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An independent chapter of the American College of Clinical Pharmacy, the DC-CCP is dedicated to improvements in pharmacotherapy practice, education, and research in the District of Columbia, Maryland, and the Commonwealth of Virginia

PRESIDENT'S LETTER

Dear DC-CCP members,

Warm greetings and Happy New Year!

As we embark on the new year, it is a wonderful time to reflect on all we have accomplished together in 2019. We kicked off the year with our fifth annual Advocacy Day on Capitol Hill, where students from Shenandoah and University of Maryland Schools of Pharmacy united to represented pharmacy. Student engaged with their respective legislators on the vital role of pharmacists within the healthcare system and the implications of the Social Security Act on the status of pharmacist providers.

At our fall CE Forum, expert speakers led innovative presentations on various clinically relevant topics including the utility of corticosteroids in ventilator-dependent neonates and enhancement of medication safety among diverse patient populations. At the residency round table following the forum, our panelists engaged with students and entertained questions on all phases of residency training.

In 2019, our newly minted Membership committee has also taken a renewed approach to enhance our association's membership. Likewise, the Awards and Philanthropy Ad-hoc committees we have instituted looked to find creative ways to streamline and expand the impact of our organization.

Our philanthropic efforts for 2019 focused on supporting the House of Ruth, a local non-for-profit organization. The goal of the ongoing End-of-Year Fundraising drive is to generate $500.00 for the House of Ruth. Please make all generous contributions to https://dcccp.wildapricot.org/donate and www.houseofruth.org to learn more about House of Ruth.

The year ahead is going to bring important and exciting opportunities to promote our profession and enhance the national impact of DCCCP.

As your current President, I encourage all members to become active participants within our various committees and to serve on our executive leadership positions.

It has been a tremendous honor to lead with our current executive committee and I am thankful for the contribution of each member to the success of DCCCP. Thank you all for stepping up whenever duty calls!

Wishing all of you a wonderful holiday and a Happy New Year!

Sincerely,

Memar Ayalew, Pharm.D.

ID Clinical Pharmacy Specialist

DC-CCP President 2019-2020

ACCP Student Chapter reports

SHENANDOAH UNIVERSITY BERNARD J. DUNN SCHOOL OF PHARMACY

Sylvie Dzobosse, 2nd year Student Pharmacist

Mock OSCE | Fall 2019

The Shenandoah University (SU) Chapter of ACCP was involved in a variety of activities throughout the fall semester of 2019. A major event we held during the fall semester was a mock OSCE with ACCP. On September 20-21, 2019, approximately 60 SU students sign up to practice their over-the-counter (OTC), communication, and physical assessment skills in a mock OSCE. ACCP provided a simulation which mimic the flow, grading, and setup of an authentic patient encounter. OTC cases focused on heartburn and cough/cold. For physical assessment, students performed blood pressure, heart rate, and respiratory rate. For communication, students provided counseling on side effects of medications. An evaluator and patient were present in the room and students received feedback shortly after the event concluded. Based on the feedback we received from our students, the mock OSCE was a rewarding experience and tremendously help boost their confidence level!

HOWARD UNIVERSITY COLLEGE OF PHARMACY

Howard University College of Pharmacy and members of ACCP partnered with Trusted Health Plan through one of our clinical faculty members. We attempted to provide access to flu vaccinations in areas where people might not have access. It was difficult because although some people expressed interest in getting vaccinated, many people did not want to because they were afraid of the vaccine. Some patients expressed fear that they would get sick, others expressed with the government mandating that they get vaccinated. Overall, multiple student organizations collaborated on the vaccination of over 50 patients. We did this working hand in hand with Giant Pharmacy staff members and they were delight to work with. They were able to provide us with educational materials and checked in with us during the vaccination sessions. We additionally spent time talking to people about vaccine schedules and other necessary immunizations- one woman even got her pneumococcal as she had already gotten her influenza vaccine. Pictured here is Willis March, ACCP president who participated in the event.

UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

Raddison Floresca, 3rd year student pharmacist

As part of ACCP-SCCP's mission, this involves getting students familiar with the many aspects of clinical pharmacy. One of the major events that the UMSOP ACCP Student Chapter had following this was our first journal club of the year, held on October 8, 2019. In addition to the knowledge acquired during our didactic courses, journal clubs expand upon these and apply the concept of Evidence-Based Medicine (EBM), utilizing the recent literature that takes emergent or existing treatment and compares these to different populations, disease states, or even against the standard of care. Journal clubs are one of the essential activities that keep clinical pharmacists to date with treatments, especially when optimizing a patient's treatment to lead to the best outcome.

