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SJU-ACCP Student Chapter Highlights

As an ACCP student chapter with Vincentian values at St. John's University, we commit ourselves to the value of service to our community while orienting our students to the practice of clinical pharmacy. Our goal is to provide information regarding career opportunities, to promote excellence in patient care, research and education, and to develop the skills necessary to work on a multidisciplinary team. Take a look at our events that shaped our amazing 2022-2023 year!

In this Issue:

Clinical Pearl Series

Every month, SJU SCCP invites a P4 PharmD student who is completing their APPE rotations to share a clinical pearl with the student chapter. Guest speakers included:

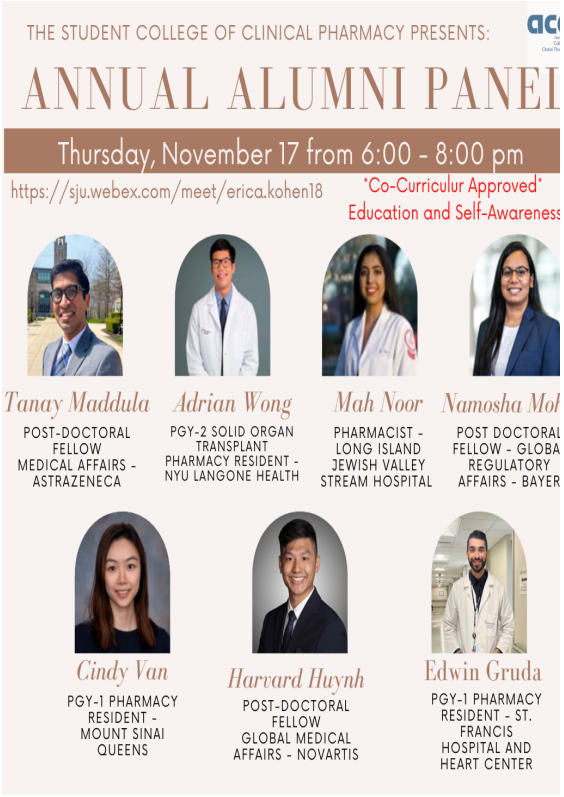
Nadin Mostafa who presented Acute Pulmonary Embolism
Mohamed Heikal who presented Heart Transplant 101 and Oncological Emergencies and Supportive Care

Our amazing speakers discussed each topic in depth, allowing students to go beyond the brief overview in class. These short lectures were wonderful opportunities for students to gain more clinical knowledge outside the scope of our Drugs and Disease courses.

APPE Informational Panel

This panel consisted of six P4 PharmD students who did an extraordinary job providing advice regarding the APPE rotations ranking process at St. John's University. They also discussed essential pearls such as switch-out periods and special experiences such as Hospital bundles at NewYork-Presbyterian and Northwell Health, as well as industry-related internships, such as Bristol Myers Squibb (BMS) that have their own application process. Members in attendance had the opportunity for a Question & Answer session at the completion of the panel to further guide them through their ranking process to get the most out of their APPE rotational experience!

It was extremely informative hearing from our APPE students and gaining exposure for the exciting upcoming experiences, especially for P3 PharmD students.



Virtual Alumni Panel

Our annual Alumni Dinner was once again revamped into a Virtual Alumni Panel this year! This event invites our bright alumni back to speak about their experiences and diverse career paths, giving our members the chance to explore a variety of post-graduation opportunities, fellowships or residencies. Our alumni were gracious enough to join us for a virtual panel, where they went in order to answer questions and share the path to their current careers. We invited a total of seven SCCP alumni who played a crucial role in our student chapter:

Dr. Tanay Maddula - Post Doctoral Fellow, Medical Affairs at Astrazeneca
Dr. Adrian Wong- PGY2 Solid Organ Transplant Pharmacy Resisent at NYU Langone Health
Dr. Mah Noor-Pharmacist at Long Island Jewish Valley Stream Hospital
Dr. Namosha Mohite- Post Doctoral Fellow, Global Regulatory Affairs at Bayer
Dr. Cindy Van-PGY1 Pharmacy Resident at Mount Sinai Queens
Dr. Harvard Huynh- Post Doctoral Fellow, Global Medical Affairs at Novartis
Dr. Edwin Gruda- PGY1 Pharmacy Resident at St. Francis Hospital and Heart Center

Thank you to our alumni for their involvement in shaping our organization and for continuously providing advice to guide us down our own career paths!

