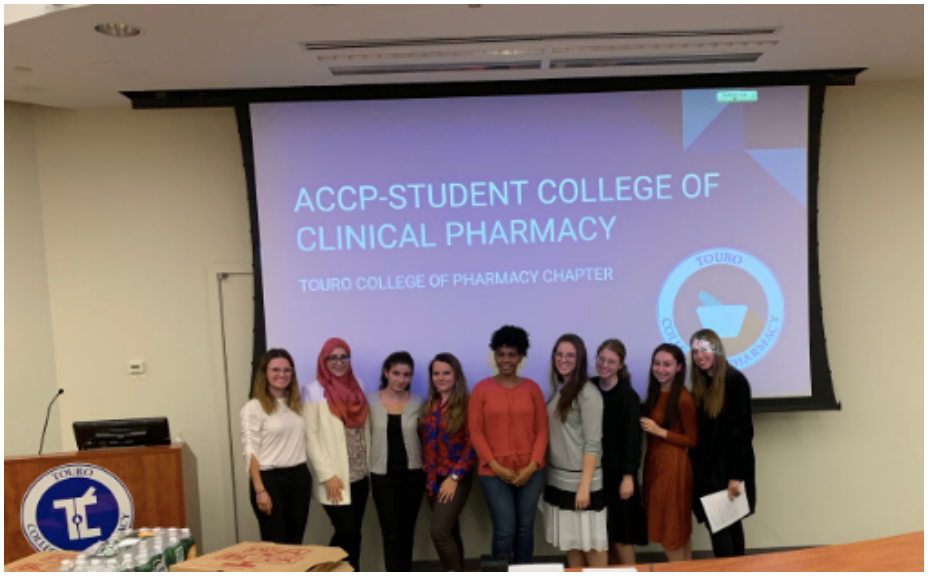
NEW YORK accp American College of Clinical Pharmacy

NYS-ACCP Insider

Touro College of Pharmacy - New York

American College of Clinical Pharmacy (ACCP) student chapter was started in Touro College of Pharmacy in January 2015 and had the main mission of improving human health by advocating and supporting professionals in clinical pharmacy. Our organization reflects the core values of ACCP and provides information and resources to guide students who aim to pursue a residency program upon graduation, as well as other postgraduate training programs, and have passion for clinical pharmacy. We ensure that our members have opportunities to engage in clinical research, academia and clinical pharmacy shadowing. Students learn how to excel in patient care and public health by serving our local Harlem community through the health fair events. We also conduct clinical skills competitions annually, have educational seminars and invite guest speakers to share their experience with students.



In September, we held our first general body meeting with the goal to introduce first-year pharmacy students to our organization. We discussed our agenda for the upcoming school year, and the role of our organization in improving patient care and advancing pharmacy practice as prospective clinical pharmacists. The general body meeting turned into a question and answer session with first-year pharmacy students and upperclassmen. First-year pharmacy students were eager and anxious of what they should know how to prepare properly for their classes throughout the semester. Students were encouraged to use relevant databases related to their classes, maintain a good support system and to reach out to upperclassmen and faculty for help when needed. It was a refreshing and motivating start for the SCCP Touro Family.

In October, SCCP joined the Leukemia & Lymphoma Society (LLS) to participate in Light The Night mission. Light The Night raises funds in support of the LLS mission to cure Leukemia, Lymphoma, Hodgkin's disease and Myeloma, and improve the quality of life of patients and their families. Thanks to the generous donation of the Associate Dean for the School of Affairs, Dr. Abraham Jeger, we raised $100 towards the team. The SCCP chapter was eager to hold a Mock Clinical Skills Competition during the spring semester which aimed to prepare students for the Annual Clinical Skills Competition. However due to the unprecedented COVID-19 pandemic, this event will be rescheduled to next semester. SCCP will continue to strive for the advancement of the community and illustrates to students day by day the important role of our clinical pharmacists in the healthcare setting through our unique events on campus.

Inna Kuligina Pharm.D. candidate class of 2021

Clinical Spotlight: Amanda Phoenix, PharmD, BCACP, CDE
Assistant Professor of Pharmacy Practice
Touro College of Pharmacy, New York, N.Y.

Where did you graduate pharmacy school?

I graduated from the University of Rhode Island, College of Pharmacy.

Why did you decide to pursue pharmacy and which area in pharmacy do you specialize in?

