

EST. 2011

RHO Rx CHI post

VOLUME 10, ISSUE 4

An award-winning, bimonthly, electronic, student-operated newsletter publication by the St. John's University College of Pharmacy and Health Sciences Rho Chi Beta Delta chapter



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AstraZeneca Sells Rights to Two Cardiovascular Drugs for \$400 Million

By: Jennifer Galvet, PharmD Candidate c/o 2024

Introduction

The British-Swedish multinational pharmaceutical and biopharmaceutical company AstraZeneca has agreed to sell its rights to two cardiovascular drugs to Germany's Cheplapharm Arzneimittel GmbH for \$400 million. This decision allows AstraZeneca to reinvest in the company's main areas of focus: cardiovascular, renal and metabolism, cancer, respiratory, inflammation and autoimmunity, infection and vaccines, and neuroscience.¹ As of recently, AstraZeneca also has a potential COVID-19 vaccine in late-stage clinical testing.¹

Atacand and Atacand Plus Therapy

On October 30, 2020, AstraZeneca sold the commercial rights to Atacand® (candesartan cilexetil) and Atacand Plus® (a fixed dose combination of candesartan cilexetil and hydrochlorothiazide) to Cheplapharm. Candesartan cilexetil is a prodrug that is hydrolyzed to candesartan during absorption from the gastrointestinal tract. Candesartan is a selective AT₁ subtype angiotensin II receptor antagonist, indicated for the treatment of hypertension and heart failure in patients with left ventricular systolic dysfunction to reduce cardiovascular death and heart failure hospitalizations.⁵ Angiotensin II is created from angiotensin I in a reaction catalyzed by an enzyme known as ACE, or angiotensin-converting enzyme. Angiotensin II is the principal antihypertensive agent of the renin-angiotensin system, affecting vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium.⁵ Candesartan inhibits the vasoconstriction and aldosterone releasing effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor. This receptor is located in many different tissues, including the adrenal glands and vascular smooth muscle. Restriction of the angiotensin system with ACE inhibitors (resulting in the inhibition of the biosynthesis of angiotensin II from angiotensin I), is used in the treatment of hypertension.⁵

Candesartan cilexetil and hydrochlorothiazide has been widely used to treat hypertension. Hydrochlorothiazide acts on the distal convoluted tubules of the kidneys and inhibits the sodium chloride co-transporter system.³ This results in diuretic action and loss of potassium in the urine. Hydrochlorothiazide is indicated as adjunctive therapy to treat edema associated with congestive heart failure, hepatic cirrhosis, corticosteroid and

estrogen therapy, and renal dysfunction, in addition to its indication for treatment of hypertension.³ Thiazide diuretics increase the excretion of sodium, chloride, and water by inhibiting sodium ion transport across the renal tubular epithelium. The major mechanism responsible for diuresis is inhibition of active chloride reabsorption at the distal portion of the distal convoluted tubule. When administered acutely, hydrochlorothiazide lowers blood pressure by decreasing cardiac output and decreasing plasma and extracellular fluid volume flowing through a person's arteries and veins. Chronic use of hydrochlorothiazide reduces blood pressure by decreasing peripheral resistance, or the resistance of the arteries to blood.³ Essentially, this medication is responsible for removal of sodium and water from the body, thus reducing blood pressure. Candesartan cilexetil and hydrochlorothiazide is indicated for the management of hypertension when monotherapy with either candesartan or hydrochlorothiazide is insufficient.²

How will this affect AstraZeneca?

Both Atacand® and Atacand Plus® are commercially available in approximately 70 countries. Ruud Dobber, Ph.D, the executive vice president of AstraZeneca's biopharmaceuticals business unit, explained that the agreement to sell the commercial rights to Cheplapharm Arzneimittel GmbH is part of the company's strategy to carefully manage its mature medicines and focus on its main therapy areas.^{1,2,4} This also includes utilizing the proceeds from the \$400 million sale for reinvestment in these main therapeutic areas. AstraZeneca will continue to manufacture both hypertension medications during a three year transition period.² When the agreement is finished in the fourth quarter of this year, Cheplapharm Arzneimittel GmbH will compensate AstraZeneca \$250 million, and then remaining \$150 million in the first half of 2021.^{1,2,4} This agreement will allow Cheplapharm Arzneimittel GmbH to expand the reach of these cardiovascular medications into additional countries.¹

This agreement will allow for funding of innovative new medications for patients and continued access of these important cardiovascular medications for patients worldwide. The continued patient access to candesartan cilexetil and candesartan cilexetil and hydrochlorothiazide will reduce the risk of fatal and non-fatal cardiovascular events such as strokes and myocardial infarctions associated with hypertension on a global spectrum.

AstraZeneca Sells Rights to Two Cardiovascular Drugs for \$400 Million

By: Jennifer Galvet, PharmD Candidate c/o 2024

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Increasing Evidence of the Benefits of Statins

By: Pallak Sharma, PharmD Candidate c/o 2022 and Rebecca Samuel, PharmD Candidate c/o 2022

Statins, some of the most well-known cholesterol lowering medications, have been demonstrating increasing evidence of safety and benefits to the elderly patient population.⁵ Statins are a class of medication that can help lower the level of low-density lipoprotein (LDL) cholesterol in the blood. LDL cholesterol is often referred to as “bad cholesterol”; and statins reduce the production of bad cholesterol inside the liver. High levels of LDL-C can be dangerous as it can contribute to the narrowing and hardening of the blood vessels (atherosclerosis), leading to cardiovascular disease.⁵

Statins are currently indicated for patients with specific risk factors that predispose them to developing cardiovascular problems in the future. One of the main groups that are recommended for statin therapy includes people with a history of heart disease, stroke, or peripheral artery disease or risk factors that give them a 10 percent or greater chance of a heart attack within 10 years. That probability is calculated using the atherosclerotic cardiovascular disease (ASCVD) score which uses pooled cohort equations to estimate the 10-year primary risk of ASCVD among patients without pre-existing cardiovascular disease who are between 40 and 79 years of age.⁴ Statin therapy is also indicated for people between the ages of 40 and 75 years old with diabetes. This patient population should be placed on moderate intensity statins and utilize risk estimates to consider high-intensity statins. Patients with diabetes and with multiple ASCVD risk factors should be considered for placement on high-intensity statins with the aim of lowering LDL-C levels by 50% or more.¹ Another group of patients recommended for statin therapy includes individuals who are between the ages of 40 and 75 years of age with LDL-C ≥ 70 to < 190 mg/dL and without diabetes. For this group of patients, the risk estimator should be used to decide which intensity of statin should be initiated. Those that fall under borderline risk (5%– $< 7.5\%$) should have a risk discussion with their provider and discuss moderate-intensity statins. Those with that fall under intermediate risk ($\geq 7.5\%$ – 20%), should have a risk discussion on use of moderate-intensity statins and increase to high intensity if needed with the presence of increasing risk. Finally, those patients that fall under high risk ($\geq 20\%$) should have a risk discussion to initiate high-intensity statin to reduce LDL-C by 50%.¹ The last group of patients recommended for statin therapy includes people between the ages of 20 and 75

years old with an LDL-C level of 190 mg/dl or higher. This group should initiate a high-intensity statin without risk assessment.¹

The cardiovascular protection that statins provide has led to its widespread use, especially in the elderly patient population. More than 60% of patients over 65 in the United States who have high cholesterol take a statin to prevent a heart attack or stroke. But in the case of many new drug trials, few subjects over the age of 75 are included. The early benefits and risks when statins were developed were not studied in the elderly population and were typically studied after the medication was on the market. However, the latest reports have been extremely reassuring.

