Ohio College of Clinical Pharmacy

# Vitals

Fall 2021, Issue 15

## Message from the President

Hello OCCP Members,

I hope everyone had an enjoyable summer!

We are busy planning our upcoming fall meeting. In order to protect the health of our members, this meeting will be virtual; however, we are hopeful to have an in-person meeting next spring. The fall meeting will feature Medication Safety and Ohio Law continuing education sessions and clinical pearl presentations. We are also excited to offer new educational programming for our resident attendees. Resident poster and platform presentations will be incorporated into the spring meeting. *Message from the President continued on page 2*

## OCCP Leadership

**Liz Fredrickson, PharmD, BCPS**
President
**Jessica Hoover, PharmD, BCPPS**
President-Elect
Steering Committee Chair
**Sarah Petite, PharmD, BCPS**
Immediate Past President
**Sneha Shah, PharmD, BCPS**
Planning Committee Co-Chair
**Molly Amos, PharmD, BCACP**
Planning Committee Co-Chair
**Bethany Crouse, PharmD, BCCCP**
Secretary/Treasurer
**Andrea Pallotta, PharmD, BCPS, BCIDP**
Membership Committee Co-Chair
**Eve Hackett-Garr, PharmD, BCPS, BCIDP**
Membership Committee Co-Chair
**Karissa Kim, PharmD, BCPS**
Membership Committee Co-Chair
SCCP chapter liaison
**Ellen Immler, PharmD, BCCCP**
Nominations Committee Chair
**Ukwen Akpoji, PharmD, BCPS**
Advocacy Committee Co-Chair
**Katelyn Simmons, PharmD, BCACP**
Advocacy Committee Co-Chair
**Kuan Sturgill, PharmD**
Residency Advisory Committee Chair
**Julia Kuroski, PharmD, BCCCP**
Communications Committee Co-Chair
**Keith Posendek, PharmD, BCPS, BCGP, BCCP**
Newsletter Editor
Communications Committee Co-Chair

## Virtual Fall Meeting

### Friday, October 29th from 8:30am - 3:00pm

We have an exciting program for the meeting, including:

- Continuing education credit for Ohio Pharmacy Law and Medical Safety (1 hour each)
- 3 focused breakout rooms with clinical pearls
  - ⇒ Track 1: Pediatrics
  - ⇒ Track 2: COVID-19
  - ⇒ Track 3: Adult Acute Care
- 2 afternoon tracks
  - ⇒ Preceptor Development Track
  - ⇒ Resident/Student Track

### Registration will be open through Friday, October 22, 2021

Registration is **FREE** for current OCCP members, residents, and students.

Registration for non-members is $50 and includes a complimentary 1-year OCCP membership.

## Message from the President continued

*President Message continued from page 1*

There is no cost to attend the meeting for students, residents, presenters, and OCCP members. Options for meeting registration and OCCP membership are available for current non-members. Please visit our website to register for the meeting and renew your membership dues.

We appreciate your feedback as we continue to plan meetings, events, and activities that meet the needs of the organization. Our committee chairs and members work hard throughout the year to ensure the success of this organization. If you are interested in getting more involved by joining a committee, please visit our website to learn more and sign up as a volunteer. If you are interested in a new leadership position, please consider running for the President Elect position in the November election.

Finally, I want to thank all members for your dedication to your patients and communities during these challenging times.

Be well,

Liz

## Planning Committee Update

The focus of the Planning Committee is to continue to provide an avenue for educational programming to our membership, as well as resident engagement. The OCCP Fall 2021 Meeting will be held virtually on Friday, October 29, 2021. The full agenda is available for review on our website and will include Law and Medication Safety CE, clinical pearl presentations, our business meeting, and resident and preceptor development programming. Registration is currently open through Friday, October 22, 2021 and is free to members, residents, and students; registration for pharmacist non-members is $50, which includes an annual OCCP membership. Please be sure to register before the deadline so you can participate in the day.