I specialize in ambulatory care pharmacy and completed a PGY-1 pharmacy practice residency at Stony Brook University Hospital on Long Island then a PGY-2 ambulatory care pharmacy residency at the James A. Haley Veterans' Hospital and Clinics in Tampa, Florida. I chose ambulatory care pharmacy because I love helping and communicating with people and managing their chronic conditions.

How has ACCP recently been important in your professional development?

ACCP is important in my career because it offers opportunities for me to stay updated on new literature and clinical guidelines. It also provided resources to become a Board-Certified Ambulatory Care Pharmacist.

What strategies do you take to keep up to date in your field?

To keep up to date, I review recently published literature, clinical studies, and treatment guidelines. Additionally, I sign up for email listservs of ACCP and other professional pharmacy organizations that email important information such as new publications related to ambulatory care pharmacy.

How would you describe what your typical workday looks like?

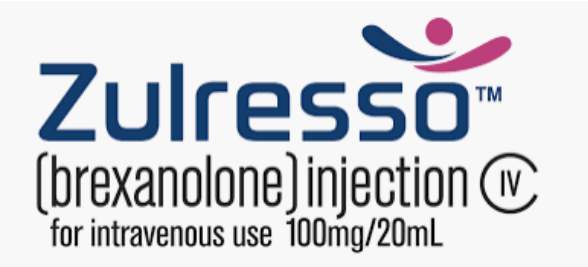
My typical workday varies, but when I am in the clinic, I start my day off by reviewing each scheduled patient's electronic medical chart. I have a Collaborative Drug Therapy Management (CDTM) Agreement in place with the primary care providers at the clinic, which allows me to initiate, modify, discontinue, or titrate medications related to diabetes, hypertension, and/or dyslipidemia. Prior to seeing patients in the clinic, I come up with a potential assessment and plan, and adjust it based on the subjective information I receive from the patient interview. After coming up with an evidence-based, individualized plan with each patient, I document the encounter in a progress note within the electronic medical record. I electronically prescribe any medications and/or equipment that is appropriate for the patient and enter any lab orders that are necessary to monitor those medications. I make sure to schedule the patient for a follow-up visit.

What advice would you give to a pharmacy student interested in a career in your pharmacy specialty?

Advice to give students who are interested in pursuing ambulatory care pharmacy would be to stay updated on treatment guidelines and literature, and gain experience interacting with patients.

Samar El Saleh Pharm.D. candidate class of 2021

Brexanolone (Zulresso) is an FDA approved drug for treatment of postpartum depression under the REMS program. Postpartum depression is a serious psychiatric disorder that is understudied (both clinically and experimentally) and underdiagnosed. It is the most common complication of childbirth, which negatively impacts the mother. Postpartum depression related suicide accounts approximately for 20% of deaths.



Postpartum depression can be treated with pharmacotherapy and psychotherapy, however the response cannot always be observed immediately. Allopregnanolone production usually declines after birth, and its low levels and inability of GABA-a receptors to adapt to this change may cause postpartum depression. Brexanolone is an aqueous formulation of allopregnanolone, which is administered intravenously for restoration of third-trimester levels and improvement of symptoms.

Package Insert

- Brexanolone injection should be dosed 30 µg/kg/h during 0-4 hours, then 60 µg/kg/h during hours 4-24, following by 90 µg/kg/h (or 60 µg/kg/h based on tolerability) during hours 24-52, then 60 µg/kg/h during hours 52-56, and lastly 30 µg/kg/h during hours 56-60.
- Side effects: sedation, dizziness and headache
- Severe side effects: presyncope, syncope and loss of consciousness
- Concern: Is this drug sustainable outside the clinical trial setting compared to traditional PPD drugs?
- Traditional postpartum depression drugs currently recommended by American College of Obstetricians and Gynecologists (ACOG) are SSRI's, SNRI's, TCA's.

Study Tools used to Measure Severity of Depression

- **Edinburgh Postnatal Depression Scale (EPDS)** uses a scale score from 1 to 30 where a score between 1 to 8 means depression not likely and a score of 14 and higher means probable depression.
- **Hamilton Rating Scale for Depression (HAM-D)** provides an indication of depression. Over time, it can be used as a guide to evaluate progress where a score of 10 - 13 means mild depression; 14-17 means mild to moderate depression and greater than 17 means moderate to severe depression.
- **Montgomery-Asberg Rating Scale (MADRS)** evaluates symptoms of depression on a scale of 0 to 6 where 0 means no depression and 6 means severe depression.
- **Clinical Global Impression-Improvement (CGI-I)** scale measures severity of depression and response to treatment. CGI-Impression rates the patient severity relative to the clinician's past experience with the patient. It uses a 7-point scale where 1 means normal, 2 means borderline mentally ill; 3 means mildly ill; 4 means moderately ill; 5 means markedly ill; 6 means severely ill; 7 means among the most extremely ill patients. The CGI-Improvement measures patient's improvement once treatment is initiated where 1 means very much improved since the initiation of treatment; 2 means much improved; 3 means minimally improved; 4 means no change since initiation of treatment; 5 means minimally worse; 6 means much worse; 7 means very much worse since the initiation of treatment.

