

VOLUME 14 | ISSUE 4 | APRIL 2025

RHO^{Rx}CHI *post*

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

LEADS Initiative: 3rd Edition

THE UTILIZATION OF REAL WORLD EVIDENCE IN PEDIATRIC DRUG APPROVALS

THE EFFECT OF ADDERALL IN HEALTHY COLLEGE STUDENTS

LIRAGLUTIDE: THE FIRST GLP-1 GENERIC REFERENCING VICTOZA

CINICAL OUTCOMES AND REAL-WORLD POTENTIAL OF ETRASIMOD IN THE TREATMENT OF ULCERATIVE COLITIS

FDA APPROVES ALYFTREK (VANZACAFTOR/TEZACAFTOR/DEUTIVACAFTOR) FOR THE TREATMENT OF CYSTIC FIBROSIS

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.

Contact Information

The Rho Chi Post
St. John's University College of Pharmacy and Health Sciences
8000 Utopia Parkway, Jamaica, NY 11439

Website: <http://rhochistj.org/RhoChiPost>
Facebook: <https://www.facebook.com/RhoChiPost>
Instagram: @sjurhochipost
Email: rhochipost@gmail.com

2024-2025 TEAM MEMBERS



Editorial Team & Production

Editors-in-Chief

Anjali Thykattil
Sharupa Azmal

Senior Content-Focused

Copy Editors

Maliha Akter
Bao Qi Chen
Warda Basher

Content-Focused Copy

Editors

Ramesa Anan
Sameeha Arshad
Amanda Kim
Laiel Bravo
Arya Singh

Senior Graphics-Focused

Copy Editors

Zainab Masood

Graphics-Focused Copy Editors

Celestine Van Sertima
Nalisha Xu

Senior Staff Editors

Jennalynn Fung
Sharupa Azmal

Staff Editors

Muskan Basra
Harsha Mattappally
Ariella Zadrina
Anya Geiling
Celine Cherian
Wajiha Uddin
Christiana Popovic

Senior Staff Writers

Christine Mauceri

Staff Writers

Paulina Maczko
Katelyn Hoosein
Reyaz Mussaleen
Rosa Kang
Rand Ayoub
Sariah Grant
Nivaj Haque
Rebecca Sabzanov
Ameena Qadri
Michelle Flores
Amanda Nakhul

Social Media & Outreach

Engagement & Outreach Managers

Celestine Van Sertima
Paulina Maczko
Bhojranie Brahmanand
Maliha Akter

Advisors

Dr. Ketan Patel

MPharm, PhD

Dr. Mohammad Rattu

PharmD, BCOP, BCPS, BCGP

The Rho Chi Society

Executive Board

President

Esther Lee

Vice President

Sharupa Azmal

Secretary

Nalisha Xu

Treasurer

Jamila Chowdhury

Historian

Isabel Gendin

Academic Committee Coordinators

Kelly Yeung

TABLE OF CONTENTS

Message from the Editor-in-Chiefs	4
The Utilization of Real World Evidence in Pediatric Drug Approvals Sharupa Azmal, PharmD Candidate c/o 2026, Sarah El-Rowmeim, PharmD Candidate c/o 2027, Akhila Ajith Kumar, PharmD Candidate c/o 2027, & Sophia Migias, PharmD Candidate c/o 2028	5
The Effect of Adderall in Healthy College Students Sumaiya Chowdhury, PharmD Candidate c/o 2026, Daniyal Khan, PharmD Candidate c/o 2027, Wajiha Uddin, PharmD Candidate c/o 2027 & Riha Chowdhury, PharmD Candidate c/o 2027	9
Liraglutide: The First GLP-1 Generic Referencing Victoza Mazal Borukhova, PharmD Candidate c/o 2026, Jacqueline Demirjian, PharmD Candidate c/o 2029, Alicia Lumia, PharmD Candidate c/o 2029, Hailey Sandoval, PharmD Candidate c/o 2029	12
Clinical Outcomes and Real-World Potential of Etrasimod in the Treatment of Ulcerative Colitis Nower Chowdhury, PharmD Candidate c/o 2026, Anastasia Jairam, PharmD Candidate 2029, John Niewinski, PharmD Candidate 2028	16
FDA Approves Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for the Treatment of Cystic Fibrosis Zainab Masood, PharmD Candidate c/o 2026, Ansha Hamid, PharmD Candidate c/o 2027, Gabriella Lamantea, PharmD Candidate c/o 2027 & Ishrat Iqbal, PharmD Candidate c/o 2027	20
Meet Our 2024-2025 Team Members	24

A Message from the Editors-in-Chief, Anjali Thykattil and Sharupa Azmal!

It is with great honor that we introduce the Rho Chi Post's fourth issue of our 14th volume. We thank you for taking time out of your day to read over our newsletter. It is our intention that this issue teaches you something new, whether it be clinical, pharmacy news, or advice from our Rho Chi Talks or 6th Year Perspective. We would like to take a moment to thank our Editorial Team, Executive Board, advisors, and readers as this newsletter would not be possible without them. With this, we leave you to the rest of the issue, and we wish the student body a wonderful spring semester!

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 reevaluated 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.

The Utilization of Real World Evidence in Pediatric Drug Approvals

By: Sharupa Azmal, PharmD Candidate c/o 2026, Sarah El-Rowmeim, PharmD Candidate c/o 2027, Akhila Ajith Kumar, PharmD Candidate c/o 2027, & Sophia Migias, PharmD Candidate c/o 2028

Introduction

Real-world evidence (RWE) is defined as clinical findings regarding the use, benefits, and risks of a drug outside of traditional clinical trials.¹ These insights are derived from real-world data (RWD), which can be collected from numerous sources, such as electronic health records (EHRs), medical claims, or product and disease registries. RWE provides a comprehensive understanding of how medical interactions function in everyday clinical settings, contrary to traditional clinical trials, which are conducted under carefully monitored conditions. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) recognize the growing significance of RWE, as shown in their Real-World Evidence Program, which strives to implement RWE into decision-making for drug approvals and safety monitoring. Under the 20th Century Cures Act, the FDA's RWE Program is required to evaluate how RWD can be used to generate RWE that demonstrates a drug's effectiveness. This can be used to support the approval of new indications or meet post-approval study requirements.²

The importance of RWE in healthcare is evident in areas where clinical trials present ethical barriers. One notable field is pediatric drug development, where conducting clinical trials in children raises a few ethical considerations. One of these is beneficence, which is the concept of ensuring that minors are not harmed and exploited due to their inability to provide assent.

There is also justice, the idea that all individuals should have equitable access to the same benefits and risks of a drug. Many factors have an impact on justice in clinical research, such as demographic differences (gender, socioeconomic status, race), mental status, and coercion of financial incentives. In particular for the pediatric population, there is the concern that monetary rewards can convince children to provide assent to participate in a study, which can be considered a conflict of interest. Therefore, if financial incentives are provided by investigators, they are thoroughly reviewed by an Institutional Review Board (IRB) before the study can proceed. Moreover, receiving informed assent can also be challenging since it may be difficult to communicate information about the study to children, especially if they are on the younger end of the spectrum.³ Overall, these are the determinants that limit the ability to recruit pediatric patients for clinical trials.

Relying on RWE can help fill gaps in pediatric drug research by using existing data to assess drug efficacy and safety without exposing children to unnecessary risks. Additionally, the FDA has accepted RWE to support drug product approvals, primarily in oncology and rare disease settings where randomized trials may be considered unethical. In these cases, single-arm interventional trials are used, and RWE consisting of historical response rates from medical records and expanded access programs are used to evaluate the drug's effectiveness.

PEDIATRIC DRUG APPROVALS

Benefits and Limitations of RWE

RWE offers several advantages that complement traditional clinical trials. For one, pediatric populations are often underrepresented in clinical research due to ethical and logistical challenges. RWE helps bridge this gap by providing data from real-world clinical use, enabling the assessment of long-term safety, rare adverse effects, and effectiveness in diverse pediatric populations, all of which are factors that may not be fully exhibited in short-term trials. Unlike traditional trials, which often have specific enrollment criteria, RWE incorporates data from a broader range of pediatric patients, including those with comorbidities or taking multiple medications. Additionally, conducting randomized controlled trials in children can be challenging, especially regarding placebo use.⁴ When an effective treatment exists, assigning children to a placebo group could deny them necessary care, potentially leading to harm. RWE offers an alternative by analyzing data from routine clinical practice, reducing reliance on placebo-controlled studies while still generating valuable evidence. RWE can expedite drug approvals by supplementing traditional trial data with real-world facts, leading to quicker access to essential medications for children. Since pediatric drug dosing is often decided from adult data, RWE helps refine dosing recommendations based on actual clinical use, ensuring safer and more effective treatment regimens. It also supports improvements in packaging instructions and manufacturer labeling to better align with pediatric needs.