A study was conducted where more than 120,000 French men and women between the ages of 75 and 79 were taking statins for up to four years. Within this select group, 10% of the subjects stopped taking the statin. Among this 10%, the risk of being admitted to the hospital for a cardiovascular event was approximately 25 to 30% greater than those who continued to take the statin.³ Another study from Israel was published in the Journal of the American Geriatrics Society. This study involved nearly 20,000 patients over the age of 65 and these subjects were followed for 10 years. The chance of dying from any cause was 34% lower among the subjects that stayed on the statin therapy than those who failed to adhere to the statin therapy. The benefits were not reduced for those older than 75 for both men and women.³ A study published in JAMA in 2020 by a team led by Dr. Ariela R. Orkaby of the VA Boston Healthcare System, involved United States Veterans with an average age of 81. There were 326,981 participants. This study showed the initiation of statin use was associated with 25% fewer deaths overall and 20% fewer cardiovascular deaths during a follow-up of approximately seven years.³

These three studies do not provide the “gold-standard” of research. Typically, “gold-standard” means a randomized clinical trial was performed, whereas these three studies were conducted retrospectively. Two studies which have not been published yet, The Staree trial and the Preventable trial, both randomized controlled clinical trials, will study the topic of statin therapy to prevent cardiovascular events in the elderly while assessing cognitive function.³ Although that data has not been collected yet, there are encouraging results from a report

Increasing Evidence of the Benefits of Statins

By: Pallak Sharma, PharmD Candidate c/o 2022 and Rebecca Samuel, PharmD Candidate c/o 2022

published in the Journal of the American College of Cardiology in 2019. This report stated there was no difference over a six-year period in the rate of decline in memory or cognitive status between those on statin therapy and those who have never taken the drugs. The report showed that those who started a statin during the study exhibited a blunted or slowed down rate of memory decline.³

Apart from the benefit that statins provide on cholesterol, an observational study published in Nature by a Swedish team found that patients over the age of 65 who were taking statins experienced beneficial effects on reaction time and fluid intelligence. There are also several reports that the lipophilic statins may have anticancer effects. A study of nearly 2,000 early-stage breast cancer survivors found a decreased five-year recurrence rate in women who started a statin within three years of the diagnosis. In a report presented by Dr. Kala Visvanathan of Johns Hopkins Medicine during a virtual meeting for the American Association for Cancer Research, a 40% reduction in deaths from ovarian cancer among more than 10,000 patients who were on statin therapy either before or after their diagnosis was observed. The population who benefited in this observational study was those who had the most common and aggressive form of ovarian cancer. Dr. Visvanathan attributes these findings to the fact that statins inhibit an enzyme in the chemical pathway of tumor growth and proliferation. There is hope to confirm these findings in a randomized clinical trial.³

All of these studies not only show statin's promise in the reduction of LDL-C, cardiovascular risk, and mortality but they also demonstrate some benefits beyond their FDA- approved indication. These results are great news for those already using these medications and should be reassuring for those over 65 thinking about starting statin therapy. Thankfully, statins have been around long enough for generics to become available and therefore they are more accessible to elderly patients. One of the best documented barriers to medication adherence is high out-of-pocket costs, even among individuals with prescription drug insurance. Numerous studies have found that increased drug copayments are associated with decreased use of prescription drugs, even for highly effective medications used to treat chronic conditions such as diabetes mellitus, hypertension, and hypercholesterolemia.² The availability and affordability

of these drugs as generics means its benefits can become widespread and easily implemented in cardiovascular care plans for the elderly if they were not included already.

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Emerging Type 3 Diabetes

By: Zarnab Jillani PharmD Candidate c/o 2022

The link between diabetes and Alzheimer's disease (AD) is a new and ongoing debate given the etiology of AD is still not fully understood. Diabetes continues to be a major public health crisis as diagnoses around the world continue to rise. Diabetes is a chronic disease that is split into two categories- type I and type II diabetes. Type I diabetes, an autoimmune disorder, is characterized by the pancreas's inability to produce insulin which is needed to store glucose. Type II diabetes is acquired and results from cells becoming resistant to insulin. According to the American Diabetes Association, in 2018, 34.2 million people had diabetes, which is linked to the leading cause of death in America, heart disease.¹ Diabetes affects both the younger and older population, since it can be either a disease one is born with or one that is acquired through lifestyle and hereditary factors.¹ On the other hand, AD is categorized as a form of dementia, in which the majority of people that are affected are 65 and older.² Recent studies suggest that the link between diabetes and Alzheimer's is closer than it may seem, despite the differences between the two disease states.

One of the most well understood theories surrounding the cause of AD is the accumulation of β -amyloid in the brain. A recent study suggests that excess insulin levels may cause accumulation of β -amyloid in the brain. Normally, an insulin degrading enzyme (IDE), known as insulysin, helps to degrade excess insulin in the body. However, research in animals and humans suggests that in patients with Alzheimer's, both insulin and the Alzheimer's protein (β amyloid) compete to be degraded by insulysin. Therefore, the insulin that is being accumulated is being degraded by insulysin whereas β amyloid does not have adequate enzyme to "clean it up". The connection between IDE and β amyloid protein was first made in 1996 by a Harvard Medical School neurobiologist, Dennis Selkoe, MD.³

A study conducted by the Mayo Clinic in Rochester, Minnesota in 1997 suggests that patients with type II diabetes were more likely to develop Alzheimer's. The study followed 1,500 patients with type II diabetes for seven years and found that they had twice the risk of developing AD as patients without diabetes of the same age and sex.¹³ However, this study like many others, does not conclude a direct correlation between insulin and the onset of Alzheimer's disease. Similarly, the Rotterdam study found that of 6,730 subjects, 126 developed dementia, of which 89 patients were diagnosed with AD. This study concluded that type II diabetes doubled the risk

of a patient having dementia and patients on insulin had four times the risk.³ These studies were conducted in the late '90s but seem to be receiving more attention now due to the growing number of people with concomitant diabetes and AD.

In order to test the correlation between the two disease states, a study was conducted in which researchers tested the effects of plasma insulin on humans when it is raised experimentally. Patients with type II diabetes were injected with either insulin or saline and after 90 minutes, their cerebrospinal fluid was collected. Each patient went through this process twice, once with saline and once with insulin so they served as their own controls. This resulted in increased β -amyloid levels after the insulin infusions, therefore providing insight into how insulin affects β -amyloid levels, which in turn can result in Alzheimer's disease.⁴ The term 'type 3 diabetes' was first coined by Suzanne De La Monte, MD, MPH, Associate Professor of Pathology and Medicine and neuropathologist at Brown Medical School when her team found that elements of type I and type II diabetes were found in patients with AD, such as a decrease in insulin production and resistance to insulin receptors.⁴

In conclusion, while not all studies confirm the connection, some evidence suggests that patients with type II diabetes are at a higher risk for developing AD. Many people with diabetes acquire changes in their brain that can be attributed to AD due to the increase of β amyloid which leads many researchers to believe that the two diseases are linked.⁵ Ongoing research is aimed at better understanding the link between the two disease states.

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Fostemsavir: New drug for the treatment of HIV-1 resistant patients

By: Bisma Sekhery, PharmD Candidate c/o 2021

Fostemsavir (Rukobia) is a new Food and Drug Administration (FDA) approved antiretroviral agent for the treatment of Human Immunodeficiency Virus (HIV). It was approved in July 2020 for multidrug-resistant HIV-1. It is a pro-drug, metabolized to its active moiety, temsavir, which binds to the gp120 subunit within the HIV-1 envelope glycoprotein gp160, thereby inhibiting the interaction between the virus and cellular CD4 receptors.² This will prevent attachment and entry of the virus into the cells. The patients who benefit from this drug are treatment-experienced adults who have failed their current antiretroviral treatment due to drug resistance, tolerance, or safety concerns.¹

The overall efficacy of fostemsavir was studied in the BRIGHT trial.² Two cohorts were utilized for this trial. The first cohort had two groups. Group 1 were patients who were failing their current antiretroviral regimen. Group 1 patients had the option of using at least 1 previously FDA-approved agent from another antiretroviral drug class, but no more than 2 drug classes, plus fostemsavir for 8 days. It was not specified in the trial which other antiretrovirals were administered to the patients. Group 2 was the control group. The placebo group received standard antiretrovirals. After 8 days, patients received open label fostemsavir with standard antiretrovirals along with it. Patients were randomized in a 3:1 ratio fostemsavir (N= 204) to control (N=68). The participants were all over the age of 18, had failed their current antiretroviral regimen and had no viable antiretroviral combination therapy options. The primary endpoint for this trial was mean change in log₁₀ level of HIV-1 RNA to less than 40 copies per milliliter from baseline to week 24. At week 24, the intervention group had 57% of patients with HIV-1 RNA copies less than 40 copies per milliliter, while the placebo group had 45% of patients (p <0.001). The use of fostemsavir also improved CD4 T cell count even in the most immunocompromised patients.²

Currently, the only FDA-approved dosage is 600 mg extended release tablets and usually it is taken one tablet twice daily with or without food.¹ Although this drug is beneficial to many patients, some contraindications still exist. If a patient has a known hypersensitivity to the drug, it cannot be administered. Drugs that are strong CYP3A4 inducers may decrease the concentration of temsavir significantly. This drug carries a warning of causing Immune Reconstitution Syndrome as well. Patients with

HIV develop this syndrome because when the immune system begins to recover after the use of antiretrovirals, the inflammatory response to infections is exaggerated, leading to worsening of the infection.¹

There are other warnings associated with this drug, however some adverse effects can be minimized. For instance, this drug is known to cause QT prolongation in doses of 4800 mg per day or more.¹ However, if the patient takes the drug as directed, which is one 600 mg tablet twice daily, this risk is minimized. Additionally, other medications that the patient is taking can be assessed to see if the patient is on other QT-prolongating drugs. Fostemsavir can also cause elevation in liver enzymes. Therefore, it may not be the best drug for patients who have liver failure or Hepatitis B or C infections. Like other antiretrovirals, when anti-hepatitis therapy is withdrawn, there is a risk for Hepatitis B reactivation. The most common adverse effect noted in the participants was diarrhea, nausea, upper respiratory tract infections, but this was manageable with appropriate medications.

