SOAP NEWSLETTER

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A NOTE FROM THE EDITOR

SOAP will forever hold a dear place in my heart and will always be among my favorite memories from pharmacy school. I have yet to meet another group of people so passionate, so dedicated to their patients. I hope every student at the COP gets to experience the camaraderie that is clearly present within this organization. I want to say a sincere thank you to everyone who wrote for the newsletter, to my fantastic exec team, and to Dr. Amber Clemmons, PharmD, for making this edition of the newsletter come to fruition.

As we continue to adjust to life in the throws of the ongoing COVID-19 pandemic, classes are no longer virtual and social distancing rules can seem like nothing more than a distant memory. And as the pre-pandemic lifestyle slowly reemerges, only a few students can recognize its familiarity. Most of the student pharmacists on campus now weren't around to see the well-oiled machine the COP once was. Thankfully, our P3 class can still recall what life was like before anyone had ever heard of COVID-19. Our VP of Membership and Education, Alexis Bevill (P3), brought back a long beloved SOAP tradition: Pillyimpics. Five teams of student pharmacists and one team made up of Drs. Seagraves, Huang, and Khail spent the afternoon engaged in cutthroat, pharmacy themed competition. It was surprising to no one when the team of professors came out on top at the end of the afternoon, but as always, they handled their win with the utmost grace and dignity. Mostly. With the help of great faculty and the hard work from our dedicated members, SOAP will continue to revive old traditions and create new ones for the classes of student pharmacists that come after us. While the patient population SOAP serves remains disproportionately affected by the risks of COVID-19, our members will continue to help them from a distance as long as we need to in order to keep them safe.

BULLETIN HIGHLIGHTS

Asciminib for Chronic Myeloid Leukemia

By: Dallas Davis PharmD Candidate of 2023

Chronic myeloid leukemia (CML) is a cancer arising from a specific genetic mutation in the myeloid lineage of the bone marrow. The genetic mutation forms in a gene called BCR-ABL, also known as the Philadelphia chromosome (Ph), which causes formation of a mutant tyrosine kinase leading to proliferation of abnormal immature myeloid cells rather than healthy cells which would normally proliferate into red blood cells, platelets, and various types of white blood cells. The majority of patients diagnosed with CML are older, median age 64 years, and are diagnosed in the chronic phase (CP) although some have accelerated phase or blast crisis, which are associated with poorer prognosis. The American Cancer Society's estimates about 8,860 new cases of CML in 2022. [1]

The standard treatment for CML is a tyrosine kinase inhibitor (TKI) specific to BCR-ABL, which causes inhibition of the excessive growth of the immature cells. The current agents are imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), bosutinib (Bosulif), ponatinib (Iclusig), and asciminib (Scemblix). Initial treatment depends on a risk stratification, which is based on the patient's Sokal score, Hasford (EURO) score, or EUTOS long-term survival score. If a patient has a low-risk score, they have the initial treatment options of imatinib, bosutinib, dasatinib, or nilotinib. If a patient has an intermediate or high risk, they have the options of bosutinib, dasatinib, or nilotinib. Treatment success is assessed by milestones such as early molecular response (MR) and complete cytogenetic response (CCyR) using the molecular quantitative polymerase chain reaction(qPCR) for BCR-ABL1. However, resistance to these first-line treatment options may occur, such as the T315I mutation for which none of the first-line agents are effective. Ergo, other agents such as ponatinib and asciminib, which do not have any contraindicated mutations, are available. [2] Ponatinib has black box warnings for arterial occlusive events, venous thromboembolic events, heart failure, and hepatotoxicity. It also has a REMS program associated with it for the risk of vascular occlusion. [3]

Asciminib (Scemblix) is a TKI indicated for the treatment of adults with Philadelphia chromosome-positive CML (Ph+ CML) in the chronic phase with the T315I mutation.[4] It is a novel, first-in-class agent specifically targeting the ABL myristoyl pocket (STAMP) that blocks BCR-ABL1 kinase activity via allosteric binding, making it different from the other TKIs used in CML currently. Therefore, the different binding site has the potential to retain activity in those patients who have a BCR-ABL mutation, such as T315I. [5] Asciminib gained its accelerated approval for patients who had failed at least 2 previous TKIs based on results of the ASCEMBL trial. This trail randomized patients with chronic phase CML who had previously been treated with at least two prior TKIs to either asciminib 40 mg twice a day or bosutinib 500 mg once a day at a 2:1 ratio. Patients were excluded from the study if they had either a T315I or V299L mutation since bosutinib is ineffective against those mutations.