Thank you,

Sneha Shah, PharmD, BCPS

Molly Amos, PharmD, BCACP

## Membership Committee Update

The committee is excited to announce that Joe Guidos will be taking over as the new Committee chair! He has been working with critical care and emergency medicine PGY2s in Ohio about doing a journal club collaboration and we will be doing these starting on 10/13. Also, we would like to continue the Mentor-Mentee pairings to allow students and residents to be paired with clinical pharmacists across Ohio to ask questions regarding career path, residency applications, CV review, etc. Please let us know if you have any interest in being a mentor or mentee! We will be sending out an email shortly regarding volunteers for mentors and will attach a form that allows the mentees to learn a little bit more about you.

Thank you,

Eve Hackett-Garr, PharmD, BCPS, BCIDP

Karissa Kim, PharmD, BCPS

Andrea Pallotta, PharmD, BCPS, BCIDP

## Advocacy Committee Update

In response to the membership to publish position statements on pertinent advocacy issues, members of the Advocacy Committee recently lettered a position paper on COVID-19 vaccine confidence in Ohio's vulnerable populations with a focus on racial minorities and pregnant women. The purpose of the position paper was to "inform on historical factors contributing to vaccine hesitancy in vulnerable populations and motivational interviewing techniques to increase patients' vaccine confidence." We were happy to obtain endorsements from the OCCP, Ohio Pharmacists Association, Ohio Health-System Pharmacists, and Ohio Northern University School of Pharmacy leadership. The position paper can be found on our Advocacy Committee website! We also explored the national impact of COVID-19 on these populations with publicly available surveillance data; our commentary (**"Exercising empathy: Pharmacists possess skills to increase coronavirus vaccine confidence"**) was published in the Journal of the American Pharmacists Association in August 2021.

Advocates from MetroHealth Hospital in Cleveland helped draft a sponsorship letter template to advocate for pharmacists as medical providers. The letter urges federal legislators to co-sponsor the "Pharmacy and Medically Underserved Areas Enhancement Act" (SB 1362 & HR.2759) that would "enable Medicare beneficiaries to access essential patient care services provided by pharmacists in medically underserved areas." This remains an important topic for the Ohio Pharmacists Association, which launched a Pharmacy Advocacy Forum in August with a follow-up meeting on October 15th. The first session of the Ohio Pharmacy Innovation Series on 10/1 focused on "Understanding Your Role in Provider Status" and featured Senator Matt Dolan. Please reach out to either MaryAnn Dzurec (mdzurec@metrohealth.org) or me for the sponsorship letter template to send to your federal representatives!

In that same vein, we are looking to poll different Ohio medical institutions as to how consult agreements are structured and explore the possibility to broaden the scope of pharmacist activities delineated for inpatient vs. outpatient pharmacists. More to come!

For additional information/updates, see https://www.occpweb.org/advocacy. There you will find the most recent "Call to Action", so please check it out! As always, if you are interested in becoming part of this committee, please reach out to me or Katie at the email(s) provided below.

Thank you,

Katie McMillan, PharmD, BCACP

Ukwen Akpoji, PharmD, BCPS, BCIDP

## Communications Committee Update

Thank you to all the individuals that submitted articles for the Fall newsletter. Thank you to our members who helped with reviewing the newsletter article submissions. If you are interested in writing an article or helping to review articles for future OCCP newsletters, please contact Keith Posendek (kposendek@westernreservehospital.org), or submit an article via our website (occpweb.org). We are looking for a clinical pearl and a new drug update for the Spring newsletter. Requirements include ≈ 500 words maximum, clinically relevant topic, and at least one author is an OCCP member.

Be sure to follow us on social media to stay up to date with all OCCP activities!

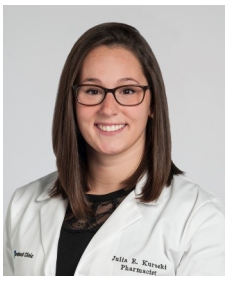
*Facebook:* Ohio College of Clinical Pharmacy *Instagram:* _OCCP

If you have any questions regarding your account or the OCCP website in general, please contact Julia Kuroski (kuroskj@ccf.org) or through the website at https://www.occpweb.org/contact.

Thank you,

Julia Kuroski, PharmD, BCCCP

Keith Posendek, PharmD, BCPS, BCGP, BCCP



## Steering Committee Update

The Steering Committee has been hard at work to maintain OCCP involvement during these uncertain times.

