SUMMIT Rewind
A LOOK BACK AT KEY SESSIONS FROM THE 2022 NCODA FALL SUMMIT

ADDRESSING FINANCIAL OBSTACLES: PAGE 7

METASTATIC MELANOMA TREATMENT UPDATES: PAGE 14

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Being a part of the NCODA Professional Student Organization (PSO) community is such a remarkable experience. Together, we keep each other updated and informed on current clinical oncology practices, while also providing opportunities that aid in developing leadership skills.”

- Jonathan Rivera
PharmD Candidate | Class of 2023
University of North Texas Health Science Center

ABOUT PSO

Our focus is to offer an international community for healthcare students with a passion in oncology and pharmaceutical industry. The NCODA Professional Student Organization (PSO) was established for students interested in oncology, association management, healthcare advocacy and policy, and industry leadership.

PSO BENEFITS

• First professional student organization for students interested in oncology/association management/industry leadership
• Opportunities to attend NCODA international meetings
• International public presentation opportunities
• Create educational materials to help impact cancer care
• International publishing opportunities (ForumRewind, SummitRewind, Inspire & Oncolytics Today publications)
• Increased networking opportunities with oncology clinical and industry professionals, and key opinion leaders
• Access to over 50+ hours of oncology video education (Student Educational Talks)
• Oncology clinical practice experience and mentorship
• Healthcare advocacy and policy experience
• Additional student opportunities:
  • 1-year post-graduate oncology fellowships
  • International elective APPE rotation in oncology
  • Participate in NCODA’s international clinical oncology competition

FOR MORE INFORMATION OR TO SUGGEST NEW CHAPTERS
Email Cooper Bailey at cooper.bailey@ncoda.org
Scan to visit, or check out www.ncoda.org/professional-student-organizations

NCODA is a grassroots, not-for-profit organization, founded to strengthen oncology organizations with medically integrated pharmacy (MIP) services.
SUMMITRewind provides summaries of key sessions from NCODA’s annual Fall Summit written by members of Professional Student Organization chapters from across North America. To view slides from presentations, scan the QR code at the end of the summaries.

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Notable On The Cover: (Center middle) Neal Dave, PharmD, Executive Director of Pharmacy Operations at Texas Oncology and the 2018 NCODA Living the Mission Award recipient, kicks off the 2022 Fall Summit by reading NCODA’s Mission and Vision. (Center lower) Jim Schwartz, RPh, Corporate Pharmacy Manager at Texas Oncology and NCODA President, introduces keynote speaker, William Roth. (Right lower) David Nash, MD, MBA, Founding Dean Emeritus at Jefferson College of Public Health, provides a keynote presentation.
**An Overview of FGFR Inhibitors & Unprecedented and Unexpected: Immunotherapy in Early-Stage Rectal Cancer**

**PRESENTERS:** Roger Orr, PharmD, BCOP | Florida Cancer Specialists and Research Institute; Courtney Cavalieri, PharmD, BCOP | Huntsman Cancer Institute

**SYNOPSIS:** This dual presentation discussed the current place of FGFR inhibitors and dostarlimab in oncology practice. FGFR inhibitors have been included in several clinical trials to establish their efficacy and to identify side effects. Orr discussed the treatment regimens, dosing, and patient-specific considerations for each FGFR inhibitor. Cavalieri provided an overview on colon cancer staging and current treatment regimens for patients diagnosed with early-stage rectal cancer. She then summarized the findings and implications of a study that utilized immunotherapy with dostarlimab in place of chemoradiation.

**PRESENTATION:** Overview of FGFR: FGFR inhibitors block downstream MAPK and PI3K/AKT pathways, thereby preventing tumor proliferation in patients with carcinomas. There are currently three FGFR inhibitors available, erdafitinib, pemigatinib and infigratinib (which will be discontinued in March 2023).

This drug class has some specific adverse drug events that require close monitoring by the oncology team. These include hyperphosphatemia, ocular toxicity, stomatitis, nail toxicities, palmar-plantar erythrodysesthesia and CYP3A4 interactions. Orr recommended early intervention to treat these side effects.

**Dostarlimab in Early-Stage Rectal Cancer:** For patients diagnosed with early-stage rectal cancer, treatment aims to cure. While being cured is a reasonable outcome, therapy comes with long-term complications and toxicities. Treatment typically consists of surgery, radiation and chemotherapy. A new study looked at a small group of early-stage rectal cancer patients who had dMMR-MSI-H disease using dostarlimab as a neoadjuvant therapy. After six months of dostarlimab, the patients underwent a standard long course of chemoradiation. Remarkably, after treatment, 100% of these patients were cured and did not have to undergo further treatment. This discovery will need further investigation, but gives hope to rectal cancer patients.

**TAKEAWAY POINTS:**
- FGFR inhibitors have a unique set of side effects that require frequent monitoring, but they are manageable with appropriate interventions.
- In a new study, dostarlimab treatment for six months provided a 100% cure rate for patients with early-stage rectal cancer.

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**Resources for Nurses to Improve Patient’s Compliance and Adherence to Oral Oncolytic Regimens**

**PRESENTERS:** April Hallatt, BSN, RN, OCN | Indiana University Health Ball Memorial Cancer Center; Amanda McCauley, BSN, RN, OCN | Norton Cancer Institute

**SYNOPSIS:** McCauley detailed a number of resources available for nurses to best support patient adherence to oral oncolytic regimens. She delivered an in-depth review of the NCODA website, giving particular attention to the “Resources” tab. Hallatt then outlined the relevance and importance of patient adherence for treatment success. She summarized different factors that can contribute to poor adherence, followed by defining clinician-patient based interventions to promote adherence.

**PRESENTATION:** McCauley discussed the tabs on the NCODA website, including “Events,” “Accreditation” and “NCODA University.” Her main emphasis was placed on the Resources tab as she highlighted key member resource offerings, including Treatment Support Kits (TSKs). TSKs allow clinicians to provide their patients with a comprehensive set of products and educational materials to best manage adverse events during oral anticancer treatment. Further patient education can be obtained through the Oral Chemotherapy Education (OCE) library. NCODA CONNECT is a virtual platform that allows members to participate in committees and share insights, as well as access medication tracking forms and patient follow-up templates.

Hallatt shifted gears by distinguishing compliance from adherence. She emphasized the negative connotation compliance can carry as it implies obedience to the healthcare practitioner. Instead, she encouraged using adherence as the word of choice. She quoted the World Health Organization, stressing “adherence is the single most important modifiable factor that compromises treatment outcomes.” Promotion of self-efficacy and resilience are strategies clinicians can use to maximize patient adherence. Moreover, nurturing honest and accessible communication through telehealth, mobile applications and patient support programs will ensure patients are comfortable conveying their needs.