Overall, this drug should not be used in pregnant women because there is no human data about the impact on this drug for pregnant women.¹ Instead there is data from rats, which showed increased embryonic death and maternal toxicity. In pregnant rats, temsavir was present in the breast milk. This is why the FDA suggests mothers to avoid breastfeeding their children while on this drug. FDA also recommends against breastfeeding for all HIV positive mothers to avoid the transmission of HIV to the neonate.¹

The novel mechanism of action, safety, efficacy, drug-drug interaction profile and lack of cross-resistance among the available antiretroviral drugs makes fostemsavir a great drug for patients who have failed almost all other drug options. The adverse effects are still concerning such as QT prolongation, hepatotoxicity, and Immune Reconstitution Syndrome, but these side effects are not common. Appropriate monitoring by clinicians can prevent these side effects from occurring. When fostemsavir is taken in combination with other antiretrovirals, it can be a viable option for treatment-experienced adults with multidrug-resistant HIV-1, who are failing their current antiretroviral regimen.

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Rybelsus: Novel Oral GLP-1 Agonist and the Future of Oral Protein Dosage Forms

By: Tanay Maddula PharmD Candidate c/o 2022

Rybelsus (oral semaglutide) was recently approved by the Food and Drug Administration (FDA) in September 2019 to help control blood sugar in adult patients with Type 2 Diabetes alongside diet and exercise. It is the first oral GLP-1 (glucagon like peptide-1) agonist as typical drugs of this class have only been subcutaneous injections.

How do GLP-1 agonists work in the body?

GLP-1 agonists work by acting as GLP-1 in the body. GLP-1 is a 30 to 31 amino acid long peptide secreted by intestinal enteroendocrine cells. GLP-1 binds to GLP receptors in the brain, stomach, cardiovascular system, pancreas, and liver, and exerts a different effect at each location (Table 1). The cumulation of all these effects results in the reduction of blood sugar in the body and better control of blood sugar for patients with type 2 diabetes.

Table 1: Semaglutide Mechanism of Action ¹

Receptor Location	Effect
Brain	Increase satiety
Cardiovascular system	Reduces blood pressure
Liver	Reduces glucose production
Pancreatic Beta Cells	Increase insulin secretion
Pancreatic Alpha Cells	Decrease glucagon secretion

Clinical Role of GLP-1 Agonists and Results of Semaglutide in Clinical Trials:

The American Diabetes Association (ADA) guidelines recommend GLP-1 agonists as second line therapy in the treatment of type 2 diabetes as an adjunct to maximum dose metformin in patients for whom atherosclerotic cardiovascular disease (ASCVD) predominates or in those who have a compelling need to lose weight and are not at their target A1C.² Oral semaglutide received FDA approval from the results found from the PIONEER trials. The PIONEER clinical trials for oral semaglutide were a global developmental program that enrolled 8845 patients with Type 2 Diabetes across 10 clinical trials. The PIONEER 4 trial, a phase 3, randomized- controlled, double-blind, double-dummy clinical trial, compared oral semaglutide to subcutaneous liraglutide and placebo. The primary end point of the study was the change from baseline to

week 26 in hemoglobin A1c (HbA1C). The non-inferiority margin or limit was set to be 0.4% difference of HbA1C.³ It was found that oral semaglutide (14mg) was noninferior to subcutaneous liraglutide (dose escalated over 26 weeks to 1.8mg subcutaneously as that is the standard dosing regimen for liraglutide) with a treatment difference of HbA1C of -0.1% (95% CI of -0.3% to 0.0; p<0.0001).³ Moreover, it was found in this trial that oral semaglutide was superior to placebo with a reduction of -1.1% (95% CI -1.2% to -0.9%; p<0.0001).³ This study also had a secondary endpoint for weight reduction from baseline to week 26. Oral semaglutide was superior in weight reduction to both placebo and liraglutide after 26 weeks with a reduction of -1.5kg (95% CI: -2.2kg to -0.9kg; p<0.0001) compared to liraglutide and -4kg (95% CI: -4.8kg to -3.2kg; p<0.0001) compared to placebo.³

The PIONEER 6 trial, a randomized, double-blind, placebo controlled clinical trial, found the cardiovascular risk associated with oral semaglutide to be noninferior to placebo. The primary end-point of this study was the first occurrence of a major adverse cardiovascular event which included death from cardiovascular causes, nonfatal myocardial infarction, or non-fatal stroke.⁴ Secondary cardiovascular outcomes included the time from randomization to the first occurrence of the following: an expanded composite outcome consisting of the primary outcome plus unstable angina resulting in hospitalization or heart failure resulting in hospitalization, a composite of death from any cause, nonfatal myocardial infarction, or nonfatal stroke, and the individual components of these composite outcomes.⁴ The trial was designed to rule out an excess of 80% cardiovascular risk for oral semaglutide compared to placebo and therefore had a non-inferiority margin of 1.8 as the upper boundary for the 95% confidence interval of the hazard ratio used to analyze the data.⁴ Primary endpoints results had a hazard ratio of 0.79 (95% CI: 0.57 to 1.11; p<0.001 for non-inferiority).⁴

This non-inferior result is consistent with the noninferiority found in the SUSTAIN-6 randomized, double-blind, placebo-controlled, parallel-group trial of subcutaneous semaglutide. This trial compared subcutaneous semaglutide with placebo to rule out excess cardiovascular risks. It has the same primary composite endpoint that was the first occurrence of a major adverse cardiovascular event which included death from cardiovascular causes, nonfatal myocardial infarction, or non-fatal stroke.⁵

Rybelsus: Novel Oral GLP-1 Agonist and the Future of Oral Protein Dosage Forms

By: Tanay Maddula PharmD Candidate c/o 2022

The non-inferiority margin was designed to rule out an excess of 80% cardiovascular risk and thus the non-inferiority margin of 1.8 as the upper boundary for the 95% confidence interval of the hazard ratio was used. The primary outcome had a hazard ratio of 0.74 (95% CI: 0.58-0.95; $p < 0.001$ for non-inferiority and $p < 0.02$ for superiority) compared to placebo.⁵ One should note that subcutaneous semaglutide based on these results from the SUSTAIN-6 trial is superior (though slightly) to placebo for cardiovascular outcomes, whereas, the oral semaglutide was only found to be non-inferior to placebo in the PIONEER 6 trial. Therefore, oral semaglutide could be considered slightly less efficacious in terms of cardiovascular benefit compared to subcutaneous semaglutide (though it still fulfilled the intent of the PIONEER-6 study to prove non-inferiority to placebo for cardiovascular outcomes).

In summary, oral semaglutide is equally efficacious to subcutaneous GLP-1 agonists on the market with the benefit of being an oral formulation opposed to an injectable formulation.

Significance of Peptide in Oral Dosage Forms and how Oral Semaglutide was made

The significance of oral semaglutide can be explained through the Biopharmaceutical Classification System (BCS). The BCS is divided into 4 categories; Class 1 is both high solubility and high permeability, Class 2 has low solubility but high permeability, Class 3 has high solubility but low permeability, and Class 4 has low solubility and low permeability. Hydrophilic peptides such as GLP-1 agonists would fit into the category of Class 3, due to their low permeability through the stomach because of the lack of passive or carrier-mediated transport or transcellular transport of such macromolecules.⁶ This is coupled with the problem of being susceptible to degradation from the high pH and enzymes of the digestive tract. This results in class of macromolecules, peptides and proteins, not being suited for the oral dosage form. Since the 1980's, over 90% of all protein or peptide-based drugs have only injectables. Oral semaglutide is a step forward in the innovation of oral peptides as this drug class requires frequent chronic dosing, which typically makes them quite hard to be oral due to the previously described limiting factors.⁶

The oral dosage form was made possible due to the use of an intestinal permeation enhancer called salcaprozate sodium (SNAC) which is a synthetic N-acetylated amino-acid derivative of salicylic acid. SNAC works by many mechanisms to increase permeability including, opening tight junctions to increase paracellular permeability, decreasing mucus viscosity, inhibition of epithelial efflux pumps, complexation of payload, increasing membrane fluidity, and (indirectly) via peptidase inhibition.⁶ It should be noted that semaglutide itself has a very long half-life of 7 days, is highly potent, and stable.⁷ This makes it easier to predict levels from the oral dosage formulation compared to less stable peptides. SNAC in pre-clinical trials has shown promise for increasing insulin bioavailability in an oral dosage form as well. Overall, with the introduction of Rybelsus, the first oral GLP-1 agonist on the market, there is hope for other peptide or protein-based injections to be introduced in oral forms in the future such as insulin.

