Shifts in Oncology
Safely Treating Patients in a Post–COVID-19 World

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IN ONCOLOGY
Safely Treating Patients in a Post–COVID-19 World
IN ER+/HER2- METASTATIC BREAST CANCER (mBC)

CAN IMPROVING ER ANTAGONISM AND DEGRADATION UNLOCK A BRIGHTER FUTURE?

Complex mechanisms of estrogen receptor (ER) signaling have been associated with tumor growth.1-3
In ER+/HER2– mBC, the ER pathways are involved in tumor progression and treatment escape mechanisms that enable endocrine resistance.1,2,4,5

To strengthen the fight against resistance, could advancements in ER antagonism and degradation help decrease the ER pathway’s downstream effects?


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The COVID-19 pandemic has lasted longer than most of us predicted, and extra demands and strain have been placed upon the shoulders of all those who work in health care—particularly nurses. As we move forward, we want to thank oncology nurses everywhere for their dedication and service. We implore you to make this year one that is focused on healing and recovery and know that we are there with you every step of the way.”

A Call for Resilience and Rest for the Oncology Nurse

If there is one thing that we are hoping to see in 2022, it is respite for the oncology nurse.

The COVID-19 pandemic has lasted longer than most of us predicted, and extra demands and strain have been placed upon the shoulders of all those who work in health care—particularly nurses. This issue’s Nurse’s Notes addresses the importance of taking personal time and resting to build resilience in everyday life. Our cover story looks ahead to the post–COVID-19 world and examines lasting practice changes, the endurance of telemedicine, adjusted visitor regulations, and more.

Similarly, in this issue, we showcase various methods of eliminating burnout. Flip over to our Medical Economics® column to read up on how a novel device can help clinicians combat mental and spiritual fatigue.

As always, our Medical World News® section keeps you up-to-date on practice-changing approvals in oncology. Follow our coverage of the 2021 accelerated approvals of asciminib (Scemblix), for the treatment of adult patients with Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase, and tisotumab vedotin-tfnr (Tivdak), for adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

In addition, our Clinical Insights column provides key updates from the most anticipated oncology conferences held toward the end of 2021, including the American Society of Hematology Annual Meeting and Exposition and the San Antonio Breast Cancer Symposium. Chimeric antigen receptor T-cell therapies continue to revolutionize the realm of hematologic malignancies, and there is potential power with oral selective estrogen receptor degraders to eliminate the need for intramuscular injections in breast cancer. Updates with both treatments can be found in this section.

The value of nurses cannot be overemphasized, and our feature story discusses how they can be at the forefront of electronic smoking cessation among young people. Moreover, our Adverse Events Report provides a primer on cannabis in the oncology space, as patients may feel more comfortable speaking to their nurse than their oncologist about their interests or concerns regarding medical cannabis. Lastly, our Advanced Practice Providers Page features a conversation about helping patients undergoing treatment manage cancer-related fatigue, and The Vitals podcast highlights how the implantation of phone triage programs can help improve wait times and make care more accessible to patients. Don’t forget to scan the QR code to listen to the full episode online.

As demonstrated by literature, palliative care can greatly improve patient outcomes. Our Partner Perspectives offers input on the value of the oncology nurse in increasing palliative care referrals at the most effective time in a patient’s treatment.

As we move forward, we want to thank oncology nurses everywhere for their dedication and service. We implore you to make this year one that is focused on healing and recovery and know that we are there with you every step of the way.

As always, thank you for reading.

Mike Hennessy Jr
President and CEO

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**The Vitals** is a twice-monthly podcast that discusses all things oncology nursing, from the latest clinical updates to hot topics that are on the minds of nurses across the country.

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Remembering Michael J. Hennessy Sr

Oncology Nursing News® regrets to inform our readers that our beloved chairman and founder of MJH Life Sciences®, Michael J. Hennessy Sr, has passed away. Hennessy was a fierce supporter of oncology nurses and was devoted to improving the lives of patients with cancer.

Hennessy spent his career turning his passion for building businesses and creating jobs into a run of successful ventures and brands. Following his graduation from Rider University in 1982, he started his career in medical publishing as a sales trainee, eventually advancing to the position of chief operating officer. In 1986, Hennessy became chief operating officer of Medical World Business Press, which was part of the launch of medical newspapers and other media products. The company prospered and was eventually sold to a Boston-based venture capital firm.