**DISCUSSION:**
- **Q:** Who contributes to the writing of the OCE sheets?
- **A:** They are a collaboration between nurses, pharmacists and pharmacy technicians.

**TAKEAWAY POINTS:**
- Proper medication adherence is enabled by collaboration between patient and clinician.
- Promotion of self-efficacy and resilience are proactive interventions to best support a patient’s care.

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**Scan the QR codes at right to view slides from presentations.**
The Roles of Pharmacy Technicians in Patient Care & Healthcare Leadership Within the Pharmacy

**PRESENTERS:** Ericka Valdez, PharmD, Texas Oncology; Ashley Kohler-Gerber, CPhT, CSPT, American Oncology Network

**SYNOPSIS:** Valdez discussed how pharmacy technicians are uniquely qualified to serve the role of clinical research coordinators (CRC). Kohler-Gerber discussed leadership opportunities for pharmacy technicians, including nontraditional roles.

**PRESENTATION:** Valdez discussed the role of a clinical research coordinator (CRC) by presenting their responsibilities and how CRCs fit into the process of clinical trials. She explained that pharmacy technicians can serve as a CRC, and why they are qualified to fill this role.

As a CRC, pharmacy technicians need to understand the complete process of a clinical trial. This includes working with other healthcare providers, following protocols, monitoring patient safety and helping the entire team work in unison for a successful clinical trial.

Valdez concluded by reiterating that these specific skills that pharmacy technicians possess are why she believes they can transition and excel in the role of a CRC.

Kohler-Gerber explained why pharmacy technicians are necessary and important to the healthcare team, including the value they add to patient care, and how pharmacy technicians can expand their career within pharmacy.

She outlined her own journey into a leadership role within the pharmacy technician field, but noted that not every pharmacy technician path will be the same. She said expanding into a leadership role does not always specifically mean management and provided some examples. These included pharmacy technicians sitting on state boards of pharmacy and specializing in billing and reimbursement.

She also discussed qualities that she believes pharmacy technicians should have that will help them grow into leadership roles.

**TAKEAWAY POINTS:**

- Pharmacy technicians are qualified to serve as CRCs and taking on the role can be a great path for pharmacy technicians to expand their careers.
- There are numerous ways pharmacy technicians can expand into leadership roles. These opportunities can vary based on practice setting and personal interests.

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What Color Bag is Best? A Practical Review of White, Brown, Clear and Gold Bagging

**PRESENTER:** Jorge Garcia, PharmD, MS, MHA, MBA, FACHE, Miami Cancer Institute/ Baptist Health South Florida

**SYNOPSIS:** Garcia reviewed the definitions of different “bagging” models and their impact on the health system's medication distribution process. After discussing the operational, quality and safety barriers of white bagging and brown bagging, he summarized key emerging regulations and provider mitigation strategies to resolve concerns associated with these models.

**PRESENTATION:** White bagging and brown bagging describe the processes of delivering healthcare-administered medications from an external payer-restricted specialty pharmacy to the healthcare provider (white bagging) or to the patient, who then brings the medication to the provider for administration (brown bagging).

Garcia said payers adopt these strategies as cost-saving initiatives that may present better convenience for the patient. However, from the health system’s perspective, these practices lead to fragmentation of care, bypass operational and clinical safety checks, and raise concerns for supply chain integrity and patient safety. The lack of ability to control product quality, handling and turnaround time results in treatment delay, increased provider liability and compromised patient safety.

In addressing solutions to these challenges, Garcia cited letters submitted by professional health system organizations to regulatory bodies regarding the safety concerns associated with white and brown bagging. Garcia also highlighted that a number of states are in the process of passing regulations to limit payer-mandated white and brown bagging practices.

TAKEAWAY POINTS:

- Increasingly prevalent payer-mandated brown and white bagging practices bypass health systems’ safety checks and raise concerns for patient safety, drug chain of custody and quality of care.
- Regulations are emerging at the state level to address the safety concerns of white and brown bagging.
- Clear bagging and gold bagging may serve as alternatives to improve health systems’ ability to control the distribution process and maintain the quality of care.

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Scan the QR codes at right to view slides from presentations.
Addressing Burnout, Retention and Engagement in Oncology Practices Today

**PRESENTER:** Stephanie Broussard, MSSW, LCSW-S, APHSW-C | Texas Oncology

**SYNOPSIS:** Broussard discussed how fundamental self-care is essential to any individual aiming for long-term success and prosperity. Working conditions have a well-known impact — either positive or negative — on employee health.

Broussard emphasized that everyone, regardless of career or background, is susceptible to burnout and they need to know what can be done to prevent it.

**PRESENTATION:** Broussard defined burnout as “feelings of depletion, exhaustion, isolation, negativism and cynicism of your job, along with fantasies of escape.” Despite burnout being present long before the COVID-19 pandemic, this catastrophe exacerbated occupational stress on healthcare workers on a global level.

According to Broussard, although self-care is becoming more recognized as a necessity by organizations to prevent burnout, they tend to implement strategies that either don’t really benefit their employees, or the needs of their employees are too expensive to provide.

Healthcare professionals must proactively protect their mental well-being so that they’re capable of helping others. This led to the creation of The Emotional PPE Project. Just as healthcare workers need physical personal protective equipment (PPE) to keep them physically safe, there must be protective processes in place to protect their mental health. Along with implementation of personal defense mechanisms, organizations need to make more of an effort to show their employees that they are valued.

In essence, when addressing burnout, prevention is key. Broussard stressed the importance of maintaining balance of eight critical dimensions of wellness: intellectual, sensual, nutritional, spiritual, physical, contextual, relational and emotional domains. Mastering this balance allows you to prioritize pivotal principles, beliefs, and values that give purpose to our life.

Equally as important, organizations must begin to tie in a culture of self-care and well-being to the company’s core values and beliefs.

**TAKEAWAY POINTS:**

- The COVID-19 pandemic showed that healthcare workers are valuable to our society, but it didn’t show them that they are valued.
- Everyone needs to establish a self-care plan surrounding the eight dimensions of wellness, as well to as practice emotional PPE.

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Summary by Reem Holozadah, PharmD Candidate (2024), Northeast Ohio Medical University.

**SESSION SLIDES:** Scan the QR code at right to view slides from this presentation.
Thanatology for Oncology Healthcare Professionals

**PRESENTER:** Robert Mancini, PharmD, BCOP, FHOPA | St. Luke’s Cancer Institute

**SYNOPSIS:** Mancini presented on thanatology — the study of death and the practices associated with it — and how it applies both academically and clinically in a healthcare setting.

**PRESENTATION:** Mancini emphasized the importance of understanding how to communicate with others when going through a tragic event. “All healthcare professionals are death educators and we never stop teaching this subject,” he said.

Not only does thanatology effect patients, but also the healthcare team as well through related guilt or blame that they put on themselves. Healthcare professionals often feel that they failed to cure the patient, made the wrong medical decision or made things worse.

