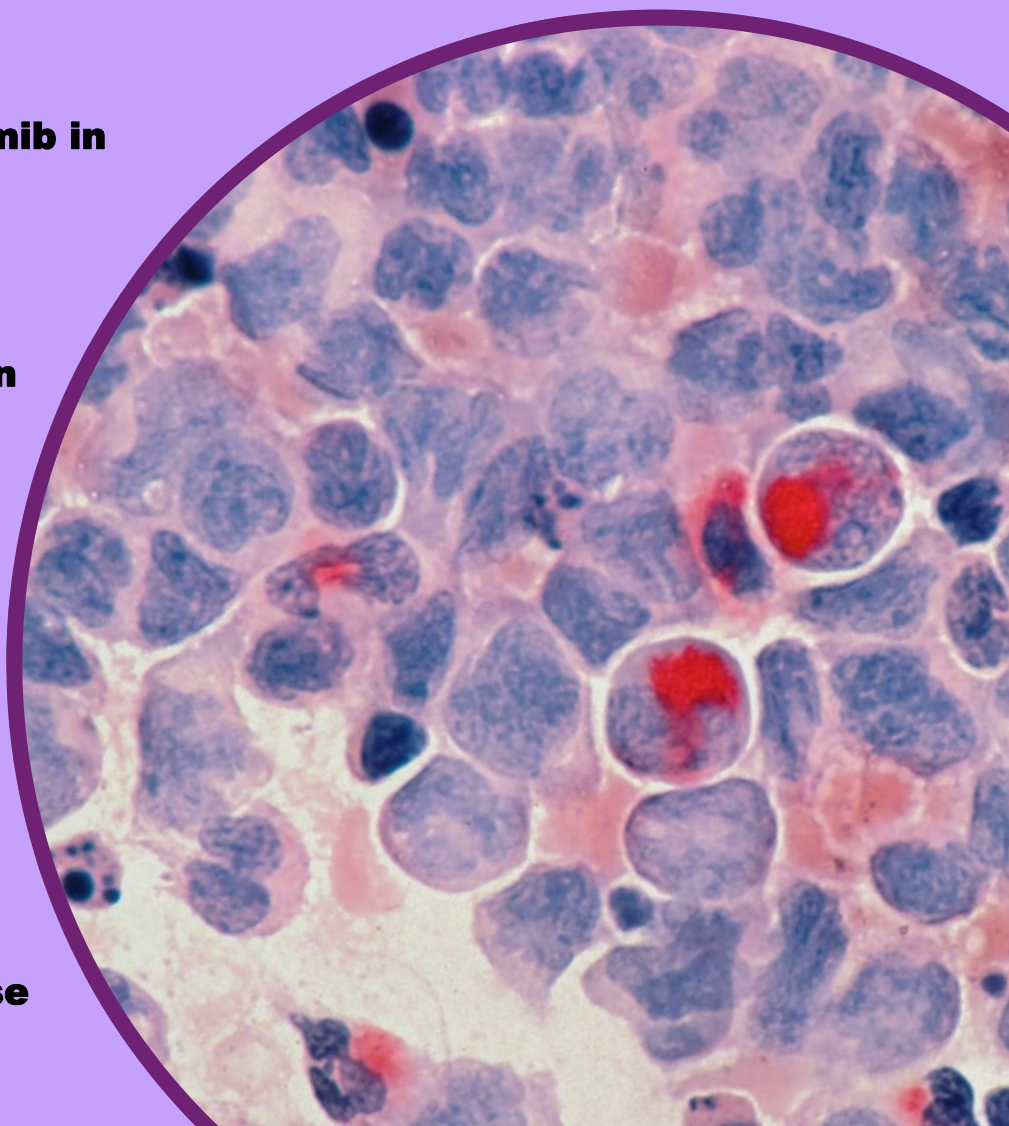
St. John's University - College of Pharmacy & Health Sciences

RHO PX CHI post

Volume 12 | Issue 3 | Feb 2023

FDA Approval of Pemazyre® as a First-in-Class Treatment for Myeloid/ Lymphoid Neoplasms with FGFR1 Rearrangement



RHO CHI post

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From The Editor

Justin Budz

A Message from the Editor-in-Chief

With the 2023 Spring Semester well underway, on behalf of the Rho Chi Post, I would like to wish all students the best of luck with their studies and personal endeavors. This semester marks an important milestone in my time at St. John's University. I am ecstatic to share that after graduation, I have accepted a two-year post-doctoral fellowship in Pharmaceutical Marketing with RevHealth. This opportunity is truly a testament of the hard work and perseverance through six years of pharmacy school, and I am very thankful for those who have aided in my professional development along the way. I would also like to share some exciting news regarding the Rho Chi Post. This semester, our newsletter will have the pleasure of debuting its first ever publication dedicated to the Rho Chi LEADS Initiative. This upcoming April Issue of the Rho Chi Post will feature articles from LEADS Initiative mentor/mentee pairs, as well as interviews from the Initiative founders. The Rho Chi Post will also be opening recruitment for 2023-2024 Editorial Team positions. Membership provides invaluable leadership experience, as well as skillset development in writing, editing, content development, data analysis, and communication. We look forward to having yet another successful semester with our St. John's community.

Frequently Asked Questions

Who can write for the Rho Chi Post Newsletter?

Anyone can write for the Rho Chi Post! Our newsletter is not exclusive to St. John's University students. The Rho Chi Post accepts articles on a daily basis!

How do I submit an article?

You can submit an article by creating an account on our website! Go to www.rhochistj.org/RhoChiPost, click the login button from the upper menu bar, and click register. Upon making an account, you will be able to submit articles to our author inbox.

Who determines article topics?

You are free to choose an article topic of your choice. Take a look at our Author Guidelines for ideas.

What happens after I upload my draft article on the Rho Chi Post website?

Our Editor-In-Chief (EIC) will either edit the article directly or assign the article to a staff editor. If any revisions are needed, the editor will upload the article back to the portal, notifying the author via email. The author can then download the edited article, make the suggested revisions, and reupload the draft back to the portal. Additional drafts will be revaluated by our copy editors and then EIC, repeating this process. Once no further revisions are needed, the article is accepted for publication.

Is there a deadline for authors to send revisions?

There is no deadline to submit revisions for an article. However, the quicker revisions are made, the quicker the article can move through our editing process. Once an article is accepted for publication, it will be moved into a queue to be placed into an upcoming issue.

About the Rho Chi Post

The Rho Chi Post was developed by the St. John's University Rho Chi Beta Delta Chapter in October 2011 as an electronic, student-operated newsletter publication with a team of three student editors and one Editor-in-Chief. Today, our newsletter boasts 12 volumes, over 90 published issues, and more than 600 unique articles to date with an editorial team of first to sixth year student pharmacists, as well as returning PharmD graduates.

The newsletter is distributed by St. John's University College of Pharmacy and Health Sciences to more than 1,500 students and faculty members. Our monthly electronic mailing list continues to extend readership far beyond campus.

Mission

The Rho Chi Post is an award-winning, 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 and faculty.

Vision

The Rho Chi Post aims to become the most creative and informative 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 sets the stage for the development of individual writing skills, collaborative team work, and leadership.

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Evaluating Efficacy of Bortezomib and Carfilzomib in Treatment of Refractory Multiple Myeloma

By: Brian Chung, PharmD Candidate c/o 2024, Peter Chung, PharmD Candidate c/o 2024, and Kevin Kim, PharmD Candidate c/o 2024

Multiple myeloma is a blood cancer that affects an individual's plasma cells. Plasma cells are white blood cells located in the bone marrow that are responsible for producing antibodies, also known as immunoglobulins.[1] Immunoglobulins play a vital role in fighting off infections by binding to foreign antigens on pathogens, resulting in an immune response.[2] In multiple myeloma, malignant plasma cells secrete nonfunctional antibodies called M proteins.[1] Asides from immunosuppression, complications of multiple myeloma also include anemia, bone disease, calcium elevations, and renal insufficiency.[3] A variety of risk factors are known to increase a person's risk of multiple myeloma, including older age, male gender, African American race, family history of multiple myeloma, and personal history of a plasma cell disease (i.e., monoclonal gammopathy of undetermined significance).[4,5]

Diagnosis and Treatment of Multiple Myeloma

The diagnostic workup for multiple myeloma will commonly involve a history and physical exam; CBC, differential, and platelet count; peripheral blood smear; basic metabolic panel; liver function tests; creatinine clearance; serum quantitative immunoglobulins; urine collection; computed tomography scan; bone marrow biopsy; and plasma cell fluorescence in situ hybridization (FISH) panel on bone marrow.[6] Multiple myeloma is staged using the Revised International Staging System (RISS), which takes into account the albumin, beta-2-microglobulin, and lactate dehydrogenase (LDH) serum concentrations, as well as the specific gene abnormalities, or cytogenetics, of the cancer. Depending on these findings, multiple myeloma is staged from 1 to 3, with stage 1 being the least advanced stage and stage 3 being the most aggressive stage.[7]

Treatment is based on patient specific symptoms and disease stage and history. Common symptoms of multiple myeloma include bone pain, nausea, constipation, loss of appetite, fatigue, weakness in arms and legs, unexplained weight loss, confusion, frequent infections, excessive thirst, and fever.[5] In general, standard treatment options for multiple myeloma consist of targeted therapy, immunotherapy, chemotherapy, corticosteroids, bone marrow transplant, radiation therapy, and supportive care.[6,8] In patients that are bone marrow transplant candidates, preferred treatment regimens include bortezomib / lenalidomide / dexamethasone or carfilzomib / lenalidomide / dexamethasone.[6] In patients not eligible for a transplant, preferred treatment regimens include bortezomib / lenalidomide / dexamethasone or daratumumab / lenalidomide / dexamethasone.[6]

