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RHO Px CHI post

VOLUME 5, ISSUE 6

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

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The Rho Chi Society encourages and recognizes excellence in intellectual achievement and advocates critical inquiry in all aspects of Pharmacy

The Society further encourages high standards of conduct and character and fosters fellowship among its members

The Society seeks universal recognition of its members as lifelong intellectual leaders in Pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession

RHO Rx CHI post

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Sang, Guang, Bianca, Rafi, Karen, and Ajla (from left to right), pictured with Dr. Zito

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RHO CHI POST: TEAM MEMBERS

@ Davidta Brown

5th Year, STJ; Editor-in-Chief

My two great loves are innovative science and quality writing; the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.

@ Katharine Cimmino, PharmD

Graduate Copy Editor [Content-Focused]

I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.

@ Bharat Kirthivasan, PhD

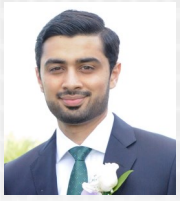
Graduate Copy Editor [Content-Focused]

I received my doctorate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Tasnima Nabi

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

Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community. I look forward to bringing pertinent information to the newsletter.



@ Fawad Piracha

6th Year, STJ; Finance and Outreach Manager

I am delighted to join the editorial team. I have the firm intention of broadening readership and facilitating growth of the Rho Chi Post.

@ Jack (Hongkai) Bao

4th Year, STJ; Staff Editor

In my 3rd year of pharmacy school, I was introduced to the Rho Chi Post, an award-winning newsletter run by students. My involvement began by simply reading monthly articles, but as time passed, my passion for writing grew. Coupled with my interest in pharmacy, I made the initiative to apply for a position. Now, as a team member, I believe that the Post is a great way for students and faculty to stay up to date concerning pharmacy news.

@ Sang Hyo Kim

4th Year, STJ; Section Editor: Puzzles

Advancing technology and medicine, as well as prolonging the lifespan and improving quality of life, have increased the geriatric population. Pharmaceutical industries and healthcare systems persistently work to find solutions to changing demands and new problems of the society. I wish to learn, educate, and prepare myself and others for the future.

@ Svetlana Akbasheva

6th Year, STJ; Section Editor: Clinical

I am very excited and honored to be part of the Rho Chi Post! In a profession that is constantly evolving with new developments, it is so important to remain informed and current. The Rho Chi Post helps do just that, and I look forward to contributing to this unique publication.

@ Nicollette Pacheco

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

As a new member of the Rho Chi Post team, I have a vast appreciation of what it means to be a future pharmacist in the rapidly evolving world of healthcare. I am looking forward to being on the team as a graphics-focused staff editor, and I hope to bring my passion for science and creativity to the Rho Chi Post.

@ Tamara Yunusova

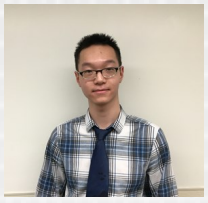
5th Year, STJ; Copy Editor [Content-Focused]

I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

@ Joshua Bliss

6th Year, STJ; Social Media Manager

By providing student-organized, reliable healthcare information, the Rho Chi Post helps us all in fulfilling our education both in and out of the classroom. Education is the tool we use to set paths for our futures, and every chance to expand our education is a chance at building a better future. I am honored to be a part of the Rho Chi Post & look forward to the future!



@ Alex Chu

3rd Year, STJ; Staff Writer

With a constantly evolving healthcare field, it is imperative that we keep ourselves up to date with the latest news. This is what led me to join the Rho Chi Post, which constantly comes out with interesting and informative topics. It is an honor to write for the Rho Chi Post, and I wish to contribute innovative and intriguing articles to this newsletter.