“When it comes to dealing with death or grief in a healthcare setting, it’s okay to feel, to cry, to be sad,” Mancini said. In order to heal, he emphasized that it’s extremely important to rely on your co-workers, take breaks and talk to others.

Mancini stated that while 95% of nursing and medical schools teach about the topic of thanatology, only 68% of pharmacy schools include some form of death education. Most pharmacists feel that they are not prepared for the end-of-life care conversation with patients, and they often rely heavily on their peers — nurses and doctors — to help them through it. He noted that 93% of pharmacists said their pharmacy degree did not prepare them for these types of interactions.

Mancini said that the topic of death is discussed almost every day in a healthcare setting, and every professional should be able to communicate with the patient and their family about what is going to happen, as well as be able to walk them through the process. Both patients and their families will turn to anyone they can during this difficult time. This is a skill that every healthcare professional needs to learn when they’re going through their respective schooling.

**TAKEAWAY POINTS:**

- It is important that healthcare professionals understand how to communicate with others through a tragic event.
- Healthcare teams should rely on each other, take breaks and talk to one another in order to heal.
- Education about end-of-life care conversations should be taught in pharmacy school in order for pharmacists to feel that they are prepared for those discussions.

**DISCUSSION:**

Q: (For Schaffner) How long is the turn-around time once a PAP application is submitted?

A: I can only speak for my company (Exelixis), but we try to get patients turned around within 48 hours.

**TAKEAWAY POINTS:**

- Free trials and samples are commonly available to patients as a bridge or short-term solution.
- If a patient is denied because of income for foundations, they may still qualify for PAPs.
- Patients can obtain a second grant from the PAN foundation if the original grant is depleted.

**ADDRESSING FINANCIAL ASSISTANCE OBSTACLES TO SUPPORT PATIENT ADVOCACY**

**MODERATOR:** Caitlyn Boltik, CPhT | Riverside Regional Medical Center

**PRESENTER:** Rich Citrenbaum, PharmD | Patient Access Network (PAN) Foundation; Tim Limback | Sanofi; Deanna Schaffner | Exelixis

**SYNOPSIS:** Charitable foundation grants and patient assistance programs (PAPs) were reviewed as well as barriers to financial assistance. Discussion on how to overcome the barriers followed.

**PRESENTATION:** Citrenbaum outlined the 21 oncology funds that the PAN Foundation supports. He encouraged everyone to take advantage of funds for all types of cancer. Some do not run out of money the way others do, but PAN’s FundFinder (fundfinder.panfoundation.org) can be used to track funding status for nine charitable organizations. A new transportation fund has been launched to assist patients with the cost of traveling and can cover hotel stays.

Schaffner explained how the Medicare Part D “donut hole” places an enormous burden on patients. Patients should be told that high out-of-pocket costs will subside once catastrophic coverage kicks in. Foundation grants can help with high out-of-pocket costs, while PAPs can help with the donut hole and deductible.

Prior authorization (PA) was discussed as one of the largest barriers. It is important to know that some manufacturers provide appeal letters to make the appeal process easier. PAPs usually require a PA denial and one appeal denial, but some require multiple appeal denials.

Limback addressed that most foundations have a 90-day look back period, which he encouraged use of for retrospective patient reimbursement. He encouraged attendees to enroll and renew patients online in an effort to expedite the process and reserve phone access to those who absolutely need it.

**DISCUSSION:**

Q: (2024), University of North Texas Health Science Center.

**SUMMARY BY:** Shannyn Gilchrist-Oates, PharmD Candidate (2024), University of North Texas Health Science Center.

**SESSION SLIDES:** Scan the QR code at right to view slides from this presentation.
**WHAT COULD THE CHANCE FOR A PROGRESSION-FREE AND TREATMENT-FREE PERIOD MEAN FOR YOUR PATIENTS WITH CLL/SLL?**

**Indication**
- VENCLEXTA is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

**VEN+G regimen:** Designed to be completed after 12 months (twelve 28-day treatment cycles): GAZYVA® (obinutuzumab) is administered in Cycles 1–6, and VENCLEXTA is taken orally 400 mg/day from Cycle 3, Day 1, after the first two cycles of GAZYVA and the 5-week VENCLEXTA dose ramp-up.

**VEN+R regimen:** Designed to be completed after 24 months (twenty-four 28-day treatment cycles after the 5-week VENCLEXTA dose ramp-up): rituximab is administered in Cycles 1–6; VENCLEXTA is taken orally 400 mg/day from Cycle 1, Day 1 of rituximab through Cycle 24.

**Effectiveness**
- **CLL14 trial design and primary endpoint:** In a randomized clinical trial of 432 patients (VEN+G: N=216; GClb: N=216) with previously untreated CLL and with a median follow-up of 28 months (range: 0–36 months), VEN+G reduced the risk of progression or death by 67% vs GClb (HR=0.33; 95% CI: 0.22–0.51 [P<0.0001]). Median PFS was not reached in either arm.

**VEN+R regimen:** Designed to be completed after 12 months (twelve 28-day treatment cycles): GAZYVA® (obinutuzumab) is administered in Cycles 1–6, and VENCLEXTA is taken orally 400 mg/day from Cycle 3, Day 1, after the first two cycles of GAZYVA and the 5-week VENCLEXTA dose ramp-up.

**MURANO trial design and primary endpoint:** In a randomized clinical trial of 389 patients (VEN+R: N=194; BR: N=195) with previously treated CLL and with a median follow-up of 23.4 months (range: 0–37.4+ months), VEN+R reduced the risk of progression or death by 81% vs BR (HR=0.19; 95% CI: 0.13–0.28 [P<0.0001]). Median PFS not reached in VEN+R vs 18.1 months in BR (95% CI: 15.0–22.3).

**Important Safety Information**

**Contraindication**
- Concomitant use of VENCLEXTA with strong CYP3A inhibitors at initiation and during ramp-up phase is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).

**Tumor Lysis Syndrome**
- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients, and during reinitiation after dosage interruption in patients with CLL/SLL. Changes in blood chemistry consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase. TLS, including fatal cases, has been reported after a single 20 mg dose.
- In patients with CLL/SLL who followed the current (5 week) dose ramp-up and the TLS prophylaxis and monitoring measures, the rate of TLS was 2% in the VENCLEXTA CLL/SLL monotherapy trials. The rate of TLS remained consistent with VENCLEXTA in combination with obinutuzumab or rituximab. With a 2- to 3-week dose ramp-up and higher starting dose in patients with CLL/SLL, the TLS rate was 13% and included deaths and renal failure.
- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Splenomegaly may also increase the risk of TLS in patients with CLL/SLL.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

**Neutropenia**
- In patients with CLL, Grade 3 or 4 neutropenia developed in 63% to 64% of patients and Grade 4 neutropenia developed in 31% to 33% of patients when treated with VENCLEXTA in combination and monotherapy studies. Febrile neutropenia occurred in 4% to 6% of patients.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia and delay treatment. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

**Infections**
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same or reduced dose.
- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

**Embryo-Fetal Toxicity**
- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

**Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone**
- In a randomized trial (BELIN; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.
With fixed-duration VENCLEXTA regimens, offer your patients the power to stop treatment and the chance for:

- **A Target Stop Date**
  - VENCLEXTA-based regimens give patients a target treatment completion date.
  - A defined end to treatment that encourages compliance and optimizes clinical outcomes.