Interprofessional SimMan Event

This interprofessional event consisted of St. John's Univeristy physician assistant students and pharmacy students in their P2-P4 year working together to solve a patient case. We solved the patient case by dividing into groups, with each group comprised of at least 2-3 pharmacy students and physician assistant students working together. Through the use of the SimMan, students were able to ausucultate its lungs, check its blood pressure, practice patient counseling, and forming a patient medication plan based on the patient's condition.

Erica Kohen, Pharm.D. Candidate, Class of 2024

Clinical Spotlight: Judith Beizer, PharmD

Clinical Pharmacist at the Stern Family Center for Rehabilitation in the Northwell Health System

1. What are your main roles and daily responsibilities as a clinical pharmacist?

   At the facility where I'm at, which is the Stern Family Center for Rehabilitation, my main role here right now is medication reconciliation for newly admitted patients. So, when people are admitted here, the students and I look at what medications were they taking at home, what were they prescribed in the hospital, and then what were they prescribed here, to make sure that everything that should be continued is continued and the things that should have been discontinued are discontinued. We educate the patients about any new medications. We answer their questions about medications. We are a source of drug information for physicians and nurses here, if we find any discrepancies in the medications we contact the physicians, and we discuss it. That's my main role here. If someone is on vancomycin, I follow the vancomycin kinetics. If somebody today is on warfarin, I'd make sure that the nurses got in touch with the doctor because the INR was too high. Every day is different."

2. Can you explain your journey to Geriatrics?

   "Well, my journey to geriatrics is one I always say was really kind of by chance. When I was doing my PGY1 residency in Philadelphia, I met a really nice young guy who had a job lined up in New York, and so when I went to the ASHP Mid-Year meeting, I thought I really should look for a job in New York, because I think I want to marry this guy. The only really interesting thing for someone at my level back then was the opportunity to do a fellowship in Geriatrics at Montefiore. They had received a grant from the National Institute on Aging, and part of it was a pharmacy project about the role of the pharmacist in making home visits. This is back in the mid-80s, so this is a long time ago. You know when I first thought of Geriatrics, everyone was saying you need a specialty and I like a lot of different things. When you think about Geriatrics, you really have to know everything. You have to know all the diseases, you have to know the cardiovascular system, pulmonary and infectious disease, nutrition, and neurology. I always turn the question not about how I got into Geriatrics but why did I stay in Geriatrics? That has to do with the team approach and the people who are caring for older adults and how they appreciate the role of the pharmacist. So, what I mean by this, you know taking care of older adults is not always pretty, but you're really caring for the person, that whole person, not just the heart failure. The people who work in geriatrics are good people, they're the people you want to be working with, care for, and appreciate the importance of pharmacists. They know how important medications can be in helping patients but also how detrimental medications can also be because of all their side effects, and so I feel very valued."

3. What was your most rewarding experience so far?

   I've been very lucky, and I feel very blessed actually, in my profession and the ability that I've had to contribute to the profession and to give back. You know it's taking care of patients, it's showing students

how to take care of patients. Also, professionally I've been involved on the organizational level. I served as the President of the American Society of Consultant Pharmacists and was able to bring the message of the role of the pharmacist to other professional organizations, physicians, nurses, etc. I'm now serving on the board of the American Geriatric Society, they save one position on the board for a non-physician and the fact that I've been entrusted with that role has been amazing. I came on to the board at the beginning of COVID and as the vaccines were being developed we were trying to get the message out about the vaccines. I was turned to several times to help with how we get the message out that vaccines are safe for older people, and that we need to be vaccinating people. I can't really say it's just one thing because it's really the whole aspect of the various things I do in my career. I remember the patients, I can walk through this building and tell you that was Bob's room and those are the long-term residents you connect to.

4. What advice do you have for someone who wants to get into this field?

I always tell students, you need to find your passion. I would love it if it was Geriatrics, but it doesn't have to be. I want you to be happy and I want you to feel fulfilled because then you'll be a better pharmacist. That's what is important because pharmacy shouldn't just be another job, you're really contributing and helping people and we make a difference. Whatever the passion is pediatric, cardiology, transplant, whatever it is, do it and do it well, and take a chance. As I said, Geriatrics came to me by accident, Geriatrics was not part of the curriculum as an undergraduate, or in my post-graduate from my post-baccalaureate PharmD, but I was like, okay, I never thought about it. Let me try it and see and was totally surprised at how much I liked it.