Hennessy launched Multimedia Healthcare Communications, LLC, in 1993 and built a portfolio of award-winning clinical journals. In 2001, Freedom Communications, Inc. acquired Multimedia Healthcare, about the time that Hennessy was pioneering a new approach to print and digital publishing with Intellisphere®, LLC (now part of MJH Life Sciences®).

Guided by the principles of innovation and entrepreneurial spirit and reflecting its founder’s dedication to improving quality of life through health care research and education, Intellisphere® publishes a variety of integrated print and digital products focusing on a range of topics in research and clinical medicine.

Hennessy’s commitment to improving the lives of patients with cancer is deeply rooted within the halls of MJH Life Sciences®. As a complement to the industry-leading OncLive® platform, he developed the Giants of Cancer Care® awards to recognize the leaders and pioneers who often go unrecognized for their contributions to advancing oncology care. He further strengthened his commitment to education by acquiring CURE Media Group in 2014, followed by the purchase of the Chemotherapy Foundation Symposium, in his quest to provide oncology professionals with focused education on innovative cancer therapy.

Later, in 2019, Hennessy elevated his role to chairman while naming his son Mike Hennessy Jr to assume the leadership role of the organization and carry on the family legacy. Under Mike Jr’s leadership, the company enhanced its global potential by entering into a long-term partnership with BDT Capital Partners, LLC, in November 2021.

Because of his broad business and educational experience and understanding of the challenges facing New Jersey, Hennessy’s counsel and insight had been sought out by several organizations including Rider University, where he served on the Board of Trustees and was elected to the executive committee. In addition to being active in state and national politics, Hennessy also had a long record of service at the local level, where he was a strong advocate for veterans and environmental issues.

Hennessy’s true passion was his relationship with his wife, Patrice “Patti” Hennessy. After meeting her in college, Hennessy devoted his life to Patti and his family, raising 4 wonderful children, Shannon, Ashley, Mike Jr, and Chris. Hennessy was Patti’s rock as she bravely battled cancer for almost 10 years until her death in January 2020. Hennessy recently honored Patti by making a donation to Rider University to expand the Science and Technology Center at their alma mater. The Mike and Patti Hennessy Science and Technology Center is set to be completed in 2022.

Hennessy’s legacy and “family first” mantra will live on through his children; their spouses Matt, Phil, Rachel, and Jordan, and his 10 grandchildren. He will be greatly missed by his family, friends, and MJH Life Sciences® family.

To hear more about trending topics from oncology nurses and others, visit OncNursingNews.com

“Hennessy spent his career turning his passion for building businesses and creating jobs into a run of successful ventures and brands. Following his graduation from Rider University in 1982, he started his career in medical publishing as a sales trainee, eventually advancing to the position of chief operating officer.”
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NURSE’S NOTES

The Face of Moral Distress and Self-Stewardship Among Oncology Nurses

by Stephanie L. Jackson, DNP, MSN, RN, AOCNS, BMTCN

Since the onset of COVID-19, the United States, Brazil, India, and Russia have maintained a status of having the highest incidence of confirmed cases. According to the World Health Organization, as of January 2022, there have been over 64 million confirmed cases in the United States. Health care workers have been severely affected by this illness and there has been a consequent increase in pressure on the nursing workforce and health care system. Anxiety, depression, fear, burnout, and posttraumatic stress disorder have played a role in increasing that pressure. Other contributing factors include the fear of contracting COVID-19, social isolation, and exposure in the workplace.

Among all populations, patients with cancer are recognized as a vulnerable group susceptible to the COVID-19 virus because of their prolonged weakened immune system. Their long-term treatment trajectory also increases their risk because of frequent visits to a health care facility and possible exposure to a patient who has the virus. Compared with other populations, these patients are also at significant risk for transfers to the intensive care unit, intubation, and death.

To date, patients with cancer have also demonstrated the highest complications associated with COVID-19. These complications manifest as physical and psychological stressors that were identified at the outset of the pandemic. Patients have expressed fears of contracting the illness, ongoing management of their treatment, and end-of-life care that limits the physical presence of their loved ones. Additionally, mental health disturbances can lead to continued worry about the trajectory of their illness, increased physiological pain, and stress related to COVID-19.