The Residency Advisory Committee will begin their second year and continue to assist with developing resident and student-focused programming for OCCP meetings, other residents and student-focused initiatives and assisting the OCCP executive committee. We are excited to see their upcoming programming!

In addition to the Residency Advisory Committee the Steering Committee is focused on providing quality virtual programming during COVID and continued travel restrictions. After the Spring OCCP meeting the Steering Committee and Planning Committee sent out a survey to all OCCP members to assess future meeting formatting and programming. This valuable feedback was used to format the upcoming fall meeting which will feature continuing education in focused areas and tracks for both preceptors and residents.

We are always looking for members to sit on the steering committee. Feel free to contact me if you would like more information on this committee!

Thank you,

Jessica Hoover, PharmD, BCPPS

## Residency Advisory Committee Update

The residency advisory committee just had our first meeting where we discussed goals and plans for the upcoming year. We are in the process of deciding which programming activities to pursue based on past success including round table discussions, the resident/student journal club, a professional development workshop series, and a layered mentor/mentee program. We also plan to reach out to the local SCCP chapters with a survey asking for their input on programs they would like to see from us and how we can increase student involvement. We are very excited for the upcoming year!

Thank you,

Kuan Sturgill, PharmD

OCCP
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## Student Chapter Update
## University of Cincinnati

Last semester, UC ACCP finished the academic year strong by hosting the annual Organ Donation Awareness Campaign. Partnered with LifeCenter and the Student Nursing Association, ACCP was able to inform students and faculty on the importance and impact of organ donation. Dr. Rita Alloway spoke to us about medication therapy optimization for patients with solid organ transplant and Missy Holiday, RN, spoke to us about the work LifeCenter provides and how to become an organ donor. We also were able to hear from an organ donor and organ donor recipient on how organ donation impacted their lives.


Members of our executive board welcoming students at a back to school event.

We also hosted the ACCP Clinical Pharmacy Challenge Local Competition for the students at our college. We had a great turnout and cannot wait to host the event again this year!

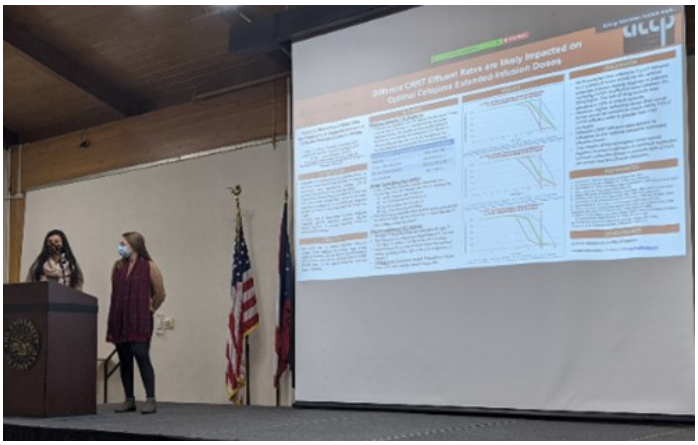
ACCP was able to virtually meet with prospective pharmacy students who were currently taking undergraduate classes at UC. Each undergraduate student was paired with a UC ACCP member where they discussed the steps the "ins and outs" of pharmacy school. UC ACCP also hosted a Residency Roundtable Event where they collaborated with other ACCP student chapters to host 15 pharmacy residents, including those from UCMC, CCHMC, Christ Hospital, and Mayo Clinic!

Last year, UC's chapter of ACCP established a PRN network where we were able to host pharmacists and other clinicians from local hospitals. This semester, we are focusing on critical care. We are excited to see the PRN network grow throughout UC pharmacy's student body and local health systems.

## Student Chapter Update
## University of Findlay

One big event we plan as a chapter is called Pharmal. This is a professional dance where we send our appreciations to our profession as well as to current pharmacists and students. Unfortunately, we have not been able to host this event in the past years. So, we planned on bringing it back this year for our Homecoming Weekend. The event provides an opportunity to make connections with alumni, professors, and other pharmacy majors.