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The trial allowed for patient crossover from bosutinib group to asciminib. The ASCEML trial aimed to show superiority of asciminib as compared to bosutinib with respect to the primary outcome of MMR at 24 weeks A sample size of 222 patients was necessary for 90% power to detect 20% difference in the rates at week 24. At 24 weeks the MMR was significantly higher at 25.5% in those receiving asciminib as compared to 13.2% in those receiving bosutinib (P =0.029). The response rate for asciminib was superior to bosutinib regardless of demographic and prognostic variables that were evaluated, such as number of prior TKI therapies, discontinuation of last TKI, and mutation status at baseline. Patients with other mutations were included in the study and asciminib showed better efficacy over bosutinib at 6/17 patients vs 2/8 patients achieving the outcome of MMR at 24 weeks, respectively. With respect to safety, asciminib had an overall lower proportion of patients who experienced adverse effects compared to bosutinib. The most common adverse effects were thrombocytopenia, neutropenia, and headache for asciminib and diarrhea, nausea, and increased ALT for bosutinib. [5].

The approval of asciminib for patients with Ph+ CML with T315I mutations was based on results from a multicenter, open label, single-arm clinical trial. The trial had 45 patients that received 200 mg asciminib twice daily. [6] All the patients included in the trial were previously treated with a TKI therapy. [4] The main outcome measure was MMR. At the 24-week mark, 42% of the patients had achieved MMR. At the 96-week mark 49% of patients had achieved MMR. [6] The trial is still ongoing with an estimated primary data completion expected March 2024. [7]

Overall, the ASCEMBL trial showed asciminib was superior to bosutinib which led to its approval in those patients who have failed 2 previous TKIs. A single-arm

trial supported approval of asciminib for patients with the T315I mutation. [5] The only other TKI for patients with T315I mutation is ponatinib, which is associated with significant adverse events, whereas asciminib has neither a black box or REMS program likely making it the best option before ponatinib in subsequent lines of therapy. Asciminib has established its place in therapy and trials are ongoing to gain more data to obtain the full FDA approval. [8]

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How can we equip pharmacists with the tools necessary to provide supportive care to cancer patients in various practice settings?

By: Emily Schafhauser PharmD Candidate of 2023

You do not have to be a Board-Certified Oncology Pharmacist to have cancer patients. More than 1.6 million Americans are diagnosed with cancer each year (CDC), making it extremely likely that our future patients will battle cancer. Therefore, it is vital that we know how to take care of these patients in any setting we find them- inpatient, ambulatory, or even at the retail pharmacy counter. We can make a difference when it comes to educating patients on adherence to their complex regimens, common side effects, and ensuring they are equipped with the proper supportive care. High-cost therapies, medication shortages, and regulatory requirements also provide numerous opportunities for pharmacists to intervene.

The National Community Oncology Dispensing Association (NCODA) website offers a reference library with patient medication information sheets for oral and IV chemotherapy agents. This website is free to access and takes minimal effort to print out an information sheet for the patient to take home at the time of their prescription pick up. This can increase drug adherence and trust between the patient and pharmacist.

Oncologic drugs can cause unbearable side effects that decrease one's quality of life (ACS). Treatments are personalized based on cancer type, staging, and genetics; therefore, no two cancer patients can expect to experience the same effects. Severe effects that require medical attention include severe nausea and vomiting, febrile neutropenia, and oncologic emergencies. If a patient is taking a drug with a highly emetogenic risk, the pharmacist can be responsible for ensuring the patient is properly medicated to prevent nausea and vomiting, in addition to a breakthrough regimen as needed (NCCN CINV). Another serious effect is febrile neutropenia that is caused from the therapy suppressing their white blood cells, putting them at risk for infection. A fever can be the only indicator of infection; pharmacists need to make sure patients monitor their temperature and seek medical help for a fever higher than 101F or 100.4F that lasts over an hour (ACS). NCODA offers treatment support kits that include some necessities for chemotherapy side effect management, such as a thermometer, anti-diarrheal, pill boxes, lip balm, dry skin cream, and a treatment calendar. Each kit is $8.99 and is personalized based on the specific chemotherapy regimen the patient is undergoing (NCODA).