- **Limited Time on Treatment**
  - No additional VENCLEXTA regimen exposure after completing treatment.

- **A Treatment-Free Period**
  - Fixed duration offers patients a return to life without a daily reminder of their treatment and disease.

- **Fixed Treatment, Fixed Cost**
  - No additional VENCLEXTA regimen patient out-of-pocket costs after completing treatment per the recommended dosing.*

*Coverage and patient out-of-pocket costs for VEN+G and VEN+R vary by health plan. Patients may still incur out-of-pocket costs for other treatments or tests as directed by their healthcare providers.

To learn more, scan the code or visit VENCLEXTAHCP.COM/CLL

Explore over 5 years of follow-up data for VENCLEXTA in both 1L and R/R CLL

**Adverse Reactions**

- In patients with CLL receiving combination therapy with obinutuzumab, serious adverse reactions were most often due to febrile neutropenia and pneumonia (5% each). The most common adverse reactions (≥20%) of any grade were neutropenia (60%), diarrhea (28%), and fatigue (21%). Fatal adverse reactions that occurred in the absence of disease progression and with onset within 28 days of the last study treatment were reported in 2% (4/212) of patients, most often from infection.

- In patients with CLL receiving combination therapy with rituximab, the most frequent serious adverse reaction (≥5%) was pneumonia (9%). The most common adverse reactions (≥20%) of any grade were neutropenia (65%), diarrhea (40%), upper respiratory tract infection (39%), fatigue (22%), and nausea (21%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of the last VENCLEXTA treatment were reported in 2% (4/194) of patients.

- In patients with CLL/SLL receiving monotherapy, the most frequent serious adverse reactions (≥5%) were pneumonia (9%), febrile neutropenia (5%), and sepsis (5%). The most common adverse reactions (≥20%) of any grade were neutropenia (50%), diarrhea (43%), nausea (42%), upper respiratory tract infection (36%), anemia (33%), fatigue (32%), thrombocytopenia (29%), musculoskeletal pain (29%), edema (22%), and cough (22%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of venetoclax treatment were reported in 2% (2/106) of patients.

**Drug Interactions**

- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.

- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.
- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

**Lactation**

- Advise women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

**Females and Males of Reproductive Potential**

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

**Hepatic Impairment**

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Please see Brief Summary of full Prescribing Information on the following pages.

References:

1. VENCLEXTA Prescribing Information.
Febrile neutropenia occurred in 4% to 6% of patients when treated with VENCLEXTA in combination and monotherapy studies. In patients with CLL, Grade 3 or 4 neutropenia developed in 63% to 64%. Risk of TLS at initiation and during the ramp-up phase of VENCLEXTA. CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase of VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Sufferingly may also increase the risk of TLS in patients with CLL. Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and diuresis, monitoring for TLS, and managing abnormalities promptly. Employ more intensive measures and manage abnormalities promptly. Employ more intensive measures.

Table 1. Adverse Reactions (≥10%) in Patients Treated with VEN+G

<table>
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<tr>
<th>Adverse Reaction</th>
<th>VENCLEXTA + Obinutuzumab (N = 212)</th>
<th>Grade ≥3</th>
<th>VENCLEXTA + Obinutuzumab + Chlorambucil (N = 214)</th>
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</table>

Adverse Reaction

Concomitant use of VEN+G with strong CYP3A inhibitors at initiation and during the 5-week ramp-up is contraindicated and in patients with CLL/SLL, the TLS rate was 13% and included deaths and renal failure. See [Adverse Reactions]. In patients with AML, who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 2% in the VENCLEXTA CL/LLL, and monotherapy studies. The rate of TLS remained consistent with VENCLEXTA in combination or obinutuzumab or chlorambucil. Dose interruption or dose reductions down to 2-3 mg/kg/m² dose ramp-up and higher in patients with CL/LSS, the TLS rate was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine (QW). See [Adverse Reactions]. In patients with CLL, Grade 3 or 4 neutropenia developed in 63% to 64%. Risk of TLS at initiation and during the ramp-up phase of VENCLEXTA. For patients with CL/LSS, coadministration of VENCLEXTA with strong CYP3A inhibitors at initiation and during the 5-week ramp-up is contraindicated and in patients with CL/LSS, the TLS rate was 13% and included deaths and renal failure. See [Adverse Reactions]. For patients with AML, reduce the dose of VENCLEXTA when coadministered with strong CYP3A inhibitors at initiation and during the 5-week ramp-up phase. For patients with CL/LSS or AML, reduce the dose of VENCLEXTA when coadministered with moderate CYP3A inhibitors or P-gp inhibitors [see Drug Interactions]. Neutropenia in patients with CL/L, Grade 3 or 4 neutropenia developed in 63% to 64% of patients. Grade 4 neutropenia developed 21% to 23% of patients when treated with VENCLEXTA in combination and monotherapy studies. Febrile neutropenia occurred in 4% to 6% of patients [see Adverse Reactions]. In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine, decitabine, or low-dose cytarabine. Neutropenia can recur with subsequent cycles. Monitor complete blood counts throughout the treatment period. Consider supportive measures, including antimicrobial and growth factors (e.g., G-CSF).

Infections

Fever and infections, such as pneumonia and sepsis, have occurred in patients treated with VENCLEXTA [see Adverse Reactions]. Monitor and advise patients of symptoms and infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution. Immunosuppression

Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until 28-day recovery occurs. The safety of VENCLEXTA in combination with azacitidine, decitabine, or low-dose cytarabine is unknown. VENCLEXTA is contraindicated in patients with CL/LSS due to the potential for increased risk of tumor lysis syndrome [see Warnings and Precautions]. Acute Myeloid Leukemia

VENCLEXTA is indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that prohibit use of an intensive induction chemotherapy regimen.