The other event we plan to hold this year is the Research Palooza. This is a new event we started last year to give our students



in their third professional year (P5's) the opportunity to practice presenting about their research. This also allows underclassmen to learn about all the possible research projects they can do in the future. This year we plan to have the event in November and trying to make it more inclusive to the younger pharmacy students. We hope to make it so that the younger students can also present about their projects they are working on, even if they have not finished it yet.

## Student Chapter Update
## Northeast Ohio Medical University

The Northeast Ohio Medical University ACCP student chapter decided to conduct fall hybrid meetings with an in person and zoom option. We were very excited to start hosting our meetings and interact with our speakers in person! So far, we had a Pharmacy 101 Survival tips panel regarding pharmacy school for students to ask any questions they had about our chapter and pharmacy school. We plan on having speakers present on topics such as ambulatory care, critical care, journal clubs, etc. We were very proud of our team for making it into round 4 of the ACCP Clinical Pharmacy Challenge. We plan on helping at a Medication Take Back Day at University Hospitals in Portage, where we will be collecting any medications patient's may no longer be taking. Overall, we are looking forward for our meetings this semester!

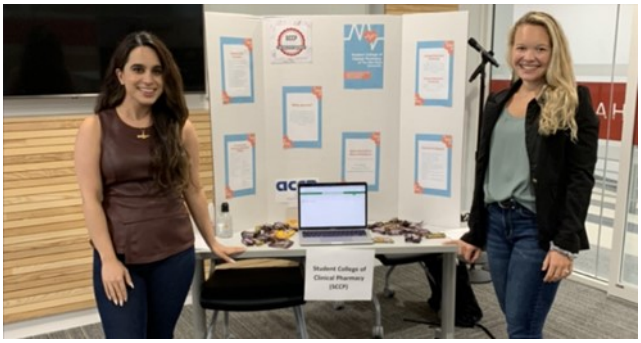
## Student Chapter Update
## The Ohio State University

This semester The Ohio State University (OSU) Student College of Clinical Pharmacy continues to exhibit the core values of clinical practice, research, and education.

In the area of clinical practice, the OSU SCCP chapter incorporates the opportunity to learn about diverse clinical pharmacy practice areas. We were honored to have behavior health patient care pharmacist Dr. Matthew Dick as the first guest speaker of the semester. The speaker discussed pediatric psychiatry and solved a patient case with SCCP members. OSU SCCP also partook in ACCP's Clinical Pharmacy Challenge, successfully completing the local competition and online round one.

Clinical Skills Competition Team 2021: (Left to Right) Andres Mariano, Andrea Malfara, Carolyn Kusoski

OSU SCCP is excited to announce the establishment of a Research Matching Program with The Ohio State University Wexner Medical Center. The Research Matching Program allows members to dig deeper into their clinical interests, present research at national meetings, and be more prepared to complete a research project as a clinical pharmacy resident. The OSU SCCP continues to work hard to create opportunities for pharmacy students to expand their research skills and has established a Research Certificate Program. Frequent research workshops including multiple research topics (i.e., how to write a proposal, IRB review) will be held starting in October.



OSU SCCP at OSU's Pharmacy Student Organization Fair: (From left to right) Sarah Hassani, Andrea Malfara

Overall, the fall semester of OSU SCCP is off to a strong start. We have further solidified the vision of our chapter, recruited new general and e-board members, and are excited to advance the area of clinical pharmacy.

## Clinical Pearl

### Can Direct Acting Anticoagulants Be Used in Obese Patients?

Natalie Tasseff, PharmD, PGY1 Resident; Frank Rigelsky, PharmD, BCPS, BCCP; and Kelsey Fink, PharmD, BCPS, BCPPS
Cleveland Clinic Hillcrest Hospital

Direct acting oral anticoagulants (DOACs) are preferred over warfarin for anticoagulation therapy in stroke prevention for atrial fibrillation patients and treatment of deep vein thrombosis (DVT) as indicated in the American Heart Association (AHA) and American College of Chest Physicians (CHEST) guidelines.[1,2] As DOACs do not require routine lab monitoring and have a consistent duration of action, these agents lessen the burden for patients to manage their anticoagulation treatment.[1,2] When DOACs were initially studied, obese (Body Mass Index [BMI] over 30 kg/m$^2$) patients were not well represented in trials; however, the Food and Drug Administration (FDA) did not place any restrictions for DOAC use in patients over a certain weight or BMI. Due to the lack of evidence, there is a lack of information regarding the safety and efficacy of DOAC use in obese patients. In 2016, the International Society on Thrombosis and Hemostasis published guidance that discourages the use of DOACs in patients above 120 kg or with a BMI over 40 kg/m$^2$ unless routine monitoring was completed.[3] However, there is not a standard protocol for monitoring DOAC agents that is well defined in guidelines or literaure.[3]