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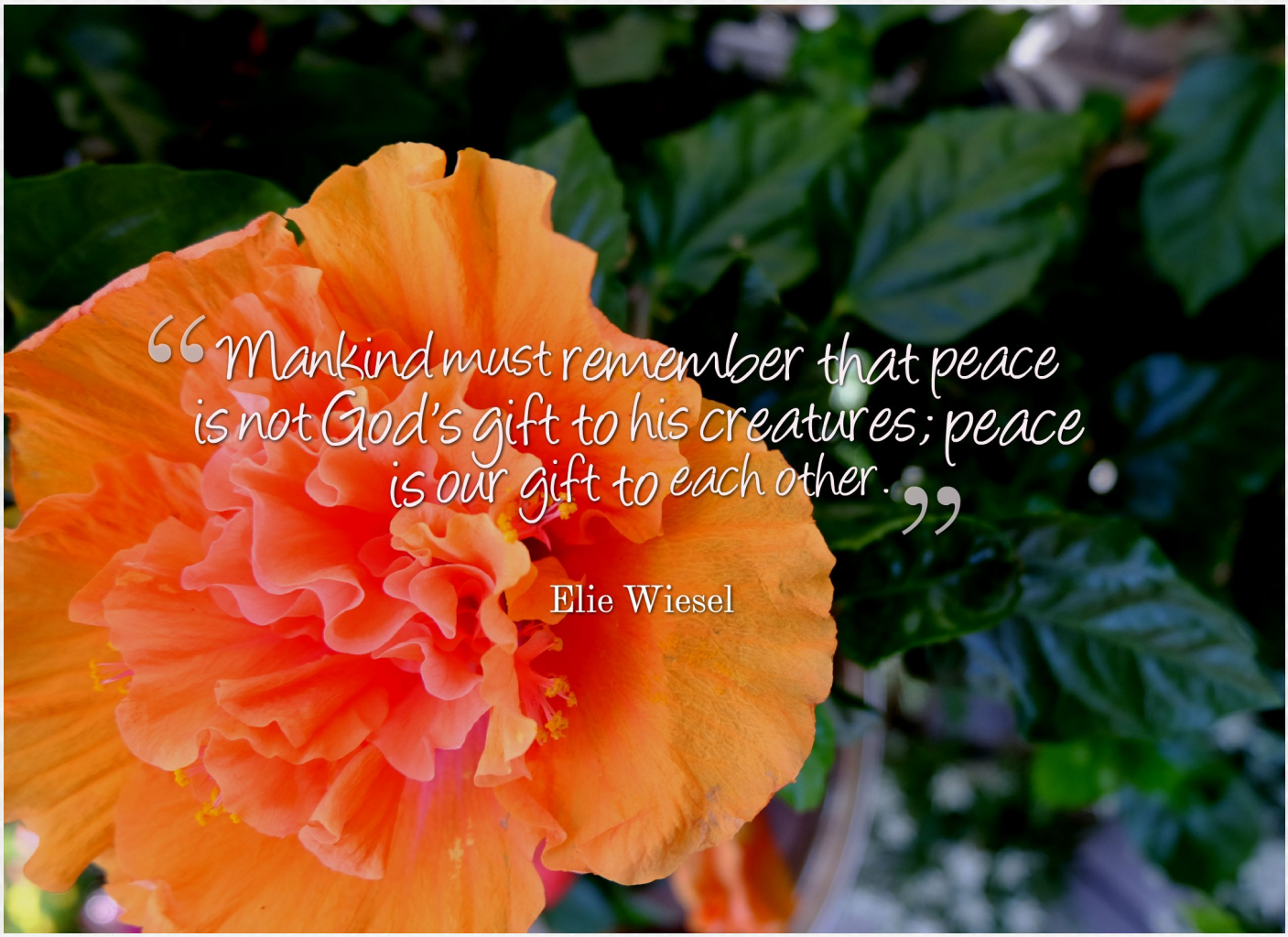
QUOTE OF THE MONTH

By: Nicollette Pacheco, Staff Editor [Graphics-focused]



A Primer on HIV Pre-Exposure Prophylaxis (PrEP)

By: Svetlana Akbasheva, Section Editor (Clinical)

Despite the advances in the treatment of human immunodeficiency virus (HIV), the incidence of HIV transmission remains alarmingly high, with about 50,000 new cases arising every year in the United States alone.[1] Recently, HIV management has turned its focus on prevention for high-risk, uninfected individuals in addition to treatment of those with established disease. Currently, the only medication approved for HIV pre-exposure prophylaxis (PrEP) is Truvada®, a once-daily combination pill containing the nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs) tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg.[2,3]