5. What contributions do you think you made to the profession as a clinical pharmacist?

I'm the co-editor of the Geriatric Dosage Handbook, which was the first dosage handbook specifically for geriatrics. That kind of brought the idea that you know, one size doesn't fit all when you're giving prescription medications for adults, particularly older adults. I think that's probably also one of my proudest moments when that first edition came out. Now we don't do a print copy of the Geriatric Dosage Handbook, but if you look into the Lexicomp references, and you see the geriatric dosage information, I co-edit the information and try to keep it up to date. I'm on the expert panel for the Beers Criteria, I've been on the updates since we started doing it in 2012. The 2023 update will be coming out very soon. I am on the VA Geriatrics Gerontology Committee. I've been able to be on other committees in New York, I'm on the Falls Prevention Coalition. All those things have been ways that I've been able to contribute back to the profession. Part of that is just again taking that step of saying yes and taking a risk of okay maybe I can do this.

Hadeel Aldasooky, Pharm.D. Candidate, Class of 2024

FDA-approved Expansion of Orkambi use in Pediatric Cystic Fibrosis Patients Ages 12 to <24 Months

On September 2nd, 2022, Vertex announced the FDA's approval of expanded use of Orkambi in pediatric patients with cystic fibrosis aged 12 to <24 months with homozygous F508del mutation in the CFTR gene.[6]

Cystic fibrosis is an inherited condition affecting the respiratory and digestive systems.[2] Thick mucus associated with cystic fibrosis can obstruct breathing, increase infection risk, and block enzyme transport, affecting digestion.[2,5] Mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene must occur in both inherited genes for disease development.[2] The F508del mutation is the most common mutation in cystic fibrosis.[1,4] Symptoms include wheezing, persistent cough, poor growth, and "salty-tasting skin"; "sweat tests"/genetic testing are used diagnostically.[2] Prior to this approval, Orkambi was only approved in pediatric patients >24 months with the F508del mutation, with the other CFTR modulators approved for different age groups/mutations, not this specific age group/mutation combination.

The study that led to the approval of Orkambi (lumacaftor/ivacaftor) in ages 12 to <24 months was an open-label, phase 3 study.[3] It consisted of two parts, with two age-based cohorts in Part A: 18 to <24 mo in Cohort 1 and 12 to <18 months in Cohort 2.[3] Part A evaluated 14 children over 15 days, addressing pharmacokinetics and weight-based dosing.[3] Part B had 46 participants observed over 24 weeks, focusing on safety and tolerability; secondary endpoints included the "absolute change in sweat chloride concentration from baseline to week 24", as well as pharmacokinetics.[3]

In Part A, all weight-based dosing regimens were given every 12 hours.[3] Weights ranged from 7 kg to >14 kg, with lumacaftor dosing ranging from 75mg-150 mg and ivacaftor dosing ranging from 94 mg-188 mg.[3] Pharmacokinetic data in Part A affirmed proper dosing regimens, while AUC exposure ranges in Part B were similar to "safe and efficacious" values in adults.[3] In Part B, 44 children (95.7%) reported adverse effects (AEs); the majority were mild (52.2%) or moderate (39.1%); five children reported serious AEs. "Cough, infective pulmonary exacerbation of CF, pyrexia and vomiting" were the most common adverse effects reported.[3]

For secondary outcomes, the mean absolute change from baseline to week 24 in sweat chloride concentration was -29.1mmol/L "(95% confidence interval, -34.8 to -23.4 mmol/L)."[3] The study reported that growth parameters stayed normal from baseline to the 24th week.[3] Improvements in pancreatic function/intestinal inflammatory markers were also noted, including fecal elastase-1, serum immunoreactive trypsinogen and fecal calprotectin.[3]

The pharmacokinetic profile, plus safety/tolerability data and reduction in sweat chloride levels helped support approval of Orkambi in children aged 12 to <24 months.[3]

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Vassilia Plakas, Pharm.D. Candidate, Class of 2024
Chrisanthy Giaburas, Pharm.D. Candidate, Class of 2025

