than 35 kilograms. It contains cabotegravir, an integrase strand transfer inhibitor (INSTI) which suppresses HIV replication by blocking integrase and preventing the incorporation of viral DNA into host CD4 cells. The second component, rilpivirine, a non-nucleotide reverse transcriptase inhibitor, suppresses HIV replication by inhibiting reverse transcriptase which prevents HIV from converting RNA into DNA. Cabenuva provides a complete two-drug antiviral treatment regimen for HIV-1 patients and can replace current antiretroviral therapy in virally suppressed patients with no history of treatment failure or resistance to cabotegravir or rilpivirine.[12,13,14]
There are two dosing schedules available for Cabenuva: every 1 month and every 2 months. Either regimen can be preceded by a one-month oral lead-in to assess tolerability prior to starting therapy with the long-acting injectable formulation. The first Cabenuva injection should be administered on the same day as the last dose of the patient's current antiretroviral or oral lead-in regimen. The standard monthly regimen is dosed at 600 mg cabotegravir and 900 mg rilpivirine at month 1 and 400 mg cabotegravir and 600 mg rilpivirine every 1 month thereafter. The every 2 month regimen is dosed at 600 mg cabotegravir and 900 mg rilpivirine at month 1, month 2, and every 2 months thereafter. Cabenuva is injected intramuscu-

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larly in the gluteal muscle and must be administered in a healthcare setting. The most commonly reported adverse reactions are injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, and nausea. Patients should be monitored for hepatotoxicity throughout treatment.[12,13,14]

The ATLAS and FLAIR clinical trials evaluated the efficacy and safety of monthly Cabenuva administration compared to daily oral antiretroviral therapy and found Cabenuva to be non-inferior to daily oral antiretroviral therapy with a similar rate of treatment failure.[15] The ATLAS-2M clinical trial compared once monthly to every 2 month dosing of Cabenuva and found every 2 month dosing to be non-inferior to once monthly dosing with a low rate of treatment failure and resistance in both groups.[16] The ATLAS, FLAIR, and ATLAS-2M clinical trials evaluated patient reported outcomes regarding the preference of Cabenuva injectable therapy compared to oral regimens and most patients reported preference for the injectable Cabenuva formulation due to the convenience of less frequent dosing.[15,16] Prescribers can consider prescribing Cabenuva to patients who will benefit from the monthly or every 2-month dosing schedule due to adherence issues and are stable and virally suppressed on their current HIV treatment regimen without resistance or treatment failure.

VONOPRAZAN, AMOXICILLIN AND CLARITHROMYCIN (VOQUEZNA)

Vonoprazan is a novel, first-in-class potassium competitive acid blocker (PCAB). It works by inhibition of the H+, K+ ATPase enzyme system (AKA proton pump) on the secretory surface of the gastric parietal cell.[17] This medication has been on the market and indicated for Japanese duodenal ulcers, reflux esophagitis, and prevention of low-dose aspirin or NSAID induced ulcer recurrence.[18]

Voquezna is a triple/dual therapy pack that was recently approved May 3rd, 2022, with plans to launch in the second half of 2022. These packs contain Vonoprazan based therapy regimens for the treatment of Helicobacter pylori infections. The triple pack consists of vonoprazan 20 mg tablets, amoxicillin 500 mg capsules, and clarithromycin 500 mg tablets. The triple pack is administered as such: vonoprazan 20 mg 1 tablet, amoxicillin 500 mg 2 capsules, and clarithromycin 1 tablet every 12 hours with or without food for 14 days. The dual pack includes vonoprazan 20 mg tablets and amoxicillin 1000 mg tablets. The dual pack is administered as such: vonoprazon 20 mg 1 tablet every 12 hours and amoxicillin 500 mg 2 capsules every 8 hours. Contraindications to the packs include hypersensitivity reactions to any component and concomitant use with ripilvirine. Additional warnings include (but are not limited to) QT prolongation, increased risk for clostridium difficile, severe cutaneous reactions.[17] The most common adverse events reported Vonoprazon's adverse effects include but are not limited to erythema and gastrointestinal symptoms. One case of erythema multiforme that was treated with steroids was reported. Other considerations would include concomitant use of CYP 3A4 substrates, as it has been reported that vonoprazon has increase 3A4 inhibition, especially in those with hepatic dysfunction.[19]

Guidelines recommend eradication of H. pylori whenever possible as it is the leading cause of peptic ulcers, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue lymphoma.[20] However, due to increasing clarithromycin resistance, H. pylori susceptibility rates have dipped below 80%. H.pylori's susceptibility rates to antibiotics is heavily influenced by gastric pH. Vonoprazan has been widely used in East Asia with great efficacy in maintaining gastric acid suppression, thus giving the potential for better H. pylori eradication. A pivotal open label phase 3 randomized control trial examined the use of therapy vonoprazan double/triple versus the standard treatment with lansoprazole triple therapy for resistant and non-resistant H.pylori eradication in 1046 treatment naïve adults.[21] A standard triple therapy regimen includes a PPI, clarithromycin, and amoxicillin or metronidazole.[22] Both the double and triple vonoprazon regimens were found to be statistically superior to the PPI-based triple therapy in clarithromycin resistant strains as well as the overall study population. Adverse events due to vonoprazon were similar to lansoprazole.

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