The U.S. Public Health Service and Centers for Disease Control and Prevention (CDC) guidelines recommend PrEP for sexually active men who have sex with men, heterosexual men and women, and injection drug users who are at high risk for acquiring HIV. PrEP is also recommended for serodiscordant heterosexual couples, in which only one partner has HIV, as a form of protection if they are trying to conceive a child. However, before any of these patients can receive PrEP therapy, they must be screened for several parameters.[2,3]

Most importantly, candidates for PrEP must have a negative HIV test, as Truvada® use alone in active HIV infection may be ineffective and breed resistance. In addition, patients must be screened for Hepatitis B infection and receive the vaccine if they have not already done so. Renal function is another baseline screening parameter, as Truvada® is potentially nephrotoxic and should not be used for PrEP in individuals with a creatinine clearance less than 60 ml/min.[2,3] Eligible individuals should receive a maximum 90 day supply of medication and need to follow up with their provider every three months for monitoring and counseling.[2] An HIV test and a pregnancy test for females needs to be administered during each follow-up visit. Renal function testing is recommended three months after initiating PrEP therapy and then every six months, though more frequent monitoring is advised if a patient has other risk factors for renal impairment such as hypertension, diabetes mellitus, or co-administration of other medications that may affect renal function. Since PrEP does not protect against other sexually transmitted diseases (STDs), patients should be counseled about the importance of using condoms in conjunction with oral PrEP therapy and should be screened for STDs every six months.[1,2]

Several key studies have demonstrated the efficacy of PrEP in preventing new HIV infections in high-risk patients. The iPrEX study was a randomized controlled trial of PrEP versus placebo in 2499 seronegative men who have sex with men which found that PrEP reduced the incidence of HIV infection by 44% (95% CI, 15% to 63%). When the results were adjusted to include only subjects with detectable drug levels, an indication of adherence to the medication, the relative risk reduction with PrEP therapy became 92% (95% CI, 40% to 99%).[4] A second study, called The Partners PrEP study, was a randomized trial of serodiscordant heterosexual couples comparing tenofovir and tenofovir-emtricitabine, respectively, versus placebo for HIV prophylaxis. The results showed that the relative risk reduction for patients on tenofovir-emtricitabine was 75% (95% CI, 55% to 87%), though it jumped to 90% for patients with detectable drug levels in their system.[5] Another trial of tenofovir-emtricitabine versus placebo in 1219 HIV-negative heterosexual men and women showed that the combination pill had 62.2% efficacy in preventing HIV infection (95% CI, 21.5% to 83.4%).6 The Bangkok Tenofovir Study focused on the efficacy of tenofovir as PrEP in another high-risk group, injection drug users.[7] This randomized, controlled trial found that tenofovir reduced HIV incidence by 48.9% compared to placebo in this population (95% CI, 9.6% to 72.2%).7 In these studies, the rates of serious adverse effects were found to be similar between the active drug and placebo groups, though tenofovir and tenofovir-emtricitabine were found to cause more nausea and decreases in bone mineral density.[4,6,7]

All of the above studies demonstrated that patients with detectable levels of drug in their system had increased protection against disease acquisition, showing that adherence is key for PrEP efficacy.[4-7] Pharmacists can play an important role in HIV prophylaxis by providing PrEP education, monitoring for adverse effects and drug interactions, and counseling patients on the importance of adherence.[8] Patients who are worried about the expense of PrEP therapy should be told that many

insurance plans cover PrEP and Gilead Sciences offers medication assistance programs for patients without insurance.[1] With no cure for HIV on the horizon yet, prophylaxis is fundamental to curbing the HIV epidemic, and the simplicity and proven efficacy of the currently recommended PrEP regimen will hopefully make this an easy pill to swallow.