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New Drug Update: Lemborexant (Dayvigo[®])

By: Cindy Van, PharmD Candidate c/o 2022, Shireen Farzadeh, PharmD, BCPS

Insomnia is a condition characterized by difficulty falling asleep, staying asleep, or both, despite an adequate opportunity to sleep. Consequently, insomnia can lead to daytime fatigue, difficulty concentrating, and irritability. This condition can be categorized into short-term and chronic insomnia. While short-term insomnia lasts for less than 3 months, chronic insomnia lasts for more than 3 months and occurs at least 3 times per week. Short-term insomnia is more common than chronic insomnia, prevalent in 30-50% versus 5-10% of the population, respectively.¹ The orexin neuropeptide signaling system plays a role in wakefulness and may contribute to insomnia. Orexin receptor antagonists are a class of medications used to treat insomnia. One example is suvorexant (Belsomra[®]) which blocks the binding of orexin A and B to receptors OX1R and OX2R, with a greater inhibition of OX2R to promote sleep. In December 2019, another orexin receptor antagonist, lemborexant (Dayvigo[®]), was approved based on the SUNRISE 1 and 2 trials.²⁻⁴

SUNRISE 1 was a randomized, double-blind, placebo- and active-controlled, multi-center, parallel-group phase 3 study, in which results were evaluated after 1 month. The study included adult female patients aged 55 years and older and male patients, aged 65 years and older, who met the DSM-5 criteria for insomnia disorder. The trial included a two-week placebo run-in period during the pre-randomization phase, which lasted up to 35 days, and a two-week period without treatment prior to the end of the study visit. Out of 1006 patients randomized, patients received the following agents immediately before bedtime: placebo (n=208), lemborexant 5 mg (n=266), lemborexant 10 mg (n=269), or zolpidem ER 6.25 mg (n=263). The study met statistical significance for the primary endpoint of change from baseline in sleep latency (time to fall asleep) to persistent sleep for lemborexant therapy vs placebo. The primary end point was measured using polysomnography after 1 month. Patients who received lemborexant 5 mg and 10 mg had a reduced sleep latency of 23% (P <0.001) and 28% (P <0.001), respectively. The study also met statistical significance for the secondary endpoints of changes from baseline in sleep efficiency and wake-after-sleep onset vs placebo, as well as the wake-after-sleep onset during the second half of the night vs zolpidem. Patients who received lemborexant 5 mg and 10 mg had an increased sleep

efficiency from baseline of 7% (P <0.001) and 8% (P <0.001), wake- after-sleep onset reduction of 24 minutes (P <0.001) and 25 minutes (P <0.001), and wake- after-sleep onset in the second half of the night reduction by 7 min (P = 0.004) and 8 min (P <0.001). Although the following severe adverse events occurred, all were determined by the investigator to be unrelated to the treatment: falls (lemborexant 5 mg: n = 4), sleep paralysis (lemborexant 5 mg: n = 10, lemborexant 10 mg: n = 3). The most common mild adverse events were headache and somnolence in both the treatment and placebo groups, but differences were not statistically significant. Limitations of the SUNRISE 1 trial included recall bias and the limited inclusion criteria of women aged 55 years and older and men aged 65 and older with sleep maintenance insomnia, yet all patients in the zolpidem group received 6.25 mg nightly, the recommended maximum dose for patients aged 65 and older. Overall, the study's results demonstrated that lemborexant was well tolerated and effective, therefore leading to the SUNRISE 2 trial.^{5,6}

SUNRISE 2 was a randomized, double-blind, placebo-controlled, multicenter trial in adult patients ranging from 18 to 84 years of age who met DSM-5 criteria for insomnia disorder. The length of the study was 12 months, consisting of a 6-month placebo-controlled period followed by a 6-month active-treatment only period. Patients ≥18 years old with insomnia were included in the trial and randomized. A total of 949 adult patients were randomized into the following groups: placebo (n=325), lemborexant 5mg (n=323), and lemborexant 10mg (n=323) which were to be taken once nightly. The study met statistical significance for the primary efficacy endpoint in mean change from baseline to end of treatment (6 months) for patient-reported subjective sleep onset latency (sSOL), with a reduction by 22 minutes, 28 minutes, and 11 minutes in the lemborexant 5 mg, lemborexant 10 mg, and placebo group, respectively (P < 0.0001). The study also met statistical significance in the secondary endpoint, subjective wake-after-sleep onset (sWASO), with a reduction by 82 minutes, 86 minutes, and 103 minutes in the lemborexant 5 mg, lemborexant 10 mg, and placebo group, respectively (P < 0.001). In addition, a significantly greater proportion of sleep onset responders was observed at the end of month 6 with lemborexant 5mg (31%; p < 0.001) and lemborexant 10mg (30%; p < 0.001) compared to placebo (18%). It is worthy to note that the findings are based on patient

New Drug Update: Lemborexant (Dayvigo®)

By: Cindy Van, PharmD Candidate c/o 2022, Shireen Farzadeh, PharmD, BCPS

reports using a sleep diary, and therefore, are subjective in nature and may pose a limitation to the study. Another study limitation was the lack of flexible dosing, in which patients were not able to titrate doses. Similar to the adverse events occurring in the SUNRISE 1 trial, none demonstrated statistical significance and the most common adverse events were somnolence and headaches. Overall, the results of the study demonstrated long-term efficacy and tolerability and led to the FDA-approval of lemborexant.⁷

Insomnia is one of the most common sleep-wake disorders with high prevalence. Not only does this condition cause social losses such as long absences, but it can also reduce productivity for students and workers alike. In this clinical study, lemborexant appears to be the first FDA- approved medication to report safety data over a 12-month period along with sleep onset and sleep maintenance efficacy data over a six-month period.² As such, it is a viable solution for patients experiencing insomnia. In the community setting, pharmacists play an important role in counseling patients to consider starting non-pharmacological therapy prior to pharmacological agents. Non-pharmacological therapy includes, sleep hygiene education, and behavioral modifications such as avoiding caffeine before bed and not going to bed unless sleepy. In the case of lemborexant, due to an increased likelihood of somnolence as compared with placebo, patients are advised to get adequate sleep and to avoid operating machinery, as it can affect cognitive performance. With appropriate non-pharmacological and potentially, pharmacological management, patients can expect to see improvements to their insomnia.

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The Cardiovascular Effects of Cannabis vs. Tobacco Consumption

By: Jeng Lee, PharmD Candidate c/o 2022

Throughout the past decade, there has been an increase in the prevalence of medical and recreational consumption of cannabis, also referred to as marijuana.¹ These numbers are expected to rise over the upcoming years in the United States as marijuana use is currently legalized in 33 states and the District of Columbia.¹ Despite that, medical marijuana is currently not approved by the US Food and Drug Administration (FDA) for the treatment of any health diseases.² Marijuana is obtained from the hemp plant, *Cannabis sativa*.³ Cannabis contains two main active ingredients, delta 9-tetrahydrocannabinol (THC) and cannabidiol (CBD).¹ These constituents can be found in varying levels depending on the species of cannabis.¹ Marijuana produces psychoactive effects and inflammatory actions via THC and CBD respectively.¹ THC binds to the Cannabinoid 1 and 2 receptors (CB1 and CB2) with high selectivity.³ CB1 receptors are primarily expressed in the brain and other tissues, such as cardiac muscle, hepatic tissue, the gastrointestinal tract, and vascular endothelium.³ On the other hand, CB2 receptors are predominantly expressed in immune cells and have newly demonstrated to be involved in the regulation of inflammatory cytokines.³ CB1 receptors are typically located in multiple locations, including the cardiovascular system (CVS), the central nervous system (CNS), and peripheral vasculature.³

Unlike marijuana, tobacco consumption has been popular since the late 18th century.⁴ Approximately 23% of the world population smokes cigarettes, with a higher prevalence in men than in women.⁴ Tobacco, also called *Nicotiana tabacum*, is derived from the leaves of the tobacco plant, and can be commonly found in cigarettes and cigars. Tobacco products often contain many other toxic substances, such as carbon monoxide, polycyclic aromatic hydrocarbons (PAHs), nicotine, and heavy metals, amongst others.⁴ These components have a concerning impact on the vascular endothelium, blood lipids, and thrombotic factors, which in turn may result in detrimental cardiovascular events, including myocardial infarction, stroke, and aortic dissection.⁵ Additionally, the inhalation of tobacco smoke leads to an increase in the levels of exogenous and endogenous free radicals in the body; thus, resulting in higher levels of oxidative stress that may disrupt the normal cell and tissue function.⁴