Although real-world evidence offers valuable information, certain limitations can interfere with its effectiveness. RWE is often derived from electronic health records, insurance claims, and patient registries, which may

contain missing, incomplete, or inaccurate data, leading to inconsistencies. Unlike randomized controlled trials, which follow strict protocols, RWE comes from uncontrolled environments, making decision-making more challenging. Additionally, variations in data collection across different clinical settings can create organizational issues and reduce data reliability. Pediatric drug dosing requires precise weight- and age-based adjustments, but RWE may lack the precision needed for accurate pediatric dosing adjustments.⁵ Variations in off-label use make it harder to understand how dosage affects response, which complicates setting proper treatment guidelines.

A Pediatric Drug Approval Based On RWE

An example of RWE being successful includes the FDA's approval of Imbruvica (ibrutinib) for the treatment of chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy. cGVHD is a life-threatening condition that occurs after patients receive a hematopoietic stem cell transplantation and the donor cells attack healthy organs and tissues in the body. This impacts multiple organs such as the skin, eyes, mouth, and lungs. Typically, patients experiencing cGVHD are provided with corticosteroid therapy. However, in this study there was a single-arm trial of 42 patients with persistent cGVHD despite receiving corticosteroid treatment. They tested the efficacy and safety of Imbruvica on these patients and the trial showed a 67% response rate, with symptom improvement lasting five months or longer in nearly half of the patients. As a result, the FDA decided to expand the approval of Imbruvica to include patients with cGVHD based on these findings. This study demonstrates how incorporating real world evidence as clinical data was able to expedite

approval and provide treatment options for patients with limited alternatives.⁷

Overall, pediatric drug development has been able to make meaningful progress due to the utilization of RWE. Many studies leveraging RWE that are submitted for regulatory review are for new drug indications or product label expansion. From 2016 and 2022 alone, a large proportion of RWE based approvals were concentrated in oncology, a therapeutic area that is characterized by significant gaps in clinical care. While RWE has played a critical role in increasing access to lifesaving medications for pediatric patients, there are still improvements that need to be made regarding the quality and utility of these studies. Moving forward, it is essential that continued efforts are made to standardize RWE methodologies while ensuring that children can benefit from novel therapies.³

References

1. U.S. Food and Drug Administration. Framework for FDA's Real-World Evidence Program, Dec. 2018, www.fda.gov/media/120060/download.
2. Antoon, J. W., Feinstein, J. A., Goldman, J. L., Kyler, K. E., Shah, S. S., & Children's Hospital Association Pharmacoeconomics and Drug Safety (Peds-Rx) Research Group (2023). Advancing pediatric medication safety using real-world data: Current problems and potential solutions. *Journal of hospital medicine*, 18(9), 865–869. <https://doi.org/10.1002/jhm.13068>
3. Horton, D. B., Blum, M. D., & Burcu, M. (2021). Real-World Evidence for Assessing Treatment Effectiveness and Safety in Pediatric Populations. *The Journal of pediatrics*, 238, 312–316. <https://doi.org/10.1016/j.jpeds.2021.06.062>
4. Alipour-Haris G, Liu X, Acha V, Winterstein AG, Burcu M. Real-world evidence to support regulatory submissions: A landscape review and assessment of use cases. *Clin Transl Sci*. 2024;17(8):e13903. doi:10.1111/cts.13903
5. Belen O, Concato J, Kraus S. FDA approval demonstrates role of real-world evidence in regulatory decision-making for drug effectiveness. *Our Perspective*. U.S. Food and Drug Administration. 2019. <https://www.fda.gov/drugs/our-perspective/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness>
6. Podany A T., PedSAP. Ethical considerations in pediatric research. *Research and Study Design in Pediatrics*. 2017:7-18. https://www.accp.com/docs/bookstore/pedsap/ped2017b1_sample.pdf

PEDIATRIC DRUG APPROVALS

7. U.S. Food and Drug Administration. FDA approves treatment for chronic graft versus host disease, Aug. 2017, <https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-chronic-graft-versus-host-disease>

The Effect of Adderall in Healthy College Students

By: Sumaiya Chowdhury, PharmD Candidate c/o 2026, Daniyal Khan, PharmD Candidate c/o 2027, Wajiha Uddin, PharmD Candidate c/o 2027 & Riha Chowdhury, PharmD Candidate c/o 2027

Adderall is a prescription drug used to treat individuals diagnosed with attention deficit hyperactivity disorder (ADHD) and narcolepsy². It does this by enhancing the release of norepinephrine, dopamine, and serotonin into the synaptic region while preventing their absorption. When taken as prescribed, Adderall can help manage the symptoms of ADHD such as inattention, hyperactivity, and impulsivity. By raising dopamine and norepinephrine levels in the brain, Adderall helps lessen the symptoms of ADHD by enhancing focus, reducing impulsivity, and lowering hyperactivity.

However, the illegal use of Adderall has been observed among college students who have not been prescribed this medication for either one of these diagnoses. This may be due to the high pressure and stress caused by academic demands¹. This is confirmed by double blind, placebo-controlled crossover pilot study conducted in 2018 on Adderall use in college students³. Pilot studies are categorized as a smaller research project conducted before starting the original large-scale study³. The goal of the pilot study is to see if Adderall has the ability to increase the cognitive abilities of the college students using this medication in order to be able to focus more or to see if there actually are no benefits of using this medication on students without ADHD.

Abuse can have detrimental effects. Although some people don't think Adderall is addictive, it can become very habit-forming, especially if taken excessively or without a prescription

Many people believe it is safe to use as needed, however it can be risky to take several doses without a doctor's supervision. Loss of appetite, weight loss, stomach pain, headache, nausea, dizziness, anxiety, and difficulty sleeping are possible adverse effects. Adults should start taking Adderall pills at a dose of 5 mg once or twice a day, with a doctor adjusting the dosage as necessary. According to studies, Adderall's effects on neurocognition are negligible at lower dosages, such as 10 mg, and are still comparatively minor even at 30 mg. Adderall improves attention by helping the brain stay focused on tasks for longer periods and reducing distractibility. It also enhances working memory, making it easier to hold and use information in the short term. Additionally, Adderall supports better decision-making by increasing impulse control and improving the brain's ability to plan and respond thoughtfully, rather than reacting impulsively.

The Experiment

The study consisted of healthy young college students ranging in age from 18 to 30 without a history of ADHD, with a normal EKG, and with no chronic medical conditions requiring medications in the last six months. This exclusion criteria does not apply to female participants on antibiotics or birth control. All participants were expected to complete pre-assessment neurocognitive tests and baseline testing of heart rate and blood pressure. Each participant then underwent two randomized, double-blind sessions.

In one session, the participants were either given a 30 mg oral dose of amphetamine mixed salts or a placebo of dextrose each session. Following administration, the participants fasted for 2 hours and repeated a neurocognitive assessment between 90- and 210-minutes post-consumption, while autonomic activity was remeasured every 30 minutes. The neurocognitive assessment includes attention tasks, memory tasks, and executive function tasks. A DEQ (Drug Effects Questionnaire) was also administered to provide a subjective perspective, and both a PA (Positive Activation) and NA (Negative Activation) scale were used to measure the emotions felt by the participants. After the first session, a 5–7-day washout period was observed before the experiment was repeated in a second session.

Discussion & Conclusion

The study exhibited mixed results. In terms of neurocognitive performance measures, the Adderall and placebo sessions were not significantly different. Participants exhibited impaired working memory performance, reduced response variability, a “worsening of participants’ ratings of their own past cognitive ability,” but an improvement in attention skills³. However, Adderall exhibited substantial effects on autonomic activity; there was an increase in heart rate, systolic and diastolic blood pressure, feeling the drug’s effect, feeling high, and positive activation (PA). This effect on autonomic activity does not correlate with an improvement in cognitive performance. Some limitations include a small sample size, the potential drug effects not being analyzed after the peak period, and low power for detecting small to moderate effects but high power for large effects.