Bortezomib and Carfilzomib Overview

Protein homeostasis is a vital biological process for the survival of malignant cells. Cancer researchers looked to develop agents to target the regulation of protein production and destruction, particularly of proteins that mediate cell proliferation. The ubiquitin-proteasome

pathway (UPP) is the primary mechanism for degradation of proteins, including those involved in cell cycle regulation, apoptosis, and angiogenesis.[9] The UPP targets proteins for recognition and for subsequent degradation via the attachment of ubiquitin molecules. The 26S proteasome complex is comprised of a 20S core catalytic component that is capped at one or both ends by a 19S regulatory component. The 19S structure recognizes and binds the protein and feeds it into the 20S core for degradation.[9] A complete blockade of the 26S proteasome complex would result in cancer cell apoptosis and obstruction of cellular homeostasis, resulting in cancer cell death.[9-11]

Bortezomib is an antineoplastic agent indicated for the treatment of adults with multiple myeloma and for adults with mantle cell lymphoma.[12] Bortezomib is administered subcutaneously or intravenously at a starting dose of 1.3 mg/m^2. [12] Bortezomib functions as a reversible inhibitor of the 26S proteasome. Studies have demonstrated that bortezomib is cytotoxic to a variety of cancer cell types in vitro and is able to delay tumor growth in vivo in nonclinical tumor models, including multiple myeloma.[12]

Carfilzomib is an antineoplastic agent indicated for the treatment of adults with relapsed or refractory multiple myeloma who have received one or more lines of therapy.[13] Carfilzomib is administered intravenously at a starting dose of 20 mg/m^2. [13] Carfilzomib is a proteasome inhibitor that irreversibly binds to the N-terminal threonine-containing active sites of the 20S proteasome. Carfilzomib exhibited antiproliferative and proapoptotic activities in vitro in solid and hematologic tumor cells, as well as a delay in tumor growth in models of multiple myeloma, hematologic, and solid tumors.[13]

Randomized Control Trial Comparing Bortezomib and Carfilzomib

The ENDURANCE trial, conducted by Kumar et al., was a multicenter, open-label, phase III randomized controlled trial set to determine the superiority of carfilzomib, lenalidomide, and dexamethasone (KRd) over bortezomib, lenalidomide, and dexamethasone (VRd).[14] The ENDURANCE trial included a total of 1053 patients divided randomly to receive induction therapy with either VRd (n=527) or KRd (n=526) for 36 weeks. Patients completing the induction phase were randomized a second time with equal allocation to indefinite vs 2 years of lenalidomide maintenance.[14] In terms of baseline characteristics, the median age was 65 years with 59% of participants being male, 86% white, 12% black, 37% with an ISS stage of 1, 36% with stage 2, and 28% with stage 3.[14] The study was conducted by the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG-ACRIN) Cancer Research Group and funded by the National Institutes of Health (NIH), the National Cancer Institute (NCI), and Amgen.[14]

Patients 18 years and older with newly diagnosed symptomatic standard-risk multiple myeloma who were ineligible to undergo autologous stem-cell transplantation (ASCT) were enrolled in this study.[14] To be included, patients must have a measurable disease defined by having one or more of the following: ≥ 1g/dL monoclonal protein (M-protein) on serum protein electrophoresis, ≥ 200 mg/24 hours of monoclonal protein on a 24-hour urine protein electrophoresis, involved free light chain ≥ 10 mg/dL and abnormal serum immunoglobulin kappa to lambda free light chain ratio of < 0.26 or > 1.65, or monoclonal bone marrow plasmacytosis ≥ 30%.[14]

The ENDURANCE trial excluded patients with high-risk multiple myeloma, defined by having one of the following: gene translocation t(14;16), t(14;20) or gene deletion del(17p) on FISH, serum LDH > 2x the upper limit of normal, > 20% circulating plasma cells on peripheral blood smear differential or 2000 plasma cells/μL on white blood cell differential of peripheral blood, or high-risk GEP70 signature by gene expression.[14] Other notable exclusion criteria included uncontrolled seizure disorder, uncontrolled hypertension, symptomatic congestive heart failure, unstable angina, or uncontrolled cardiac arrythmias.[14]

Patients in the VRd group received treatment in 3-week cycles for 12 cycles.[14] Bortezomib was administered subcutaneously or intravenously at a dose of 1.3 mg/m^2 on days 1, 4, 8, and 11 for cycles 1 to 8. From cycle 9 through 12, bortezomib was administered on days 1 and 8. In the VRd regimen, lenalidomide 25 mg was administered by mouth once daily on days 1 to 14, and dexamethasone 20 mg was administered by mouth on days 1, 2, 4, 5, 8, 9, 11, and 12 for cycles 1 to 4. From cycle 5 through 8, the dose of dexamethasone was reduced to 10 mg. From cycle 9 through 12, dexamethasone 10 mg was administered on days 1, 2, 8, and 9.[14]

In the KRd group, patients received treatment in 4-week cycles for 9 cycles.[14] On days 1 and 2 of cycle 1, carfilzomib was administered intravenously at 20 mg/m^2. After these first two reduced doses, carfilzomib was given at a dose of 36 mg/m^2 on days 1, 2, 8, 9, 15, and 16 of each cycle. In the KRd regimen, lenalidomide 25 mg was administered by mouth once daily on days 1 to 21, and dexamethasone 40 mg was administered by mouth on days 1, 8, 15, and 22 for cycles 1 to 9. From cycle 5 through 9, the dose of dexamethasone was reduced to 20 mg.[14]

The primary endpoint for the induction phase of the ENDURANCE trial was progression-free survival (PFS), defined as the time from induction randomization until the earliest progression or death due to any cause.[14] The primary endpoint for the maintenance phase was overall survival (OS), defined as the time from maintenance randomization to death due to any cause.[14] Secondary endpoints included overall response rate (ORR), time to progression (TTP), duration of response (DOR), OS, and minimal residual disease (MRD) negative rate measured by flow cytometry.[14] The Kaplan-Meier method was used to estimate survival distributions by induction arm. A stratified log-rank test was used to compare survival distributions between induction arms. Treatment hazard ratios (HR) were estimated with the use of a stratified Cox proportional hazards regression model. It was estimated that there was 80% power at a 1-sided 0.025 significance level to detect a 25% reduction in the HR.[14]

Regarding efficacy data, results showed that the median PFS was 34.6 months (95% confidence interval [CI] 28.8 to 37.8) in the KRd group and 34.4 months (95% CI 30.1 to NE) in the VRd group. The overall HR of KRd compared to VRd was 1.04 (95% CI 0.83 to 1.31; p=0.74).[14] The best ORR of a partial response or better during induction was achieved by 444 (84%) participants in the VRd group and 456 (87%) participants in the KRd group (p=0.26). A complete response or better was observed in 78 (15%) participants in the VRD group compared to 96 (18%) participants in the KRd group (p=0.13).[14] In patients with a complete response, MRD negativity was seen in 38 (7%) participants treated with VRd compared to 54 (10%) treated with KRd (p=0.08).[14] Lastly, the estimate for 3-year OS probability is 0.84 (95%

CI 0.80 to 0.88) for the VRd group and 0.86 (95% CI 0.82 to 0.89) for the KRd group. The median OS was not able to be established by the time of publication. The HR for death in the KRd group compared to the VRD group was 0.98 (95% CI 0.71 to 1.36; p=0.92).[14]

Regarding safety data, the VRd group had 218 (41%) grade 3 or higher non-hematologic treatment-related adverse events (TRAE) observed (95% CI 37% to 46%) compared to 254 (48%) in the KRd group (95% CI 44% to 53%).[14] Grade 4 to 5 hematologic plus non-hematologic TRAEs were reported in 61 (12%) of participants in the VRd group compared to 70 (13%) in the KRd group.[14] Grade 3 to 5 serious adverse events occurred in 116 (22%) participants in the VRd group compared to 234 (45%) participants in the KRd group.[14] A grade 3 or higher composite cardiac, pulmonary, and renal toxicity was noted among 84 (16%) participants in the KRd group compared to 25 (5%) participants in the VRd group ($p < 0.001$).[14] The most common (≥ 3%) TRAEs were heart failure, diarrhea, fatigue, lung infection, hyperglycemia, peripheral sensory neuropathy, dyspnea, maculopapular rash, hypertension, and thromboembolic event.[14] Overall, 91 (17.3%) participants in the VRd group and 52 (9.9%) participants in the KRd group discontinued therapy because of adverse events.[14]

Conclusion

The ENDURANCE trial concluded that carfilzomib was not superior to bortezomib when used in combination with lenalidomide and dexamethasone in refractory multiple myeloma.[14] Overall, efficacy results regarding PFS and 3-year OS probability were similar between carfilzomib and bortezomib. Furthermore, there were more TRAEs with statistically significant margins observed in the carfilzomib regimen compared to the bortezomib regimen. Although both medications have a place in therapy for patients with multiple myeloma, the high incidence of adverse effects in carfilzomib makes it unconvincing to recommend first over bortezomib.

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Rho Chi Talks: Tips to Acquire a Post-Doctoral Fellowship

Featuring: Kamran Khan, PharmD Candidate c/o 2023
By: Justin Budz, PharmD Candidate c/o 2023

Kamran Khan is a sixth-year pharmacy student at St. John's University. Growing up, Kamran had a lot of family members in healthcare, instilling an interest in medicine from an early age. While at St. John's, Kamran got to experience many different career paths in pharmacy, including community experience at CVS, hospital experience at Northwell Health, and even industry experience at a Medical Communications agency. Kamran's industry experience came while he was on his APPE rotations, sparking his interests to pursue post-doctoral fellowship opportunities. After interviewing with different programs, Kamran was fortunate to accept a post-doctoral fellowship in Medical/Regulatory Affairs at Ipsen Pharmaceuticals in conjunction with Northeastern University.

What is a fellowship?

A fellowship is a one- to two-year program where you have the opportunity to learn about the pharmaceutical industry and a specific functional area within it. For me, I'm going to start a fellowship at Ipsen Pharmaceuticals in Medical and Regulatory Affairs, but there's plenty of functional areas that you can look into like Clinical Research & Development, Health Economics & Outcomes Research, Pharmacovigilance & Safety, and Pharmaceutical Marketing. Fellowships are similar to residencies but are more structured towards the pharmaceutical industry, whereas residencies prepare you for practicing in a hospital setting.