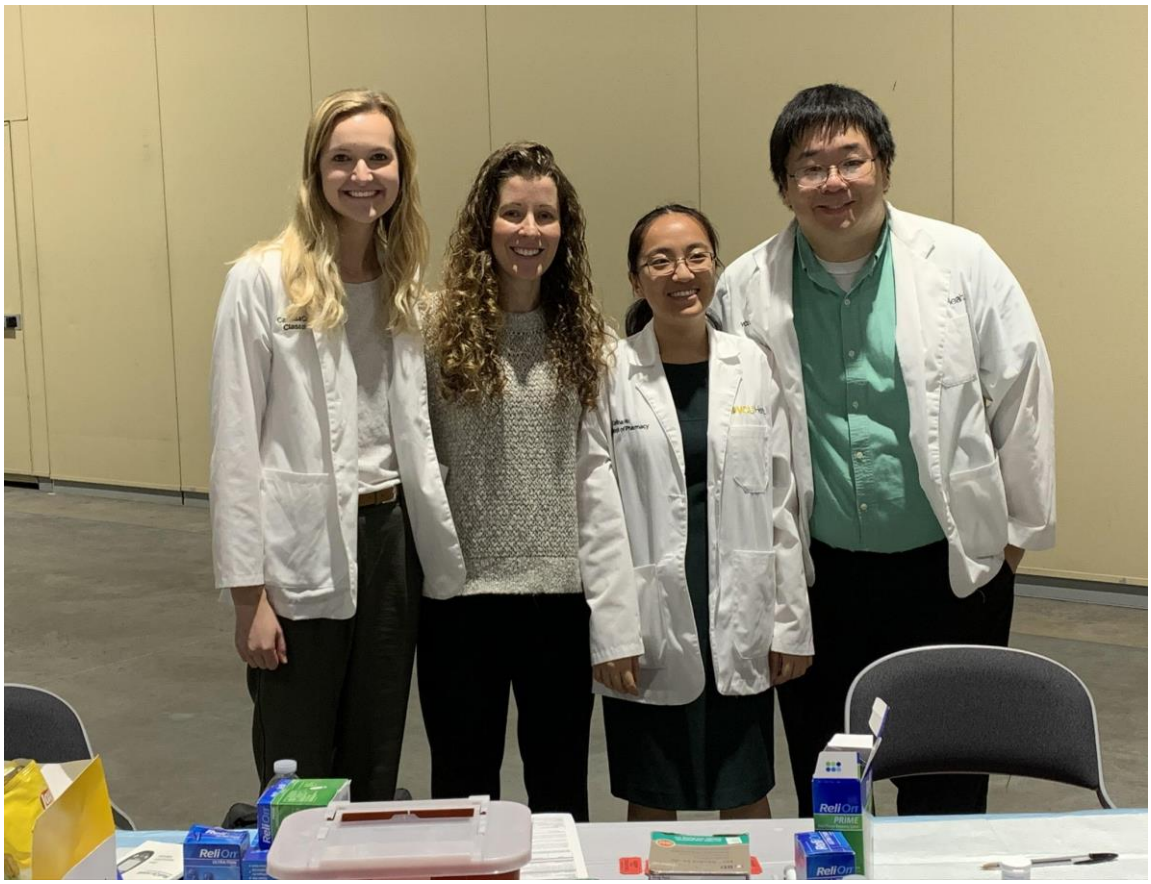
We had Dr. Ashley Barlow, a PGY1 resident at the University of Maryland Medical Center come in and discuss "Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction." Dapagliflozin is primarily indicated for the treatment of Type II Diabetes Mellitus as a SGLT2 inhibitor. However, when used in patients without diabetes and with HFrEF, this led to a significant reduction in worsening heart failure or mortality from cardiovascular causes. Nonetheless, Dr. Barlow reminded us that regardless of the results, we can only utilize the results to practice if our patient population at our site aligns with the subjects used in the study. We hope to have more students join us in our future journal club!

VIRGINIA COMMONWEALTH UNIVERSITY SCHOOL OF PHARMACY

Katie Jones, 3rd year student pharmacist

The Virginia Commonwealth University Chapter of ACCP-SCCP coordinated a community outreach event at the Spirit of the Heart Health and Wellness Fair hosted by the Association of Black Cardiologists. This event was free to the Richmond community and provided opportunities for health screenings, such as body mass index assessments and education on chronic disease management. Community members were also given the chance to get up to date on vaccinations!