Despite the challenges brought about by the pandemic, patients with cancer deserve staff who are not only competent but prepared to stand by them through diagnosis, treatment, and outcomes. Nurses who are resilient have demonstrated a higher level of engagement, care, and dependability. This engagement leads to higher patient satisfaction as well as improved outcomes.

Self-care and organizational strategies are 2 significant evidence-based interventions that have proved to reduce psychological distress, especially during health care crises.

Self-Care Strategies to Reduce Psychological Distress

Health care workers will soon have to make sense of this crisis. They will need assistance to reshape their lives and practice self-care to reduce the risk of burnout. When health care providers are not emotionally well, it can be extremely challenging for them to heal others. Self-care builds moral resilience and enables nurses to respond positively to stressors. Resilience allows “one to maintain perspective, keep a situation in context, and understand that some conditions are out of one’s control.” Nurses can build this skill through activation of the parasympathetic nervous system, which reduces their response to stress and exercises mindfulness. Strategies such as breathing exercises or guided meditation through the help of mobile apps can be useful in assisting nurses to find meaning in their work.

Self-stewardship is also an important strategy for maintaining resilience. It is defined as the “skill of tending to and nurturing one’s well-being,” an important skill during this current pandemic given its ability to help one cultivate an accurate perspective of stressors. It helps nurses to understand that they have done nothing wrong during this public health crisis. Self-stewardship can be cultivated through psychological interventions, professional forums, and even safe spaces that allow individuals to express their frustrations.

Organizational Strategies to Reduce Psychological Distress

Leaders within the health care system who want to reduce moral distress and burnout among their staff must provide evidence-based interventions. For example, 9 strategies were implemented at the Mayo Clinic to promote engagement and reduce caregiver burnout.

1. Allowing staff to have sincere discussions with leaders to solve burnout and promote overall well-being.
2. Seeking to understand what motivates staff and provide meaning in their work.
3. Developing targeted interventions that foster improvements in each department.
4. Developing community among colleagues by sharing ideas such as debriefing, pausing to remember patients who have died, and Schwartz rounds.
5. Using rewards and incentives to show respect and encouragement for staff.
6. Aligning values to foster a healthy workplace culture.
7. Promoting work-life balance among staff to produce the best work.
8. Providing resources to promote resilience and self-care such as meditation.
9. Facilitating and funding research that other organizations also can use to reduce burnout and promote staff well-being.

This pandemic has lasted longer than anyone could have anticipated. As we move forward, it is time for health care workers and administrators to work together to implement solutions and provide relief. It is time to begin to heal.

For a full list of references, see the article on OncNursingNews.com
Asciminib Approved for Treatment of 2 CML Subtypes

The FDA has granted an accelerated approval to asciminib, which treats chronic myeloid leukemia by binding to the ABL myristoyl pocket.

by Lindsay Fischer

In October 2021, the FDA granted accelerated approval to asciminib (Scemblix) for the treatment of adult patients with Philadelphia chromosome–positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) who have received prior treatment with 2 or more tyrosine kinase inhibitors (TKIs), as well as for the treatment of adult patients with Ph+ CML-CP and a T315I mutation. The novel agent, also known as a STAMP inhibitor, functions by binding to the ABL myristoyl pocket. The accelerated approval program dictates that continued approval is contingent upon verification and confirmatory evidence of clinical evidence.

“The introduction of TKIs 20 years ago revolutionized treatment for CML. However, there remain many patients who do not respond adequately to at least 2 available treatments and often experience challenging [adverse] effects [AEs] that add a burden to their daily lives,” Lee Greenberger, PhD, chief scientific officer of the Leukemia and Lymphoma Society, said in a press release. “The approval of Scemblix may offer hope to patients by addressing gaps in CML care.”

The approval was based on findings from the phase 2 ASCEMBL trial (NCT03106779), which showed that asciminib resulted in a major molecular response (MMR; 25%), double that of bosutinib (Bosulif; 13%) at 24 weeks ($P = .029$) in previously treated patients with Ph+ CML-CP.

In addition, 7% of the 156 patients receiving asciminib needed to discontinue treatment because of AEs, compared with 25% in the bosutinib cohort.

Notable AEs from the trial included laboratory abnormalities, upper respiratory tract infections, musculoskeletal pain, a decrease in platelet and neutrophil counts, a decrease in hemoglobin level, and an increase in triglycerides, creatine kinase, and alanine aminotransferase levels.