It is widely known that smoking can have various negative effects on the body. Tobacco use is one of the most preventable causes of cardiovascular diseases (CVDs).⁵ Cigarette smoking can cause damage via multiple pathways, including but not limited to inflammation, endothelial dysfunction, prothrombosis, altered lipid metabolism, and increased demand for but reduced supply of myocardial oxygen and blood, also known as demand-supply mismatch.⁵ Furthermore, tobacco consumption impacts the cardiovascular system by increasing catecholamine release, which results in vasoconstriction as well as an increase in cardiac output and heart rate.⁵ Inflammation is the primary mechanism of CVD as it is involved in atherosclerosis initiation and progression, and the occurrence of cardiovascular events.⁵ Inflammatory markers, such as white blood cells, fibrinogens, interleukin-6, and other proteins, act as indicators for blood vessel damage, and are found to be elevated in tobacco users.⁵ Various chemicals in tobacco smoke play a role in the development of CVD by influencing the oxygen demand-supply balance of the heart muscle.⁵ Nicotine stimulates the sympathetic system, leading to an increase in myocardial oxygen demand by heart rate and blood pressure elevation along with an increase in myocardial contractility. Simultaneously, myocardial blood supply is diminished via endothelial dysfunction and vasoconstriction.⁵

Currently, marijuana is viewed as safe or even beneficial by the general population. However, this may be an issue as there is insufficient and conflicting data in regard to the effects of cannabis on many health conditions, including CVDs.⁶ The endocannabinoid system (ECS) exerts its effects through both the sympathetic and parasympathetic nervous systems.¹ As a result, cannabis consumption causes an immediate rise in heart rate and supine blood pressure, with the tachycardia mediated primarily via activation of the CB1 receptor.¹ Similarly to tobacco use, the consumption of marijuana also has a negative impact on myocardial oxygen demand and supply, where there is an increase in the former and a decrease in the latter.¹ This is the result of high levels of carboxyhemoglobin from smoking marijuana.¹ As a consequence, cannabis users can develop transient myocardial ischemia and can experience other cardiovascular effects, such as a reduction in exercise-related cardiac performance or weakened myocardial contraction.¹

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Furthermore, there have been several case reports, such as Basnet et al. and Gunawardena et al., indicating an association between THC and coronary vasospasm-induced cardiomyopathy.³ Both case studies involved young and otherwise healthy individuals, who demonstrated symptoms of CVD along with elevated ST-segment in the electrocardiogram (ECG) and high blood troponin levels.³ Both individuals admitted to marijuana consumption.³ Since both patients were young and had no medical conditions, the case studies appear to show some correlation between the use of cannabis and these cardiovascular adverse effects.

Comparable to tobacco, marijuana also contains many toxic compounds, such as acetaldehyde, ammonia, benzene, carbon monoxide, hydrogen cyanide, PAHs, and so on.³ Thus, these chemicals may be responsible for the cardiovascular effects experienced by marijuana users.³ Additionally, it is common that fungi spores invade into the marijuana plant.³ The main fungal species of concern is the *Aspergillus* species, which can generate aflatoxins.³ This is potentially harmful as it can result in severe acute cardiovascular effects, including but not limited to, protein synthesis disruption in cardiac muscle cells and mitochondrial disruption in the heart tissue.³ Moreover, aflatoxins can persist for long periods of time on the cannabis plant, in marijuana joints as well as the water used in “bongs”.³ Therefore, increasing the exposure of cannabis users to these destructive cardiovascular effects.

In contrast, there have also been a few studies demonstrating no connection between marijuana consumption and CVDs. A moderate-ROB (risk of bias) CARDIA-based (Coronary Artery Risk Development in Young Adults) study assessed the correlation between cumulative lifetime marijuana consumption and cardiovascular mortality.⁶ The investigation found no association between cannabis consumption, with a cumulative of 5 or more years, and cardiovascular mortality.⁶ Additionally, this study examined the composite outcome of cardiovascular mortality, stroke, and coronary heart disease, which also found no correlation between marijuana consumption of 5 or more years and the composite outcome.⁶ Another moderate-ROB prospective study, based on CARDIA, once again found that there was no association between the exposure to cannabis and stroke.⁶

Overall, although marijuana has a lot of similar substances and mechanisms of action as tobacco on the cardiovascular system, it still remains unclear if cannabis has the same negative impact on the heart that tobacco does. Despite that, it is also uncertain that marijuana consumption can have positive and beneficial cardiovascular effects. Hence, users may be advised to limit marijuana consumption, if possible, or to evaluate the advantages and disadvantages of cannabis use depending on their circumstances. More research studies are required on the effect of cannabis use and CVDs as there is currently still inadequate evidence on the subject.

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Who is COVID-19 hitting the hardest?

By: Pooja Dasgupta and Sonya Wadhawan, PharmD Candidates c/o 2025

The coronavirus, also known as SARS CoV-2 or COVID-19, has widely affected various people globally. The study of SARS CoV-2 has shifted from studying individuals and their unique symptoms during their disease duration to studying different populations and their backgrounds that increase the risk of getting and surviving the disease. There were a multitude of reasons as to why public health officials widened their scope, including the fact that they did not learn much from simply knowing one's age and preexisting health conditions. Researchers have discovered that factors such as race, gender, occupation, education, and even one's housing are just as crucial as age when gauging an individual's likelihood of surviving the disease.¹

There has been staggering evidence indicating that some racial and ethnic minority groups have suffered disproportionately from COVID-19.¹ In a new study conducted by researchers at the MIT Sloan School of Management, it has been shown that the higher percentage of Black residents in a county, the higher its death rate from COVID-19.¹ Statistically, the average county-level death rate is 12 deaths per every 100,000 people. However, this number is proven to be 85% higher in Black communities. In turn, there is an increased hospitalization of Black people due to more severe disease states. As Malika Fair, an emergency medicine physician in Washington D.C. and senior director of health equity programs at the Association of American Medical Colleges said, "Black people are dying of COVID-19 at a rate more than twice our share of the population".¹ In addition, more recent studies have found that life expectancy for minorities have been reduced significantly compared to Whites as the life expectancy for Blacks decreased by 2.10 years and for Latinos by 3.05 years.⁴ This decrease in life expectancy for Black and Latino population is 3 to 4 times larger than for Whites and could be explained by the underlying social disparities. These minorities are more likely than Whites to hold low paying jobs, which are often in industries that could not work remotely and have suffered great job losses during the pandemic. Not only did this create significant high unemployment rates for both Blacks and Latinos but as well as a higher rate of health insurance loss.⁴

This concerning increase in death rates among the Black community is not only due to factors such as poverty, age, sex, or chronic health conditions, but results from deeper rooted

issues such as systemic racism. When trying to determine the factors that contributed to such an increase of Black deaths, factors that are impacted by racism such as the quality of insurance African Americans have and the quality of health care received have shown to be significant factors. People with Medicaid or high-deductible plans are more likely to not have a primary care physician. In the United States, 34% of African Americans and 15% of white people are covered by Medicaid.¹ As a result, people that do not have a relationship with a primary care doctor are much less likely to go and get tested. According to George Benjamin, a physician and the executive director of American Public Health Association, when Black people do go to see their doctors, they are less likely to receive a COVID-19 test even though they presented with the cornerstone symptoms of the disease because they do not have a proper relationship with their primary care provider to begin with. Benjamin states that, "someone without a primary care doctor doesn't get into the ER as fast as someone whose doctor calls ahead. At what point were your symptoms severe enough that you got into the health care system?"¹ For people of color, it was likely later, he suggests. This is one reason Black people may not bother going to see a doctor at all. Additionally, it has been historically proven that a lack of trust exists between doctors and the Black community. This can be seen through The Tuskegee trials, which consisted of experiments conducted on 600 Black men, of whom 399 had syphilis and 201 who did not have syphilis. The purpose of the experiments was to try to find a cure for syphilis, however, was deemed "ethically unjustified" as the experiments were done without informed consent. The trials were highly inappropriate as the men who participated were misled and never given all the facts about the study which were needed in order to provide informed consent. They were told they were being treated for their ailments, but in reality, never received the proper treatment needed to cure their illness. Even after 1947, when penicillin became the drug of choice for syphilis the researchers did not offer it to the participants of the study.³ As a result of the unethical Tuskegee trials, the lack of trust between doctors and the Black community, which was already present from past discriminatory events, became further reinforced and still holds today.

Also, due to the embedded systemic racism in our society, when Black people do reach out for help through the system, the

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By: Pooja Dasgupta and Sonya Wadhawan, PharmD Candidates c/o 2025

quality of care they receive is significantly poorer. Research has shown that this has been prevalent for Black people getting treatment for several different health ailments such as cardiovascular heart disease.¹ As a result of receiving improper care for underlying medical conditions, the risk for COVID-19 in Black people is higher. Evidence has suggested that people with pre-existing cardiovascular disease, diabetes, or hypertension are at higher risk of severe illness from COVID-19.¹ In a control study conducted in China, it was found that the estimated mortality risk for COVID-19 in patients with coronary heart disease was three times greater than patients without coronary heart disease.² Unfortunately, racism is apparent in the health care system and because there are differences in the quality of care amongst races, minorities continue to suffer.

A multitude of people are being affected by COVID-19, however Black communities have been hit the hardest. A prominent factor for this is systemic racism in our society that affects the type of insurance, treatment, and quality of healthcare people of color have received. There needs to be a change in the system itself so that everyone can receive the best opportunity for appropriate healthcare. In such strenuous times, it is imperative that we connect and support each other. To prevent the spread of COVID-19, we must all work together to ensure that all communities have equal access to resources such as healthcare information, affordable testing, and medical care to manage their health.