Our student volunteers provided blood pressure and glucose screenings and answered questions while providing feedback on patients' results. Education and counseling focused on patient-centered lifestyle modifications provides information on the effects of consistent exercise and healthy diet choices. Medication adherence was another impactful topic of discussion with patients. Students offered support for patients who reported frequent missed doses of medications by emphasizing how adherence affects the success of treatment and making recommendations for improvements. Usage of weekly pill boxes and medication reminders were some interventions utilized along with providing information on cost-effective ways to obtain prescriptions in a timely manner. Having that conversation alongside the screening process was a valuable motivational tool for patients, and we hope to have made a lasting impact on our community!



FDA approves oral semaglutide for the treatment of type 2 diabetes

Jessica Woodward, PharmD Candidate 2020, University of Maryland School of Pharmacy

The FDA approved the first oral glucagon-like peptide 1 (GLP-1) receptor agonist, semaglutide (Rybelsus), on September 20, 2019 for the treatment of Type 2 Diabetes in adult along with diet and exercise to improve control of blood glucose.[1] This approval is a potentially significant advancement in the treatment of type 2 diabetes by offering a non-injectable formulation of a GLP-1 receptor agonist. Clinicians and patients may be more willing to use a GLP-1 receptor agonist now that it is in a more convenient formulation which could potentially expand the utilization of this effective medication class.[2]

Clinical Trial[3,4]

The trial *Efficacy and Safety of Oral Semaglutide Versus Placebo in Subjects with Type 2 Diabetes Mellitus Treated With Diet and Exercise Only* (PIONEER 1) was a multicenter, randomized, double-blind, placebo-controlled trial that included adults with type 2 diabetes that was uncontrolled with diet and exercise. Patients were randomized to either oral semaglutide 3 mg, 7 mg, 14 mg, or placebo. The primary end point was the change in HbA_{1c} from baseline to week 26. This study showed a change in HbA_{1c} of -1.2 and -1.4 in patients receiving oral semaglutide 7 mg and 14 mg respectively, compared with a change of -0.3 in those receiving placebo. Patients taking oral semaglutide 7 mg and 14 mg daily also achieved a HbA_{1c} <7% in 69% and 77% of the patients compared with 31% of patients taking placebo. The adverse events observed were similar with those in the GLP-1 receptor agonist class with the most common being gastrointestinal adverse events.

In conclusion, this trial showed that oral semaglutide alone significantly lowered HbA_{1c} compared with placebo while having similar adverse events as other GLP-1 receptor agonists.

References:

1. FDA approves first oral GLP-1 treatment for type 2 diabetes. FDA. http://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-glp-1-treatment-type-2-diabetes. Published September 20, 2019. Accessed October 14, 2019.
2. FDA approves Rybelsus® (semaglutide), the first GLP-1 analog treatment available in a pill for adults with type 2 diabetes. Novo Nordisk. http://www.novonordisk-us.com/media/news-releases.html. Published September 20, 2019. Accessed October 14, 2019.
3. Aroda VR, Rosenstock J, Terauchi Y, et al. PIONEER 1: Randomized Clinical Trial of the Efficacy and Safety of Oral Semaglutide Monotherapy in Comparison With Placebo in Patients With Type 2 Diabetes. *Diabetes Care*. 2019;42(9):1724-1732. doi:10.2337/dc19-0749
4. Rybelsus (semaglutide) [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2019.

FDA Approves Xenleta, A New Antibiotic for the Treatment of Community-Acquired Bacterial Infection

Elodie Tendoh, PharmD Candidate 2020, University of Maryland School of Pharmacy

The FDA recently approved Xenleta (lefamulin), an antibiotic for the treatment of community-acquired bacterial infection (CABP). CABP is a lung infection that is caused by bacteria in the community such as Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae and Chlamydophila pneumoniae.[1] Lefamulin is both bactericidal and bacteriostatic to these causative bacteria and works by inhibiting their protein synthesis[2]. Prior to the approval of lefamulin on August 19, 2019, CABP was treated empirically with amoxicillin, doxycycline or a macrolide.[3] This new antibiotic serves as an additional option for the treatment of CABP.[4] Lefamulin has two formulations, including an intravenous option and an oral option. It is dosed twice a day and the duration of treatment is 5 to 7 days.[2] Some common adverse effects include nausea, diarrhea, injection site irritation. QT prolongation is one of the serious adverse effects caused by this medication and so should be avoided in adults taking other medications such as haloperidol or quetiapine which also prolong the QT interval.[2]

Clinical Trials[5,6]