“CML can be difficult to treat when currently available treatments fail patients, when treatment [adverse] effects cannot be tolerated, or sometimes both,” said Michael J. Mauro, MD, hematologist and leader of the Myeloproliferative Neoplasms Program at Memorial Sloan Kettering Cancer Center. “The addition of Scemblix into the CML treatment landscape gives us a novel approach to combat this blood cancer, helping address clinical challenges in patients struggling after switching to a second treatment, as well as in patients who develop the T315I mutation and face significantly worse outcomes.”

**REFERENCE**

FDA OKs Tisotumab Vedotin for Patients With Recurrent or Metastatic Cervical Cancer

The regulatory decision represents the first antibody-drug conjugate approval for adults with recurrent or metastatic cervical cancer.

by Kristi Rosa

In September 2021, tisotumab vedotin-tftv (Tivdak) received accelerated approval from the FDA for adults with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.1

The regulatory decision is based on data from the phase 2 innovaTV 204 trial (NCT03438396). The antibody-drug conjugate (ADC) elicited an objective response rate (ORR) of 24% (95% CI, 15.9%-33.3%) per independent review committee (IRC) using RECIST 1.1 criteria in patients with recurrent or metastatic cervical cancer who received prior doublet chemotherapy and bevacizumab (Avastin).2

Among those who responded to treatment, 7% experienced a complete response and 17% had a partial response. The median duration of response (DOR) with tisotumab vedotin was 8.3 months (95% CI, 4.2-7.5) not reached). The median time to response (TTR) with the ADC was 1.4 months (range, 1.1-5.1), and activity was noted within the first 2 treatment cycles.

“Once recurrent or metastatic cervical cancer progresses, there is a need for more options for these patients,” Robert L. Coleman, MD, chief scientific officer at US Oncology Research and lead investigator of the trial, stated in a press release. “This is an important development for patients with recurrent or metastatic cervical cancer.”

The single-arm, multicenter innovaTV 204 trial enrolled a total of 101 previously treated patients with recurrent or metastatic cervical cancer who received tisotumab vedotin intravenously at a dose of 2.0 mg/kg every 3 weeks until disease progression or unacceptable toxicity.

To be eligible for enrollment, patients had to have recurrent or extrapelvic metastatic disease, experienced disease progression during or after doublet chemotherapy with bevacizumab (if eligible), received 2 or fewer prior systemic therapies, and have an ECOG performance status of 0 to 1.

The primary end point of the trial was confirmed overall response (OR) per RECIST 1.1 criteria and IRC assessment. Secondary end points included ORR per investigator assessment and RECIST criteria, overall survival (OS), and safety.

DOR, TTR, and progression-free survival (PFS) per IRC and investigator served as additional end points. Investigators also evaluated biomarkers and health-related quality of life with the treatment.

The median age of study participants was 50 years; 95% were White and 58% had an ECOG performance status of 0. Moreover, 68% of patients had squamous cell carcinoma, 27% had adenocarcinoma, and 5% had adenosquamous carcinoma. Almost all patients, or 94%, had extrapelvic metastatic disease at baseline.

Fifty-four percent of participants had received prior cisplatin plus radiation therapy and 70% had received 1 prior line of systemic treatment for recurrent or metastatic disease. Additionally, 63% of patients had received prior bevacizumab and doublet chemotherapy as first-line treatment and 56% had not responded to their last systemic treatment.

Patients received treatment for a median duration of 4.2 months at a median of 6 doses; a high-dose intensity of 95.9% was reported with the agent. Four patients continued to receive treatment and 65% discontinued treatment because of radiographic progression. Thirteen percent of patients discontinued treatment because of toxicities, 8% because of clinical progression, 5% because of withdrawn consent, 4% because of death, and 1% per investigator decision.

Additional data presented during the 2020 European Society for Medical Oncology Virtual Congress demonstrated that 4% of patients who received the ADC achieved disease stability whereas 24% experienced disease progression per IRC. Seventy-nine percent of participants also experienced a reduction in target lesions.

Notably, participants experienced clinically meaningful responses irrespective of tumor histology, lines of previous treatment, responses to previous systemic treatment, and whether they had received frontline bevacizumab or doublet chemotherapy. The investigators also observed responses irrespective of membrane tissue factor (TF) expression level.