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Insulin Monitoring System for Pediatric patients

By: Lyana Sayilar, PharmD Candidate c/o 2022

On August 31, 2020, the FDA approved the first automated diabetes management device for patients aged 2 to 6-years old. The MiniMed 770G System automatically adjusts basal insulin doses based on glucose levels, facilitating the lives of the patient and caregiver. Prior to its approval, patients and/or caregivers had to continuously monitor blood glucose levels throughout the day and inject insulin using a syringe, pen, or pump.³ Type 1 diabetes is a condition generally affecting the juvenile population where the pancreas produces little to no insulin due to an autoimmune attack of the beta islet cells. Without adequate insulin, blood glucose is unable to enter cells to be used as energy and remains in the blood.¹

The MiniMed 770G System measures blood glucose levels every five minutes and either administers or suppresses insulin delivery. The system consists of a sensor with a wire that attaches to the skin of the abdomen and measures glucose levels and should be changed every 2- 3 days, an insulin pump that straps to the body with an infusion patch connected to the pump, and a catheter that delivers insulin from the pump.³ The sensor, which is inserted up to seven days, is used on the abdomen or buttock for patients 2-13 years old and for patients 14-years and older, the sensor is used on the abdomen or arm. The MiniMed 770G System also contains the Accu-Chek Guide TM Link Blood Glucose meter and test strips. Users or caregivers have to calibrate the sensor at least two times a day. To calibrate the sensor, the glucose values from the Accu-Chek Guide TM Link Blood Glucose meter are transmitted by Bluetooth low energy to the pump. For calibration purposes, the meter should measure blood from the fingertip only. 5 Risks of the system may include hypoglycemia, hyperglycemia, skin irritation, and redness near the infusion patch. The MiniMed 770G System is a prescribed device and is not approved for patients who require less than eight units of insulin per day or more than 250 units of insulin per day.^{3,4}

MiniMed 670G System is an earlier version of this device that does not have the Bluetooth capability that the MiniMed 770G System has and was only approved for ages 7 and up. The MiniMed 770G System extends its use for ages 2 and above. The sensor of the MiniMed 770G System wirelessly transmits the glucose level values through Bluetooth low energy to the pump screen and the patient and caregiver can visualize glucose patterns on a cell phone screen. The system has a

manual and auto mode. In the manual mode, basal insulin is delivered at a constant rate until the glucose levels fall below or are predicted to decrease below a predetermined value. In the auto mode, basal insulin is automatically adjusted and continuously increasing, decreasing, or suppressing insulin based on glucose values detected. At mealtime, the patient or caregiver manually requests bolus insulin doses based on the amount of carbohydrates being consumed. Additionally, the system provides alerts if hyperglycemic or hypoglycemic levels are detected.⁴ The patient or caregiver can view the previous 90 days of glucose trends and the glucose data can be automatically shared with a healthcare professional.²

The MiniMed 770G System should always be removed before entering a room for an x- ray, MRI, diathermy (use of high-frequency electromagnetic currents to provide heat for a medical purpose), or CT scan because the magnetic fields and radiation can damage the part of the pump that delivers insulin or make the device nonfunctional. The system should always be kept away from magnets. A low or high glucose alert should always be confirmed with a glucose meter.² With advancements in technology, the lives of patients or caregivers become facilitated and guidance to proper therapy can be more accurately achieved.

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Bamlanivimab for the treatment of COVID-19**By: Daniela Farzadfar, PharmD,PGY-1 Resident at Long Island Jewish Medical Center**

In March 2020, the World Health Organization (WHO) declared coronavirus disease- 2019 (COVID-19) a global pandemic.¹ To date, over 30 million cases of COVID-19 have been reported in the United States and drug companies have been scrambling to develop therapies for the treatment of COVID-19.² In early November 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for one of the first investigational monoclonal antibody therapies, bamlanivimab. Under the EUA, this agent is authorized for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive SARS-CoV-2 test results who are ≥ 12 years, weighing ≥ 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. High-risk patients include those with a body mass index (BMI) ≥ 35 , chronic kidney disease, diabetes, an immunosuppressive disease, age ≥ 65 years, as well as those with certain other chronic medical conditions. It is also recommended that the drug be administered as soon as possible after a positive test for SARS-CoV-2 and within 10 days of symptom onset.³

The benefits of bamlanivimab have not been observed in patients hospitalized due to COVID-19 and monoclonal antibodies may actually be associated with worse clinical outcomes in hospitalized patients requiring high flow oxygen or mechanical ventilation due to COVID-19. Bamlanivimab is, therefore, not authorized for use in patients who are hospitalized or require oxygen therapy due to COVID-19 or who require an increase in baseline oxygen flow rate due to COVID-19, specifically among those who are on chronic oxygen therapy due to an underlying non-COVID-19 related comorbidity.³

How exactly does bamlanivimab work? Monoclonal antibodies are proteins made in a laboratory that mimic the immune system by fighting off harmful pathogens.⁴ Bamlanivimab is a recombinant neutralizing human IgG1 κ monoclonal antibody to the spike protein of SARS-CoV-2. By binding to the spike protein, it blocks attachment to the human ACE2 receptor.⁵ In this way, it is thought to neutralize the virus by blocking viral attachment.³

Although the safety and efficacy of this agent is still being studied, the FDA says that bamlanivimab has been shown

to reduce COVID-19 related hospital admissions or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo.

This statement is based on an interim analysis from a phase two randomized, double-blind, placebo-controlled clinical trial called BLAZE-1, which included 465 non-hospitalized adults with mild-to-moderate COVID-19 symptoms. One hundred and one of these patients received 700 mg of bamlanivimab, 107 received 2800 mg of bamlanivimab, 101 received 7000 mg of bamlanivimab, and 156 received a placebo within 3 days of obtaining the clinical sample for the first positive SARS-CoV-2 test. The primary endpoint was a change in viral load from baseline to day 11 for bamlanivimab vs. placebo while the secondary endpoint included COVID-19-related hospitalizations or emergency room visits within 28 days after treatment. Hospitalizations and ER visits occurred in 3% of patients at high risk for disease progression treated with bamlanivimab compared to 10% in those patients treated with placebo. The reduction in hospitalizations and ER visits as well the effects on safety were similar in patients receiving any of the 3 doses of bamlanivimab.^{4,6} The current recommended dose is 700 mg as a single dose administered as an intravenous infusion over 60 minutes or more.⁵ In terms of safety, there is a risk of serious hypersensitivity reactions with bamlanivimab including anaphylaxis and infusion-related reactions, which may include fevers, chills, nausea, bronchospasm, hypotension, and angioedema.³

While the results of the secondary endpoint seem promising, looking closer at the interim analysis of the BLAZE-1 trial, the results of the primary endpoint actually show that only one of the three doses of bamlanivimab accelerates the natural decrease in the viral load while the other doses had not done so by day 11. The 2800 mg dose of bamlanivimab demonstrated a statistically significant decrease in the viral load compared to placebo. The 700 mg and 7000 mg doses, however, showed smaller differences from placebo in the change from baseline viral load by day 11 and these results were actually not statistically significant. Yet, the interim analysis does indicate a reduction in hospitalizations and ER visits with all 3 doses of bamlanivimab when compared to placebo, which is of significance.⁶

Bamlanivimab for the treatment of COVID-19**By: Daniela Farzadfar, PharmD, PGY-1 Resident at Long Island Jewish Medical Center**

The EUA for bamlanivimab presents providers with an additional tool for the treatment of COVID-19 and demonstrates the potential for development of new COVID-19 therapies. In fact, additional EUAs for monoclonal antibodies, casirivimab and imdevimab administered together as well as bamlanivimab and etesevimab to be used together for the treatment of mild- to-moderate COVID-19, have also been recently issued.^{7, 8} Although these agents are still being evaluated and have not yet been approved, this progress in the development and access of new COVID-19 therapies has shown some promise.

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RHO CHI POST: TEAM MEMBERS



@ Katharine Russo

6th Year, STJ; Editor-in-Chief

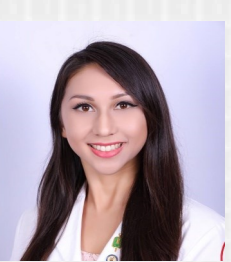
The Rho Chi Post has been a forum for students, faculty, and staff to advance their knowledge in the field of pharmacy since 2011. The platform allows for students to practice their written communication skills while offering an innovative and creative workspace to bring together various aspects of the pharmacy profession. I am proud to continue this tradition by fostering a publication suited to keep our readers up-to-date, especially in these unprecedented times during the COVID-19 pandemic.