Two clinical trials were carried out to evaluate lefamulin. The first trial enrolled 551 patients and was conducted from September 2015 to May 2017. It was a randomized double-blind, double-dummy study comparing the efficacy and safety of lefamulin to moxifloxacin with or without linezolid for the treatment of CABP. Participants included in this trial were adults older than 18 who had signs and symptoms of CABP and who had not taken any medications. The second trial enrolled 738 participants and was carried out from August 2016 to January 2018. It was also a randomized double-blinded double-dummy study comparing the efficacy and safety of lefamulin to moxifloxacin in the treatment of CABP. In this trial, linezolid was excluded and only the oral formulations for both medications were used. The studies included consented adults older than 18 years who were acutely ill with signs and symptoms consistent with that of CABP. Both trials enrolled 1289 patients in more than 100 sites around the world including the United States, Europe, Africa, and Asia.

The primary endpoint of both studies was the relief of at least 2 symptoms common with CABP (dyspnea, purulent cough, pain when coughing, difficulty breathing) after 72 to 120 hours of initial treatment. The results of the studies were consistent with the primary endpoint which resulted in the approval of lefamulin as another antibiotic option for the treatment of CABP.

Place in Therapy

Lefamulin is the first drug of the newest antibiotic class pleuromutilin approved by the FDA, increasing the options for the treatment of CABP[2,4]. For this reason, it is less susceptible to resistance, unlike older classes of antibiotics.[1] It is also very expensive compared to other therapeutic options that are being used today such as Amoxicillin, doxycycline, macrolides. This might prevent patients and providers from readily considering it as an option for CABP.

References:

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2. Accessdata.fda.gov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211672s000,211673s000lbl.pdf. Published 2019. Accessed October 8, 2019.
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New Drug Updates: Recarbrio™ (imipenem, cilastatin, and relebactam) for the Treatment of Complicated UTI and Complicated Intra-abdominal Infection

Yujin Noh, PharmD Candidate 2020, University of Maryland School of Pharmacy

In July 2019, the FDA approved a new antibacterial combination, Recarbrio™, for use in patients 18 years of age and older with complicated urinary tract infection (cUTI) including pyelonephritis and complicated intra-abdominal infection (cIAI)[1]. It is recommended to be used in patients with limited treatment options.[1] The combination contains imipenem which is a penem antibacterial drug covering gram negative bacteria including Enterobacteriaceae, Klebsiella, and Pseudomonoas.[1] Cilastatin does not have antibacterial activity, but prevents renal metabolism of imipenem.[1] Prior to this new drug approval, Primaxin (imipenem-cilastatin) was already being used for confirmed multidrug-resistant (MDR) bacterial infections. However, with growing concerns for development of carbapenem-resistant pathogens, a novel small molecule beta-lactamase inhibitor, relebactam, is an aid to preserve or restore its activity against resistant-strains.[2]

Clinical studies[2,3]

Two phase 2 randomized trials have been conducted to evaluate dosing, efficacy, and safety of using Recarbrio™ in patients with cUTI and cIAI. In both studies, common baseline pathogens were *E. coli*, *K. pneumoniae*, and *P. aeruginosa*.

Study 1 (NCT01505634) is a non-inferiority study that involved 298 patients who met the inclusion criterion for cUTI. Participants of the study were randomized to 3 intervention groups: imipenem/cilastatin + relebactam 250mg (n=99), imipenem/cilastatin + relebactatm 125mg (n=99), or imipenem/cilastatin + placebo (n=100). Patients who showed adequate clinical response to IV therapy was converted to oral ciprofloxacin after 4 days (maximum IV therapy = 14days). Relebactam 250mg and relebactam 125mg group showed 95.5% and 98.6% microbiological response while placebo group showed 98.7% response with similar clinical responses across all groups. 95% CI above -15% indicated non-inferiority between the groups and it was concluded that both doses of imipenem/cilastatin + relebactam were well tolerated and were not inferior to imipenem/cilastatin alone therapy.

Study 2 is another non-inferiority study group that involved 351 patients with cIAI. The intervention groups in this study were same as that of the study 1. However, unlike study 1, transition to oral antibiotic therapy was not permitted. Complicated appendicitis, cholecystitis, and perforated hollow viscus were some of the common clinical diagnoses in the patient population. In this study, both relebactam 250mg and relebactam 125mg group were not inferior to the placebo group with microbiological response rate of 97.6%, 100%,

and 97.6% respectively. 7 out of 40 imipenem non-susceptible gram-negative infections had adequate clinical and microbiological responses to relebactam. However, most of the non-susceptible pathogens were not reactive against relebactam, because of their different mechanisms of resistance.