What made you want to pursue a fellowship?

I have a family friend who's in the pharmaceutical industry so I've always known about the pharmaceutical industry, but I didn't know if I would be interested in it. However, after working at the Medical Communications agency, I fell in love with Medical Affairs. I also had a rotation at the Accreditation Council of Medical Affairs which not only grew my interest in Medical Affairs but also in Regulatory Affairs. What really drove me to apply to the pharmaceutical industry was the idea that I could work on big scale projects that had an influence on a large community of patients.

How do you begin researching fellowships?

For me, the first step was looking towards the Industry Pharmacists Organization (IPhO) website. It's a great resource for any pharmacy student wanting to learn about the pharmaceutical industry. This is where I learned about the different functional areas. Another thing that really helped me was reaching out to people on LinkedIn. I would network with current first- and

second-year fellows to learn more about their roles. After having a better understanding of the different functional areas, I tried to figure out what universities offered these fellowships. Through IPhO, I was able to learn about different fellowship programs, like the ones at Northeastern University, Massachusetts College of Pharmacy and Health Sciences (MCPHS), Rutgers, and others in the Southern and Western parts of the country.

Did you have the opportunity to meet with fellowship programs prior to applications?

Yes, there are plenty of opportunities to meet with different programs. St. John's itself has a lot of different webinars where you can meet fellows and learn about their experiences. A lot of the companies that you're going to be applying to will also have their own networking webinars. They're all available and advertised through the IPhO website. These events are great to help you decide if you can see yourself working at a particular company.

Around what time do you apply for fellowships and how do you submit applications?

Applications start to open around late September and early October. For almost every fellowship that I applied to, they would require a CV and a letter of intent. Some programs also required your school transcripts. Alongside these requirements, you also had to send over three letters of recommendation. A lot of people will say that your letter of recommendation should be from an industry-related experience, but I don't think that's true. I think it's more important to get a letter of recommendation from someone who has worked with you for some time, like a faculty member or work supervisor, who knows you very well and is able to speak positively about you and your work ethic.

What experiences should students focus on while they're still in school to help them stand out on their CV or applications?

For younger students in their first three professional years, I recommend applying for industry internships. Internships are a great way to gain experiences in specific functional areas. However, if you couldn't get those experiences and you're towards your final year of pharmacy school, it's okay! I know a lot of students who didn't have any industry-related experiences and were still able to get fellowships. I think the best experiences to help you stand out should relate to your work ethic and projects that you've worked on. For example, I had a publication done with a faculty member at St. John's. During interviews, I was able to speak a lot about the soft skills that I used while working on that publication. Being able to talk about the work you put into your experiences, even if they're not related to industry, goes a long way and helps you shine bright in interviews.

What can students expect during fellowship interviews?

Every company has their own way of conducting interviews. For some companies, I had up to three interviews whereas for other companies, I would have one or two interviews before being called in for a final round interview. The biggest thing that helped me was being able to talk about myself and my experiences. You should go into interviews with a couple of stories or experiences in mind that you can speak on really well. One interview technique to help you structure your responses is called the STAR method, which lays out the Situation,

Task, Action, and Result of a story or experience. You should also be prepared to tell fellowship programs about yourself. This is the first thing every company is going to ask you. If you have a very strong response to this question, it helps conduct how the remainder of your interview will go. You definitely want to be very honest during these interviews and let your personality shine through.

What is Midyear and how is it related to the fellowship process?

Midyear is a convention held every year through the American Society of Health System Pharmacists (ASHP). Any pharmacy student can attend Midyear. For fellowship applicants, a lot of final round interviews could occur in-person at Midyear, however, not all companies will require attendance at this conference. For me, I went to Midyear because I did have a few final rounds here, but also because I was going to present research. At Midyear, if you do make it past the final round, they will often invite you to a reception that same night. Receptions will usually include the top three candidates that a company has in mind for each of their fellowships. The reception isn't an interview per se, but in a way programs are still trying to learn more about who you are as a person. They may look at how you interact with other candidates and other members of their team.

When can students expect to find out about fellowship acceptances?

In previous years, every company would tell you right away if you were offered a fellowship. However, for my class this year, many programs joined the Academic Industry Fellowship Alliance and agreed to send out fellowship offers no sooner than December 7, 2022.

What is your biggest tip for students going into the fellowship process?

I think networking is going to be the most important thing for a lot of students because many people may not be able to gain experience through internships or rotations. Being able to speak to fellows helps you learn about their roles and can help you decide if a specific company or functional area is the right fit for you. You should also keep in mind that if you don't get a fellowship, that doesn't mean it's the end. There are many ways to get into the pharmaceutical industry, whether that's through entry level positions or by working for an agency and then transferring over to a pharmaceutical company. You should go into the fellowship process with an open mind. It was one of the biggest learning experiences for me and I've grown so much out of the process.

On behalf of the Rho Chi Post, we would like to thank Kamran for sharing his experience through the fellowship process with our RCP community!

Want to learn more about the Pharmaceutical Industry? Visit the Industry Pharmacists Organization website at:

www.industrypharmacist.org

Relyvrio: A New FDA-Approved Medication for Amyotrophic Lateral Sclerosis

By: Yu Jeng Lee, PharmD Candidate c/o 2023

Amyotrophic lateral sclerosis (ALS), also referred to as Lou Gehrig's disease, is a progressive neurodegenerative disorder that affects both the upper motor neurons (UMN) and lower motor neurons (LMN). This disease causes muscle weakness, which progresses to disability, and subsequently death, primarily due to respiratory failure.[1,2] There are approximately 1.6 new cases of ALS per 100,000 persons annually worldwide, with higher occurrences seen in patients that are Caucasian, male, and ≥ 55 years of age.[1,2] Despite these risk factors, there is currently no single cause identified for ALS.[1,2] However, multiple mechanisms have been proposed, predominantly via genetic mutations (i.e., superoxide dismutase type 1 mutations).[1] Patients with ALS often present with a combination of UMN and LMN signs and symptoms. Symptoms associated with UMN involvement include hyperreflexia, spasticity, muscle weakness, and slowness, while LMN involvement symptoms include fasciculations, amyotrophy, muscle weakness, and atrophy.[1]

Current ALS Therapeutic Landscape

The clinical practice guideline for the management of ALS was published by the American Academy of Neurology (AAN) in 1999, with the most updated version revised in 2009.[3] AAN's practice parameter aims to provide evidence-based recommendations for optimal care in ALS patients. Currently, there is no cure for ALS, hence treatment is focused on symptom management and quality of life prolongation.[1] Depending on a patient's symptoms, various nonpharmacological and pharmacological options can be utilized. Some therapies include noninvasive positive pressure ventilation for respiratory insufficiency, percutaneous endoscopic gastrostomy tube placement for dysphagia, mexiletine for muscle spasms, nonopioid analgesics for pain, and amitriptyline for sialorrhea, depression, insomnia, and pseudobulbar affect.[1,3] Currently, there are three medications approved by the Food and Drug Administration (FDA) to slow the progression of ALS: Relyvrio (sodium phenylbutyrate-taurursodiol), Rilutek (riluzole), and Radicava (edaravone).[2,3]

Relyvrio was FDA-approved in September 2022 for the treatment of ALS in adults.[4,5] There are two active ingredients in Relyvrio: sodium phenylbutyrate and taurursodiol.[4] The exact mechanism of action is unknown, however, it is proposed that both components work in conjunction to reduce neuronal cell death, as sodium phenylbutyrate reduces ameliorating toxicity from endoplasmic reticulum stress while taurursodiol increases the cellular apoptosis threshold.[4,6] Sodium phenylbutyrate-taurursodiol is available as a suspension and can be administered either orally or through a feeding tube. Abdominal pain, diarrhea, nausea, and upper respiratory tract infection were the most common (≥ 5%) adverse effects (AE) observed with the use of this medication.[4] The approval of sodium phenylbutyrate-taurursodiol for the treatment of ALS was based on the results of the CENTAUR trial.[5]

Overview of the CENTAUR Trial

The CENTAUR trial was a 24-week, random-

ized, multicenter, placebo-controlled, double-blinded, phase 2 clinical trial conducted at 25 centers of the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) in the United States.[6] Eligible patients included adults ≥ 18 years of age with a definite ALS diagnosis, as defined by the revised El Escorial criteria, who were within 18 months of ALS symptom onset, and had a slow vital capacity (SVC) greater than 60% of the predicted value for that patient's specific demographic. Any patients on riluzole had to be at a stable dose for at least 30 days prior to screening to be included.[6] Exclusion criteria included abnormal liver function tests greater than 3x the upper limit of normal, renal insufficiency, and uncontrolled hypertension.[6]

A total of 137 patients were randomized in a 2:1 ratio to receive either sodium phenylbutyrate-taurursodiol (n=89) or placebo (n=48) for 24 weeks.[6] The typical patient in this study was a 58 year old white male with a body-mass index of 27, history of riluzole use, SVC score of 84%, Revised ALS Functional Rating Scale (ALSFRS-R) total score of 36, and Accurate Test of Limb Isometric Strength upper-limb score of 54 and lower-limb score of 57. On average, included patients were within 14 months of ALS symptom onset and 6 months of ALS diagnosis.[6]

The primary endpoint of this study evaluated the efficacy of sodium phenylbutyrate-taurursodiol based on the rate of decline in ALSFRS-R score from baseline through week 24.[6] ALSFRS-R is a validated questionnaire-based scale that is used for the assessment of the physical function of ALS patients. The score is comprised of 12 items across 4 subdomains (bulbar, fine motor, gross motor, and respiratory function). Each item is scored on a scale from 0 (total loss of function) to 4 (normal function) points, with a possible total score ranging from 0 to 48 points.[7]