Overall, Adderall is shown to improve attention but cannot enhance academic performance. The growing issue of non-medical use is contributed by informal channels, which are often the ones supplying college students with access to Adderall. These informal channels are peer-to-peer diversion, dark web markets, social media forums, and as plain as taking it from a relative’s medication cabinet⁴. Among college students in particular, there is a growing misconception that Adderall is safe to use off label and can help with increased concentration and cognitive function or can be used recreationally for weight loss or partying. Although healthy individuals can have slight cognitive benefits, the side effects like daydreaming, sadness, heightened anxiety, and irritability, showcase that the behavioral risks of using Adderall without a prescription make it an unwise choice.

References

1. DeSantis, Alan D., and Audrey Curtis Hane. "Adderall is Definitely Not a Drug: Justifications for the Illegal Use of ADHD Stimulants." *Substance Use & Misuse*, vol. 45, no. 1-2, 2010, pp. 31-46. <https://www.tandfonline.com/doi/10.3109/10826080902858334>.
2. Ahmann, Elizabeth, et al. "Placebo-Controlled Evaluation of Amphetamine Mixture—Dextroamphetamine Salts and Amphetamine Salts (Adderall): Efficacy Rate and Side Effects." *Pediatrics*, vol. 107, no. 1, 2001, e10. <https://publications.aap.org/pediatrics/article/107/1/e10/66525>.

3. Weyandt, Lisa L., et al. "Neurocognitive, Autonomic, and Mood Effects of Adderall: A Pilot Study of Healthy College Students." *Frontiers in Psychology*, vol. 9, 2018, article 2326.

<https://pmc.ncbi.nlm.nih.gov/articles/PMC6165228>.

4. Lakhan, S. E., & Kirchgessner, A. (2012). Prescription stimulants in individuals with and without attention deficit hyperactivity disorder: Misuse, cognitive impact, and adverse effects. *Brain and Behavior*, 2(5), 661–

677.<https://pmc.ncbi.nlm.nih.gov/articles/PMC3489818/>

Liraglutide: The First GLP-1 Generic Referencing Victoza

By: Mazal Borukhova, PharmD Candidate c/o 2026, Jacqueline Demirjian, PharmD Candidate c/o 2029, Alicia Lumia, PharmD Candidate c/o 2029, Hailey Sandoval, PharmD Candidate c/o 2029

Type 2 diabetes mellitus (T2DM) is a chronic disease that occurs when the body is unable to regulate blood glucose levels. There are many risk factors that can contribute to the development of T2DM, including family history, poor diet, lack of exercise, obesity, and individuals 45 years or older. Some lifestyle modifications patients can make are maintaining a balanced diet, weight reduction, and engaging in moderate to high intensity exercise for at least 150 minutes a week, spaced across at least three days.^{1, 10} There are several pharmacological treatments available for the management of T2DM, and recently, Glucagon-Like-Peptide-1 Receptor Agonists (GLP-1 RA) have become increasingly popular as a form of first-line therapy.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone that helps lower serum glucose levels by stimulating the release of insulin from the pancreas. For patients whose bodies have a difficult time producing insulin or whose cells are desensitized to insulin, a GLP-1 agonist can promote the secretion of insulin, thereby bringing their hyperglycemia under control.² Victoza, the brand name for liraglutide, is an example of a long-acting GLP-1 RA, which is commonly used as an agent for T2DM. When used alongside appropriate diet and exercise, liraglutide improves glycemic control in patients 10 years or older. Liraglutide is administered via subcutaneous injection in either the upper arm, thigh, or abdomen, and can be taken with or without food. Common side effects of liraglutide may include

irritation at the injection site, decreased appetite, constipation, and headache.⁹

Generic medications are extremely important within modern healthcare. They can help in providing alternatives to brand-name drugs while also having the same therapeutic benefits. The availability of generics increases patient access to needed treatments, lowers overall healthcare costs, and promotes medication adherence.³ “According to the FDA, the cost of a generic drug can be 80%–85% lower than the innovator’s branded product”¹² This price difference is usually because of less research, development, and marketing costs since generics do not need extensive trials when the patent for the brand name drug expires. The FDA requires generic medications to have the same standards for safety, efficacy, and quality as their brand-name counterpart. These generic drugs have to show bioequivalence, meaning they bring the same active ingredient into the bloodstream at nearly the same rate as the name-brand drug. This ensures that generics have the same medicinal effects without any change in treatment outcomes.¹²

Generic drugs being available to patients promotes competition within the pharmaceutical industry, which can impact the pricing of all drugs. When multiple manufacturers make the same generic medication, it makes costs even lower, which is beneficial to patients and healthcare systems.⁶ The high cost of medication can often

lead to non-adherence, where patients skip or discontinue treatment because of financial burdens. Generics provide an affordable alternative, which can help reduce financial burdens and improve the likelihood of patients adhering to their prescribed treatment regimens. This is especially important in patients with chronic conditions where continuous medication use is necessary for disease management.³ Additionally, generic medications are necessary for a sustainable healthcare system. They have the same effectiveness as their brand-name counterparts at a much lower cost, improving patient access and adherence while also reducing the overall healthcare costs for the public. When more patents expire and generics enter the market, their role in making healthcare more affordable and accessible continues to grow.⁸

Victoza by Novo Nordisk was initially approved by the FDA in January 2010 for the treatment of diabetes. Its indication was further expanded in June 2019 for the use of pediatric patients who are at least 10 years old.¹¹ The authorized generic of Victoza was released by Teva Pharmaceuticals in June 2024, while the traditional generic by Hikma Pharmaceuticals was released in December 2024.^{13,7} This raises a question: if Hikma Pharmaceuticals is recognized by the FDA as the manufacturer of the first generic of liraglutide, then how could Teva's authorized generic be released earlier? The answer lies in the differences between an authorized generic and a traditional generic. According to the FDA, an authorized generic is “an approved brand name drug that is marketed without the brand name on its label.”⁵ Essentially, all the components of the authorized generic mimic that of the brand, except for the labeling on the packaging.

The brand-name manufacturer can choose to either release the authorized generic themselves or give permission to other manufacturers to do so. A traditional generic, on the other hand, is the “same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling.”⁵ Traditional generics tend to have differences with their inactive ingredients, provided that those ingredients do not interfere with the drug’s safety or effectiveness. Additionally, manufacturers must submit an Abbreviated New Drug Application (ANDA) to the FDA. By submitting an ANDA, the manufacturer states that the traditional generic and the brand name are bioequivalent and that the generic has the same standards of quality and manufacturing as the brand-name drug.⁵ With this understanding, it becomes clear that while Teva did produce an authorized generic of liraglutide, it was done under Novo Nordisk’s original NDA and not through the traditional ANDA approval process. Although Teva submitted an ANDA to the FDA, it has not yet been approved.¹⁴ This, coupled with the fact that Teva’s formulation is identical to the brand-name drug, explains why Teva’s generic is classified as an authorized generic. Therefore, Hikma Pharmaceuticals is the first to produce a traditional generic referencing Victoza through an approved ANDA.

Generics of essential medications play a crucial role in providing the public with more accessible and affordable medications that are not compromised in their efficacy, safety, and quality. By providing more affordable options for treatment in patients who are in need, generic medications are able to empower patients to increase their adherence to their treatment regimen.

LIRAGLUTIDE

Dr. Iilun Murphy, M.D., the director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research, emphasized the importance of generic medications by stating, "Generic drugs provide additional treatment options which are generally more affordable for patients. [Liraglutide's] approval underscores the FDA's continued commitment to advancing patient access to safe, effective, and high-quality generic drug products."⁴ As more medications for T2DM are being developed, the availability of these generics will increase over time. This is crucial for diabetic patients, who will likely require long-term treatment, as it will lessen their financial burden and allow them to continue with the appropriate therapy needed to manage their condition.