Brexanolone Efficacy

1. **NCT02285504 (Kanes et al)** evaluated the efficacy of brexanolone. Participants of the study had HAM-D score of ≥20, major depressive disorder during the third trimester, had ceased breastfeeding and were admitted in inpatient psychiatric unit 2 to 20 weeks postpartum. The study was conducted for 35 days and included a 60-hour brexanolone infusion with follow up on days 11 and 35, and monitoring of efficacy and safety at hour 84. The HAM-D, a 17-item scale for depression, was used to assess test results, with a score of ≥24 indicating severe depression. The mean HAM-D score in this study was 26.5 at baseline, correlated with severe depression vs 1.8 after hour 60, which demonstrated a drop of 24.7 points with P = 0.001, which revealed a clinically significant improvement of postpartum depression. EPDS is a 10-item scale for postpartum depression degree of severity measurement with a score ≥13 indicating severe depression. This scale was chosen as it is more used in clinical studies to screen for PPD and to measure for symptom burden. EPDS score in this study decreased from baseline to end of infusion, but the P value was not reported. HAM-D and EPDS scores both reduced by hour 84, and P value is unknown. A GGI-I scale is a 7-point scale measuring improvement of treatment with a score of ≤ 2 being clinically relevant, and it was improved among all the participants. A small sample size of only four participants, concomitant use of SSRIs antidepressants which may have confounded the results of the study, inconsistent report of outcomes are all limitations.

2. **NCT02614547 (Kanes et al)** is a double-blind, multicenter randomized controlled trial assessing the efficacy and safety of brexanolone. It included healthy participants between 18 and 45 years old with major depressive disorder during the third trimester, excluding individuals with active psychosis, history of seizures, bipolar disorder, or substance abuse. The study was conducted for 30 days, and an intervention was administration of a 60-hour infusion of brexanolone or placebo with monitoring until hour 72 and follow-up on days 7 and 30. The mean HAM-D score at the end of the infusion fell 20.97 points from baseline in the brexanolone group vs 8.8 points in placebo recipients, with a difference of 12.2 points between the two groups and P = 0.0075. The results were statistically significant. HAM-D score at infusion end was improved in 7 participants in the brexanolone group and 1 placebo recipient, with P = 0.0364 statistically significant. It was sustained at day 30, P = 0.0499. The mean reduction in MADRS score from baseline to hour 72 was 28.66 points in the brexanolone group vs 12.46 points in placebo recipients with between-group difference of 16.2 points, and P = 0.0090. Results were statistically significant for all tests. Limitations include small sample size of 21 participants, eligibility restriction to participants with HAM-D scores of ≥26, excluding women with mild to moderate postpartum depression, limited monitoring after 30 days.

3. **NCT02942004 (Meltzer-Brody et al) Part 1** is a 2 double-blind, multicenter RCTs, the first of which further assessed the efficacy of brexanolone for postpartum depression. Included individuals were 18 to 45 years old with ceased lactation and major depressive disorder during the third trimester. Study was conducted for 30 days and used a 60-hour infusion of brexanolone at dose of 60 or 90 µg/kg/h, and was monitored until post infusion hour 72 with a follow up on days 7 and 30. For the primary outcome, the mean HAM-D scores at infusion end fell 19.5, 17.7, and 14 points from baseline in the brexanolone 60 µg/kg/h, brexanolone 90 µg/kg/h, and placebo groups, respectively (P = 0.0013 for brexanolone 60 µg/kg/h vs placebo use; P= 0.0252 for brexanolone 90 µg/kg/h vs placebo use). Limitations include restriction of eligibility to participants with HAM-D scores of ≥26, excluding women with mild to moderate postpartum depression, limited monitoring after 30 days.

4. **NCT02942004 (Meltzer-Brody et al) Part 2** used the same methods and outcomes as Study 1 and had similar eligibility criteria. It included individuals who were 18 to 45 years old with ceased lactation and

major depressive disorder during the third trimester and HAM-D score between 20 and 25. Study lasted 30 days and used a 60-hour infusion of brexanolone at dose of 60 or 90 µg/kg/h, and was monitored until post infusion hour 72 with a follow up on days 7 and 30. The mean infusion-end HAM-D score fell 14.6 points from baseline with brexanolone use and 12.1 with placebo use (P = 0.0160), which represents a statistically significant improvement.