Regarding primary efficacy data, results were statistically significant and demonstrated a slower decline of patients' ALSFRS-R scores in the treatment group compared to placebo.[6] In the modified intention-to-treat population, the mean rates of change of the total ALSFRS-R scores in the sodium phenylbutyrate-taurursodiol and placebo groups were –1.24 and –1.66 points per month, respectively (Mean Difference [MD] 0.42; 95% confidence interval [CI] 0.03 to 0.81; p=0.03). The mean ALSFRS-R total score was 29.06 points in the sodium phenylbutyrate-taurursodiol group and 26.73 points in the placebo group (MD 2.32; 95% CI 0.18 to 4.47).[6] Additionally, analyses of ALSFRS-R subdomain scores were also conducted. The ALSFRS-R fine motor score was the only subdomain that favored sodium phenylbutyrate-taurursodiol over placebo with a MD of 1.04 points (CI 0.20 to 1.87). There was no statistical significance between sodium phenylbutyrate-taurursodiol and placebo for the remaining three subdomains, although the data for each subdomain leaned towards sodium phenylbutyrate-taurursodiol in being clinically superior to placebo.[6]

Regarding safety data, gastrointestinal-related events were the most common type of AE for both the sodium phenylbutyrate-taurursodiol and placebo groups, with an incidence of 67% and 60%, respectively. Approximately 20% of patients in the sodium phenylbutyrate-taurursodiol group discontinued the trial regimen due to either an AE (19%) or serious AE (1%) compared to 14% of patients in the placebo group (AE 8%; serious AE 6%). Diarrhea and respiratory failure were the two most common AE that resulted in trial regimen discontinuation.[6] An open-label extension trial

was conducted to analyze and evaluate the long-term safety of sodium phenylbutyrate-taurursodiol for up to 132 weeks. Participants who have completed the study were eligible for enrollment in the open-label extension.[6,8]

Conclusion

Overall, ALS is a rare, progressive, and incurable neurodegenerative disease with a median survival from onset of approximately three to five years.[1] Therefore, managing symptoms and slowing disease progression are the mainstay therapies for ALS patients. In the CENTAUR trial, use of sodium phenylbutyrate-taurursodiol led to a slower decline in the function of daily activities.[6] This can be clinically significant as there are only two other FDA-approved medications for the treatment of ALS in addition to sodium phenylbutyrate-taurursodiol. Sodium phenylbutyrate-taurursodiol can act as an alternative option for patients with ALS who are unable to tolerate riluzole or edaravone or have demonstrated limited efficacy on these medications. Despite the results from the CENTAUR trial, larger and longer studies are required to provide more data on the efficacy and safety of sodium phenylbutyrate-taurursodiol in ALS patients. There are many factors to take into consideration prior to initiating sodium phenylbutyrate-taurursodiol. Thus, interprofessional collaboration along with shared decision making with both the patient and their families is crucial to providing optimal care to patients with ALS.

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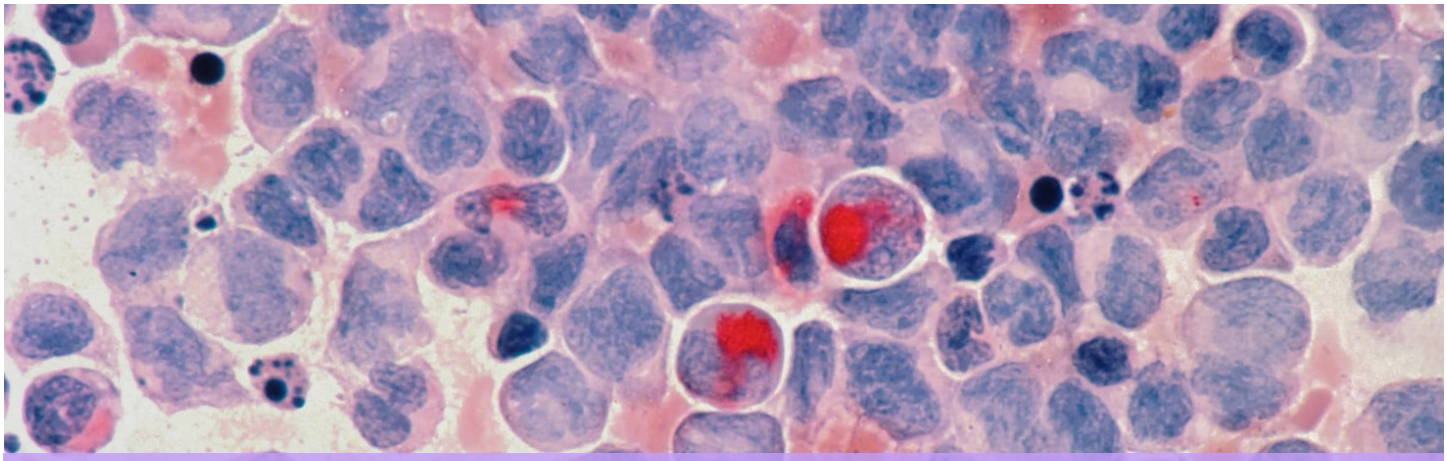

FDA Approval of Pemazyre® as a First-in-Class Treatment for Myeloid/Lymphoid Neoplasms with FGFR1 Rearrangement

By: Jennifer Galvet, PharmD Candidate c/o 2024

Fibroblast growth factor receptors (FGFRs) are a family of receptor tyrosine kinases expressed on the cell surface of both developmental and adult cells. Aberrant expression of FGFRs has been implicated in a wide variety of cancers and is considered an oncogenic signaling pathway.[1] FGFRs are activated by the binding of fibroblast growth factors (FGFs) and subsequent receptor dimerization-induced intracellular kinase transautophosphorylation events.[2] When normally regulated, the FGF and FGFR signaling pathway is involved in embryogenesis, angiogenesis, tissue homeostasis, wound repair, and the cell cycle. Aberrant activation of FGFRs can lead to the development of malignant tumors, primarily caused by gene amplification, mutation, and gene fusion.[2]

Myeloid and lymphoid neoplasms (MLNs) associated with the rearrangement of FGFR1 are hematologically and genetically heterogenous.[3] MLNs with FGFR1 rearrangement are caused by chromosomal translocations on the FGFR1 gene, ultimately impacting cell differentiation, proliferation, and survival.[4] FGFR1 gene rearrangements result in the production of multiple chimeric proteins that can self-dimerize to activate the FGFR1 tyrosine kinase and downstream signaling pathways, contributing to the pathogenesis of these neoplasms.[3] MLNs with FGFR1 rearrangement may present with chronic or blast phase involvement of bone marrow with or without blast phase extramedullary disease (EMD).[5] Current therapies, such as hydroxyurea, multikinase inhibitors, or multi-agent chemotherapy, often lead to partial or complete responses for short durations.[5] Incyte, a global biopharmaceutical company, developed Pemazyre® (pemigatinib) as a potential new treatment for MLNs with FGFR1 rearrangement.

Pemigatinib is a small-molecule kinase inhibitor that targets FGFR1-3. Inhibition of the phosphorylation and signaling activity of these receptors results in decreased cell viability in cancer cell lines with activating FGFR amplifications or fusions while also preventing constitutive activation of FGFR signaling.[6] In August 2022, the Food and Drug Administration (FDA) approved pemigatinib, the first and only targeted treatment for adults with relapsed or refractory MLNs with FGFR1 rearrangement.[6] This marks the second indication for pemigatinib, which first received accelerated FDA approval in 2020 for adults with previously treated, unresectable locally advanced or metastatic cholan-

giocarcinoma with a FGFR2 fusion or other rearrangement.[7]

Overview of the FIGHT-203 Trial

FIGHT-203 is an on-going phase 2, open-label, single-arm, multicenter trial conducted throughout the United States, Canada, and Europe.[8,9] The data from this trial was used by the FDA to support their approval of pemigatinib. FIGHT-203 aimed to evaluate the safety and efficacy of pemigatinib in patients with relapsed or refractory MLNs and FGFR1 rearrangement.[8,9] Eligible patients had a documented lymphoid or myeloid neoplasm with 8p11 rearrangement known to cause FGFR1 activation. Included patients had to also either have relapsed after allogenic hematopoietic stem cell transplantation (allo-HSCT), relapsed after other disease modifying therapy, or not be current candidates for allo-HSCT or other disease modifying therapies.[8,9] Exclusion criteria included any prior receipt of a selective FGFR inhibitor, a history of ectopic mineralization/calcification, any current corneal disorder/keratopathy, and use of any cytochrome P450 3A4 inhibitors or inducers within 14 days of the study.[8,9]

41 patients were enrolled in FIGHT-203. The mean age was 58.3 years (range: 23-78) with 53.7% of patients being female. All participants received 13.5 mg of pemigatinib daily on a continuous schedule.[8,9] The longest duration of pemigatinib administration was 192.4 weeks with a median dosing duration of 29.3 weeks.[5] The primary endpoint measured the proportion of patients who achieve a complete response (CR) based on response criteria for myeloid/lymphoid neoplasms with FGFR1 rearrangement.[8,9] Secondary endpoints included the proportion of subjects who achieved a complete cytogenetic response (CCyR) and safety and tolerability assessment.[8,9] Complete and partial cytogenic responses were defined as 100% or at least 50% reduction in 8p11-rearranged metaphases or cells, respectively, on karyotyping or fluorescence in situ hybridization.[5,8]

40 patients were analyzed for efficacy results, 35 of which had previous therapies and 5 were treatment naïve. The average number of previous therapies was 1.0 (range: 1-11).[8] Efficacy analysis on the primary outcome involved a total of 38 patients, including both those that were previously treated and treatment naïve. 28 patients (73.7%) were able to achieve a CR. In patients with chronic phase disease only (n=21), 19 (90.5%) were able to achieve a CR. In patients with blast phase disease with or without EMD (n=17), 9 (52.9%) were able to achieve a CR.[8] A separate efficacy analysis on the primary outcome was also done on the 33 patients who received previous therapies. In this group, 25 (75.8%) were able to achieve a CR. In patients with chronic phase disease only (n=19), 17 (89.5%) were able to achieve a CR. In patients with blast phase disease with or without EMD (n=14), 8 (57.1%) were able to achieve a CR.[8]