References

- 1) CDC. Diabetes. CDC. <https://www.cdc.gov/diabetes/risk-factors/index.html>. Published 05/15/2024.
- 2) Collins L, Costello RA. Glucagon-Like Peptide-1 Receptor Agonists. In: StatPearls. Treasure Island (FL): StatPearls Publishing; February 29, 2024. <https://pubmed.ncbi.nlm.nih.gov/31855395/>
- 3) DrugPatentWatch. The Impact of Generic Drugs on Healthcare Costs - DrugPatentWatch - Make Better Decisions. Published August 21, 2024. <https://www.drugpatentwatch.com/blog/the-impact-of-generic-drugs-on-healthcare-costs/>
- 4) FDA. FDA Approves First Generic of Once-Daily GLP-1 Injection to Lower Blood Sugar in Patients with Type 2 Diabetes. U.S. Food & Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-once-daily-glp-1-injection-lower-blood-sugar-patients-type-2-diabetes>. Last Updated 12/23/2024.
- 5) FDA. FDA List of Authorized Generic Drugs. U.S. Food & Drug Administration. <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>. Last Updated 01/13/2025.
- 6) FDA. Generic Competition and Drug Prices. U.S. Food & Drug Administration. <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>. Last Updated 10/17/2024.
- 7) Hikma. Hikma receives FDA approval and launches the generic version of Victoza®, Liraglutide, in the US. Hikma. <https://www.hikma.com/news/hikma-receives-fda-approval-and-launches-the-generic-version-of-victoza-liraglutide-in-the-us/>. Last Updated 12/26/2024.
- 8) Kritz F. AAM 2024 Report Shows Billions in Biosimilar and Generic Savings. Specialty Pharmacy Continuum. <https://www.specialtypharmacycontinuum.com/Online-First/Article/11-24/Biosimilars-Generics-445-Billion-Savings/75360>. Published 11/05/2024.
- 9) Liraglutide. In: Lexi-Drugs. UpToDate Inc. Updated February 26, 2025. Accessed March 5, 2025. https://online-lexi-com.jerome.stjohns.edu/lco/action/doc/retrieve/docid/patch_f/2144379?cesid=2RnaNEL5k06&searchUrl=%2Ffco%2Faction%2Fsearch%3Fq%3Dliraglutide%26t%3Dname%26acs%3Dfalse%26acq%3Dliraglutide
- 10) Raveendran AV, Chacko EC, Pappachan JM. Non-pharmacological Treatment Options in the Management of Diabetes Mellitus. *Eur Endocrinol.* 2018;14(2):31-39. doi:10.17925/EE.2018.14.2.31 <https://pubmed.ncbi.nlm.nih.gov/30349592/>
- 11) Stewart J. Victoza FDA Approval History. Drugs.com. <https://www.drugs.com/history/victoza.html>. Last Updated 11/12/2024.

12) Straka RJ, Keohane DJ, Liu LZ. Potential Clinical and Economic Impact of Switching Branded Medications to Generics. *Am J Ther.* 2017;24(3):e278-e289.

doi:10.1097/MJT.0000000000000282

<https://pubmed.ncbi.nlm.nih.gov/26099048/>

13) Teva. Teva Announces Launch of Authorized Generic of Victoza® (liraglutide injection 1.8mg), in the United States. Teva. <https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2024/Teva-Announces-Launch-of-Authorized-Generic-of-Victoza-liraglutide-injection-1.8mg-in-the-United-States/default.aspx>. Published 06/24/2024.

14) Teva. Teva Confirms Generic Victoza® Patent Challenge in the United States. Teva. <https://www.tevapharm.com/news-and-media/latest-news/teva-confirms-generic-victoza-patent-challenge-in-the-united-states/>. Published 02/02/2017.

Clinical Outcomes and Real-World Potential of Etrasimod in the Treatment of Ulcerative Colitis

By: Nower Chowdhury, PharmD Candidate c/o 2026, Anastasia Jairam, PharmD Candidate 2029, John Niewinski, PharmD Candidate 2028

Introduction

Ulcerative colitis (UC) is a chronic autoimmune condition that significantly impairs the quality of life for many individuals in the United States. In 2023, UC affected approximately 414 per 100,000 individuals nationwide. UC is a type of inflammatory bowel disease (IBD) characterized by inflammation that starts from the mucosal layer of the colon and can spread to the rectum and proximal colon. Among those affected, 32-46% experience moderate symptoms, while 13-14% have debilitating manifestations such as frequent diarrhea, loss of appetite, and severe rectal cramping.¹

In addition to gastrointestinal complications, UC can increase the risks of extraintestinal conditions such as respiratory disease, colorectal cancer, lymphoma, and skin cancer. Although the disease-specific mortality rate for UC remains low, the presence of comorbidities significantly elevates overall mortality risk. This highlights the need for effective, long-term therapies that can improve both disease control and quality of life.

Sphingosine-1-phosphate (S1P) receptor modulators have recently emerged as a novel class of oral small molecule therapy for UC, providing a targeted approach to immune modulation.² S1P receptors are membrane-bound lysophospholipid signaling molecules involved in lymphocyte trafficking.³ By modulating these receptors, S1P modulators can reduce the presence of lymphocytes at sites of gastrointestinal tissue, thereby reducing inflammatory responses.

The first S1P receptor modulator approved for clinical use was fingolimod, a non-selective agent indicated for multiple sclerosis. However, due to its lack of selectivity, fingolimod was associated with significant adverse effects, including cardiovascular complications and reduced pulmonary function. Ozanimod, a more selective S1P modulator, was later approved for both multiple sclerosis and UC, demonstrating an improved safety profile. However, ozanimod required a 7-day titration regimen, which delayed symptom relief for patients with active UC.

Etrasimod (marketed as Velsipity®) was developed to address the limitations of current UC therapies. While conventional treatments such as oral corticosteroids, TNF α antagonists, anti-integrin antibodies, anti-interleukin (IL)-12/23 agents, and Janus kinase (JAK) inhibitors remain widely used, many are associated with delayed onset of action, loss of efficacy over time, and the need for parenteral administration. These limitations highlight the need for safer, more convenient oral therapies with sustained clinical benefit. Etrasimod is a selective S1P receptor modulator with high affinity for S1P1, S1P4, and S1P5, and received FDA approval in October 2023 for the treatment of moderate to severe active UC. By preventing lymphocyte egress from lymph nodes into the bloodstream, etrasimod reduces intestinal inflammation and offers a once-daily oral alternative with a favorable safety profile.³

This paper will discuss the clinical development of etrasimod, with a focus on its mechanism of action, pivotal trial outcomes, safety considerations, and its emerging role in the treatment landscape for moderate to severe UC.

Methods

Pfizer conducted multiple Phase III randomized, double-blind, and placebo-controlled trials to assess the safety and efficacy of etrasimod in patients with moderate to severe UC. Study participants included men and women aged 18-80 years diagnosed with moderate to severe UC, confirmed by endoscopic and histologic evidence. Furthermore, they must have displayed an inadequate, or lack thereof, response to approved therapies for ulcerative colitis. This included conventional therapies such as, TNF α antagonists, anti-integrin antibodies, anti-IL-12/23 antibodies, and JAK inhibitors.²

Notable exclusion criteria for the trial were severe extensive colitis and diagnosis of Crohn's disease or intermediate colitis. Severe extensive colitis was indicated by a required colostomy or ileostomy within 12 weeks of trial randomization, complications like fulminant colitis, toxic megacolon, or bowel perforation, or a history of total or partial colectomy.³

ELEVATE UC 52 was conducted in 315 medical centers in 40 countries. 821 patients were enrolled, of which 433 underwent random assignment. The primary endpoint of UC 52 was the proportion of patients achieving clinical remission at weeks 12 and 52.³ Further, secondary endpoints included endoscopic improvement, symptomatic remission, and endoscopic improvement with histologic remission at weeks 12 and 52.³

They also assessed corticosteroid-free remission at week 52 and sustained clinical remission over time.

Trial ELEVATE UC 12 was performed amongst 407 centers in 37 countries, with 606 patients enrolled and 354 randomly assigned. The primary endpoint of UC 12 was clinical remission at week 12.³ Key secondary endpoints included the endoscopic improvement, symptomatic remission, and endoscopic improvement with histologic remission at week 12.³

In both trials, patients received either a 2 mg once-daily oral dose of etrasimod or a matching placebo in a 2:1 ratio under double-blind conditions. Treatment was not disclosed to investigators, study site staff, patients, sponsor personnel or study vendors involved with the conduct of the study.