Patients take on a huge financial burden during cancer treatment. Pharmacists are the ones that understand insurance coverage, catch prior authorizations, and know what medications are on backorder. Medicationassistancetool.org is a financial resource patients can use to find co-pay cards and enroll in Pharmaceutical Patient Assistance Programs to help with cancer therapy related costs. The FDA currently has 9 oncologic drugs with the status of "currently in shortage" (FDA). To avoid

therapy interruptions, pharmacists can be the one to contact the physician to select an alternative when needed.

There is currently an oncologist shortage, making this a great field for pharmacists to be present in! If you are interested in specializing in oncology, ASHP recognizes 121 PGY-2 oncology programs in the US as of now. A residency can aid you in the process to pass the Oncology Pharmacy Specialty Certification Exam to become Board Certified. Specialized or not, these patients require and deserve support from their pharmacists.

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Impact of Health Disparities on Lung Cancer Patients

By: Adesuwa Utomwen, PharmD Candidate of 2024

According to the Healthy People 2030 Publication, health disparities can be defined as a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantages.(1) Health disparities can have an impact on minority patients' access to appropriate screening, prompt diagnosis, and adequate treatment of various conditions including chronic disease states and life-threatening cancers. Early detection and diagnosis significantly improve the quality of life for patients and improves their disease prognosis. Limitations to this standard of care do exist in the minority patient populations, specifically regarding cancer care management.

The American Cancer Society notes that African Americans have a higher cancer burden and experience worse outcomes when compared to other ethnic groups.(2) Specifically, in the realm of lung cancer, the presence of health disparities has played a drastic role in the early screening of this specific patient population. Some sources of these disparities include implicit bias, lack of access to care, housing stability, and ineffective patient provider relationships.(3,10) All of these factors interconnect and directly relate to the reduced health outcomes and inadequate patient education. The American Lung Association (ALA) concluded that African American patients with lung cancer were 18% less likely to be diagnosed early and 21% less likely to survive five years compared to Caucasian Americans. Nationally, only 25% of all lung cancer cases have been reported to have an early diagnosis.(4)

The ALA report also analyzed each state's burden of lung cancer as it relates to incidence, screenings, management, and treatment of their respective patients. Currently, Georgia ranks 39th out of 49 states with available data in the nation for early diagnosis for lung cancer. This organization also reported in the "State of Lung Cancer" analysis that people of color are the least likely to be considered for early screening/ diagnosis and more likely to not be provided treatment.(4) One observational study that analyzed the rate of lung cancer surgical treatment in African Americans and Caucasian patients showed that even after accounting for confounding variables (sex, access to care, and SES), African American patients were still 12.7% less likely to be treated. Many other studies have found this pattern of inequality that exists in providing treatment to African American patients. Implications of low rates of treatment includes increased mortality and morbidity among these individuals.(5)

According to the United States Preventive Services Task Force (USPSTF), the first line recommendation for lung cancer screening is the low dose computed tomography (LDCT). The 2013 updated criteria states that to become eligible for screening, patients must be between 50 to 80 years of age and have a 20-year pack history.(6) This update which expands the screening eligibility, is still to some degree decreasing the detection rate in those

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with lower smoking risks that develop lung cancer at an early age. Using the baseline comparator of age and pack year as sole factors in screening does not take into account associations between health disparities and cancer management. According to the American Thoracic Society, African American smokers under this new criteria would still be less likely to qualify for lung cancer screenings than the counterpart ethic group (27% vs 36%).(7) The national lung cancer screening criteria are not influenced by the racial, gender, and socioeconomic differences that exist in lung cancer risk and predisposition.(8) Specific recommendations for the nonsmoking population and for patients with environmental risk factors would provide a more equity based screening tool.

With this knowledge of cancer disparities lies the pressing question: how can we make a difference?

One of the first steps towards improvement includes increasing awareness to the healthcare related challenges that African Americans face and the history of how these disparities influence screening, diagnosis, and treatment of lung cancer. Providing continuing education courses on cultural competence and cross-cultural communication should be expanded into all areas of practice. In addition to this, engaging in educational outreach programs in underserved communities across the nation will provide a solution to improving the provider to patient relationship. Project Implicit, a non-profit organization, provides tools and services that identifies unconscious bias that exists in an individual and can be of use for physicians in their efforts to improve their joint decision-making processes with specific patients.(9) Along with this, more guidance on how to incorporate individualized management of screening and diagnosis in minority patients also need to be provided. Overall, improving cancer care for African American patients lies in recognizing where implicit biases exist, increasing timely access to treatment centers, and broadening the inclusion factors for early-stage screening criteria.

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