The efficacy analysis on the secondary outcome regarding the proportion of patients achieving CCyR involved 40 patients, including both those that were previously treated and treatment naïve. 28 patients (70.0%) were able to achieve a CCyR. In patients with chronic phase disease only (n=21), 18 (85.7%) were able to achieve a CCyR. In patients with blast phase disease with or without EMD (n=17), 8 (47.1%) were able to achieve a CCyR.[8] A separate efficacy analysis was also done on this secondary outcome for the 35 patients who received previous therapies. In this group, 25

(71.4%) were able to achieve a CCyR. In patients with chronic phase disease only (n=19), 16 (84.2%) were able to achieve a CCyR. In patients with blast phase disease with or without EMD (n=14), 7 (50.0%) were able to achieve a CCyR.[8]

Regarding the safety analysis (n=41), the most common treatment-emergent adverse events (TEAEs) were hyperphosphatemia (73%), alopecia (56%), diarrhea (56%), stomatitis (46%), dry eye (34%), and dry mouth (34%). Grade ≥3 TEAEs were stomatitis (17%) and anemia (15%).[8] By the end of the efficacy analysis of the 40 evaluable patients, only 19 (47.5%) were still undergoing treatment. Reasons for treatment discontinuation included: bridging to allo-HSCT (20%), progressive disease (15.0%), adverse events (7.5%), physician decision (5.0%), patient decision (2.5%), and death (2.5%).[8]

Current NCCN Guidelines for MLNs with Eosinophilia and Tyrosine Kinase Fusion Genes

In October 2022, the National Comprehensive Cancer Network (NCCN) published updated guidelines for the treatment of MLNs.[10] Therapy considerations were based on whether the bone marrow/peripheral blood and/or EMD components were present, as well as whether the disease was in the chronic phase or blast phase. For chronic phase disease, preferred regimens include enrollment into a clinical trial or pemigatinib. Other recommended regimens include the use of tyrosine kinase inhibitors (TKI) with activity against FGFR1, such as midostaurin or ponatinib. For blast phase disease, preferred regimens include enrollment into a clinical trial or pemigatinib. Early referral to an allo-HSCT should also be considered if the patient is eligible. In blast phase disease with myeloid lineage, a TKI with activity against FGFR1 +/- acute myeloid leukemia induction chemotherapy is recommended, followed by allo-HSCT if eligible.[10] In blast phase disease with lymphoid lineage, a TKI with activity against FGFR1 +/- acute lymphocytic leukemia induction chemotherapy is recommended, followed by allo-HSCT if eligible.[10]

The Future for Patients with MLNs with FGFR1 Rearrangement

Patients with relapsed or refractory MLNs with FGFR1 rearrangement being treated with pemigatinib in the FIGHT-203 study were able to achieve high rates of CR and CCyR in chronic phase disease. The high rates of CCyR in patients with blast phase disease is clinically meaningful, considering the poor response from existing treatments such as hydroxyurea, multikinase inhibitors, and intensive multi-agent chemotherapy. Pemigatinib may be the first step in researching additional pathways to address treatments for rare blood cancers.

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Evaluating Treatments and Preventative Measures for Monkeypox

By: Sairah Sheikh, PharmD Candidate c/o 2024

As Coronavirus Disease 2019 (COVID-19) cases started to decrease in the United States (US), many Americans breathed a sigh of relief. However, on May 17, 2022, fear of a new infectious disease struck the nation. The first case of the monkeypox outbreak in the US was reported in a person from Massachusetts.[1] As of February 2023, the Centers for Disease Control and Prevention (CDC) has documented over 30,000 cases in the US and over 85,000 cases globally.[2] Although monkeypox commonly occurs in central and western African countries, the US held approximately 35% of the world's cases in 2022.[2]

Monkeypox can spread through direct contact with monkeypox lesions, respiratory secretions, or objects (e.g., bedding) used by an infected individual.[3] During the monkeypox outbreak in the US, the virus was primarily transmitted through sexual contact, including kissing, hugging, and vaginal, anal, and oral sex.[3] Most of these cases were reported in gay, bisexual, and other men who have sex with men.[4] As a result, monkeypox is commonly mislabeled as a sexually transmitted disease (STD), however, since the virus does not exclusively spread through sexual intercourse, it cannot be deemed as such.

The hallmark symptom of monkeypox is a rash consisting of contagious lesions, predominantly occurring on the face, hands, and feet. The rash evolves from macules to papules, vesicles, pustules, and crusts. Once the lesions heal, the person is no longer considered contagious.[5,6] Other common characteristics of monkeypox include having flu-like symptoms such as fever, chills, headache, muscle aches, exhaustion, sore throat, nasal congestion, and cough. Altogether, symptoms may last for 2 to 4 weeks.[5] Fortunately, the death toll for monkeypox remains low; since May 2022, there have been 28 deaths linked to monkeypox in the US.[2]

Currently, there are no specific treatments for monkeypox, however, since monkeypox is a member of the orthopoxvirus genus, tecovirimat, a medication indicated for human smallpox disease, can be given to those at a higher risk of infection from monkeypox.[7,8] Tecovirimat inhibits orthopoxvirus VP37 protein, a protein found in all members of the orthopoxvirus genus. Inhibition of the VP37 protein blocks its interaction with cellular Rab9 GTPase and TIP47. As a result, the virus is unable to form enveloped virions necessary for dissemination throughout the body.[8]

Additionally, there are two available vaccines for monkeypox: the JYNNEOS vaccine and the ACAM2000 vaccine.[9,10] Both can be used for the prevention of monkeypox, however, the ACAM2000 vaccine has been associated with more frequent side effects and is not recommended for those who are immunocompromised.[9] The ACAM2000 vaccine is approved for patients 1 year of age and older. It is administered via percutaneous route, using a bifurcated needle to deliver a 0.0025 mL droplet of reconstituted vaccine as a single dose. Serious adverse effects include myocarditis, pericarditis, and vaccinia virus transmission.[9]

The JYNNEOS vaccine is given in two doses, administered 28 days apart.[10] It is typically administered subcutaneously at a dose of 0.5 mL, but due to supply shortages, it can be given intradermally at a dose of 0.1 mL.[10] The two routes of administration are interchangeable, meaning that if a patient received the vaccine subcutaneously for their first dose, they can get their second dose intradermally, and vice versa.[10] The efficacy of both routes of administration are similar, however, local side effects such as hyperpigmentation, rash, or redness may be more severe with the intradermal vaccine, potentially persisting for several weeks to months.[10] Other local side effects of the vaccine may include pruritus, edema, and pain. Systemic side effects may include myalgia, fatigue, headache, chills, nausea, and fever.[10]

With the current monkeypox outbreak, the CDC reports that unvaccinated individuals have 14 times the risk of contracting the disease compared to those who are vaccinated.[11] The CDC recommends vaccination for those who had known or suspected exposure to monkeypox, had sexual intercourse in the past 6 months with a partner diagnosed with monkeypox, or are immunocompromised.[12] For the remaining patient population, it is important to provide education on risk factors and measures to be taken to reduce exposure to the virus. Doing so will help prevent a future uptick in cases, as well as ensuring that patients have the appropriate resources to stay safe from monkeypox.

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Want to learn more about the Monkeypox Outbreak? Visit the Centers for Disease Control and Prevention website at:

www.cdc.gov

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6th Year Perspective: APPE Rotations at the Westchester Medical Center Bundle

Featuring: Justin Budz, PharmD Candidate c/o 2023
By: Isabelle Lim, PharmD Candidate c/o 2024

Justin Budz is a sixth-year pharmacy student at St. John's University. While at St. John's, Justin participated in multiple organizations, which ultimately led him to discover the career path he wanted to pursue. Most notably, Justin served as the Development and Outreach Coordinator of the Rho Chi Honor Society and currently serves as the Editor-in-Chief of the Rho Chi Post. Following his graduation from St. John's, Justin will begin a two-year Post-Doctoral Fellowship in Pharmaceutical Marketing with RevHealth.

Why did you choose to go to pharmacy school?

I liked the idea of pharmacy practice because there was a good balance between providing treatments to patients and educating both patients and healthcare professionals. Also, there was the aspect of being able to read more into the background and pharmacology behind drugs, which really spoke to me since I was very interested in science growing up. Pharmacy school ended up being a very happy medium between healthcare and science.

What drove you to apply for a clinical bundle? Why did you choose the Westchester Medical Center bundle over others that were offered?

I was interested in a bundle after I spoke with older students about their experiences with bundles. On one hand, bundles may be more work at times, however, the upside is that you gain a very thorough and great learning experience. You're at a site for a much longer period of time compared to a normal rotation, which is about one month. I was at Westchester for three to four months in total and I was able to stay with those preceptors for long periods of time. Not only did I get to know them better, but I also got a better learning experience being at one facility and seeing the different aspects of healthcare it was able to offer. I ended up choosing Westchester compared to other bundles because of location. I also heard great things about this site from previous students, so putting these two things together, Westchester seemed like a great fit for me.

What do you need to apply for a bundled rotation?

Different bundles will have different requirements, but in general, I would expect all bundles to require a CV. The Westchester bundle also required a letter of intent and two letters of recommendation. It's a little bit more work but in the end, it's worth it for having a more impactful learning experience at one location.

Summarize your time at Westchester Medical Center.

I had three rotations at Westchester. My first rotation was in the emergency room (ER). Here, you never knew what was going to come in through the doors each day. One unique case that I won't forget was a skydiving accident. That was definitely something you don't see every day. The coolest thing about the ER is that you have to think on your feet a lot. It was incredible to see how smart and professional my preceptor was in this fast-paced environment. There's a unique set of medications in the emergency room. You have a variety of emergency, pain, and other medications that you will need for different codes. Learning about these medications was my biggest takeaway from this rotation.

My next rotation at Westchester was in oncology, which was very different compared to other clinical rotations I've had. Physicians were kind of the artists of all things – they weren't always following guidelines to a T, instead, the physicians determined the right treatments from their past experiences. For instance, if a patient would come in with a particular type of cancer, based on the physician's past experiences with treating that cancer, they'll recommend a certain regimen based on what they have seen work. Of course, they would still be basing the therapy off some kind of guideline, but they would fine tune it to their liking. It was interesting to see because as different physicians would switch off, sometimes they wouldn't agree with each other and would go back and forth about what regimens to proceed with. As a pharmacist, a lot of our focus, asides from the chemotherapy regimens, would be on checking other medications that the patient is on - making sure there are no drug interactions, paying attention to supportive care, etc. One of the coolest things I got to do on my oncology rotation was assisting in a bone marrow biopsy. I'm just proud of myself for not getting too dizzy during the procedure.