@ Anna Diyamandoglu, PharmD

Graduate Copy Editor [Content-Focused]

Throughout my time in the PharmD program, my understanding of pharmacy as a profession has evolved and deepened as much as my desire to create awareness, particularly to non-science students, about the diverse role pharmacy plays in various healthcare and non-healthcare settings. I have always had an affinity for writing and look forward to combining my interests in literary composition, editing and pharmacy to produce relevant issues which both pharmacy students and non-pharmacy students alike will find relatable and take an interest in.



@ Shireen Farzadeh, PharmD

Graduate Copy Editor [Content-Focused]

I am excited to join Rho Chi Post and contribute to the award-winning newsletter for students to share ideas, opinions, and pertinent topics! Writing for the Rho Chi Post is an opportunity to express our appreciation for pharmacy and educate ourselves and our peers. I hope to inspire students to discover their passion for writing and to stay up to date on our evolving profession!



@ Daniela Farzadfar, PharmD

Graduate Staff Writer

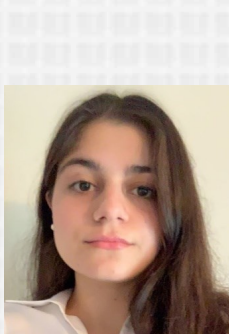
Pharmacy is a constantly evolving profession. Writing for the Rho Chi Post gives me the opportunity to enlighten my peers and myself on changes occurring in the field that we are often not taught in the classroom. The Rho Chi Post serves as a creative outlet where students can express their opinions and share new information by combining their passion for writing and the pharmacy profession. I hope that my contribution to this newsletter inspires others to improve patient outcomes by staying up to date on recent changes.



@ Kathleen Horan, PharmD

Graduate Copy Editor [Content-Focused]

I have always loved writing, and I hope to couple my passion for writing with my interest in clinical pharmacy by becoming a writer and staff editor for the Rho Chi Post. As a writer and staff editor for the Rho Chi Post, I hope to write and edit informative and interesting articles that relate to the world of healthcare and pharmacy. I am so excited to join this team of student pharmacists and writers.



@ Evanthia Siozios, PharmD

Graduate Staff Writer

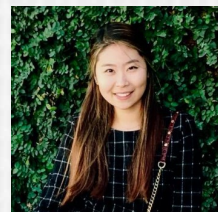
Rho Chi Post is a newsletter that gives students the opportunity to learn and write about novel topics and broaden their knowledge while demonstrating their writing skills. For me, being involved with this newsletter is not just about learning something new but also sharing relevant topics which have an impact on patients' lives. I have learned so much from writing for the Rho Chi Post and hope to inspire others with my words. As a future pharmacist I want to learn to teach and get to give.



@ Michael Lim, PharmD

Graduate Staff Writer

In the spirit of advancing the pharmacy profession, the Rho Chi Post never ceases to produce valuable content showcasing the innovation and diversity of the career. As a Staff Writer for the Post, I am honored to have the opportunity to use writing to both educate and push readers to strive for excellence in their professional pursuits. I hope that my contributions to the newsletter are able to foster growth in an informative and accessible manner.



@ Judy Koag

6th Year, STJ; Copy Editor [Graphics-Focused]

I am so excited to join the Rho Chi Post, a newsletter which strives to create high quality and creative content. I look forward to working with the team to promote the profession of pharmacy and communicate ideas that inspire and attract readers through the use of graphic design. Graphic design has always been my passion and I hope my contributions continue the Rho Chi Post's mission.

RHO CHI POST: TEAM MEMBERS



@ Lexie Villariasa

5th Year, STJ; Copy Editor [Graphics-Focused]

With the world of pharmacy changing day by day, it can be challenging to keep up with all the updates. The Rho Chi Post provides an excellent platform for students to share their insights and thoughts on the happenings within the field. I'm excited to join the Rho Chi Post and a team that is passionate about the profession. With a passion in graphic design, I hope to continue the vision the newsletter has and am grateful for the opportunity to do so!



@ Jason Ifeanyi

5th Year, STJ; Social Media Manager, Staff Editor

The Rho Chi Post has a clear mission: to advance the profession of pharmacy by instilling the desire in others to pursue intellectual excellence and critical inquiry. I could not be more excited to join the Rho Chi Post. This an interactive platform that affords me a unique opportunity to contribute to the process of educating readers on advances made in drug discovery and development, modifications in treatment guidelines, and the implications these changes have on the practice of Pharmacy. I am eager to work on this team of equally motivated students, and I look forward to utilizing my skills, past work and volunteer experiences to assist the Rho Chi Post in achieving their goals.



@ Alisha Kuriakose

5th Year, STJ; Finance & Outreach Manager

I wanted to be part of Rho Chi Post as it provides a platform for students to express their ideas and educate others on global healthcare issues. As a future pharmacist, this is my way of contributing to the change I want to see in our growing profession and make my voice heard. I am very excited for the privilege to work alongside the editorial board to produce a newsletter and serve as the 2020-2021 Finance and Outreach Manager!



@ Carolina Guerreiro

6th Year, STJ; Staff Editor

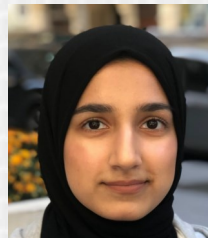
As a student of the arts and sciences all my life, I have always been interested in the intersection between the two. The most exciting part about being a Staff Editor for the Rho Chi Post is not only the ability to share the most exciting and clinically relevant healthcare news with our audience, but also having the opportunity to tap into my creative side while relying on my clinical knowledge and previous scientific writing experience. When I'm not busy editing, I am working to capture stories that raise awareness about the diverse roles pharmacists can play in healthcare settings worldwide. I strive to share my vision of untamed areas of pharmacy practice and hope to inspire you as readers to explore them for yourselves



@Edwin Gruda

5th Year; STJ; Staff Writer

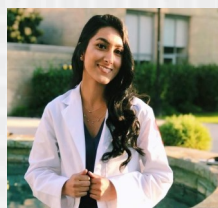
My name is Edwin and I am a Doctor of Pharmacy student at St. John's University. My favorite aspect of pharmacy school is learning about the clinical and therapeutic components of drugs and diseases. As a kid, I was interested in both the math and sciences. The reason I chose pharmacy over other health care professions is because a lot of people rely on their medications to make them feel better. Pharmacists are the most accessible healthcare providers and are able to help patients optimize their drug therapy in order to improve their health. Throughout the beginning of pharmacy school, I volunteered at Columbia University Medical Center on the oncology department for one year. After that, I have been working as a pharmacy intern at Sandcastle Pharmacy, which is primarily an HIV specialty pharmacy. As a staff writer, I want to highlight the critical role of clinical pharmacists within an interdisciplinary team, in improving and enhancing a patient's quality of life.



@Rubab Hassan

5th Year, STJ; Staff Writer

The Rho Chi Post gives pharmacy students the opportunity to explore their interests, whether it be editing, writing, or graphics, while also enhancing their skills and knowledge as student pharmacists. I am excited to be a part of the Rho Chi Post because it is a great way to expand on what I have learned during my time in pharmacy school and also keep developing my writing skills. Being a writer gives me an outlet to raise awareness on the advancements that are constantly happening in the field of pharmacy and allows me to be part of an amazing team in hopes of providing other students with our best work.



@ Zarnab Jillani

5th Year; STJ; Staff Writer

The Rho Chi Post is a great platform for students to not only apply what they have been learning in school, but to break norms and report on pharmacy related events that are not always addressed in an academic setting. I look forward to writing for the Rho Chi Post because it will give me a way to delve deeper into what I'm studying at the moment and give me a chance to share that with my peers. Moreover, with the constantly changing world of pharmacy it is important to stay up to date and present the information in a creative way.



@ Natalia Loomis

5th Year STJ; Staff Writer

The profession of pharmacy and what a pharmacist entails is an ever evolving journey. Rho Chi Post becomes an excellent resource in tracking these advances. It provides student pharmacists to not only read and become educated on what other paths might be in store for them, but to become part of the team and create their path. I am so thankful and excited for the opportunity to become a staff writer for the RCP; allowing myself to use my creative ability to not only create my path, but write content to shed a light on all the amazing opportunities that of being a pharmacist entails.

RHO CHI POST: TEAM MEMBERS



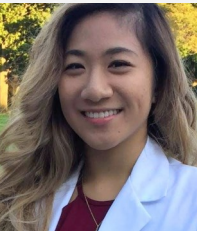
@ Jeremy Mesias
5th Year, STJ; Staff Editor

The field of pharmacy is constantly growing and improving with every coming day. Today's headlines become tomorrow's history. As healthcare leaders in a dynamic field, it is important to stay up to date. The Rho Chi Post serves as an excellent tool to help students become more informed about our profession, as well as providing them with the opportunity to contribute their own two cents to the conversation. I am excited to join the team and look forward to contributing to keeping students on top of current pharmacy advancements.