Relyvrio (sodium phenylbutyrate/taurursodiol) New Drug Update

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder that kills nerve cells responsible for controlling voluntary muscles.[1] As a result of the deterioration of these nerves, the muscles become weak and eventually leads to paralysis. Most people die from ALS within three to five years of the onset of symptoms due to respiratory failure.[2]

In September 2022, the Food and Drug Administration (FDA) approved Relyvrio (sodium phenylbutyrate/taurursodiol) to treat patients with ALS based on the CENTAUR trial.[3] Although the mechanism is not completely understood, it is known that the combination of the two compounds works to inhibit stress signals within the mitochondria, and the endoplasmic reticulum, with the aim of preventing nerve cell death.[4]

The CENTAUR trial is a phase II, 24 weeks, randomized, double-blind, placebo-controlled study that evaluated the safety and effectiveness of Relyvrio. The inclusion criteria consisted of patients between 18-80 with a definite diagnosis of sporadic or familial ALS and at least 18 months of symptom onset.[6] Patients would be administered the drug or placebo by mouth or via feeding tube for 24 weeks once daily for the first three weeks and then twice daily for the remainder of the study as tolerability permits.[6] The primary outcome is the rate of decline in the total score on the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R), which ranges from a score of 0-48, with higher scores indicating better function. The results show that the mean rate of change in the ALSFRS-R score is -1.24 points per month with the active drug and -1.66 points per month with placebo (difference, 0.42 points per month; 95% confidence interval, 0.03 to 0.81; P = 0.03).[6] The secondary outcomes of the study are the rates of decline in isometric muscle strength, and plasma phosphorylated axonal neurofilament H subunit levels, and the results did not differ significantly between the two groups.[6] It can be concluded that the twenty-four-week study found that the treatment with sodium phenylbutyrate-taurursodiol resulted in slower functional decline, as measured by the ALSFRS-R score, compared to placebo.

Some limitations of this study include that it was sponsored by the creator of the drug, Amylyx Pharmaceuticals, had a relatively small study sample, and was performed in a very short time frame. Further

research, involving longer and larger trials, is needed to determine the efficacy and safety of Relyvrio in individuals with ALS. Furthermore, although FDA approved sodium phenylbutyrate/taurursodiol after phase II, a phase III trial for ASL (Phoenix) is currently underway that involves an increased number of participants and a longer duration for a more complete analysis.[7]

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Ahsanullah Shirzad, Pharm.D. Candidate, Class of 2027

Updates on the Role of SGLT2i in the 2022 AHA/ACC/HFSA Heart Failure Guidelines

Heart failure (HF) is characterized by signs or symptoms resulting from cardiac structure or function impairment.[1-3] It occurs when the heart cannot adequately pump at a rate corresponding to the body's needs[2] due to diminished ventricular filling or ejection.[3]

HF is categorized into 4 stages by the American Heart Association (AHA) and American College of Cardiology (ACC): stage A (at risk for HF), stage B (pre-HF), stage C (symptomatic HF), and stage D (advanced HF).[1-3] Additionally, the New York Heart Association classifies physical functional status from class I to IV, with higher disability severity as the class increases.[2,3] HF classifications based on the left ventricular ejection fraction (LVEF) include HF with reduced EF (HFrEF; ≤40%), HF with improved EF (HFimpEF), HF with mildly reduced EF (HFmrEF; 41-49%), and HF with preserved EF (HFpEF; ≥50%).[1-3] This determines appropriate treatment regimens, referred to as guideline-directed medical therapy (GDMT).[4]

The 2022 clinical practice guideline for HF management was developed by the AHA, ACC, and Heart Failure Society of America (HFSA).[3] In this guideline, HFrEF management was revised to add sodium-glucose transport protein 2 inhibitors (SGLT2i) to existing GDMT with beta-blockers (BB), mineralocorticoid receptor antagonists (MRA), renin-angiotensin system inhibitors (RASi), and diuretics as needed.[3] The inclusion of SGLT2i is due to evidence supporting its effectiveness in reducing the risk of hospitalization and cardiovascular

death in HF patients with or without type II diabetes mellitus (T2DM). The DAPA-HF trial assessing dapagliflozin and EMPEROR-Preserved trial assessing empagliflozin demonstrated a 30% reduction in HF hospitalization, 18% reduction in the risk of cardiovascular death, and 17% risk of all-cause mortality in comparison to a placebo.[3,5,6] Other outcomes in those treated with SGLT2i included decreased frequency of serious renal outcomes and reduced rate of decline in estimated glomerular filtration rate (eGFR).[3,7]