My last rotation was an administrative rotation, which can really differ depending on which hospital you're at. At Westchester, I was paired with the pharmacy director who entrusted me with a lot of big projects. For one project, they were moving the pediatric satellite which was relatively outdated. The satellite didn't use a lot of electronic means of storing medication information, so a lot of their medications were stored in bins rather than in an automated medication dispensing system. I was in charge of essentially taking note of all inventory to see what they had in the satellite and compare it to the most common fast movers on the pediatric floor. My project helped aid in moving everything down from the satellite to the main pharmacy and storing all records electronically. I had a large impact in this project to which my preceptor would even joke that upon creation of the new pediatric satellite, they would name it after me.

Of the three rotations you recounted, which was your favorite and why?

My favorite rotation was definitely the administrative APPE. I think it comes down to each student's individual personality. I really liked the aspect of managing projects. A lot of those projects assigned to me didn't have many set requirements. My preceptor would just tell me the objective and would ask what I wanted to do or thought we should to do to get that project accomplished. I really liked that aspect of collaboration as it helped me develop my project management skills.

What was the most valuable thing you learned through this bundle?

I think the most valuable thing that I learned is that the effort you put into the bundle, or any rotation in general, is what you get out of it. A lot of my preceptors challenged me with presentations, unique opportunities, and even research. These opportunities weren't required, but taking them on helped supplement my experience at Westchester. After all, we are essentially paying for these experiences, so you might as well get the most out of each rotation. By taking on additional responsibilities, I got to learn more in depth about different disease states and medications while building communication and research skills.

What would you say was your biggest achievement?

I was very involved, so I got to know everyone very well, especially the pharmacy director and the clinical pharmacy team. With that being said, I am proud of myself for all the extra initiatives I took for the Westchester team. Also, this bundle was around the same time I was doing a lot of fellowship applications and interviews, so I am proud of myself for being able to balance all my APPE responsibilities with my personal and work life.

What would you do differently if you could do it again?

I wish I could have taken more time to learn more about some of the medications that I saw in the ER and oncology settings. I wasn't too familiar with some of these medications, especially since they were medications that you don't typically see in community settings or learn about in school. I wish I had more time to deep dive into these medications just so I could be more comfortable with them overall.

How did your experience at this bundle compare to other clinical rotations you've had?

For some of the other clinical rotations I've had, for example, my general inpatient and pediatric ICU rotations, the biggest downside is that you're there for a short duration. I had a lot of great experiences at those sites just from my patient interactions and assigned projects, but as soon as you got comfortable it was time to switch experiences. What I really liked about the bundle is that you got to know your team very well. Because it was a large site with many rotation opportunities, I also got to meet a lot of students from different schools. The longer duration is unique not only for the learning experience but also for networking and getting jobs down the line.

What advice would you give underclassmen that may be unsure of whether they want to pursue a bundle for APPEs?

I think an uncertainty that I had before applying for bundles was the idea that you may be there for three or four months. Some students may worry that they won't end up liking the site or their preceptors, which are potential risks, but one way to clear things up is by talking to upperclassmen who have had experiences you're curious in learning more about. I think it is definitely worth trying to apply for a bundle since you will have multiple experiences all in one hospital. This way, you get to see how that hospital functions in different areas. I think bundled rotations are a bigger bang for your buck, especially if you put in the effort and seek additional opportunities to learn.

What tips would you give students to get the most out of a bundle experience?

Definitely be open to any unique opportunities. For example, I got to sit in many different codes that happened in the ER. Another example is from my oncology experience where I got to be part of a bone marrow biopsy, which is definitely outside the scope of your traditional pharmacist role. By being open to different experiences, you really don't know what you're going to learn and it's great because you get to see how different healthcare professionals function both individually and interprofessionally. So my biggest tip, regardless of whether it's a regular rotation or a bundled rotation, is to always be open to different opportunities that come your way.

On behalf of the Rho Chi Post, we would like to thank Justin for taking the time to share his pharmacy experiences with our RCP community!

Mark Your Calendars!

Join the Rho Chi Post this upcoming 2023 Spring Semester as we prepare to host the following events:

Mar. 27th: Writing Workshop

RHO PX CHI post

Enjoying this issue? Check out previous issues on our website:

http://rhochistj.org/RhoChiPost

Stay up to date with new articles and events by following our social media accounts:

http://fb.com/RhoChiPost

@sjurhochipost

Have Questions? Feel free to email us at **RhoChiPost@gmail.com**

Assessing the Efficacy of Cholecalciferol Versus Ergocalciferol for Vitamin D Repletion in Chronic Kidney Disease

By: Nancy Yousry, PharmD Candidate c/o 2024

Vitamin D is a multifaceted nutrient needed to maintain homeostasis and proper health. In addition to its role in building and maintaining healthy bones, vitamin D also regulates many important cellular functions in the body, serving as an anti-inflammatory, antioxidative, and neuroprotective agent.[1] In general, the two main sources for vitamin D supplementation are from diet and direct sunlight. Vitamin D can be found among foods in the pescetarian diet, including salmon, mackerel, and sardines. Certain foods can also be fortified with vitamin D, like orange juice and dairy products. Furthermore, the time of day, season, and geographical location serve as environmental factors that may influence the productivity of vitamin D.[1]

Regardless of its source, vitamin D is absorbed biologically inert and must undergo two hydroxylations to become active. The first hydroxylation occurs in the liver where vitamin D is converted into 25-hydroxyvitamin D [25(OH) D], also known as calcidiol. The second hydroxylation occurs in the kidney, forming 1,25-dihydroxyvitamin D [1,25(OH)2D], also known as calcitriol, the physiologically active form of vitamin D.[2] However, in patients with renal disease, this conversion to calcitriol will be reduced. Chronic kidney disease (CKD) is a condition characterized by damage to the kidneys, resulting in a gradual loss of their ability to filter fluid and waste from the blood.[3] Patients with renal disease have shown reduced activity of 1-α hydroxylase, the enzyme that converts calcidiol to calcitriol in the kidneys.[4]

Low serum concentrations of calcidiol in patients with CKD have been associated with a higher risk of all-cause mortality and a faster progression of kidney disease.[4] Serum calcidiol levels less than 12 ng/mL are associated with vitamin D deficiency, levels between 12 to 20 ng/mL are insufficient for overall health, and levels greater than 20 ng/mL are sufficient.[1] Two forms of supplemental vitamin D currently exist for the correction of vitamin D deficiency. Patients can either use vitamin D2 (ergocalciferol), a plant-based sterol, or vitamin D3 (cholecalciferol), an animal-based sterol.[1] Although both cholecalciferol and ergocalciferol can be found as dietary supplements and in fortified foods, their efficacy may not be equal.

A randomized, two-arm, parallel clinical trial, published in the British Journal of Nutrition, was conducted by Wetmore et al. to test the efficacy of different vitamin D formulations in CKD patients.[5] The study included patients with an eGFR of < 60 ml/min per 1.73 m^2 and serum concentrations of calcidiol < 30 ng/ml. Exclusion criteria included dialysis dependence, presence of gastrointestinal disorders, liver cirrhosis, and current treatment with vitamin D.[5] A total of 44 non-dialysis-dependent patients with stage 3-5 CKD were included and equally randomized into two treatments arms receiving either cholecalciferol 1250µg (50,000 IU) once weekly or ergocalciferol 1250µg (50,000 IU) once weekly.[5] The primary outcome assessed the change of serum calcidiol concentrations over the 12-week treatment period.[5] The investigators found that after

12 weeks of therapy, patients on cholecalciferol had a mean change in total calcidiol of 45.0 (Standard Deviation [SD] 16.5) ng/mL while patients on ergocalciferol saw a mean change of 30.7 (SD 15.3) ng/mL ($P < 0.01$).[5]

Secondary outcomes of this trial included assessing changes in total calcidiol from baseline to week 18 and changes in parathyroid hormone (PTH).[5] Regarding calcidiol, total change in serum concentrations seemed to be similar between the cholecalciferol and ergocalciferol groups from baseline to week 18, six weeks after stopping treatment. The mean change from baseline was 22.2 (SD 12.7) ng/mL for cholecalciferol and 17.6 (SD 8.9) ng/mL for ergocalciferol ($p = 0.17$).[5] Regarding PTH, patients receiving cholecalciferol appeared to have a greater mean reduction in serum PTH compared to those receiving ergocalciferol. The mean change from baseline was -15.3 (SD 34.5) pg/mL for cholecalciferol and 2.3 (SD 38.3) pg/mL for ergocalciferol ($p = 0.02$).[5]

In summary, results from this randomized clinical trial by Wetmore et al. indicate that cholecalciferol was able to generate a greater initial increase in total serum calcidiol concentrations compared to ergocalciferol. However, the efficacy of cholecalciferol was deemed to be transient, as discontinuation of therapy for 6 weeks caused calcidiol concentrations to dramatically decline.[5] To address vitamin D deficiency and insufficiency, the Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines do not suggest a preference between cholecalciferol and ergocalciferol. Instead, they recommend using general treatment strategies.[6] The recommended dietary allowance for vitamin D is 10 µg (400 IU) for those up to 12 months of age, 15 µg (600 IU) for those between 1 to 70 years of age, and 20 µg (800 IU) for those over 70 years of age.[1] Although cholecalciferol may initially be superior to ergocalciferol in raising calcidiol serum levels, it is more important to stay adherent to vitamin D maintenance therapy in CKD patients to prevent possible complications from vitamin D deficiency.