Based on the trials conducted, one can deduce that brexananlone can be used in severe PPD disease when a rapid response is required. However, some setbacks are enrollment in the REMS program and efficacy in the long-term clinical setting which needs to be further evaluated. Hence more studies are needed to adequately assess safety and efficacy in clinical settings.

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Khrystyna Bondarau Pharm.D. candidate class of 2021

New Drug update: US FDA approves only triple-combination tablet Trijardy™ XR for adults with type 2 diabetes

On January 27, 2020, the Food and Drug Administration approved Trijardy XR® marketed by Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly and Company for the management of type 2 diabetes along with diet and exercise [1].

Trijardy XR® is a single tablet that combines three different active medications namely empagliflozin, linagliptin, and metformin hydrochloride extended release. It is taken once daily in the morning after breakfast [1].
Oral tablet, extended release Empagliflozin/Linagliptin/Metformin Hydrochloride combination is available in four different dosages including: 5 mg/2.5 mg/1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/2.5 mg/1000 mg, 25 mg/5 mg/1000 mg [2] [6].

Mechanism of Action

- **Empagliflozin** (Jardiance®), the sodium-glucose cotransporter 2 (SGLT2) inhibitor reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion [2].
- **Linagliptin** (Tradjenta®) the dipeptidyl peptidase-4 (DPP-4) inhibitor, increases the concentrations of active incretin hormones, (glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) thus stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation [2].
- **Metformin** improves glucose tolerance in patients with type 2 diabetes mellitus, lowering both basal and postprandial plasma glucose by decreasing hepatic glucose production, decreasing intestinal absorption of glucose, and improving insulin sensitivity by increasing peripheral glucose uptake and utilization [2].

As per the 2020 American Diabetes Association (ADA) guidelines, metformin is the preferred initial pharmacologic agent for the treatment of type 2 diabetes [3]. However, due to the complexity and progressive nature of type 2 diabetes, many individuals often require multiple antidiabetic medications to achieve target A1C levels. In addition to diabetes, many patients battle with other existing comorbidities. Adding multiple drug regimens increases the pill burden which can be challenging for some patients. The innovation of a combination pill that can help improve glucose control without the increased pill burden is vital in the management of blood glucose.

The approval of Trijardy XR® by the FDA was based on two randomized open-label trials. One study evaluated the efficacy and safety of empagliflozin/linagliptin as second-line therapy in patients with type 2 diabetes who were poorly controlled on metformin. The results of the study revealed that combinations of empagliflozin/linagliptin as second-line therapy for 52 weeks significantly reduced HbA1c compared with the individual components and were well tolerated. Treatment with empagliflozin 10 mg or 25 mg used in combination with linagliptin 5 mg also resulted in a statistically significant reduction in body weight compared to linagliptin 5 mg among patients already taking metformin [4].

Another study called EMPA-REG OUTCOME study was a multicenter, multinational, randomized, double-blind parallel-group trial. The trial compared the effects of empagliflozin with placebo, on cardiovascular morbidity and mortality in patients with type 2 diabetes at high risk for cardiovascular events who were receiving standard care. The findings of the study showed that empagliflozin significantly reduced the rate of death from cardiovascular causes, hospitalization for heart failure and death from any cause risk. There were no significant between-group differences in the rates of myocardial infarction or stroke [5]. Hence, Trijardy XR® is a potential drug of choice along with diet and exercise for patients with type 2 diabetes at high risk for cardiovascular events or have known cardiovascular disease who need to reduce their risk of cardiovascular outcomes and mortality without the pill burden.

Trijardy XR® is not recommended for individuals with type 1 diabetes or diabetic ketoacidosis, and it has not been tested in patients with a history of pancreatitis. The combination also has a warning for lactic acidosis, a rare, but serious, condition that can arise with metformin accumulation [6].

The most common adverse reactions associated with Trijardy XR ® (5% or greater incidence) were upper respiratory tract infection, urinary tract infection, nasopharyngitis, diarrhea, constipation, headache, and gastroenteritis [6].

The innovation of three different diabetes medications in a single tablet is a notable important progress in diabetes treatment. This will decrease the pill burden for many patients who are already taking multiple medications drug regimen while they incorporate the necessary dietary and lifestyle changes.

References:

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