SGLT2i were first approved for T2DM management in adults and includes four medications: canagliflozin (Invokana®), dapagliflozin (Farxiga®), empagliflozin (Jardiance®), and ertugliflozin (Steglatro®). SGLT2i act on the sodium-glucose co-transporter 2 in the renal proximal convoluted tubules to inhibit glucose reabsorption from the tubular lumen, thus promoting urinary excretion of glucose and reduction in serum glucose. These medications are initiated at the lowest dose and may be renally adjusted based on eGFR. Additionally, SGLT2i are contraindicated in dialysis patients.[8]

In conclusion, HF is caused by structural or functional deficiencies in the heart, resulting in impaired blood ejection or ventricular filling. The 2022 AHA/ACC/HFSA Guideline for the Management of HF updated the GDMT upon HFrEF diagnosis to include SGLT2i, BB, MRA, RASi, and diuretics as needed.[3] This modification is due to evidence demonstrating the efficacy of SGLT2i in reducing HF-related hospitalizations in patients with or without T2DM and cardiovascular deaths in DAPA-HF and EMPEROR-Preserved trials, which studied dapagliflozin and empagliflozin, respectively.[5,6]

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Use of Livtencity (Maribavir) in the Treatment of Resistant Cytomegalovirus (CMV) in Post-Transplant Patients

Cytomegalovirus (CMV) is part of the herpesvirus family and infects most humans. CMV is transmitted by direct contact with infectious body fluids, sexual contact, transplant, blood transfusion, and vertical transmission. Immunocompetent patients will likely be asymptomatic or present with mild symptoms like that of mononucleosis. However, in immunocompromised patients, CMV can cause substantial morbidity and mortality.[2]

Standard treatment of CMV involves an antiviral such as valganciclovir, ganciclovir, foscarnet, or cidofovir. In cases of resistant or refractory CMV, standard treatment is ineffective. Livtencity (maribavir) is manufactured by Takeda Pharmaceuticals and was FDA-approved in November 2021 for the treatment of resistant or refractory CMV. Livtencity, a benzimidazole riboside, works by competitively inhibiting the protein kinase activity of the CMV enzyme, pUL97, which inhibits the phosphorylation of proteins. Livtencity is associated with less severe adverse events compared to other treatment options and is the only oral agent other than valganciclovir available.[3]

A phase 3 randomized clinical trial was conducted to assess "Maribavir for Refractory Cytomegalovirus Infections With or Without Resistance Post-Transplant". In this trial, Livtencity was tested against standard treatment options in the safe and efficacious treatment of resistant or refractory CMV infection in hematopoietic cell- and solid-organ transplant recipients. 352 were randomized into the Livtencity group or investigator-assigned treatment (IAT) group and were treated for 8 weeks and followed for 12 weeks after treatment. Participants in the Livtencity group were given 400 mg tablets to be taken twice daily. Participants in the IAT group were treated according to standard recommendations. The primary outcome, confirmed CMV viremia clearance by week 8, was achieved by 55.6% of the Livtencity group and 23.8% in the IAT group. Additionally, a higher percentage of patients in the Livtencity group maintained CMV clearance and symptom control throughout weeks 8 to 20 compared to the IAT group. Dysgeusia, altered taste, was reported in 87% of patients in the Livtencity group. On the other hand, valganciclovir and ganciclovir caused neutropenia in 33.9% of IAT group participants. Overall, this study demonstrated the safety and efficacy of Livtencity in the treatment of resistant or refractory CMV.[1,4]

Livtencity is dosed at 400 mg orally twice daily and does not require any renal or hepatic dose adjustments. From previous trials, Livtencity has been proven to be both safe and effective in the treatment of CMV infection in transplant patients with resistant or refractory CMV infection.