The ELEVATE UC 52 trial lasted for 52 weeks, with a 12-week induction period followed by a 40-week maintenance period and a 4-week follow-up. After the initial 12-week period, patients could continue treatment into the 40-week period. Patients who felt their disease state had not improved or had worsened were allowed to terminate the treatment. Patients who completed the 52-week period were eligible to enroll in an open-label extension (OLE) study or participate in a 4-week follow-up visit.

The ELEVATE UC 12 trial was designed for a 12-week induction period followed by a 4-week follow-up. Similar to the ELEVATE UC 52 trial, patients could enroll in an OLE study after the induction period or participate in the follow-up period.

Results & Discussion

In ELEVATE UC 52, a significantly greater proportion of patients in the etrasimod group achieved clinical remission than patients in the placebo group at both 12-week induction period (27% vs. 7%) and at week 52 (32% vs. 7%).³ Similarly, ELEVATE UC 12 showed that 25% of patients in the etrasimod group were in clinical remission at week 12 compared to 15% in the placebo group at the end of the 12-week induction period.³

Key secondary endpoints also demonstrated the efficacy of etrasimod, including endoscopic improvement, symptomatic remission, and endoscopic-histologic remission. In ELEVATE UC 52, 32% of patients reached corticosteroid-free remission by week 52, and 18% of patients experienced sustained remission during weeks 12 and 52.³ Symptom improvement was observed starting at week 2 in ELEVATE UC 52 and week 4 in ELEVATE UC 12.

These findings suggest that etrasimod serves as an effective induction and maintenance therapy for patients with moderate to severe UC. The continuous "treat-through" design of ELEVATE UC 52 closely mirrors clinical practice, allowing for a more realistic assessment of long-term treatment benefit. The increase in clinical remission from week 12 to week 52 indicates that some patients experience a delayed yet sustained response with continued therapy, reinforcing the value of long-term treatment adherence. Efficacy was observed across both treatment-naïve and treatment-experienced subgroups. Treatment-experienced patients exhibited slightly decreased treatment effect, similar to how patients taking other alternative advanced therapies respond. Overall, etrasimod can be considered a suitable therapeutic choice compared to available biologics and

small molecules with once-daily oral dosing, rapid onset of action, and ability to induce steroid-free remission.

Safety

The safety profile of etrasimod suggests it is generally well tolerated. In ELEVATE UC 52, adverse events (AEs) were reported in 71% of patients receiving etrasimod compared to 56% in the placebo group.³ The most frequently reported AEs included anemia, headache, and worsening of UC. Most AEs were mild or moderate in severity. Serious AEs (SAEs) like bradycardia and macular edema were less common and comparable between groups (7% in etrasimod vs 6% in placebo), suggesting cardiac and ophthalmologic monitoring for the S1P modulator drug class. The absence of significant differences in SAEs between treatment groups supports the overall tolerability of etrasimod in a real-world clinical setting

Conclusion

Etrasimod presents as a promising advancement in the treatment of moderate to severe ulcerative colitis. Etrasimod was shown to significantly improve outcomes of clinical remission, endoscopic outcomes, symptomatic relief, and steroid-free remission compared to placebo in pivotal Phase III trials. Its once-daily oral administration and favorable pharmacokinetics and safety profile makes it an appealing alternative to existing S1P modulators and biologics in both induction and maintenance phases.

Given its recent FDA approval and entry into clinical practice, etrasimod should further be explored for its long-term impacts on patient quality of life, health economics, medication adherence, and payer reimbursement models to better define its place in Real-World Care

Continued post-marketing surveillance and real-world evidence will also be essential in confirming these findings across broader, more diverse patient populations.

References

1. Canadian Agency for Drugs and Technologies in Health (CADTH). Etrasimod (Velsipity): Reimbursement Review. Ottawa, ON: CADTH; December 2024. SR0795_Velsipity_Combined_Review.
2. Bencardino S, D'Amico F, Faggiani I, et al. Efficacy and Safety of S1P1 Receptor Modulator Drugs for Patients with Moderate-to-Severe Ulcerative Colitis. *J Clin Med*. 2023;12(15):5014. Published 2023 Jul 30. doi:10.3390/jcm12155014
3. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies. *The Lancet*. 2023;0(0). doi:[https://doi.org/10.1016/S0140-6736\(23\)00061-2](https://doi.org/10.1016/S0140-6736(23)00061-2)

FDA Approves Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for the Treatment of Cystic Fibrosis

By: Zainab Masood, PharmD Candidate c/o 2026, Ansha Hamid, PharmD Candidate c/o 2027, Gabriella Lamantea, PharmD Candidate c/o 2027 & Ishrat Iqbal, PharmD Candidate c/o 2027

Cystic fibrosis is a chronic genetic disorder that follows an autosomal recessive inheritance pattern which affects children and adults.¹ There is a genetic mutation on chromosome 7 that codes for the CFTR protein, a chloride channel that regulates salt and water balance in the body.¹ Defects in this protein disrupts chloride ion transport, leading to thick mucus accumulation, organ dysfunction, and electrolyte imbalances.¹ Symptoms can appear in infancy through childhood and be diagnosed through newborn screening and genetic testing.¹ Adults exhibit cystic fibrosis with symptoms affecting multiple organs such as the lungs, pancreas, and liver. Patients with cystic fibrosis are estimated to live until their forties before requiring lung transplantation.¹

There is currently no cure for cystic fibrosis; however, there are treatments to manage the respiratory symptoms, such as CFTR modulators and antibiotics. These treatments have several functions, which include, minimizing respiratory infections, clearing out mucus in airways, optimizing nutritional status with pancreatic enzyme supplements, and treating any other health complications that may arise. CFTR modulators are a class of drugs that focus on enhancing the CFTR protein by folding this protein correctly and allowing it to reach the cell surface. These therapies are intended to improve the production, intracellular processing, or function of the CFTR protein caused by

the mutated gene, with each targeting a distinct dysfunction caused by a gene mutation.

An example of a CFTR modulator is Ivacaftor. For patients with the G551D mutation, the CFTR protein is not able to open correctly. The drug Ivacaftor opens a chloride channel and restores the flow of chloride ions through the cell membrane by the CFTR protein. For patients with the F508del mutation in which the CFTR protein misfolds, drugs like Lumacaftor help the CFTR protein fold correctly. Individuals with cystic fibrosis tend to have severe lung infections, in which antibiotics are used to treat them. Moreover, for end stage lung disease, a lung transplant is used to replace the diseased lung. Some symptoms that affect people with cystic fibrosis are coughs with thick mucus, constipation, abdominal pain, and salty-tasting sweat. Mucus thinners like Pulmozyme break down mucus by cleaving extracellular DNA.² Stool softeners help with constipation. In addition, those with cystic fibrosis may have a dysfunctional pancreas which does not create enzymes necessary for digestion. Pancreatic enzyme supplements help with this issue as it contains all three main groups of digestive enzymes (lipase, amylase, and protease).³ Ongoing advancement in treatments continue to create more options. Alyftrek, a newly approved CFTR modulator, joins the list of cystic fibrosis treatments.

On December 20, 2024, the Food and Drug Administration (FDA) approved Vertex's ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor) for patients 6 years and older with at least one F508del mutation or another responsive mutation in the CFTR gene.⁴ Alyftrek is a fixed-dose combination of vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50mg for ages 6 to 12 years. For ages above 12, the fixed-dose combination is vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125mg. It is recommended that Alyftrek be taken orally with fat-containing food, once daily, at the same time each day.⁴

Common adverse reactions to ALYFTREK include cough, nasopharyngitis, upper respiratory tract infection, headache, and increase in liver enzymes. It can also cause cataracts, a condition where the lens of the eye becomes cloudy, resulting in blurred vision. Therefore, eye examinations before and during the treatment of the medication is necessary. Liver enzymes must be checked before administering the drug and throughout the course of the treatment. If a patient experiences pain, swelling, or discomfort in the upper right stomach, nausea and vomiting, darkened urine, yellowing of the white part of the eye, fluid in your stomach area, the medication must be stopped immediately.