Kaplan and colleagues completed a retrospective case-control analysis of patients with atrial fibrillation who were taking a DOAC agent and evaluated the events of ischemic stroke and systemic embolism across multiple BMI ranges. The majority of patients were taking apixaban (n=3356) or rivaroxaban (n=2785) compared to edoxaban (n=10). After the completion of the trial, there was not a statistically significant difference in ischemic stroke risk from patients who had a normal BMI, compared to those in the obese BMI ranges as shown in the table below.[4]

Table 1: Evaluation of Ischemic Stroke Risk

| BMI Range | Hazard Ratio | 95% Confidence Interval | *P* value |
|---|---|---|---|
| 25-30 kg/m$^2$ | 1.252 | 0.581-2.701 | 0.566 |
| 30-35 kg/m$^2$ | 1.217 | 0.516-2.873 | 0.654 |
| $\geq$ 35 kg/m$^2$ | 0.684 | 0.233-2.008 | 0.490 |

Kido and colleagues completed a meta-analysis and found no statistically significant difference between using warfarin or a DOAC agent in stroke prophylaxis for obese patients with atrial fibrillation. The researchers evaluated DOAC agents (dabigatran, rivaroxaban, apixaban, or edoxaban) and warfarin in obese patients by collecting data from five trials. Obese patients were defined as a BMI greater than 40 kg/m$^2$ or weight greater than 120 kg. From the five studies evaluated, authors evaluated stroke risk or systemic embolism (SE) in two of the studies. There was no statistically significant difference between stroke or SE events with patients that were treated with either a DOAC or warfarin (OR: 0.85; 95% CI: 0.60, 1.19; p=0.52; $I^2$=0%). However, DOAC agents were associated with less major bleeding than warfarin in four of the studies (OR: 0.63; 95% CI: 0.43, 0.94; p=0.02; $I^2$=30%).[5]

Barakat and colleagues evaluated 39,094 patients with nonvalvular atrial fibrillation with a CHA2DS2-VASc score of one or greater in a retrospective cohort. The patient population included multiple BMI ranges and took either a DOAC agent or warfarin. The risk of ischemic stroke and significant bleeding was evaluated over 3.8 years. Patients with a BMI over 30 kg/m$^2$ and 40 kg/m$^2$ did not show a statistically significant difference from warfarin therapy for preventing ischemic stroke or a higher risk of bleeding.[6]

Stecker and colleagues compiled a review for DOAC use which provided guidance for choosing a DOAC agent in patients with BMI over 40 kg/m$^2$ or weight over 120 kg. Caution is recommended when using rivaroxaban and apixaban in obese patients, while dabigatran, edoxaban, and betrixaban should be avoided unless specific laboratory monitoring is used. Select laboratory parameters can include of prothrombin time, activated factor X, plasma drug concentration, complete cell count and complete metabolic panel. Apixaban and rivaroxaban were associated with less bleeding risk and thrombosis than dabigatran, while data is lacking for edoxaban and betrixaban.[7]

Kuchnir and colleagues evaluated 795 patients taking either warfarin or a DOAC agent for stroke prevention in nonvalvular atrial fibrillation (n=429) or venous thromboembolism (VTE) treatment (n=429) in a single-center

*Clinical Pearl continued on page 8*

**Can Direct Acting Anticoagulants Be Used in Obese Patients?**

Natalie Tasseff, PharmD, PGY1 Resident; Frank Rigelsky, PharmD, BCPS, BCCP; and Kelsey Fink, PharmD, BCPS, BCPPS
Cleveland Clinic Hillcrest Hospital