The median PFS reported with the ADC was 4.2 months, and the OS was 12.1 months. The PFS rate at 6 months was 30%, whereas the OS rate at this time point was 79%.

The ADC had a manageable safety profile. The prescribing information for the agent includes a boxed warning for ocular toxicity, as well as a warning for peripheral neuropathy, hemorrhage, pneumonitis, and embryo-fetal toxicity.

The adverse events (AEs) most frequently reported with tisotumab vedotin included decreased hemoglobin (52%), fatigue (50%), decreased lymphocytes (42%), nausea (41%), peripheral neuropathy (39%), alopecia (39%), epistaxis (39%), conjunctival adverse reactions (37%), hemorrhage (32%), and decreased leukocytes (30%). Further AEs included increased creatinine (29%), dry eye (29%), increased prothrombin international normalized ratio (26%), prolonged activated partial thromboplastin time (26%), diarrhea (25%), and rash (25%).

 “[Tisotumab vedotin’s] approval as a monotherapy in the United States is an important milestone for women with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy…They are in need of a new treatment option and we look forward to making it available to them,” Jan G. J. van de Winkel, PhD, president and chief executive officer at Genmab, stated in a press release.

“The journey toward the approval of [tisotumab vedotin] started nearly 2 decades ago with innovative research by scientists at Genmab and Seagen and reflects on our purpose of making an impact in the lives of cancer patients and their families. Today’s announcement marks Genmab’s evolution into a fully integrated biotechnology company and we would like to thank patients, caregivers, investigators, and our collaborators for their participation in our clinical studies.”

For a full list of references, see the article on OncNursingNews.com
The Giants of Cancer Care® recognition program celebrates individuals who have achieved landmark success within the global field of oncology.

Help us identify oncology specialists whose dedication has helped save, prolong, or improve the lives of patients who have received a diagnosis of cancer.

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PROGRAM OVERVIEW

• Nominations are open through February 28, 2022.
• The Giants of Cancer Care® Steering Committee will vet all nominations to determine finalists in each category.
• A selection committee of more than 120 oncologists will vote to determine the 2022 inductees.
• The 2022 Giants of Cancer Care® class will be announced in spring 2022.

NO PURCHASE NECESSARY. Contest begins on or about November 4, 2021 at 12:01 am ET and ends on February 28, 2022 at 11:59 p.m. ET. Open only to those who are 18 years of age or older at the time of entry and who are a licensed healthcare professional (i.e., MD, DO, PhD, and/or RN) working in the oncology space at the time of application and award. Subject to Official Rules. See Official Rules at www.giantsofcancercare.com for additional eligibility restrictions, prize descriptions, restrictions, and complete details. Odds of winning depend on the number of eligible entries received. Void where prohibited. Sponsor: Intellisphere, LLC.
When the COVID-19 pandemic began, oncology units faced a daunting challenge. They had to adapt to providing cancer treatments without sacrificing the health and safety of immunocompromised patients, their families, and oncology staff. Today, as COVID-19 persists and new variants emerge, oncology units have implemented a variety of safety measures that allow them to coexist with the coronavirus, while ensuring the continuum of cancer care.

“Post pandemic, medical care will never be the same,” said Anna L. Rodriguez, MSN, MHA, RN, OCN, NEA-BC, chief nursing officer and vice president of nursing and patient care services at Fox Chase Cancer Center in Philadelphia, Pennsylvania. “The coronavirus pandemic has highlighted the ability of hospitals to quickly adapt their care models in response to external factors, to ensure a safe environment for staff and patients.”

Rodriguez expects many of the rigorous safeguards implemented to protect patients and staff to remain in place long after the pandemic ends. As one example, she points to the use of technology platforms for virtual staff meetings and patient visits. “Having this flexibility has allowed health care organizations to maintain business operations while allowing for required social distancing as the current conditions dictate, to protect our patients and workforce,” she said. “I believe the efficiencies, work-life balance, and accessibility offered by these platforms will ensure their continued use.”

Telehealth Surges During the Pandemic

At City of Hope, a leading cancer research and treatment hospital near Los Angeles, California, use of the hospital’s telehealth platform skyrocketed during the pandemic. The Hope Virtual platform offered a way for doctors and nurses to safely communicate with patients.