The clinical effect of Alyftrek was studied by the VX18-561-101 trial and the VX18-121-101 trial, which were two phased, randomized, double-blind, controlled, studies. The VX18-561-101 trial was conducted at 40 sites in North America, Europe, and Australia which assessed deutivacaftor monotherapy in people with cystic fibrosis aged 18 years or older with a CFTR gating mutation and who were previously stable on ivacaftor monotherapy.⁵ VX18-121-101 was conducted

USA, UK, Germany, Netherlands, and Portugal to evaluate the safety and efficacy of vanzacaftor–tezacaftor– deutivacaftor in adults with cystic fibrosis aged 18 years or older who were homozygous for the F50del mutation (F/F genotype) or heterozygous for F508del and a minimal function mutation (F/MF genotype).⁵ People with a history of cirrhosis with or without portal hypertension, risk factors for Torsade de Pointes and other ventricular arrhythmias, upper or lower respiratory infection, pulmonary exacerbation, lung infections, history of organ transplantation, pregnant or nursing were excluded from the study.⁵

In the VX18-156-101 trial, deutivacaftor monotherapy was compared with ivacaftor monotherapy. Participants received a 4-week ivacaftor monotherapy after which they received varying doses of deutivacaftor (25mg, 50mg, 150mg, or 250mg) once daily or ivacaftor 150 mg every 12 hours for 12 weeks.⁵

The primary endpoint for the VX18-156-101 trial was absolute change in ppFEV1 from baseline at week 12.⁵ ppFEV1 is used to indicate lung function and is measured by the percent predicted forced expiratory volume in one second.⁶ A low value of ppFEV1 indicates reduced lung function. The mean absolute change in ppFEV1 from baseline at week 12 was 3.1 percentage points for deutivacaftor 150 mg once daily and 2.7 percentage points for deutivacaftor 250 mg once daily. However, Ivacaftor 150 mg every 12 hours showed a -0.8 percentage point absolute change from baseline at week 12. These findings suggest that deutivacaftor outperformed ivacaftor in improving lung function over 12 weeks.

The secondary endpoints were safety and tolerability and absolute change in sweat chloride concentration from baseline at week 12.⁵ Sweat chloride concentration is a measurement in mmol/L of chloride in a person's sweat.⁷ It is a diagnostic method for cystic fibrosis. A sweat chloride level of 60 mmol/L or above is indicative of cystic fibrosis.⁷ The mean change in sweat chloride concentration from baseline at week 12 was 3.3 mmol/L (95% CI -4.6 to 11.2) for deutivacaftor 150 mg and -6.5 mmol/L (-14.1 to 1.2) for deutivacaftor 250 mg, compared with 0.9 mmol/L (-9.5 to 11.3) for ivacaftor 150 mg.⁵ These values do not show statistical significance, but deutivacaftor 250 mg shows the greatest improvement in sweat chloride concentration suggesting that it can provide greater restoration of CFTR function.⁵

The VX18-121-101 trial was conducted in two parts. In part 1, participants with F/MF genotypes received varying doses of vanzacaftor (5 mg, 10 mg, or 20 mg) in triple combination with tezacaftor–deutivacaftor or triple placebo for 4 weeks with an 18 day wash-out period.⁵ In the washout period, the vanzacaftor groups received tezacaftor–deutivacaftor and the triple placebo group received dual placebo. In part 2, participants received a 4-week tezacaftor–ivacaftor run-in period after which the participants with F/F genotype received either 20 mg vanzacaftor in triple combination with tezacaftor–deutivacaftor or tezacaftor–ivacaftor alone for 4 weeks.⁵

The primary endpoints for parts 1 and 2 of the VX18-121-101 trial were safety and absolute change in ppFEV1 from baseline to day 29.⁵

The mean absolute changes from baseline in ppFEV1 for the treatments that included vanzacaftor 5 mg, 10 mg, and 20 mg combination in participants with F/MF genotypes were 4.6 percentage points (95% CI -1.3 to 10.6), 14.2 percentage points (10.0 to 18.4), and 9.8 percentage points (5.7 to 13.8), respectively, to day 29 compared with an absolute mean change of 1.9 percentage points (-4.1 to 8.0) for participants receiving placebo.⁵ These values suggest that Vanzacaftor at 10 mg and 20 mg showed statistically significant improvement in lung function. There was also an increase in the ppFEV1 through day 29 in participants with F/F genotypes given the vanzacaftor 20 mg combination (15.9 percentage points [95% CI 11.3 to 20.6]) compared with participants receiving tezacaftor–ivacaftor alone (-0.1 percentage points (-6.4 to 6.0)). These values offer evidence that vanzacaftor 20 mg triple combination offers improvement in lung function as compared to the standard treatment.

Secondary efficacy endpoints were absolute change from baseline at day 29 in sweat chloride concentration and cystic fibrosis questionnaire-review (CFQ-R) respiratory domain score.⁵ Improvements in both, the sweat chloride concentration and CFQ-R respiratory domain score in participants with F/MF and F/F genotypes were seen.⁵ Mean changes in sweat chloride concentration from baseline to day 29 in participants with F/MF genotypes given vanzacaftor 5 mg, 10 mg, and 20 mg combination were -42.8 mmol/L (95% CI -51.7 to -34.0), -45.8 mmol/L (-51.9 to -39.7), and -49.5 mmol/L (-55.9 to -43.1), respectively, and 2.3 mmol/L (-7.0 to 11.6) for participants receiving placebo.⁵ Compared to the placebo, the three doses of vanzacaftor combination led to greater reductions in sweat chloride.

Additionally, these participants with F/MF genotypes that were given vanzacaftor 5 mg, 10 mg, and 20 mg combination had mean changes in CFQ-R domain score at day 29 of 17.6 points (95% CI 3.5 to 31.6), 21.2 points (11.9 to 30.6), and 29.8 points (21.0 to 38.7), respectively, while the participants receiving placebo had a mean change of 3.3 points (-10.1 to 16.6).⁵ These values emphasize that patients with F/MF genotype felt significantly better on the vanzacaftor combination with improved symptoms.

In participants with the F/F genotype who were given the vanzacaftor 20 mg combination had a mean change in sweat chloride of -45.5 mmol/L (-49.7 to -41.3) compared with -2.6 mmol/L (-8.2 to 3.1) for participants receiving tezacaftor-ivacaftor alone.⁵ Moreover, these participants had a mean change of 19.4 points (10.5 to 28.3) while those who received tezacaftor-ivacaftor had a change of -5.0 points (-16.9 to 7.0).⁵ These values suggest the strong improvement in CFTR function caused by the vanzacaftor combination.

In conclusion, the study shows that vanzacaftor in triple combination with tezacaftor and deutivacaftor is efficacious in adults with cystic fibrosis who have F/MF or F/F genotypes. The triple combination marks a promising addition to the list of treatments for cystic fibrosis. Clinical trials demonstrate that this therapy is well tolerated and offers improvements in lung function, respiratory symptoms, and CFTR function.⁵

References:

1. Yu E, Sharma S. Cystic Fibrosis. National Library of Medicine. Published December 11, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK493206/>
2. Pulmozyme® (dornase alfa) Mechanism of Action (MoA). pulmozyme. <https://www.pulmozyme.com/hcp/about/moa.html>
3. Somaraju URR, Solis-Moya A. Pancreatic enzyme replacement therapy for people with cystic fibrosis. *Cochrane Database Syst Rev.* 2020;8(8):CD008227. Published 2020 Aug 5. doi:10.1002/14651858.CD008227.pub4
4. ALYFTREK (Vanzacaftor, tezacaftor, and Deutivacaftor tablets) [package insert] (2024)
5. Uluer AZ, MacGregor G, Azevedo P, et al. Safety and efficacy of vanzacaftor-tezacaftor-deutivacaftor in adults with cystic fibrosis: randomised, double-blind, controlled, phase 2 trials. *Lancet Respir Med.* 2023;11(6):550-562. doi:10.1016/S2213-2600(22)00504-5
6. David S, Edwards CW. Forced Expiratory Volume. PubMed. Published October 14, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK540970/>

MEET THE TEAM

Meet the 2024-2025 Team Members



Editorial Team & Production



Anjali Thykattil
Editor-in-Chief

The Rho Chi Post serves as both a creative and educational platform that allows students and faculty to collaborate in sharing their knowledge with the pharmacy community. Unlike other pharmacy organizations at St. John's, it also allows for the unique experience of expanding research and writing skills outside of the classroom setting. As pharmacy students, it is imperative we continue to educate ourselves as the world of healthcare is ever-changing. I am honored to be a part of the Rho Chi Post's Editorial Team and look forward to serving as this year's Editor-in-Chief!