Table of Adverse Reactions

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>VENCLEXTA + Obinutuzumab (N = 212)</th>
<th>Grade ≥3</th>
<th>VENCLEXTA + Obinutuzumab + Chlorambucil (N = 214)</th>
<th>Grade ≥3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>16</td>
<td>11</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13</td>
<td>&lt;1</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>Fatigue</td>
<td>28</td>
<td>4</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>Infections</td>
<td>19</td>
<td>0</td>
<td>22</td>
<td>1</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>13</td>
<td>0</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10</td>
<td>1</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>21</td>
<td>23</td>
<td>17</td>
<td>17</td>
</tr>
</tbody>
</table>

Adverse Reaction

Other clinically important adverse reactions (All Grades) reported in <10% of patients treated with VENCLEXTA and VENCLEXTA + Obinutuzumab are presented below: Blood and lymphatic system disorders: febrile neutropenia (4%) Gastrointestinal disorders: vomiting (8%) Infections and infestations: sepsis (2%) Metabolic and endocrine disorders: tumor lysis syndrome (1%) Table 2 of Laboratory Abnormalities in Table 4 of the package insert. Other clinically important adverse reactions (All Grades) reported in <10% of patients treated with VENCLEXTA + Obinutuzumab are presented below: Blood and lymphatic system disorders: febrile neutropenia (4%) Gastrointestinal disorders: vomiting (8%) Infections and infestations: sepsis (2%) Metabolic and endocrine disorders: tumor lysis syndrome (1%)

Table 3. Adverse Reactions (≥10%) in Patients Treated with VEN+R

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>VENCLEXTA + Rituximab (N = 194)</th>
<th>Grade ≥3</th>
<th>VENCLEXTA + Rituximab + Chlorambucil (N = 188)</th>
<th>Grade ≥3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>9</td>
<td>5</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>27</td>
<td>14</td>
<td>37</td>
<td>29</td>
</tr>
<tr>
<td>Infections</td>
<td>25</td>
<td>15</td>
<td>39</td>
<td>33</td>
</tr>
<tr>
<td>Lower respiratory tract infection</td>
<td>12</td>
<td>&lt;&lt;1</td>
<td>16</td>
<td>&lt;&lt;1</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>21</td>
<td>29</td>
<td>17</td>
<td>21</td>
</tr>
</tbody>
</table>

Adverse Reaction

Other clinically important adverse reactions (All Grades) reported in <10% of patients treated with VENCLEXTA and VENCLEXTA + Obinutuzumab are presented below: Blood and lymphatic system disorders: febrile neutropenia (4%) Gastrointestinal disorders: vomiting (8%) Infections and infestations: sepsis (2%) Metabolic and endocrine disorders: tumor lysis syndrome (1%)

Table 4. New or Worsening Clinically Important Laboratory Abnormalities (≥10%) in Patients Treated with VEN+G in CLL14

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>Grade 1 or 2 (%)</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit</td>
<td>87</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Neutrophil</td>
<td>92</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Lymphocyte</td>
<td>92</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>63</td>
<td>63</td>
<td>56</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>68</td>
<td>28</td>
<td>71</td>
</tr>
<tr>
<td>Anemia</td>
<td>63</td>
<td>53</td>
<td>16</td>
</tr>
</tbody>
</table>

Table 4 of Laboratory Abnormalities in Table 4 of the package insert.
Table 4. New or Worsening Clinically Important Laboratory Abnormalities (% (≥10%) in Patients Treated with VEN+R in MIRANO

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>VENCLEXTA + Rituximab (N = 194)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
<th>VENCLEXTA (N = 302)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>84</td>
<td>46</td>
<td>83</td>
<td>86</td>
<td>49</td>
<td>83</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>81</td>
<td>56</td>
<td>79</td>
<td>84</td>
<td>56</td>
<td>79</td>
</tr>
<tr>
<td>Anemia</td>
<td>85</td>
<td>64</td>
<td>87</td>
<td>90</td>
<td>68</td>
<td>86</td>
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<tr>
<td>Thrombocytopenia</td>
<td>50</td>
<td>12</td>
<td>63</td>
<td>49</td>
<td>15</td>
<td>60</td>
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<tr>
<td>Hematology</td>
<td></td>
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<tr>
<td>Leukopenia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphopenia</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
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</tr>
<tr>
<td>Chemistry</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Blood creatinine</td>
<td>77</td>
<td>&lt;1</td>
<td>78</td>
<td>83</td>
<td>&lt;1</td>
<td>86</td>
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<tr>
<td>Hypocalcemia</td>
<td>62</td>
<td>5</td>
<td>56</td>
<td>62</td>
<td>5</td>
<td>56</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>36</td>
<td>33</td>
<td>35</td>
<td>35</td>
<td>33</td>
<td>35</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
| Adverse reactions were reported in ≥25% of patients treated with VEN+R included neutropenia (31%), lymphopenia (16%), leukopenia (6%), thrombocytopenia (6%), hyperuricemia (4%), hypocalcemia (2%), hyperkalemia (2%), and hyperglycemia (2%).

Table 5 presents laboratory abnormalities identified in these trials.

Table 6. Laboratory Abnormalities Identified in ≥10% (All Grades) or ≥5% (Grade ≥3) of Patients who Received VENCLEXTA Monotherapy

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>VENCLEXTA (N = 302)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3 or 4 (%)</td>
<td>31</td>
<td>42</td>
<td>40</td>
</tr>
<tr>
<td>Grade ≥3 (%)</td>
<td>37</td>
<td>50</td>
<td>47</td>
</tr>
</tbody>
</table>

Table 7 presents adverse reactions identified in VALE-E.

Table 7. Adverse Reactions (% (≥10) in Patients with AML Who Received VEN+AZA with a Difference Between Arms of ≥5% for All Grades or for Grade 3 or 4 Reactions Compared with PBO+AZA in VALE-E

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>VENCLEXTA + Azacitidine (N = 100)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
<th>Placebo + Azacitidine (N = 104)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Diaphoresis</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
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<td>3</td>
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<tr>
<td>Hemorrhage</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Other clinically important adverse reactions (≥10%) that did not meet criteria for Table 7 or <10% are presented below:

Hepatobiliary disorders: cholestasis (10%), infections and infestations: pneumonia (13%)

Table 8 presents laboratory abnormalities identified in VALE-E.

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>VENCLEXTA + Rituximab (N = 194)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
<th>VENCLEXTA (N = 302)</th>
<th>Grade 3 or 4 (%)</th>
<th>All Grades (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukopenia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphopenia</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 7 presents adverse reactions identified in VALE-E.
In patients with AML, dose reductions in 9%, and dose interruptions in 63%.

Permanent discontinuation of VENCLEXTA due to adverse reactions occurred in 38% of patients. The most frequent adverse reaction leading to permanent discontinuation was pleural effusion (9%).

Dose reductions of VENCLEXTA due to adverse reactions occurred in 15% of patients. The most frequent adverse reaction leading to dose reduction (≥5%) was neutropenia (16%), and sepsis (excluding fungal; 12%). Fatal adverse reactions were reported in 65% of patients who received VENCLEXTA with azacitidine (15%) or decitabine (15%).