Susan J. Brown, PhD, RN, senior vice president of patient care services and chief nursing officer at City of Hope, believes that telehealth has replaced many routine oncology appointments by allowing oncology team members to communicate with patients over a secure video platform via smartphone, tablet, or computer. “Telehealth is used when patients, or someone they are in close contact with, are symptomatic with COVID-19 or the flu, when they have transportation issues, or when they would like a family member to join the appointment from another location,” Brown said. “Prior to the pandemic, we conducted approximately 10% of visits using telehealth. Today, approximately 35% to 40% of patient visits are conducted using telehealth.”

Brown said nurses can safely evaluate patients with cancer using telehealth; they can also manage the adverse effects of treatment, review laboratory and scan results, answer questions, and include family members in the patient’s care. City of Hope plans to expand their telehealth program to include remote chemotherapy support, tele-genetics, and much more.
Ensuring Safety for Patients and Staff

In February 2020, UC Davis Medical Center in Sacramento, California, reported the first case of community transmission of COVID-19 in the United States. This led to important changes in the Centers for Disease Control and Prevention (CDC) guidelines for novel coronavirus testing.

Devon Trower, BSN, RN, OCN, a nurse manager in adult infusion at UC Davis Comprehensive Cancer Center, said the entire medical center quickly implemented safety procedures. These included limiting the number of visitors, screening patients and employees for infection daily, maintaining social distancing, mandating masks, and providing ample sanitizer and hand-washing facilities.

If an oncology patient tests positive for COVID-19 but is asymptomatic, their doctor will balance the risk of postponing their treatment with their diagnosis. If the patient is exhibiting symptoms, the doctor will determine whether they have recovered enough to undergo treatment.

“We now have several isolation rooms that use negative air pressure where we can administer medications intravenously to oncology patients who have tested positive for COVID-19,” Trower said.

Since the beginning of the pandemic, the oncology unit has been working closely with the hospital's infection control staff to safeguard the health of patients and oncology team members. “The pandemic has given us all a heightened awareness of infection prevention,” Trower noted. “While we always wore PPE [personal protective equipment] when administering chemo[therapy], our staff now wears N95 or surgical masks all the time.”

Findings from a survey released in March 2021 by the American Society for Radiation Oncology showed that enhanced safety protocols remained widespread at radiation therapy clinics. Masking for patients and staff (99%), social distancing in the clinic (100%), and screening patients and staff for COVID-19 exposure (95%) were nearly universal. Increased sterilization (93%), face shields for staff during procedures (80%), and no-visitor policies (73%) were also common.

Adjusting to the New Normal

At the beginning of the pandemic, according to Brown, City of Hope quickly began implementing new screening protocols and safety measures recommended by the CDC, as well as guidelines offered by the Oncology Nursing Society. As PPE was only available in limited quantities, City of Hope changed their policy to preserve supplies.

“Staff used to don a mask when entering a hematology patient’s room and throw it away when exiting; it wasn’t unusual to go through 50 to 60 masks in 1 day,” Brown said. “We changed our policy to 1 mask per employee per day and haven’t experienced any increases in infection.”

In fact, in the midst of the pandemic, City of Hope was awarded the prestigious Magnet recognition from the American Nurses Credentialing Center, a distinction bestowed on only 9% of hospitals in the United States. Brown says the pandemic also underscored the importance of supporting and celebrating nursing staff, while ensuring their safety.

“When we presented our nurses with DAISY awards over the past 2 years, we practiced social distancing by decorating golf carts and parading the award winners around our campus,” she explained. “It’s been so well received that we plan to continue the tradition post COVID-19.”

Brown noted that one safety protocol that will probably be altered is the hospital’s visitor policy.

“Inpatients can only have 1 visitor at a time and each visitor must provide proof of full COVID-19 vaccination or a negative [result from a] COVID-19 test taken within the prior 72 hours of each visit,” she said. “Visitors must also be masked at all times.”

Although the practice safeguards the health of patients and staff, Brown noted the policy has been hard for both nurses and patients.

“Patients miss having their families present and our nurses have realized how much families not only help with patient morale, but also assisting with simple things such as bringing their loved one a glass of water,” Brown said. “Patients have been largely communicating with their extended family via iPads or smartphones.”

Visitor policies have also changed in the outpatient setting. Brown says trained City of Hope escorts meet patients in the lobby and accompany them to infusion and radiation treatments.