Sharupa Azmal
Editor-in-Chief

The Rho Chi Post serves as a testament to the dedication and intellectual curiosity of the pharmacy community at St. John's University, providing a platform for our students to share knowledge and grow as healthcare professionals. It is my privilege as the Editor in Chief to continue our mission to amplify the voices of our writers and educate our readers regarding current events in healthcare and the dynamic landscape of pharmacy.



Bao Qi Chen
Senior Content-Focused Copy Editor

The Rho Chi Post is a bridge between students and the world we will soon enter once we graduate. My ambition is to promote intellect, values, and opportunities that not only allow students to be heard but also impact the pharmacy profession as a whole. I am honored to be a part of the Rho Chi Post's editorial team and work with colleagues who share this ambition. I am excited and grateful for this opportunity, and I look forward to working with everyone!



MEET THE TEAM



Warda Basher

Senior Content-Focused Copy Editor

Joining this esteemed team excites me with the opportunity to gain invaluable experience and insights into the latest trends in pharmacy. I am eager to expand my professional network and make significant contributions to the field. As a member of the editorial team, I'll be at the forefront of disseminating the most current news and knowledge, effectively impacting pharmacy professionals worldwide with timely and relevant information.

Ramesa Anan

Content-Focused Copy Editor

Being in the Rho Chi Post means being part of an environment that allows me to grow both academically and professionally in the field of pharmacy. It means being able to participate with like minded individuals who strive to grow in the field of pharmacy by publishing newsletters with relatable and useful content. I hope to contribute to the continuing success of this student-operated newsletter and aid my team to the best of my ability.



Sameeha Arshad

Content-Focused Copy Editor

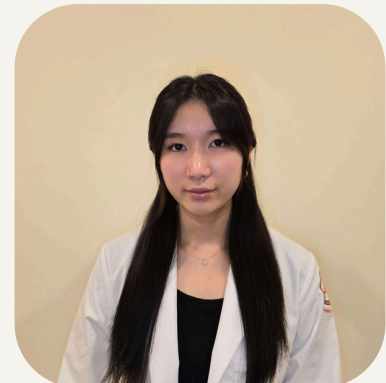
To me, being a part of the Rho Chi Post means being part of a community that values knowledge sharing, collaboration, and making a positive impact in the field of pharmacy. It provides me with a platform to contribute meaningful insights, engage with fellow pharmacy students, and inspire others through informative articles and discussions. The opportunity to be a part of this publication is both rewarding and enriching, allowing me to grow professionally and connect with a diverse audience passionate about pharmacy and healthcare.



Amanda Kim

Content-Focused Copy Editor

Being part of the Rho Chi Post means having the opportunity to help actively contribute to the advancement of the pharmacy profession. As an editor, I will be able to enhance my own writing, be inspired, and share the new innovations/issues within healthcare with my peers. I am very excited to join the team this year!



MEET THE TEAM



Laiel Bravo
Content-Focused Copy Editor

The Rho Chi Post has been a segway for pharmacy students to immerse themselves in valuable research work, advancements, and issues within the field. As future pharmacists, it is important to be informed of the latest news and gain insight from the experiences/ideas of others so that we are equipped to further improve the healthcare system. I aspire to use this opportunity to not only enhance my own preparedness but also to help enhance my peers in being ideal professionals who provide exemplary care to patients.

Zainab Masood
Senior Graphics-Focused Copy Editor

Being part of Rho Chi Post, which provides information on discoveries and research to others, is an honor. Taking insight from professionals and peers to educate others is a rather significant effort in the expanding and evolving role of pharmacists. I look forward to collaborating with the team in pushing this effort further while also learning from them.



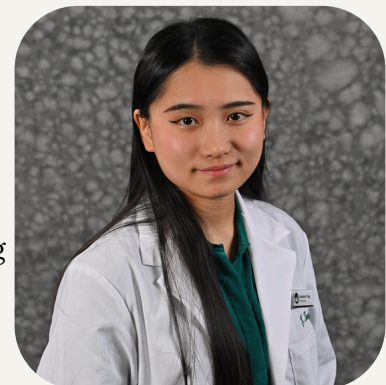
Nalisha Xu
Graphics-Focused Copy Editor

By becoming a part of the Rho Chi editorial team, I wish to learn more about the pharmacy field and community by gaining insight through our publications. This position will not only allow me to broaden my views on the profession of pharmacy, but also explore topics related to the medical field as a whole. Through Rho Chi's team, I will utilize this experience to grow professionally, develop leadership skills, and be more involved in our community to improve my confidence and professionalism on my journey to becoming a pharmacist.



Jennalynn Fung
Senior Staff Editor

I am thrilled to have the opportunity to express my creativity, critical thinking, and research skills through contributing to the Rho Chi Post. The mission to promote intellectual discourse and showcase diverse perspectives aligns with my values; I look forward to putting my writing and editing experience to use in each issue, and hope that my involvement can ensure that future cohorts will also have this valuable platform available to them.



MEET THE TEAM



Sharupa Azmal
Senior Staff Editor

The Rho Chi Post serves as a notable forum for pharmacy students who wish to expose themselves to medical journalism. Being a staff editor of the Rho Chi Post means amplifying the voices of our writers and educating our readers regarding current events in healthcare. This role provides me with the opportunity to present insightful stories that are relevant to the pharmacy community and contribute to the advancement of the profession through writing.

Anya Geiling
Staff Editor

Hello! My name is Anya, and I am very grateful to be a part of Rho Chi Post. As a rising Sophomore studying Nursing, I have a passion for understanding and sharing research about the medical field. I am ecstatic to be able to utilize my editing skills to assist with medical-related articles.



Wajiha Uddin
Staff Editor

The Rho Chi Post is a robust community of pharmacy students that are dedicated to fostering growth and sharing newest technologies and innovations in pharmaceutical practice. Being part of the Rho Chi Post means being involved in the supportive network of peers that share a passion for pharmaceutical education, practice, and the drive for contributing to the advancement of pharmaceutical knowledge.



Christiana Popovic
Staff Editor

As a member of the Rho Chi Post, I would be part of a professional community that shares insights, advancements, and challenges within the field of pharmacy. The Rho Chi Post not only empowers and educates, but it shapes the future of pharmacy through its engaging and concise writing.



MEET THE TEAM



Christine Mauceri
Senior Staff Writer

Every student deserves a voice, and to me, being a part of the Rho Chi Post allows us to make that voice heard. Whether it's through opinion pieces, talking about personal experiences, or educating on new pharmacy advancements, this newsletter sticks to its mission of promoting the pharmacy profession. As a Staff Writer, I am excited to learn, grow, and make meaningful contributions to the profession!

Rand Ayoub
Staff Writer

Being in Rho Chi Post gives us the opportunity to shed light on crucial topics within healthcare to the St. John's Community. By using the skills and information given to us in our academic classes, this organization offers a chance for people to build on those skills and be able utilize them for the better. I look forward to contributing to Rho Chi Post as well as learning from an amazing group of people!



Nivaj Haque
Staff Writer

Joining the Rho Chi Post will allow me to merge my analytical skills with my passion for public health, within the rapidly evolving field of pharmacy. This role helps keep us at the forefront of pharmacy innovations and enables me to contribute to keeping our pharmacy community well-informed. I'll explore new research and policy changes, aiming to enhance our collective understanding and application of pharmacy practices that positively impact patient care and healthcare delivery. I'm excited about starting this role and engaging in discussions that shape the future of our profession.



Rebecca Sabzanov
Staff Writer

Being part of Rho Chi Post is an exciting opportunity for me to merge my passions for writing and pharmacy in a prestigious organization. I'm enthusiastic to contribute to such a respectful organization and collaborate with other members of the Rho Chi Post to produce meaningful content that will impact others.



MEET THE TEAM



Ameena Qadri
Staff Writer

Being a member of the Rho Chi post means a great deal to me because it is the perfect outlet for me to write about pharmacy related topics that interest me the most. I feel that the Rho Chi post will also allow me to develop my writing skills both professionally and creatively. I sincerely appreciate your consideration and I am looking forward to joining the team!