Serious adverse reactions were reported in 65% of patients who received VENCLEXTA with azacitidine, the most frequent (≥10%) being sepsis (43%), fatigue (34%), neutropenia (33%), and pneumonia (30%). One (8%) fatal adverse reaction of baclofen occurred within 30 days of starting treatment.

Permanent discontinuation of VENCLEXTA due to adverse reactions occurred in 38% of patients. The most frequent adverse reaction leading to permanent discontinuation was pleural effusion (9%).

Dose reductions of VENCLEXTA due to adverse reactions occurred in 69% of patients. The most frequent adverse reactions leading to dose reductions in 5%, dose reductions in 9%, and dose interruptions in 63%.

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### Female and Male Reproductive Potential

**VENCLEXTA** may cause fetal harm when administered to pregnant women (see Use in Specific Populations).

**Pregnancy Testing**
Verify pregnancy status in females of reproductive potential prior to initiating VENCLEXTA.

**Contraception**
Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.

**Infertility**
Based on findings in animals, VENCLEXTA may impair male fertility.

**Pediatric Use**
The safety and effectiveness of VENCLEXTA have not been established in pediatric patients.

**Juvenile Animal Toxicity Data**
In a juvenile toxicology study, mice were administered venetoclax at 10, 30, or 100 mg/kg/day by oral gavage from 7 to 60 days of age. Clinical signs of toxicity included decreased activity, dehydration, skin pallor, and hunched posture at ≥30 mg/kg/day. In addition, mortality and body weight effects occurred at ≥100 mg/kg/day. Other venetoclax-related effects were reversible decreases in lymphocytes at ≥10 mg/kg/day; a dose of 10 mg/kg/day is approximately 0.06 times the clinical dose of 400 mg on a mg/m² basis for a 20 kg child.

**Geriatric Use**

**Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**

Of the 352 patients with previously treated CLL/SLL evaluated for safety from 3 open-label trials of VENCLEXTA monotherapy, 57% (201/352) were ≥65 years of age and 18% (62/352) were ≥75 years of age. No clinically meaningful differences in safety and effectiveness were observed between older and younger patients in the combination and monotherapy studies.

**Acute Myeloid Leukemia**

Of the 283 patients who received VENCLEXTA with azacitidine in VIALE-A, 96% were ≥65 years of age and 60% were ≥75 years of age. Of the 13 patients who received VENCLEXTA in combination with decitabine in M14-358, 100% were ≥65 years of age and 62% were ≥75 years of age.

Of the 142 patients who received VENCLEXTA in combination with low-dose cytarabine in VAE-C, 92% were ≥65 years of age and 57% were ≥75 years of age.

Clinical studies of VENCLEXTA in patients with AML did not include sufficient numbers of younger adults to determine if patients 65 years of age and older respond differently from younger adults.

### Renal Impairment

Due to the increased risk of TLS, patients with reduced renal function (CLcr <80 mL/min, calculated by Cockcroft-Gault formula) require more intensive prophylaxis and monitoring to reduce the risk of TLS when initiating treatment with VENCLEXTA (see Warnings and Precautions). No dose adjustment is recommended for patients with mild, moderate or severe renal impairment (CLcr ≤15 mL/min).

### Hepatic Impairment

No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment. Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for adverse reactions.

### OVERDOSAGE

There is no specific antidote for VENCLEXTA. For patients who experience overdose, closely monitor and provide appropriate supportive treatment; during ramp-up phase interrupt VENCLEXTA and monitor carefully for signs and symptoms of TLS along with other toxicities. Based on venetoclax large volume of distribution and extensive protein binding, dialysis is unlikely to result in significant removal of venetoclax.

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A Member of the Roche Group
South San Francisco, CA 94080-4980
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Updates In Treatment of Metastatic Melanoma & Metastatic Uveal Melanoma

**PRESENTERS:** Jocelyn Joseph, PharmD, BCOP | MD Anderson Cancer Center; Anna Jan, PharmD, BCOP, MD Anderson Cancer Center

**SYNOPSIS:** Joseph reviewed updates in treatment recommendations for adults with newly diagnosed stage IV metastatic melanoma. She discussed literature that supported the use of LAG-3 inhibitors in treatment and their place in therapy. She compared the safety profile of nivolumab and relatlimab to nivolumab plus ipilimumab. Jan reviewed treatment options for uveal melanoma. She discussed the role of new treatment options for metastatic uveal melanoma and described the administration and management of toxicities associated with the treatment options for uveal melanoma.

**PRESENTATION:** Joseph discussed the role of immune checkpoint inhibitors in the treatment of metastatic melanoma and how advancements in these therapies are providing newer treatment opportunities. She noted that in the treatment of metastatic melanoma, there are three main types of medications used: PD-1 inhibitors, BRAF and MEK inhibitors and dual checkpoint inhibitors. The data currently shows that using checkpoint inhibitors with different mechanisms of action results in enhanced T-cell function and overall better response rate. She reviewed the response rates of nivolumab + relatlimab and discussed their role in the treatment of metastatic melanoma. The data suggested that combination therapy with a LAG-3 agent performed better in treating patients with stage IV metastatic melanoma.

Jan discussed the impact of different therapies for metastatic uveal melanoma. While it is a rare disease, it is the most common form of intraocular melanoma. She discussed tebentafusp, which is a new Category 1 recommendation per the National Comprehensive Cancer Network guidelines for individuals with HLA-A*02:01-positive unresectable or metastatic uveal melanoma.

**TAKEAWAY POINTS:**
- LAG-3 therapies like relatlimab have compelling data for their use in metastatic melanoma.
- Tebentafusp has been shown to be more effective than current treatments available for HLA-A*02:01-positive unresectable or metastatic uveal melanoma.

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Updates in HER2-Low Breast Cancer & Updates in ITP: From TPO to SYK

**PRESENTERS:** Sydney Schultz, PharmD | Mayo Clinic; Alexis Kuhn, PharmD, BCOP | Mayo Clinic

**SYNOPSIS:** Schultz discussed the results of the DESTINY-Breast04 trial and the adverse events that may occur with treatment of trastuzumab deruxtecan. Kuhn discussed therapeutic updates for immune thrombocytopenia (ITP) in both children and adults.

**PRESENTATION:** Schultz discussed the treatment landscape of HER2-low categorized breast cancer. The subgroup, HER2-low, includes patients who were previously considered to be triple-negative, as well as those who were considered to be HER2-positive. According to Schulz, about 60% of patients previously considered HER2-negative are now considered HER2-low. The treatment discussed was trastuzumab deruxtecan, an antibody drug conjugate that differs from traditional TDM1 therapy. Schulz presented the bystander effect as the biggest difference between traditional TDM1 and T-DXd therapy. This effect was described as the antiHER-2-directed antibody acting as a homing system that brings the cytotoxic payload to cells expressing the HER2 protein. Because of the tetrapeptide-based cleavable linker, the topoisomerase 1 inhibitors payload breaks away from the antibody and the membrane permeability allows the cytotoxic payload to affect the neighboring cells. The DESTINY-Breast04 trial for this therapy was randomized in a 2:1 fashion of HER2-low, unresectable or metastatic breast cancer patients. Patients received trastuzumab deruxtecan or physician's choice. The primary endpoint was progression-free survival with HER2-low expression.