“At our main campus, 1 visitor may accompany adult patients and 2 visitors for those under 18 when they meet a physician for the first time and for presurgery anesthesiology testing, before and after surgery, and urgent care visits,” she said.

To ensure patients test negative for the disease prior to undergoing surgery, City of Hope also implemented drive-through COVID-19 testing to screen patients.

“If they test positive, the surgery might still be conducted if deemed urgent,” Brown says. “If not, the surgery will be postponed.”

Rebecca Farrell, MSN, RN, clinical nurse manager of ambulatory care at Fox Chase Cancer Center, added that interventions to screen and prescreen patients for COVID-19 symptoms prior to their treatments may also become the new normal. These screening tests evaluate for symptoms such as a new or worsening cough within the past 14 days, shortness of breath, fever, and possible COVID-19 exposure.

“Prescreenings and pretesting might become part of our oncology playbook,” she said. “We’ve also seen how team-based nursing care models can be effectively used to care for critical patients during the COVID-19 surge, with nursing staff cross-training in various specialties and departments.”

Some nurses see safety measures such as increased masking and hand-washing stations throughout the hospital remaining.

“While we’ve always been concerned about infection prevention, we’ve seen how these enhanced safety measures taken to prevent the spread of COVID-19 have also squashed the transmission of seasonal influenza and respiratory viruses and maximized safety for our patients,” said Trower.

For a full list of references, see the article on OncNursingNews.com
In the treatment of newly diagnosed, transplant-ineligible multiple myeloma:

**ADD TO THE MOMENTUM WITH DARZALEX® + Rd IN FRONTLINE**

Reach for a treatment that significantly extended progression-free survival vs Rd alone in a clinical trial

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**IMPORTANT SAFETY INFORMATION**

**DARZALEX® AND DARZALEX FASPRO®:**

**CONTRAINDICATIONS**

DARZALEX® and DARZALEX FASPRO® are contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase (for DARZALEX FASPRO®), or any of the components of the formulations.

**DARZALEX®: Infusion-Related Reactions**

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, and pulmonary edema.

Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and anaphylaxis. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

When DARZALEX® dosing was interrupted in the setting of ASCT (CASIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, i.e., 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX® therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate medical management.
Powerful efficacy to start the treatment journey\textsuperscript{1,4}\n
After a median ~30 months\textsuperscript{*} of follow-up, mPFS was not reached with DARZALEX\textsuperscript{®} + Rd vs 31.9 months with Rd alone.\textsuperscript{1,4}

\begin{itemize}
  \item 70.6% of patients had not progressed with DRd vs 55.6% of patients in the Rd group (DRd: 95% CI, 65.0–75.4; Rd: 95% CI, 49.5–61.3)\textsuperscript{3}
\end{itemize}

\textbf{44%} reduction in the risk of disease progression or death with DRd vs Rd alone (HR=0.56; 95% CI, 0.43–0.73; P<0.0001)

Demonstrated safety profile (median treatment duration of 25.3 months)\textsuperscript{1,5,6}

- The most common adverse reactions (≥20%) were upper respiratory infection, neutropenia, IRRs, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia
- Serious adverse reactions with a 2% greater incidence in the DRd arm compared with the Rd arm were pneumonia (DRd 15% vs Rd 8%), bronchitis (DRd 4% vs Rd 2%), and dehydration (DRd 2% vs Rd <1%)

\textbf{IMPORTANT SAFETY INFORMATION CONTINUES ON NEXT PAGE

Efficacy in long-term follow-up\textsuperscript{2,3}\n
At median ~5 years (56 months)\textsuperscript{2} of follow-up, mPFS was not reached with DRd vs 34.4 months with Rd alone.\textsuperscript{2}

\begin{itemize}
  \item 53% of patients had not progressed after ~5 years of treatment with DRd vs 29% with Rd alone (DRd: 95% CI, 47–58; Rd: 95% CI, 23–35)\textsuperscript{1,4}
\end{itemize}

\textbf{47%} reduction in the risk of disease progression or death with DRd vs Rd alone (HR=0.53; 95% CI, 0.43–0.66)

These ~5-year analyses were not adjusted for multiplicity and are not included in the current Prescribing Information.