Michelle Flores
Staff Writer

My name is Michelle Flores and an incoming fourth year pharmacy student. Having the opportunity to be a Staff Writer gives me the chance to educate others about pharmacy news. Pharmacy is a field that is constantly evolving and as future pharmacists, it is our responsibility to continue learning. Maintaining current knowledge benefits not only our patients but also enriches our own expertise. I'm thankful and excited to be a part of Rho Chi Post as a Staff writer this upcoming year!



Amanda Nakhul
Staff Writer

Hello! My name is Amanda Nakhul, I'm a rising sophomore and biomedical sciences major. I'm rather new to St. John's, so being a part of a high-quality collaborative organization such as the Rho Chi Post means the world to me. As a Staff Writer I am able to incorporate my passion for writing with my appreciation for Pharmacy and medicine. The Rho Chi Post provides a foundation for student-operated publications and it is an honor to be included in this journey.



Royal Mussaleen
Staff Writer

As a member of the Rho Chi Post, I see this as an opportunity to enhance the pharmacy profession. By highlighting the diverse roles pharmacists play; from ensuring medication safety and efficacy, conducting research, advocating for patient safety, to analyzing healthcare trends like telepharmacy and personalized medicine, and advancements in gene therapy and immunotherapy; I aim to showcase the impact pharmacists have on society's well-being. I intend to offer engaging perspectives on pharmaceutical developments, healthcare policy changes, and the role of pharmacists in regulatory affairs. Through my contributions, I hope to spark curiosity in our readers to explore the underlying reasons and mechanisms behind these processes.



MEET THE TEAM



Ariella Zadrina

Staff Writer

As a pharmacy student and future pharmacist, I believe it is a quintessential duty to educate ourselves on current media regarding the medical field and continuously adapt to the new ideas we may face as we enter the pharmacy profession. With topics from emerging diseases to scientific advances made, it is important to be accustomed to new ideas that pertain to our potential responsibilities as a pharmacist. As a Rho Chi Staff Writer, I hope to discuss matters that will inform not only pharmacy students but the St. John's community as a whole on topics that have to do with general health and scientific developments. With my interest in writing and the pharmacy field, I hope to touch upon subjects passionate to me that can benefit our community and inspire our readers to integrate themselves into the ever-growing profession of pharmacy.

MEET THE TEAM

Social Media & Outreach



Maliha Akter

Engagement & Outreach Manager

In my pursuit of becoming a knowledgeable and skilled pharmacist, I remain committed to staying informed about disease treatment and public-health policy. Being a part of Rho Chi Post provides an excellent platform for continuous education and knowledge-sharing with peers. Engaging with individuals from diverse backgrounds fosters critical viewpoints and discussions, all focused on enhancing patient-centered care. Additionally, the newsletter enables me to nurture my lifelong passion for writing while staying updated on the latest healthcare developments. As I embrace this transformative journey, I am dedicated to adapting, learning, and making a positive impact on patient well-being as a compassionate and competent pharmacist.

Bhojranie Brahmanand Engagement & Outreach Manager

The Rho Chi Post uses its platform to spread knowledge of groundbreaking discoveries that are changing the standard of care for society. It delivers a creative and innovative scope of the pharmacy world. As a school of pharmacy, it is pivotal to become aware of healthcare matters. In turn, we can strengthen our understanding of the field and become more competent pharmacy practitioners. I am excited to be joining the team this year as a staff writer. I look forward to working alongside like-minded individuals in cultivating writing pieces that will share the importance of this profession.



Paulina Maczko

Engagement & Outreach Manager

As pharmacy students, I believe we have an obligation of staying informed on current healthcare topics, topics that the Rho Chi Post sheds light on.

To be part of such a team is an honor, as students are granted the opportunity of a creative outlet, whether that is by writing the articles or organizing the newsletter. As a copy editor, I look forward to seeing first-hand how students voice their opinions, thoughts, and academic learnings. I'm grateful to be part of a team that allows students to understand what they are capable of, and simultaneously advance their writing, comprehension, and communication skills.



MEET THE TEAM

Social Media & Outreach

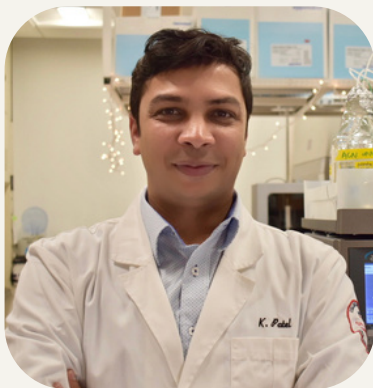


Celestine Van Sertima
Engagement & Outreach Manager

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.

MEET THE TEAM

Advisors



Dr. Ketan Patel
MPharm, PhD

It is an honor to serve as a faculty advisor of Beta Delta Chapter of a 100-year-old prestigious society of pharmaceutical professionals – The Rho Chi Society. With great enthusiasm, I am committed to assist the Rho Chi member's endeavors in: (1) disseminating the latest information/technology in healthcare system; (2) promoting pharmaceutical field & career propulsive networking of current students, alumni, and faculties; and (3) facilitating the scholastic activities and recognizing the scholars.

Dr. Mohammad Rattu
PharmD, BCOP, BCPS, BCGP

I am thankful to have been the 2012 editor-in-chief of the Rho ChiPost 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.



The Rho Chi Society

Executive Board

Esther Lee

President



Rho Chi Society is an academic honor society comprised of only the brightest in pharmacy that embodies its core values of intellectual achievement, critical inquiry, ethical standards, collaboration, and fellowship. Through various opportunities that Rho Chi, and other pharmacy organizations alike, have provided us, the members of Rho Chi are thankful for the guidance of the pharmacy professionals who preceded us and feel a profound sense of responsibility to extend the same support and mentorship to future generations. Driven by the same commitment to academic excellence and desire to both advance and contribute to the profession, our various academic committees, networking events, and service to community initiatives, have provided an abundance of opportunities for each member to develop their personal and professional skills, explore their interests in pharmacy, form valuable relationships, and mentor the next generation of pharmacists.

Sharupa Azmal

Vice President

The Rho Chi Society cultivates intellectual curiosity and fosters students to be strong leaders and advocates for the pharmacy profession. Over the years, the events and initiatives offered by Rho Chi have played a pivotal role in shaping my sense of professionalism while nurturing a constant desire to reach my full potential. Being a member of Rho Chi signifies a commitment to excellence in every aspect of pharmacy. As Vice President, I hope to inspire both my peers and underclassmen to pursue their best selves, not only academically but personally, while embodying the core values of leadership, integrity, and service that are at the heart of our organization.



Nalisha Xu

Secretary

Rho Chi's society creates an environment for everyone to support each other on their way to professionalism. It connects everyone through a foundation of pharmacy society to sharpen and promote communication, networking, and leadership skills. It is a community that gives everyone a sense of belonging and inclusiveness, as well as providing room for each individual to explore their own specialty and impact on the pharmaceutical field.



Jamila Chowdhury

Treasurer

Rho Chi Pharmacy Honor Society is a prestigious organization that promotes academic excellence, leadership, and community among future leaders in pharmacy. By fostering collaboration and encouraging the pursuit of high scholarly achievements, Rho Chi members are able to learn from each other and maximize their growth as future healthcare professionals. The society provides a platform for aspiring pharmacists to lead with integrity, share knowledge, and make a positive impact on the field of pharmacy and healthcare as a whole.



The Rho Chi Society

Executive Board



Isabel Gendin

Historian

Rho Chi Pharmacy Honors Society provides an environment that fosters academic excellence among pharmacy students and also explores the various aspects of the pharmacy field. As the Historian and Development and Outreach Coordinator, I view this organization as a powerful platform to encourage one another to aim for success within our academics, as well as building communication, leadership, and professional growth. Not only are we growing our pharmacy knowledge within the classroom, but Rho Chi allows students to explore the diverse pathways within the field through networking, leadership events, and collaboration. I am very honored to be part of a society that drives both personal and professional growth, and I am dedicated to upholding our mission to uplift future leaders in pharmacy.

Kelly Yeung

Academic Committee Chair

Rho Chi Society is a distinguished academic honor society where students can collaborate and help each other, while following the core values of professionalism, service, and leadership. I am honored to accept my position on the executive board of this academic year and I hope to fulfill my duties so I can contribute to allow Rho Chi to positively impact the pharmacy society and help other fellow pharmacy students.