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retrospective analysis. There was a low recurrence of VTE across all agents (apixaban [1/47], rivaroxaban [3/152], and warfarin [2/167]) with little difference between each anticoagulant. No groups differed in the incidence of major bleeding or clinically relevant non-major bleeding in VTE treatment.[8] Clinically relevant non-major bleeding is defined as any sign or symptom of hemorrhage that does not fit ISTH definition but includes either healthcare professional intervention, hospitalization or increased level of care, or leads to an in person evaluation.[9] There was no difference in the anticoagulants when used in atrial fibrillation cohorts in regards to stroke incidence or composite bleeding.[8]

Past data lacked to prove the safety and efficacy of DOAC agents in obese patients (BMI over 40 kg/m2 or weight over 120 kg); however, new information has provided evidence that DOACs are not associated with greater risk of stroke in atrial fibrillation when compared to patients treated with warfarin or to patients in lower BMI classes. More research is required to confirm pharmacokinetic effects of DOAC agents in extreme weight categories ranging from weights under 60 kg to over 120 kg, as current literature remains inconclusive. DOACs, when used with appropriate lab monitoring, may have benefit for obese patients by decreasing the burden of care and increasing patient adherence without forgoing efficacy.

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# Lumakras™ (sotorasib) for KRAS$^{G12C}$ Positive Non-Small Cell Lung Cancer

Matthew Schultz, PharmD Candidate, The Ohio State University College of Pharmacy, Class of 2022
Alisha Mazur, PharmD, Clinical Pharmacist, MetroHealth Specialty Pharmacy

Author's Note: Per standard nomenclature convention, *KRAS* refers to the gene, whereas KRAS refers to the protein coded by the gene.

**Background**

On May 28, 2021, the FDA granted accelerated approval status to Lumakras™ (sotorasib) after clinical trial data showed a significant response rate for some patients with non-small cell lung cancer (NSCLC).[1,2] NSCLC makes up 85% of lung cancer cases and has a low median 5-year survival rate of 30%, due largely to the lack of early-stage detection and the high mutation rate of associated oncogenes.[3] One of the most well-established oncogenes implicated in NSCLC is *KRAS*, a gene which encodes for a GTPase protein responsible for cell cycle regulation. KRAS$^{G12C}$, the result of a single point mutation to the *KRAS* oncogene, causes increased GTP binding which is believed to hold the protein in an active conformation causing uncontrolled cell proliferation.[4-7] Previously thought to be an untreatable target due to the mutated protein's unique surface groove, KRAS$^{G12C}$ has been observed in 13% of NSCLC patients.[2,6,8] Sotorasib is the first oral chemotherapy shown to target and treat KRAS$^{G12C}$ mutation-positive metastatic NSCLC by inactivating KRAS, thereby halting cell division and cancer cell growth.

**Accelerated Approval**

Sotorasib's approval by the FDA was based on results from the CodeBreak 100 trial: a phase I/II single-arm, open-label, multicenter study with 124 participants over the age of 18 with measurable disease at baseline.[9] The primary endpoints of the study were safety, overall response rate (ORR) and duration of response (DOR), with response defined by RECIST 1.1 criteria. Data showed that 37.1% of participants had a confirmed response to sotorasib with a median duration of response of 11.1 months.[1,9] (Table 1)

**Role in NSCLC Therapy**

Recommended first line treatment for patients with advanced, KRAS$^{G12C}$ positive NSCLC is a platinum doublet (such as cisplatin/docetaxel) or a combination of platinum-based therapy and immunotherapy (pembrolizumab/carboplatin/pemetrexed) (Category 1).[10] Options for patients who fail to achieve clinical response from first-line treatment include targeted oral medications to treat actionable mutations. Until CodeBreak 100, no oral treatments were found to selectively target KRAS$^{G12C}$ cancer cells.[11]

Current National Comprehensive Cancer Network (NCCN) guidelines now recommend sotorasib for patients who have tried at least one other systemic therapy and have been diagnosed with locally advanced or metastatic NSCLC (Category 2A).[10] A KRAS$^{G12C}$ mutation must be confirmed using biomarker testing approved by the FDA for this purpose. Recently approved tests include Gardant360 CDx and Qiagen Therascreen.[1]