Recommended dosage[4]

The recommended dosage for cUTI and cIAI is 1.25g (imipenem 500mg, cilastatin 500mg, relebactam 250mg) IV over 30 minutes every 6 hours for 4-14 days depending on the severity, location of infection, and clinical response. It should be dose adjusted in patients with CrCl <90mL/min. Recarbrio™ should not be used in patients with CrCl <15mL/min.

Adverse events[1,4]

Common adverse events that patients could experience are diarrhea, nausea, vomiting, headache, injection site reaction, hypertension, increased liver enzymes, or fever. In addition, package insert includes some reported cases of seizures and *Clostridium difficile* associated diarrhea.

Formulation and stability[1,4]

Recarbrio™ comes in a single-dose glass vial containing a sterile powder which should be diluted with NS, D5W, D5-0.9% NaCl, D5-0.45% NaCl, or D5-0.225% NaCl. Diluted product should be further diluted in the infusion bag which is stable for 2 hours at room temperature (up to 30C°) or for at least 24hours when refrigerated (2°C to 8°C).

Reference:

1. Recarbrio™ [package insert]. Whitehouse Station, NJ: Merk&Co., Inc., 2019.
2. Prospective, randomized, double-blind, Phase 2 dose-ranging study comparing efficacy and safety of imipenem/cilastatin plus relebactam with imipenem/cilasatin alone in patients with complicated urinary tract infection. Sims M, Mariyanovski V, McLeroth P, et al. *J Antimicrob Chemother.* 2017 Sep;72(9):2616-26.
3. Phase 2, dose-ranging study of relebactam with imipenem-cilastatin in subjects with complicated intra-abdominal infection. Lucasti C, Vasile L, Sandesc D, et al. *Antimicrob Agents Chemother.* 2016 Sep;60(10):6234-43.
4. Recarbrio™. DRUGDEX®. In: IBM Micromedex® [Internet]. Truven Health Analysis, Greenwood Village, Colorado. USA.

DC-CCP Fall CE Forum

DC-CCP hosted its annual Fall CE Forum at the Holy Cross Hospital, located in Silver Spring, Maryland on November 9th, 2019. The CE event was led by current clinical pharmacists with goals of providing pharmacy education, collaboration, and networking for pharmacy students and pharmacists. The learning sessions covered various topics including the importance of understanding cultural aspects of dynamic patient populations as a pharmacy professional. Additionally, pharmacy students had an opportunity to build network with current pharmacy residents, preceptors, and school faculty members. Overall, the DC-CCP Fall CE Forum was a perfect time to branch out and exchange career information as well as the most up-to-date clinical knowledge.

Andrew Lee
DC-CCP Communication Committee Student Chair
University of Maryland School of Pharmacy
Class of 2020

Special thanks to our peer reviewers:
Jessica Pyhtila, PharmD, BCPS, BCGP

Interested in contributing an article for the DC-CCP Summer newsletter or becoming a peer reviewer?

Please contact **dcccpnewsletter@gmail.com**

DC-CCP Upcoming Events

Interested in a leadership position at DC-CCP? Please use the link below to view available positions and submit nominations.

https://docs.google.com/forms/d/e/1FAIpQLSfO4BrbN3fMpEWJ8PIs6oiuemYqTY1iLfvlzEHjhXskypmK6w/viewform

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About DC-CCP

DC-CCP is a non-profit professional association and an independent chapter of the American College of Clinical Pharmacy dedicated to improvements in pharmacotherapy practice, education, and research in the Washington D.C. Capital Region, including the District of Columbia, State of Maryland, and Commonwealth of Virginia. Membership will be open to any licensed or registered health care professional or health care professional student in the Capital Region. Membership in the American College of Clinical Pharmacy is not required to become a member of our organization.

Purpose and Goals of DC-CCP

(A) To promote the rational use of drugs in society

(B) To advance the principles and practice of clinical pharmacy

(C) To promote the full-time, advanced practice of clinical pharmacy

(D) To provide an advanced level of continuing education programs in the area of clinical pharmacy and objectives of ACCP as outlined in its constitution and bylaws.

(E) To provide a forum for the expression of opinion on pharmacy practice, education, and research from the perspective of clinical pharmacists

(F) To support, promote, and advance the goals and objectives of ACCP as outlined in its constitution and bylaws

(G) To provide a local recruiting base for ACCP

For more information or to become a member of DC-CCP please visit our website or social media pages:

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