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Hala Hassan Pharm.D. Candidate, Class of 2023

Eisai and Biogen's Lecanemab Granted Accelerated Approval for Treatment of Early Stage Alzheimer's Disease

Alzheimer's disease is the most common cause of dementia, with an increasing incidence worldwide. In the United States, approximately 6.5 million people 65 years and older are living with Alzheimer's dementia. Diagnosed patients experience a progressive decline in cognitive function, with amyloid plaques and neurofibrillary tangles as disease indicators. The current theory of pathogenesis suggests the accumulation of pathological forms of Aβ produced by the cleavage of APP in the brain is the primary cause. This process is driven by an imbalance between Aβ production and Aβ clearance.[3]

Current FDA-approved medications only treat Alzheimer's symptoms, rather than the pathology. Lecanemab, a humanized IgG1 monoclonal antibody, has shown to be promising for people with mild Alzheimer's disease. Recently, the FDA granted accelerated approval to Lecanemab (Leqembi) due to uncertainty surrounding whether it targets a biological element like amyloid protein and medications indicated for diseases with limited treatment options. This accelerated approval was based on Phase 2 trial data and from a large Phase 3 trial.[1] It will cost $26,500 per year. Continued approval for Leqembi may be contingent upon the confirmation of clinical benefit in a confirmatory trial.[2]

This drug selectively binds to neutralize and eliminate soluble Aβ protofibrils, thought to cause the neurodegenerative process in Alzheimer's disease.[9] Leqembi is currently being developed as the only anti-Aβ antibody that can be utilized for the treatment of early Alzheimer's without the need for titration and shows the potential in delaying progression.

Eisai's Clarity AD study was a global placebo-controlled, double-blinded, parallel-group, randomized confirmatory phase 3 trial that took place at 235 different sites scattered amongst Asia, Europe, and North America. Of the 1,795 participants with early Alzheimer's, 898 people received Lecanemab 10 mg/kg IV every other week, while the remaining 897 individuals received the placebo. The participants in this study had a range of comorbidities and anticoagulants. Different races and ethnic groups were represented in the study with 4.5 and 22.5% of U.S. participants being Black and Hispanic, respectively. Significant results were observed after 18 months as it was found to slow cognitive decline by 26%. The most common effects observed were infusion reactions, cerebral hemorrhages, edema, and effusion. No deaths were related to Lecanemab.[8]

Alzheimer's disease is a progressive disorder with a significant impact on cognitive function. Lecanemab has brought hope to patients as data suggest that Lecanemab may slow the rate of disease progression by 2.5-3.1 years. Lecanemab slowed the decline of daily activities by 37%, thereby giving patients

the potential to remain in the earlier stages of Alzheimer's disease for longer.[9] It is imperative to increase funding for Alzheimer's research to find a cure for this disease.

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Novel Bispecific Monoclonal Antibody for Multiple Myeloma

Multiple myeloma (MM) is an incurable malignant cancer of plasma cells, an immune cell essential for defending the body from pathogens. However, in MM, myeloma cells instead produce antibodies that concentrate in the blood and urine impairing the kidneys and other organs[1]. MM is characterized by uncontrolled growth of plasma cells in the bone marrow, typically leading to bone fractures due to substances produced by myeloma cells that deteriorate the bone[2,3]. The excess plasma cells may inhibit the growth of red blood cells, platelets, and white blood cells resulting in anemia, thrombocytopenia, leukopenia, and infection susceptibility respectively[1,3].

Bispecific Antibodies (bsAbs) emerged as a promising therapeutic agent against cancer cells. BsAbs bind simultaneously to a cancer cell and a cytotoxic immune cell facilitating the lysis of the cancer cell[4]. Elranatamab is a bispecific antibody that targets B-Cell Maturation Antigen (BCMA), a highly expressed antigen on multiple myeloma cells, and a cluster of differentiation 3 (CD3) on T cells which accelerates the T-cell mediated lysis of the MM cell[5].

Elranatamab is currently undergoing Phase II and III trials through Pfizer's MagnetisMM clinical research program[6,7]. During the preliminary Phase I trial of Elranatamab, the data showed a favorable safety and efficacy profile. The study contained n=30 (number) patients with a median of 8 treatments, triple refractory disease, and other qualifying criteria. The participants received a weekly dose of elranatamab subcutaneously at 80 (n=6), 130 (n=4), 215 (n=4), 360 (n=4), 600 (n=6), 1000 (n=6). Adverse effects (AE) were observed in patients in varying severities[8]. G1 (Grade 1) is defined as mild, G2 as moderate, G3 as severe, G4 as life threatening, and G5 as death[9]. G3-G4 AE present were lymphopenia (n=25), anemia (n=18), neutropenia (n=16), and thrombocytopenia (n=16). G2-G1 AE were cytokine release syndrome (n=22) and injection site reaction (n=15). The overall response rate (ORR) for doses ≥215 mcg/kg was 70% (14/20) and for doses at 1000 mcg/kg was 83% (⅚)[8].