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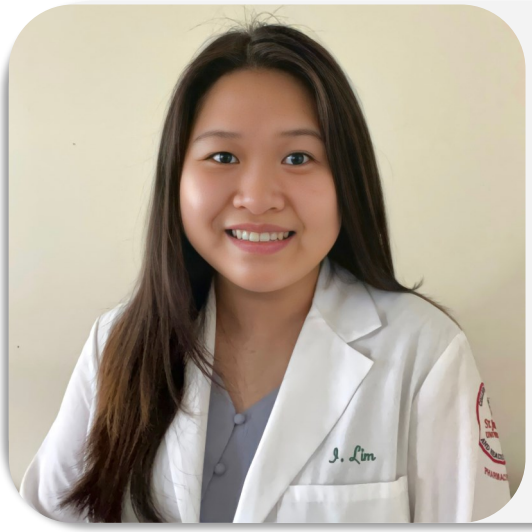
RHO Rx CHI post

Meet Our 2022-2023 Editorial Team

Editorial Team & Production

Justin Budz
Editor-in-Chief

Over the past year, I had the pleasure of serving as the Development and Outreach Coordinator for the Rho Chi - Beta Delta Chapter. The most invaluable aspect of serving a role on their executive board was to continue the tradition of developing and distributing resources to stimulate intellectual leaders in our college of pharmacy student body. As the new Editor-In-Chief, I look forward to working alongside the talented students and graduates to produce publications that will follow advancements in healthcare and pharmaceutics in order to continue that same tradition of promoting intellectual leadership among our readers.



Isabelle Lim
Managing Editor

The Rho Chi Post serves as a platform for students and faculty to collaborate in sharing their knowledge and ideas with the pharmacy community. As future pharmacists, it is important that we keep ourselves updated as well as voice our opinions on healthcare matters. Engaging in the Rho Chi Post helps us accomplish this while also providing students with a unique experience to develop their writing and editing skills outside of the classroom. I am honored to be a part of the Editorial Team and look forward to serving as a Managing Editor!

John Ortiz

Content-Focused Copy Editor

Rho Chi Post is an opportunity for students to foster their writing and investigative skills concerning pharmacy practice. By honing our understanding of new innovations and developments in pharmacy, we will be better at providing accurate information to readers and maintaining the continuous education expected of pharmacists.

Helen Li

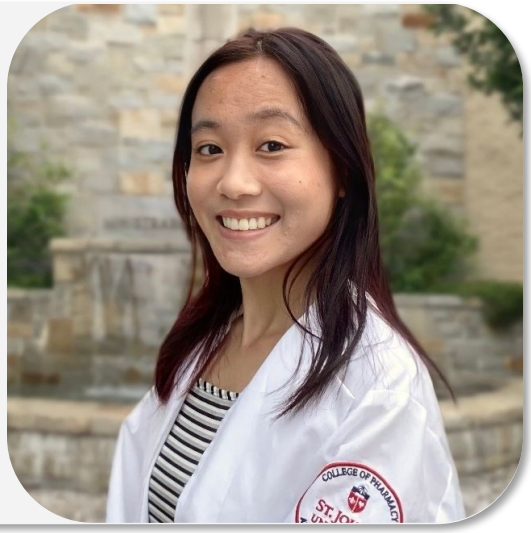
Content-Focused Copy Editor

The Rho Chi Post allows pharmacy students the opportunity to be well informed about the amazing contributions in the field of pharmacy. It is a great platform for students to report current advancements in healthcare. My passionate for writing began at a young age as I began to understand just how powerful words can be to communicate. I look forward to being a part of the editorial team and to share new information to my peers. I am so excited to be a part of the Rho Chi Post team.

Joanne Fung

Content-Focused Copy Editor

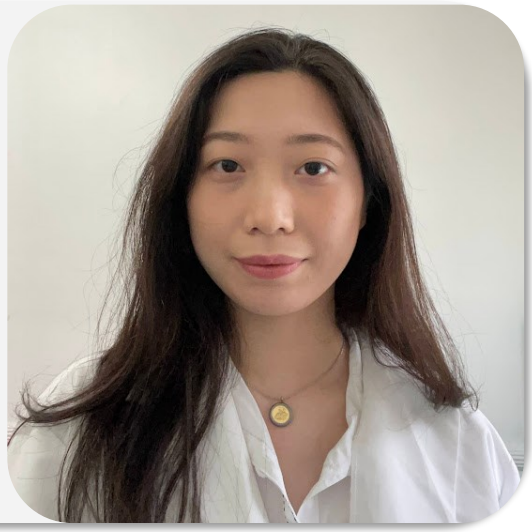
If there is one thing that pharmacists and students should understand, it is that the world's knowledge regarding drugs, disease states, and public health matters is ever-growing. As a pharmacy student, I feel responsible for keeping myself and others up to date. Being a part of the Rho Chi Post's editorial team is a unique and creative way to educate myself and help relay important information to my peers. It is also an excellent opportunity to expose myself to a variety of perspectives. I appreciate the newsletter for providing me an opportunity to not only pursue one of my lifelong interests of writing, but to start delving even deeper into the field of pharmacy unlike ever before.



Mandy Zheng

Senior Graphics-Focused Copy Editor

The Rho Chi Post allows pharmacy students the opportunity to be well informed about the amazing contributions in the field of pharmacy. It is a great platform for students to report current advancements in healthcare. My passionate for writing began at a young age as I began to understand just how powerful words can be to communicate. I look forward to being a part of the editorial team and to share new information to my peers. I am so excited to be a part of the Rho Chi Post team.



Ruksabha Zaman

Graphics-Focused Copy Editor

It is an honor to be able to contribute to the Rho Chi Post, a publication that promotes intellect, values, and inclusivity in order to allow student voices to make an impact, not only in our school, but in the pharmacy profession as a whole. The role of pharmacists is constantly evolving and it is more important than ever for us to not only be aware of the changes and new discoveries that are occurring in our field of practice but to be able to collaborate with other professionals on our team as well. The Rho Chi Post serves as a bridge between students, faculty, pharmacists, and other healthcare professionals outside of the classroom. I look forward to gaining new knowledge on current events from my peers and providing my own insight to further the excellence of this newsletter.

Celestine Van Sertima

Graphics-Focused Copy Editor

When applying to the Rho Chi Post, I was initially fascinated by their goals of providing the highest quality of information to the St. John's community through a student operated newsletter that cultivates both student spirit and expansion of knowledge. Through my passion for writing and health care, combined with my experience in graphic designing, I look forward to what I can contribute to the Rho Chi Post.

Emily Kelley

Staff Editor

As a part of the Rho Chi Post team, I aspire to expand the importance of the health education programs by empowering and educating the community to live healthier lives. Knowing that my work and research could change the lives of millions is inspiring and motivating.

Sana Ahmed

Staff Editor

I believe the Rho Chi Post is a means to serve the university and impact its professional and health-oriented student community through its various stories. With exposure to a myriad of areas of the healthcare field throughout my work experience, I have secured much knowledge from assisting a diverse array of patients. I will prioritize staying up to date and aiding student writers in presenting the latest pharmaceutical and medical advancements. Through the Rho Chi Post, I intend to promote the pharmacy profession through creativity and effective communication. I am honored to serve as a Staff Editor for this organization and hope it will facilitate meaningful connections with my peers.

Geraldine Ciaccio

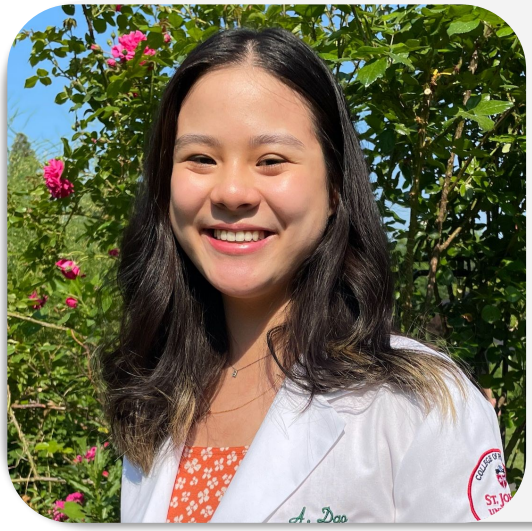
Staff Writer

The pharmacy profession is constantly growing as it drives for discovery. The Rho Chi Post allows student pharmacists to expand their knowledge of pharmacy while offering a space of collaboration and encouragement. I have always enjoyed writing, and I am so honored to be a Staff Writer for the Rho Chi Post this year. This opportunity will allow me to explore my personal interests within the pharmacy profession as well as encourage my peers to do the same. I am excited to collaborate with and learn from faculty, alumni, and my fellow students. These conversations are vital for change and discovery to occur. Taking a step beyond the classroom and building on previous knowledge is all it takes to grow as professional student pharmacists

Jennifer Galvet

Staff Writer

With the pharmacy profession constantly evolving and shifting its focus to advanced patient care, it is important to be knowledgeable of these changes. Although never formally part of the Rho Chi Post e-board before, I was able to utilize this platform in the past to share my writing on various pharmacy topics. I am looking forward to serving as a staff writer this upcoming year and continuing to share my passion about vital developments in healthcare through my writing. As I enter my fifth year of pharmacy school, I hope to keep fellow students informed, while simultaneously inspiring them to expand their knowledge on our ever-changing profession.



Ashley Dao

Staff Writer

The Rho Chi Post offers a place for students, alumni, and faculty to collaborate and share their experiences. Last year, I had the opportunity to serve as the Website Liaison of RCP and I am happy to come back this year as a Staff Writer. As someone who has always had a love for writing, I am grateful for the voice that the Rho Chi Post has given me. I hope that I can encourage more students to contribute to the Rho Chi Post. After all, without conversations, there can be no change.

Imaan Sekhery

Staff Writer

As students in pharmacy, it's our responsibility to educate and update, not only our peers on new medical advancements, but also educate ourselves. Being apart of the Rho Chi Post team allows us to consistently keep up to date with the ongoing improvements and innovations within the pharmaceutical field. There is only so much we can learn from our day-to-day classes, Rho Chi Post stands as another gateway to familiarizing ourselves with the professional world we will soon enter. The world around us continues to evolve, it is up to us to remain in the know. As a staff writer, I am delighted to join the editorial team and look forward to contributing in the aspect of benefitting the pharmacy community as a whole.