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FDA Approves New Combo Pill Genvoya® for HIV-1 Infection

By: Alex Chu, Staff Writer

On November 5th 2015, the U.S Food and Drug Administration approved Genvoya®, a once daily tablet containing a combination of elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (TAF) for the treatment of HIV-1 infections in adults and pediatric patients age 12 or older.[1]

Genvoya® is a combination of antiretroviral drugs that target the HIV virus in different ways. Elvitegravir is an integrase strand transfer inhibitor, which prevents proviral gene incorporation into human DNA.[2] Emtricitabine is a cytosine analogue, and tenofovir alafenamide is converted to an analog of adenosine 5'-monophosphate.[2] They interfere with HIV DNA polymerase production, therefore inhibiting viral replication. Cobicistat is a CYP3A subfamily enzyme inhibitor, which enhances systemic exposure to elvitegravir.[2]

A contributing factor towards the approval of Genvoya® was its favorable outcome during the clinical trial phase. Five clinical trials were conducted targeting the safety and efficacy of Genvoya® in various populations. Studies 104, 111, and 109 compared the safety and efficacy of Genvoya® as compared to tenofovir disproxil fumarate (TDF) treatments in both treatment naive and virologically suppressed adults over the course of 48 weeks, while Studies 112 and 106 tested the safety and efficacy of Genvoya® in virologically suppressed adults with renal impairment, and in treatment-naive adolescents over 12 years of age through 24 weeks.[3]

In Studies 104 and 111, 1,733 treatment naive adults were randomly assigned either Genvoya® or Stribild® 1:1 in a randomized, double blinded, actively controlled trial.[3,4] Stribild® is another form of antiviral treatment that contains the same active ingredients as Genvoya®, except that it contains TDF instead of TAF. Of the 1,733 participants, 866 received Genvoya® with 92% having an HIV RNA viral value of >50 copies/mL.[3] 867 received Stribild® with 90% having a viral value of >50 copies/mL.[3] The results of the 48 week trial determined that there was no difference in efficacy of viral treatment between Genvoya® and Stribild® Additionally, there was no statistical difference in frequency of adverse reactions.[3] Study 109 determined efficacy of treatment in patients switching from a current HIV treatment regimen containing TDF (Atripla®, Truvada®, or

Stribild®) to Genvoya®. The subjects had a suppressed viral value of >50 copies/mL.[3] Results have shown that Genvoya® is statistically non-inferior as compared to antiviral treatment containing TDF (96%[n=799] vs 93% [n=397]).[3]

The renal and bone density effects of Genvoya® vs. Stribild® in treatment-naive subjects were analyzed and found to be statistically significant in favor of Genvoya®. Renal laboratory parameters yielded an estimated glomerular filtration rate (eGFR) of -2.0 mL/min compared to Stribild®'s -7.5 mL/min eGFR ($p<0.001$) , a bone mineral density (BMD) decrease of 1.30% vs 2.86% at the spine and 0.66% vs 2.95% at the hip.[5] The percentage of subjects who had a 5-7% reduction of BMD in the spine and hip was less in Genvoya® subjects than in Stribild® subjects (7-10% vs 19-22%).[5] In virologically suppressed adults, the BMD results were similar but there was less of a difference between Genvoya® and TDF-treated subjects (1.86% vs 1.95% for total hip, 0.11% vs 0.14% for lumbar spine).[5] Declines of total hip and spine BMD occurred more frequently in TDF-treated subjects than in Genvoya® subjects (4-6% vs 1%).[3] The safety profile of Genvoya® with 23 treatment-naive pediatric subjects was similiar to that in adults (mean BMD 1.7% increase at the lumbar spine and 0.8% increase in total body).[3] Two Genvoya® subjects had a 4% decrease in BMD at the lumbar spine.[3] There is no data of the long term effects Genvoya® may cause in terms of BMD.