In a Phase II trial of Elranatamab, MagnetisMM-3, patients refractory to either proteasome inhibitors, immunomodulatory drugs, or anti-CD38 antibodies were admitted and separated into two parallel cohorts, patients naive to BCMA therapies and those who are not. All 60 naive patients experienced G3-G4 treatment-emergent adverse effects, the most common being neutropenia (36.7%), anemia (36.7%), and thrombocytopenia (30%). Infections occurred in 46.7% of patients with 11.7% being upper respiratory tract infections. 10 patients died due to MM progression (n=8), septic shock (n=1), unknown (n=1)[9].

Although there's much progress left, elranatamab exhibits great potential for the treatment of multiple myeloma and exemplifies the fascinating development of drug discovery.

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New Treatment for H. Pylori Infections in Adults

Early May 2022 Phantom Pharmaceuticals' new entity Voquezna Triple/ Dual Pak was approved for the treatment of Helicobacter Pylori infections in adults. H. pylori infections affect around 30% to 40% of adults in the United States each year.[1] This infection affects the gastrointestinal tract of adults inducing peptic ulcers. The lining of the stomach becomes inflamed and produces symptoms of aching, burning, nausea, vomiting and bloating.[2] Most often this infection is caused by ingesting contaminated food and or water and can be passed directly between persons and then is treated with antibiotics[2].

Firstline treatment therapy for H pylori infection without any risk factors for antibiotic resistance includes a proton pump inhibitor (PPI) plus a macrolide (clarithromycin) and beta-lactam inhibitor (amoxicillin).[3] Voquezna Triple/ Dual Pak is a co-packaged treatment therapy that includes vonoprazan, a potassium-competitive acid blocker, amoxicillin, and clarithromycin. H. pylori bacteria lives in our gastric mucosa and in order for the bacteria to survive the harsh conditions of the stomach it secretes an enzyme called urease allowing the pH of the stomach to neutralize and create better conditions for its survival.[4] Vonoprazan works by inhibiting gastric acid through the inhibition of the H^+K-ATPase pump. Vonoprazan is a reversible H^+K-ATPase inhibitor producing a faster and long-acting acid suppression effect in both resting and active parietal cells.[5]

A recent 2022 trial conducted in the United States and Europe included patients older than 18, with at least one of the following conditions: dyspepsia, non-bleeding peptic ulcer, a positive H. pylori infection confirmed by C-urea breath test, and treatment-naive.[6] The sample size was 1046 patients randomized into the 3 groups of either vonoprazan dual therapy or double-blind triple therapy (vonoprazan 20mg or lansoprazole 30mg twice a day).[6] All patients underwent treatment for 14 days and after 6 weeks were assessed to determine the eradication of H. Pylori. At the conclusion of the therapy the data shows 84.7% of patients using vonoprazan triple therapy saw an eradication of H pylori infection as compared to 78% while using lansoprazole triple therapy.[6] The main difference 5.9%; 95% CI, -0.8 to 12.6; noninferiority $p< 0.001$ this accepts the criteria of the trial and has proven that vonoprazan-based therapy is evidently superior in eradicating H. pylori infections as compared to PPI based therapy. There was an 80.8% eradication seen in patients that used vonoprazan triple therapy, 77.2 % using vonoprazan dual therapy, and 68.5% eradication using lansoprazole triple therapy in patients that had some resistance towards either amoxicillin or clarithromycin.[6] Overall, this trial has statistically and clinically proven the consideration of vonoprazan-based therapy for the treatment of H. pylori in adults.

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Tylenol Induced Neurodivergence

Acetaminophen, also known as Tylenol/Paracetamol, is a widely used analgesic and antipyretic that has been the universal recommendation for use in many patient populations including pregnant and lactating mothers. It is classified by the US Food and Drug Administration as category B for safety in pregnancy, meaning that no risks have been found in humans. Because of this and the increasing rates of RSV, and Flu this virus season, there is a shortage of children's Tylenol.