Sairah Sheikh

Staff Writer

Ever since I was little, writing has always been a passion of mine. I would find joy in editing my friends' and family's works of writing. I would create short stories and eagerly read them out loud to entertain guests at social gatherings, which they would take great joy in listening to. As a staff writer now for the Rho Chi Post, I am excited to merge the knowledge I have gained in pharmacy school with my love for writing to create thought-provoking pieces for our community to read. Since pharmacy is an ever-evolving profession, it is important for our community to stay informed on the latest events in our field and I am looking forward to playing a small part in that as a member of the incredible editorial team.

Urooj Malik

Staff Writer

The Rho Chi Post is a valuable platform that connects students and faculty with the most up-to-date information within the pharmacy profession. The field of pharmacy is constantly expanding with vital developments, so it is important for us to stay informed in the world of healthcare. The Rho Chi Post serves as a creative outlet for student pharmacists to voice their various perspectives and ideas for others to utilize as an educational resource. As a staff writer, I hope to channel my passions and interests through this newsletter in an effort to impact those around me .

Aditi Ghosh

Staff Writer

Being a part of the Rho Chi Post allows me to share news, updates, and information with the St. John's community. It is very rewarding to have the opportunity to write about topics pertaining to healthcare while also being able to educate our readers.

Social Media & Outreach

Noor-ul-ain Buksh

Engagement & Outreach Manager

I am incredibly grateful to be serving as an Engagement and Outreach Manager for the Rho Chi Post. As someone who has frequently seen people silenced in the media, I strongly feel that it is important that our newsletter displays diverse perspectives on pharmaceutical topics and I hope to play a meaningful part in helping that happen. Oftentimes, it is easy to lose connection with the student community. I want to avoid that and prioritize the opinions of our readers and writers. While upholding the Rho Chi Post's mission, I plan to work my hardest to promote inclusivity and stay connected with the student body. The pharmaceutical world is never static so I am excited to learn and work alongside my peers.

Anjali Thykattil

Engagement & Outreach Manager

I am beyond grateful for this opportunity, and I am excited to have the honor of serving on the executive board as the Engagement and Outreach Manager. The Rho Chi Post is not only a creative outlet for students, but also one that is invariably relevant to the ever-changing world of healthcare. In this position, I aim to further expand the growth of the Rho Chi Post among pharmacy students here at St. John's. Let's not forget, it is us as students who will become the healthcare leaders of tomorrow.

Nancy Yousry

Engagement & Outreach Manager

It was such an amazing opportunity to become part of Rho Chi Post's Editorial Board last year, and I am really excited to continue being a part of Rho Chi Post this year! I believe one of our responsibilities as Student Pharmacists is to be aware of the current events impacting our profession as well as the critical and unique role Pharmacists play in a variety of healthcare settings . As incoming Staff Writer, I look forward to bringing these current events to light and to serve as an educational resource for passionate readers and writers alike.

Dr. Elsen Jacob

PharmD, MS, BCPS, BCGP, CPPS

As the faculty advisor for the Rho Chi Society and Rho Chi Post, I've had the opportunity to work closely with exceptional students who have a genuine passion for learning, service, leadership, and innovation. I look forward to what Rho Chi will accomplish this year!

Dr. Joseph Etzel

PharmD

Dr. Joseph Etzel is serving as the Rho Chi Post's interim faculty advisor for the 2022-2023 academic school year. Dr. Etzel is not new to our organization, as he has previously served as the faculty advisor for the Rho Chi Honor Society. He has been a huge influence to the success of Rho Chi in the past, and we look forward to working with him this year!

Dr. Mohammad Rattu

PharmD, BCOP, BCPS, BCGP

I am thankful to have been the 2012 editor-in-chief of the Rho Chi Post newsletter, as well as on the 2019 alumni honor roll of the national Rho Chi organization. This is one of the most successful longitudinal projects at my alma mater, as evidenced by its decade-long persistence and teams of highly-motivated students. I remain available for professional support and assistance with the new year's initiatives.

Meet Our 2022-2023 Rho Chi Executive Board

Executive Board

Vassilia Plakas
President

Rho Chi represents academic excellence, professional development, and service to our younger peers and fellow colleagues. Our programs and events reflect the value of scholastic leadership. Being part of Rho Chi has been such a wonderful experience so far; I am humbled and grateful to work with a strong executive board and a dedicated fifth year class.

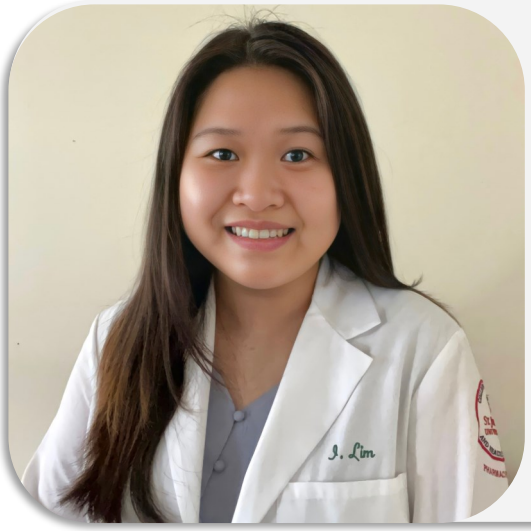
Frances Alexis Dela Cruz
Vice President

Rho Chi is a community that promotes academic excellence and service to others. By providing academic assistance and professional development opportunities, we strive to foster a supportive space for our members and younger peers to succeed. Rho Chi has played a significant role in my pharmacy journey thus far, and I am honored and humbled to be a part of this organization.

Rachel Kneitel

Secretary

Rho Chi to me is a collaborative space where students can encourage and support each other to excel. This organization allows students to spark stimulating conversations about pharmacy and healthcare as a whole.



Isabelle Lim

Treasurer

Rho Chi serves as an opportunity for students to academically support and collaborate with one another. Over the years, I personally have come to appreciate Rho Chi's study materials and review sessions as an integral resource when preparing for exams. I am honored to be a part of Rho Chi in a way where I can help other students just as Rho Chi has helped me in previous years.

Amanda Schleider

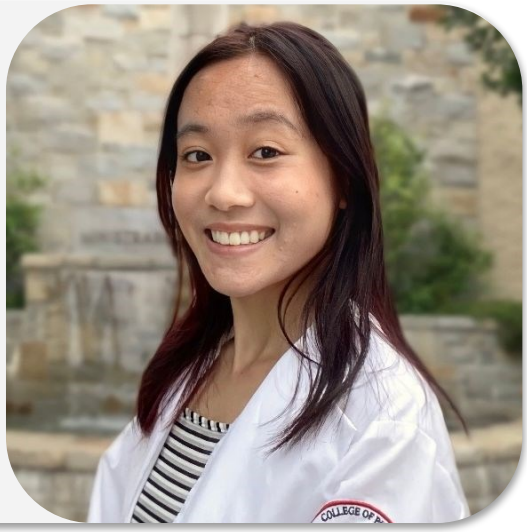
Historian

As the top students in our class, we have a unique opportunity to help our fellow classmates and younger pharmacy students succeed. This is a challenging program, and we all want to get through it. I am proud to be part of an organization that values assisting pharmacy students with their studies and connecting them with alumni and faculty members at our famous coffeehouse chats!

Joanne Fung

Development & Outreach Coordinator

To me, Rho Chi is a great opportunity for all pharmacy students to advance themselves. This society offers something to everyone, whether you are a member of the society, a part of the newsletter staff, or a student taking advantage of the resources offered by Rho Chi. The effort put forth by every person affiliated with Rho Chi is amazing, and I will always appreciate this society's mission and values.



Shankun Lin

Academic Committee Coordinator

Rho Chi is an honor and an accomplishment that I am proud of. As a Rho Chi member, we should be humble and give back to our community for intellectual and professional success

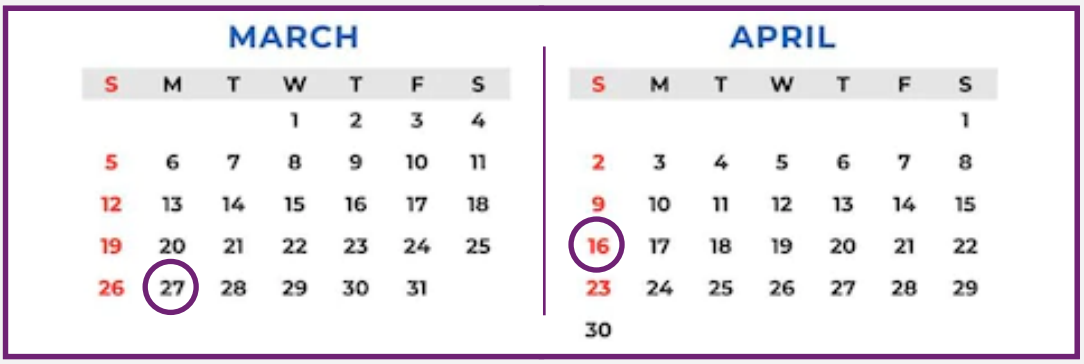
Riya Vinoy

Academic Committee Coordinator

Rho Chi is a collaboration of individuals that are committed to advancing the field of pharmacy that recognizes and promotes intellectual leadership. This collaboration fosters the growth of intellectual leaders by providing resources that can assist in achieving academic excellence.

RHO Rx CHI post

Mark Your Calendars for our 2023 Spring Semester Events!



Mar. 27th: Writing Workshop

Apr. 16th: 2023-2024 Editorial Team Applications Due

Interested in writing for the Rho Chi Post?

Go to http://rhochistj.org/RhoChiPost and click on the login option from the menu bar to make an account! With an account, you'll have access to the article submission portal where you can submit your writing for publication in an upcoming issue!

Remember, you do NOT have to be a member of Rho Chi, a member of the editorial team, or a student of St. John's to write for our newsletter!

Interested in joining our 2023-2024 Editorial Team?

The Rho Chi Post currently has applications open for staff writers, staff editors, content-focused copy editors, and graphics-focused copy editors. Scan the QR Code below to learn more about these positions and to apply for a spot on our editorial team!