Kuhn discussed updates in ITP therapy for adults and pediatrics. ITP has three distinct duration-based phases including “new,” “persistent” and “chronic.” The ASH guideline update form 2019 included treatment options for both pediatrics and adults. Kuhn presented information for persistent and chronic phases with first-line options being TPO agonists and splenectomy being reserved as a last-line therapy.

**TAKEAWAY POINTS:**
- The DESTINY-Breast04 trial showed a prolongation of overall survival from 16.8 months with chemotherapy vs 23.4 months with T-DXd.
- Nausea, vomiting and lung toxicity proved to be higher in the T-DXd group than in the physician’s choice group.
- While adult patients may progress to chronic ITP, the incidence of children progressing to the chronic stage is low.

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Summary by Kimi Breede, PharmD Candidate (2024), ETSU Bill Gatton College of Pharmacy.

**SUMMIT Rewind**

**SUMMIT Rewind**

**UPCOMING EVENT:** ETSU Bill Gatton College of Pharmacy.

**PRESENTERS:** Alexis Kuhn, PharmD, BCOP | Mayo Clinic; Sydney Schultz, PharmD | Mayo Clinic

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The Impact of Equity and Diversity Challenges Amongst Oncology Patients

**PRESENTERS:** Kashyap Patel, MD | Carolina Blood and Cancer Care Associates; Margaret Caldwell, Patient

**SYNOPSIS:** Patel discussed the importance of addressing cancer patients’ equity and diversity challenges and how they have managed them at Carolina Blood and Cancer Care Associates.

**PRESENTATION:** Patel stated that five different areas primarily impact oncology patients’ outcomes based on social determinants of health. He noted that lack of diversity in next-generation sequencing and related tests negatively impacts outcomes.

He went on to discuss the lack of diversity in genetic databases for patients outside of European descent, which complicates the availability for actions to be taken on those with varying ancestries. Lack of testing results in improper care and an increase in cost to the healthcare system.

**DISCUSSION:**

**Q:** What are two things that we can take back to our practices?

**A:** Create a third-party insurance fund to help supplement all healthcare costs. Focus on the patient as a human being, not a tumor, and talk about the financial impact on the patient and not just the healthcare system.

**Q:** How do we increase trial participation in under-represented populations?

**A:** Help the patient understand and make them comfortable with the trial and ultimately establish a more human connection with the patient.

**TAKEAWAY POINTS:**

- The five main areas impacting outcomes are lack of Next-generation sequencing, cancer screenings, access to clinical trials, payer-related factors and financial toxicities.
- Fixing these issues requires making a human connection with patients and keeping them at the center of the practice.

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**Drug Interactions for Oral Chemotherapy Management**

**PRESENTER:** Paige Reid, PharmD | Texas Oncology

**SYNOPSIS:** Reid addressed the importance of understanding how herbal products, dietary supplements and common foods can cause interactions with chemotherapy.

**PRESENTATION:** Many patients take herbs and supplements to maintain health and prevent, alleviate or cure disease.

Patients undergoing chemotherapy or who have cancer may utilize Complementary and Alternative Medicine (CAM) for various reasons, including coping with treatment side effects, comforting worries or trying to treat or cure their cancer. Commonly used herbal products to be familiar with include black cohosh, saw palmetto, red yeast rice, DHEA, echinacea, St. John’s Wort, ginkgo and ginseng. Patients using these products alone or in combination with other medication therapy may experience side effects including, but not limited to, GI distress, increased risk of hormone-sensitive cancers, hepatotoxicity, increased risk of bleeding and drug metabolism interactions.

Cancer affects every aspect of a patient’s health, including appetite and diet. Common foods can cause interactions with a patient’s chemotherapy in addition to herbal and natural supplements. Patients should be counseled on “good foods” to fuel their bodies, including plant-based proteins, healthy fats and carbs, and vitamins and minerals.

It is also important for both healthcare providers and patients to be aware of how recent meals and fat content of meals can interfere with bioavailability and absorption times of oral chemotherapy agents.

Additionally, patients receiving cancer treatment have compromised immune systems and should limit the risk of exposure to foodborne illness. Foods to consume with caution include grapefruit juice, orange juice, raw meats and uncooked foods.

**TAKEAWAY POINTS:**

- Medication reconciliation is a great opportunity to inquire about a patient’s use of herbal products, supplements and dietary habits.
- It is important to determine the therapeutic benefit of patients taking herbal products and supplements and have a conversation to address the necessity of them taking it.
- Be knowledgeable about frequently used products and research for natural products that patients report taking.

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Molecular Testing for Non-Small Cell Lung Cancer

**PRESENTER:** Jill Kolesar, PharmD, BCOP | University of Kentucky

**SYNOPSIS:** Kolesar encouraged utilizing next-generation sequencing (NGS) through molecular tumor boards (MTBs), to target specific receptors for patients battling Non-Small Cell Lung Cancer. Using NGS not only improves outcomes, but it also diminishes the chance of resistance to anticancer agents. Her efforts in molecular cell testing have helped transform the idea of cancer as an acute death sentence to more of a chronic disease state.

**PRESENTATION:** According to the World Health Organization, lung cancer has been a leading cause of death worldwide for years due to the complexity of the cancer. Fortunately, researchers have been working to create targeted therapies to prolong survival. The Molecular Tumor Board at the University of Kentucky was created to bridge the gap between patients and doctors related to targeted therapies and genomics sequencing. MTBs act as consultant services and review each patient’s case individually. Information is entered in electronic health records, along with recommended therapy to be administered. Often to ensure patients receive proper targeted therapy, more tests are required per MTB standards.

To see the true impact of MTB, Kolesar and her team assembled a case-control study from 2017-2019 to compare the results of patients who had molecular testing done and were placed on targeted therapy against the patients who did not. Results showed that patients who had molecular testing prior to receiving therapy had an eight times higher survival rate than patients who did not receive testing.

Kolesar and her team decided to take the study a step further and asked if it mattered where patients got treated, comparing community to academic settings. In both settings, the number of patients receiving their targeted therapy was about equal, meaning location of therapy did not matter.

Overall, it is shown that molecular testing is very useful in increasing a patient’s life expectancy.

**TAKEAWAY POINTS:**

- MTB next-generation sequencing technique is effective in increasing survival with patient battling non-small cell lung cancer regardless of location.
- A future goal of MTB is to reach more patients who have a socioeconomic barrier.