**Therapy Considerations**

Sotorasib is available in 120mg tablets and has a recommended dosage of 960mg (8 tablets) once daily. No dose adjustments are required for renal or hepatic dysfunction.[12]

The most commonly reported side effects (≥20%) of patients taking sotorasib were diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity and cough (Table 1). If sotorasib becomes intolerable due to side effects, a dose reduction to 480mg once daily is recommended. If intolerable side effects persist, the dose can be reduced to the minimum daily dose of 240mg.[9,12]

Hepatotoxicity from sotorasib may lead to liver damage and hepatitis. Liver function tests should be assessed prior to initiating treatment and then every 3 weeks for the first 3 months of therapy. After 3 months, liver function can be assessed monthly but should be checked more frequently if labs indicate elevated transaminase or bilirubin levels. Fatal cases of pneumonitis and interstitial lung disease were also reported in the CodeBreak 100 trial (0.8%). Patients should immediately discontinue sotorasib if pneumonitis or interstitial lung disease develops as a result of treatment.[12]

Sotorasib is a substrate for CYP3A4. Concurrent use with strong or moderate CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin, St. John's Wort) is likely to cause a subtherapeutic response and should be avoided. Sotorasib is absorbed best in an acidic environment and should not be taken with proton pump inhibitors, H2-receptor antagonists or other gastric acid lowering medications.[2,12]

Although not *New Drug Update continued on page 10*

**Lumakras™ (sotorasib) for KRAS$^{G12C}$ Positive Non-Small Cell Lung Cancer**

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Alisha Mazur, PharmD, Clinical Pharmacist, MetroHealth Specialty Pharmacy

*New Drug Update continued from page 9*

part of exclusion criteria, sotorasib was not studied in nursing or pregnant women.

**Conclusion**

Sotorasib is a novel second-line chemotherapy option for patients with a *KRAS*$^{G12C}$ mutation. Although targeted oral therapies exist, sotorasib is the first treatment shown to selectively target KRAS$^{G12C}$. As with any chemotherapy treatment, there are risks of serious side effects, but clinical trial data suggests a favorable risk/benefit ratio. Further clinical data will be needed to compare efficacy of sotorasib to previously recommended second-line therapy, but at present, sotorasib offers hope to patients diagnosed with this difficult-to-treat mutation.

**Table 1 – Results of CodeBreak 100**

| | **Phase I** [1,9] | **Phase II**[1,9] |
|---|---|---|
| Primary Endpoints | Determine safety/tolerability<br>Determine max daily dose | Overall Response Rate (ORR)<br>Duration of Response (DOR) |
| Participants | 129 : 59 NSCLC, 42 colorectal cancer, 28 other | 124 |
| Design | Single-arm, open-label, multi-center trial | |
| Methods | Patients were started on 180mg and titrated to 360mg, 720mg, and 960mg daily until disease progression, intolerable side effects, withdrawal of consent, or end of study | Patients were given 960mg once daily and monitored for tumor size and disease progression |
| Inclusion | ≥18 years old with measurable disease at baseline<br>KRAS$^{G12C}$ mutation<br>Failed at least one other systemic therapy | ≥18 years old with measurable disease at baseline<br>KRAS$^{G12C}$ mutation-positive NSCLC<br>Failed at least one other systemic therapy |
| Exclusion | Untreated, active brain metastases<br>Radiation within 2 weeks of initiation<br>Unable to take oral medication | |
| Results | Most common (≥20%) adverse effects: diarrhea (42%), musculoskeletal pain (35%), nausea (26%), fatigue (26%), hepatotoxicity (25%), cough (20%)<br>Daily dose: 960mg with minimum daily dose of 240mg<br>ORR: 37.1%<br>Median DOR: 11.1 months | |
| RECIST version 1.1 criteria[13] | Complete Response (CR): Disappearance of all tumors for at least 1 month<br>Partial Response (PR): - ≥30% decrease in diameter of largest tumor<br>Stable Disease (SD): Neither a response nor progression<br>Disease Progression (DP): >20% increase in diameter of largest tumor | |

*New Drug Update continued on page 11*

**Lumakras™ (sotorasib) for KRAS$^{G12C}$ Positive Non-Small Cell Lung Cancer**

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*New Drug Update continued from page 10*

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