A big advantage Genvoya® has over other HIV medications is that Genvoya® is the first FDA approved drug to use TAF. During testing, TAF was found to be at a high intracellular and low blood concentration.[5] During Studies 104 and 111, a 10 mg oral dose of TAF from Genvoya® resulted in a 91% reduction of concentration of tenofovir in plasma as compared to a 300 mg oral dose of TDF in Stribild®. Based on clinical trial data, it can be seen that usage of TAF causes less of an effect on BMD and renal eGFR.[5]

The recent approval of Genvoya® for HIV-1 treatment not only sets a higher standard of safety for HIV treatment regiments, but also gives patients another treatment option. With the use of Genvoya® compared to other TDF-containing drugs, HIV patients can switch their antiviral treatment with less of a risk for development and age-related comorbidities, such as renal impairment and low bone mineral density.

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An Alternative for Pulmonary Hypertension Approved

By: Jack (Hongkai) Bao, Staff Editor

On December 21st 2015, the FDA approved selexipag (Uptravi®), marketed by Actelion Pharmaceuticals US, Inc. for the treatment of pulmonary arterial hypertension (PAH) in adults.[1]

Selexipag offers a newer treatment alternative for PAH, the conventional therapy of which originally included vasodilators such as Epoprostenol (Flolan®) and Treprostinil (Remodulin®) as well as Phosphodiesterase-5 Inhibitors (PDE-5i) such as Sildenafil (Revatio®) and Tadalafil (Adcirca®). Selexipag however, is an IP (prostacylin) receptor agonist. It mimics the effects of prostacyclin, which is a major product of cyclooxygenase that causes potent vasodilation.[1]

This vasodilation is necessary in patients with PAH. PAH is a condition characterized by high blood pressure affecting the arteries of an individual's lungs. This condition can occur when arteries or capillaries in the lungs become occluded, forcing the right side of the heart to work harder to pump blood to the lungs. Ultimately, PAH can cause the right side of the heart to fail and can lead to fatal events.[2] PAH is usually asymptomatic in the first few months or years of progression. However as it continues, more serious symptoms can manifest, such as dyspnea while exercising or at rest, fatigue, dizziness, chest pain, and peripheral edema in the ankles and legs.[2] PAH can also lead to a number of complications such as cor pulmonale (right-sided heart failure), thrombosis and eventual pulmonary embolism, arrhythmias, and hemorrhage in the lungs, which can lead to hemoptysis.[2] By vasodilating the pulmonary arteries, selexipag allows blood to flow more easily, reducing the workload of the heart.

The GRIPHON trial studied the long-term effects of selexipag on morbidity, mortality, as well as its general safety and efficacy in patients.[3] Patients had a 50:50 chance of receiving either selexipag or placebo, and patients on selexipag were titrated up to the maximum tolerable dose of 200 µg to 1600 µg twice daily.[4] Of the 1,156 patients studied, selexipag had a significant impact on morbidity and mortality by reducing the risk of events occurring by 40% when compared to placebo.[4] The main adverse effects observed during the GRIPHON trial included nausea, diarrhea, myalgia, arthralgia, flushing, and pain in extremities.[4]

Selexipag was given orphan drug designation, which means that the manufacturer received the typical incentives for developing and manufacturing drugs for rare disease states such as PAH.[1] The introduction of selexipag into the market will offer an alternative for patients suffering from PAH which has been proven to be safe and efficacious.

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PUZZLES

Matching Column:

OTC Generic—Brand Names

By: Sang Hyo Kim, Section Editor (Puzzles)

1. Polyethylene Glycol	A. Orajel
2. Miconazole	B. Miralax
3. Permethrin	C. Nexium
4. Caffeine	D. Pepto Bismol
5. Benzocaine	E. Oscal
6. Combination of Calcium and Vitamin D	F. Nix
7. Famotidine	G. Monistat
8. Ranitidine	H. Pepcid
9. Bismuth Subsalicylate	I. Zantac
10. Esomeprazole	J. NoDoz

Answers
on next page

Lexi-Comp Online™, Lexi-Drugs Online™, Hudson, Ohio: Lexi-Comp, Inc.

PUZZLES: ANSWERS

1. B 2. G 3. F 4. J 5. A 6. E 7. H 8. I 9. D 10. C

We are always looking for creative and motivated students to join our team!

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

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

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

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

VALUES

Opportunity

Teamwork

Respect

Excellence

GOALS

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

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

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

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

To contribute ideas and innovations to the Pharmacy profession