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Legislative Roundtable: Reform, Leadership & Policy Updates

**MODERATOR:** Jessica Nagro, PhRMA

**PRESENTERS:** Jasey Cárdenas, McKesson, John McDonald III | New York State Assembly member, Jerrica Mathis, MSeD | Cardinal Health

**SYNOPSIS:** The panel talked about the impact of the Inflation Reduction Act of 2022 (IRA) on the pricing of drugs. Panelists discussed how the midterm elections would affect the IRA. They encouraged professionals in the oncology field to get more involved and suggested ways they can promote change by being involved in legislation.

**PRESENTATION:** Congress passed the IRA in August 2022 and it was signed into law by President Biden. Mathis discussed the drug-pricing changes and how they will benefit the patients. Some of the benefits include limiting drug price increases and pricing negotiations for Medicare Part D, with manufacturers getting penalized for refusing to negotiate. Legislation approved $3 billion for the fiscal year 2022 to implement drug price negotiations over the 2021-2023 period. Cárdenas mentioned the impact IRA will have on providers as they won’t be caught up in the middle of negotiations and, inevitably, hurt patient care.

McDonald talked about the importance of the midterm elections and how they will affect pharmacy. He stressed the importance of the two parties coming together, noting, “Government usually works best when people are divided. People will have to compromise and it forces parties to start talking about legislation.” Bipartisan agreement could lead to greater transparency.

All presenters stressed the importance of pharmacy involvement with the legislation. McDonald said, “Pharmacists don’t realize how impactful they are in the legislative process.”

McDonald and Mathis challenged the audience to invite legislators to their pharmacies to show what they do in practice. Cárdenas said that legislators aren’t aware of the medical process. Allowing legislators to understand what pharmacies do helps them do their job better.

**DISCUSSION:**

**Q:** What are the biggest challenges facing oncology?  
**A:** Bipartisan agreement to increase access to patient care.

**TAKEAWAY POINTS:**

- IRA is going to change the landscape of how drug pricing is negotiated.
- The importance of the profession of pharmacy being involved with legislation.

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**Sean A. Palmatier, PharmD Candidate (2024), University of Minnesota.**
FALL 2022

**Anatomy of a Collaborative Practice Agreement**

**PRESENTERS:** Benyam Muluneh, PharmD, BCOP | University of North Carolina Medical Center; Jessie Modlin, PharmD, BCOP | St. Luke’s Health System, Idaho

**SYNOPSIS:** Muluneh discussed the misconceptions, changing of interpretation, benefits and challenges involved with Collaborative Practice Agreements (CPAs). Muluneh analyzed the legal considerations, important components involved and resources available to start or modify CPAs.

**PRESENTATION:** Modlin introduced a call to action from the Hematology/Oncology Pharmacy Association (HOPA) that discussed CPAs, including labs and symptom management of oral oncology. This stressed that CPAs should exist where oncology pharmacists are critically involved in the interdisciplinary care team.

Modlin reviewed the importance of thoroughly reviewing the laws and regulations due to the ambiguity among the different states, and utilizing that information to determine and define what those important components of the CPA will be. Included with the legal considerations and components, Muluneh discussed in detail the misconceptions surrounding CPAs and how interpretation of the laws have changed over time compared to initially being more prescriptive.

Muluneh further discussed that utilizing CPAs has shown improvement in patient education, adherence, frequency of clinical assessments, toxicity management and financial outcomes. He also discussed the challenges of provider status, available billing codes for pharmacists, familiarity by payer, direct and indirect billing, and facility fee billing.

**DISCUSSION:**

**Q:** When making changes to therapy using a CPA, do you usually inform the prescribing physician or NP?

**A:** Muluneh and Modlin agreed that it depends on the patient scenario such as dose change, therapy change, or adverse reactions being experienced.

**Q:** How do you overcome physician resistance to CPAs in a small practice, or when APP staff perform most of the functions within the scope of pharmacy and CPAs are not mandated or part of state law?

**A:** Practices must understand what is important to the physicians. It’s important to build trust and promote areas of the pharmacist’s expertise that don’t overlap with the physicians. Start small by taking one simple task off the physician’s agenda to make their day easier.

**TAKEAWAY POINT:**

- It is important to build a foundation of trust and utilize the CPA to continue to grow and augment your patient care practices.

Summary by Abbey Pendley, PharmD Candidate (2024), Auburn University.

**SESSION SLIDES:** Scan the QR code at right to view slides from this presentation.

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**The 4-1-1 on 420: A Clinical and Legal Review of Medical Cannabis**

**PRESENTER:** Maya Leiva, PharmD, BCOP | Inova Schar Cancer Institute

**SYNOPSIS:** Leiva discussed clinical strategies and pharmacology regarding medical cannabis. Leiva also talked about the challenges regarding its legality for medical and recreational use across the United States – as well as changing legislation that may shift these conversations.

**PRESENTATION:** Leiva discussed in detail the major relevant cannabinoids and their potential benefits. The National Academy of Sciences commissioned and published a large systematic review in 2017. The review determined that medical cannabinoids, such as CBD and THC, may prove beneficial in multiple indications including chronic pain, chemotherapy-related nausea and vomiting, AIDS-related cachexia, neuropathic pain, anxiety disorders, and sleep disorders.

Proper dosing and safety should be considered for any medical indication. Though there are no real dosing guidelines for CBD, the average daily doses range from one to three grams. For symptom control and functional improvement, the lowest dose of THC should be targeted. Dosing should be adjusted or increased based on patient response. Although marijuana-based products are federally classified as Schedule I drugs, individual states have their own regulations regarding use of recreational and medicinal marijuana. The H.R. 3617 "MORE Act" was passed by Congress in April 2022. This act has now been moved to the Senate, and if passed, would remove marijuana from the list of Schedule Substances from the federal Controlled Substances Act, as well as eliminate criminal penalties.

**DISCUSSION:**

**Q:** Why are clinical trials that include cannabinoids, particularly THC, such a challenge when there’s so much interest?

**A:** The main challenges surround the chain of custody and getting the DEA and FDA approval for Schedule I drug trials.

**Q:** Besides immunotherapy, are there any oral oncology that have a contradiction with cannabis?

**A:** Drugs that rely on T-cell activation in the tumor microenvironment may be of concern. However, this is not an absolute contraindication and interactions have not been thoroughly studied.

**TAKEAWAY POINTS:**

- Cannabinoids may prove useful to patient’s well-being in a variety of different indications, including but not limited to, chemotherapy-related nausea and vomiting.

- Patients should start on the lowest effective dose and be increased based on response and tolerability.

Summary by Nathan Uk, PharmD Candidate (2024), University of Minnesota.

**SESSION SLIDES:** Scan the QR code at right to view slides from this presentation.
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Guiding the Future of Oncology Patient Care
INDIANAPOLIS, IN  | MARCH 15-17, 2023
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