However, in recent years, evidence has presented that exposure to acetaminophen during pregnancy and early infancy has been associated with harmful effects influencing neurodevelopment, giving rise to neurodivergent disorders. Tylenol autism lawsuits are being filed around the country with a new Tylenol Autism

class action lawsuit pending certification in federal court. New medical research linking autism and Tylenol is strong. It suggests that in-utero exposure to Tylenol (acetaminophen) may be linked to higher rates of autism and other neurologic disorders.

In 2021, a consensus statement was developed and signed by 91 scientists, clinicians, and public health professionals. The consensus allocated both animal and human studies regarding acetaminophen administration and neurodivergence and concluded the association between the two. Advising against the administration of acetaminophen towards the pregnant population unless otherwise instructed by a medical professional. The statement called to prioritize and further research, and for precautionary action against recommending acetaminophen to the pregnant population.

One of the studies mentioned in the 2021 consensus was published by the European Journal of Epidemiology the same year. The study found that prenatal exposure to acetaminophen increased the likelihood of the development of ASD by 19% and ADHD by 21%. An NIH-funded study identified a significant positive association between cord plasma acetaminophen metabolites and the risk of ADHD diagnosis and the risk of ASD in childhood. The study found that children with the highest levels of acetaminophen and its metabolites in their umbilical cord blood were 3.62 times more likely to be diagnosed with ASD and 2.86 times more likely to be diagnosed with ADHD.

A meta-analysis was also done in regard to the misinformation about acetaminophen and prenatal safety. The study determined that a total of 52 papers published between 1974 and 2017 concluded that acetaminophen usage is safe in pregnancy. However, the median follow-up time of these experiments was 48 hours, with none of the studies monitoring the neurodevelopment of the child.

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FDA Accepts CAMZYOS for Symptomatic Obstructive Hypertrophic Cardiomyopathy

On October 21, 2022, Bristol Myers Squibb announced that the Food and Drug Administration (FDA) has approved its supplemental new drug application for the prospective medication, CAMZYOS, for the reduction of the need for septal reduction therapy in patients with Symptomatic Obstructive Hypertrophic Cardiomyopathy.

Hypertrophic Cardiomyopathy (HCM) is a disease that causes your heart muscle to enlarge (hypertrophy). Hypertrophic Cardiomyopathy can cause the thickening of the heart muscle's ventricle and lower heart chambers, particularly left ventricular stiffness, mitral valve, and cellular changes. HCM can generally be diagnosed at any age and can affect a wide range of patient populations, from neonatal to the elderly population. However, most commonly, Hypertrophic Cardiomyopathy develops by an individual reaching their late teens into early twenties. Physiologically, the thickness does not change once hypertrophy is attained, but obstructive changes start to arise.

Obstructive Hypertrophic Cardiomyopathy can be symptomatic or asymptomatic. A patient with symptomatic obstructive hypertrophic cardiomyopathy may have associated symptoms of heart murmur, shortness of breath, lightheadedness, and palpitations.

Since Obstructive Hypertrophic Cardiomyopathy appears to be asymptomatic to some at first, physicians do not generally screen for this condition unless one or more of the following risk factors/instances are presented: family screening is performed after an adult in the family is found to be affected, A doctor observes a heart murmur and the patient is evaluated by a cardiologist, An abnormal ECG is found before a medical procedure or the person appears to have athletically-induced asthma, and is given more advanced screening.

According to the New York Heart Association, Septal reduction therapy is recommended in patients that are categorized in the NYHA III or IV class, accompanied by symptoms such as chest pain, syncope during exertion interfering with daily activity as a result of Left Ventricular obstruction, or measure of peak gradient of ≥50mmHg at rest.

However, the Septal Reduction Therapy procedure can be contraindicated in certain patient populations with certain septal thickness and septal perforator obstructions. Such populations include Patients with a septal thickness<15 mm as it would increase the risk of VSD, or ventricular septal defect, Patients with septal hypertrophy but without a major septal perforator vessel, Septal perforator supplying the larger area of the myocardium than the focused area and LVOT obstruction that mainly contributed by mitral valve pathology. For such reasons, medications such as CAMZYOS play a role in assisting in reducing the need to have septal reduction therapy. The anticipated efficacy of CAMYZOS will continue to be monitored.

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