@ Aiša Mrkulić
5th year, STJ; Staff Writer

It is admirable of the Rho Chi Post to provide us student pharmacists with a platform to use our voice. Home to the free-exchange of thoughts, opinions & ideas, all are welcome to contribute—so don't count yourself out! Eager to use my voice more than ever before, I counted myself in. As a Staff Writer, patient advocacy, furthering of public health initiatives & diversifying public perception of pharmacists all suddenly become possible. After all, who if not us is to showcase the value of America's most-trusted healthcare professional? I encourage both our loyal & first-time readers to please, read on with us. To learn to read is to learn to write and to learn to write is to become better communicators—disseminators of information. When this occurs, the quality of patient care improves...& that is always the goal.



@ Nicole Ng
5th Year, STJ; Website Liaison

Being able to join the Rho Chi Post not only gives me the opportunity to expand my knowledge of the profession of pharmacy, but also allows me to be a part of educating students about the constant changes within the field. Through my involvement, I hope to increase the accessibility of our content and motivate students to broaden their knowledge and stay up-to-date. I am excited to work with the team to produce a newsletter that effectively and efficiently communicates all news that affects our healthcare profession.



@ Mah Noor
6th Year, STJ; Staff Writer

Rho Chi Post is an amazing student-operated newsletter publication that is doing an astonishing job delivering updated news as well as giving students the opportunity to give back to the pharmacy community. As a staff writer, I hope to play a key role in educating students on the different aspects of pharmacy and how much growth takes place in this field. Reading the Post since freshman year has helped me gain a better understanding of what it means to be a pharmacist and I hope to achieve that same understanding in students who read my articles.



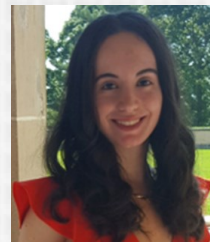
@ Tolulope Omisakin
5th Year, STJ; Staff Editor

As an avid reader, I have always taken an interest in how things were written. Whether it be novels, journal articles, or magazine columns, there is always a peculiar way in which a writer tells a story. The real story is only 50% of what is written and the rest is in how the writer decides to disseminate that information. The Rho Chi Post serves as an amazing outlet for student pharmacists, allowing us to delve into the intricacies of different perspectives and ideas in the world of pharmacy. It also gives us the opportunity to decide how we want to detail these new found perspectives and ideas to our audience. As an incoming editor for The Rho Chi Post, I hope to enhance and curate the way each writer tells their stories and help them reach their audience at new levels.



@ Preethi Samuel
6th Year, STJ; Staff Writer

As future drug experts, we student pharmacists have a responsibility to take initiative and educate ourselves on advancements in healthcare, so as to improve the quality of patient care. The Rho Chi Post serves as a great platform for students to get information that is both accessible and accurate. To be a voice for my future, fellow pharmacists is to be heard and my patients cared for---as pharmacists are their best, sometimes their only, advocates. I hope that my contributions to the RCP spark readers' curiosity, and inspire conversations of how we may become better pharmacists.



@ Lyana Sayilar
5th Year, STJ; Staff Writer

I am thankful for the opportunity Rho Chi Post provides by engaging students, pharmacists, and faculty to learn from each other and spark new ideas, thoughts, and interests. The pharmacy profession is an ongoing and lifelong learning path and Rho Chi Post emphasizes and mirrors the importance of learning to provide pharmacists at our current jobs and patients in the future with recent information to improve patient care and outcomes. With the help of Rho Chi Post we can practice analyzing the literature that we read to improve our decision-making skills and communicate our findings with other members of the healthcare team.



@ Holly Nguyen
3rd Year, STJ; Staff Editor

I am actively involved with the IPhO and St. John's Wellness Peer Educators. Through the Rho Chi Post, I look forward to helping review and share the latest pharmaceutical news.

RHO CHI POST: TEAM MEMBERS

@ Bisma Sekhery

6th Year, STJ; Staff Writer

There are two things I am passionate about one which is pharmacy and the second which is writing. The Rho Chi Post is a professional newsletter, which allows students to educate as well as learn more about the field of pharmacy as it evolves. I am beyond excited to contribute to this newsletter and provide my fellow classmates and peers interesting news about pharmacy. I have always enjoyed reading The Rho Chi Post articles throughout pharmacy school. The articles were interesting and educational. This allows me to make an important contribution to society and spread awareness not only of new drugs and advancements in the field, but current issues in the pharmacy world. Having a voice is very important and writing for this newsletter allows me to have one.

@Erica Tonti

5th Year, STJ; Staff Writer

The profession of pharmacy is constantly evolving and adapting to the ever-changing field of healthcare. The Rho Chi Post serves as an amazing outlet for students to be informed, as well as to inform others, on the most up to date and relevant information. I could not be more excited to join the Rho Chi Post. This opportunity allows myself and my peers to take initiative and raise awareness of the advancements in the field of pharmacy. As a staff writer, I look forward to contributing to the Rho Chi Post and am grateful for the opportunity to educate students on the growth within our profession.

@ Arya Firoozan

4th Year, STJ; Staff Writer

Joining the Rho Chi Post is an opportunity to remain updated with new advancements in the science of pharmacy. The Post provides students with a platform to present the rest of the student body with interesting articles regarding new medications and important changes in the field. Keeping up with new developments and innovations is key to becoming a capable pharmacist. I am quite excited to join a team that is a voice of research and knowledge and look forward to contributing in a way that will benefit the pharmacy community.

@ Tiffany Dominic

5th Year, STJ; Staff Writer

My name is Tiffany Dominic and I am currently a fifth year pharmacy student. After being a dedicated reader of Rho Chi Post for years, I wanted to give back and be a part of this amazing community of writers and editors who work tirelessly to publish quality pieces of knowledge, news, and opinions. Being part of Rho Chi Post allows me to shed light on issues that aren't touched upon in our didactic courses and helps me connect students to real-world applications and approaches in pharmacy. I am beyond grateful that Rho Chi Post has given me the opportunity to continue my love for writing while also promoting patient advocacy and public health. I look forward towards writing about current events and essential healthcare issues while being part of this incredible team!

@ Richa Tamakuwala

5th Year, STJ; Staff Editor

Growing up, reading was always my favorite hobby. The way the authors were able to create such vivid images, the way they could make you feel what the characters were feeling, the way they captured their readers' attention so tightly that nothing else mattered in the moment all motivated me to start writing. Since starting pharmacy school, my writing has unfortunately been placed on hold, but after learning about Rho Chi Post, I'm excited to start writing again. Writing for Rho Chi Post will allow me, along with many other students, to do something I enjoy while updating fellow future pharmacists on the ever-changing field of pharmacy.

@ Nishanth Viswanath

5th Year, STJ; Staff Writer

The profession of pharmacy is continuously expanding to meet new demands and offer novel platforms for innovation in healthcare. With an abundance of new information and guidance being published everyday, it can become difficult for students and professionals to stay updated with relevant information and find new outlets to learn. The Rho Chi Post not only allows us to be informed about the current state of our profession, but also allows students to voice their opinions and connect with each other through literature. I am excited to be part of its team, and hope to provide meaningful and resourceful contributions.

@ Dana Weinstein

5th Year, STJ; Staff Writer

I am so excited to be a part of the Rho Chi Post team. This opportunity allows both myself and my peers to be well informed about the ever-changing profession of pharmacy and the vital developments in science and healthcare. Beyond the classroom setting, this newsletter fills in the gaps for the most up-to-date and current advancements for students and faculty. As a staff writer, I look forward to acting as an educator, a motivator, and an executor to further the mission and goals of the Rho Chi Post.

@ Anjali Rana

2nd Year, STJ; Staff Writer

My desire to learn about medicine and its effect on the human body began with a nebulizer. I had asthma as a young girl. At the age of ten, the vaporous gases from the pump never ceased to amaze me. My sickness, although unfortunate, fueled my interest in the functions, limitations, and exploitations of drugs. I have always had a passion for advocating for change and believe the Rho Chi Post adds great value to the community. As the world grows and develops each individual has an opportunity to express their thoughts on its development. Having the chance to become a Staff Writer provides me an opportunity to learn information about my peers to better assess the nature of their situation. When people begin discussing concepts at a younger age, they are able to influence people of their generation to care more about their own health. Combining concepts learned from pharmacy school with the mission to help those in need will create a stronger foundation for future healthcare professionals.

MISSION

The Rho Chi Post is an award-winning, monthly, electronic, student-operated, faculty-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION

The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John's University College of Pharmacy and Health Sciences

Our newsletter continues to be known for its relatable and useful content

Our editorial team continues to be known for its excellence and professionalism

The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy

VALUES

Opportunity

Teamwork

Respect

Excellence

GOALS

To provide the highest quality student-operated newsletter with accurate information

To maintain a healthy, respectful, challenging, and rewarding environment for student editors

To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits

To have a strong, positive impact on fellow students, faculty, and administrators

To contribute ideas and innovations to the Pharmacy profession