Safety results in long-term follow-up (median treatment duration of 47.5 months)\textsuperscript{2}\n
At median ~5 years of follow-up\textsuperscript{2,3}:

- Most frequent TEAEs\textsuperscript{7} ≥30% were diarrhea, neutropenia, fatigue, constipation, peripheral edema, anemia, back pain, asthenia, nausea, bronchitis, cough, dyspnea, insomnia, weight decreased, peripheral sensory neuropathy, pneumonia, and muscle spasms
- Grade 3/4 infections were 41% for DRd vs 29% for Rd
- Grade 3/4 TEAEs ≥10% were neutropenia (54% for DRd vs 37% for Rd), pneumonia (19% vs 11%), anemia (17% vs 22%), lymphopenia (16% vs 11%), hypokalemia (13% vs 10%), leukopenia (12% vs 6%), and cataract (11% vs 11%)

These ~5-year analyses are not included in the current Prescribing Information.

\begin{itemize}
  \item With an ~3 to 5 minute subcutaneous injection, DARZALEX\textsuperscript{®} can be administered substantially faster than intravenous daratumumab\textsuperscript{1,5,6}
\end{itemize}

See the latest data rolling out. Visit FrontlineMomentum.com

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emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX\textsuperscript{®} infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

DARZALEX FASPRO\textsuperscript{®}: Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO\textsuperscript{®}. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO\textsuperscript{®}.

Systemic Reactions

In a pooled safety population of 832 patients with multiple myeloma (N=639) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO\textsuperscript{®} as monotherapy or in combination, 9% of patients experienced a systemic administration-related reaction (Grade 2: 3.5%, Grade 3: 0.8%). Systemic administration-related reactions occurred in 8% of patients with the first injection, 0.4% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 9 minutes to 3.5 days). Of the 129 systemic administration-related reactions that occurred in 74 patients, 110 (85%) occurred on the day of DARZALEX FASPRO\textsuperscript{®} administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO\textsuperscript{®}.

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\textbf{CI}=confidence interval; DRd=DARZALEX\textsuperscript{®} (D) + lenalidomide (R) + dexamethasone (d); HR=hazard ratio; IRR=injection-related reaction; mPFS=median progression-free survival; PFS=progression-free survival; Rd=lenalidomide (R) + dexamethasone (d); TEAE=treatment-emergent adverse event.

*Range: 0.0–41.4 months.*

\textsuperscript{1} Kaplan-Meier estimate.

\textsuperscript{2} Range: 0.03–69.52 months.

\textsuperscript{3} TEAEs are defined as any adverse event (AE) that occurs after start of the first study treatment through 30 days after the last study treatment; or the day prior to start of subsequent antimyeloma therapy, whichever is earlier; or any AE that is considered drug related (very likely, probably, or possibly related) regardless of the start date of the event; or any AE that is present at baseline but worsens in toxicity grade or is subsequently considered drug related by the investigator.

\textsuperscript{4} 3 to 5 minutes refers to the time it takes to administer DARZALEX FASPRO\textsuperscript{®} and does not account for all aspects of treatment. For intravenous daratumumab, median durations of 16 mg/kg infusions for the first, second, and subsequent infusions were approximately 7, 4, and 3 hours, respectively.

\textsuperscript{5} MAIA Study Design: A phase 3 global, randomized, open-label study, compared treatment with DRd (n=368) to Rd (n=369) in adult patients with newly diagnosed, transplant-ineligible multiple myeloma. Treatment was continued until disease progression or unacceptable toxicity. The primary efficacy endpoint was PFS.\textsuperscript{1}

\textsuperscript{6} With an ~3 to 5 minute subcutaneous injection, DARZALEX\textsuperscript{®} can be administered substantially faster than intravenous daratumumab.\textsuperscript{1,5,6}

\textsuperscript{7} TEAEs are treatment-emergent adverse events.
Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed [defined as occurring the day after administration] systemic administration-related reactions.

Local Reactions
In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5.5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management.

DARZALEX® and DARZALEX FASPRO®: Neutropenia and Thrombocytopenia
DARZALEX® and DARZALEX FASPRO® may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX® or DARZALEX FASPRO® until recovery of neutrophils or for recovery of platelets.

In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

DARZALEX® and DARZALEX FASPRO®: Interference With Serological Testing
Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient’s serum. The determination of a patient’s ABO and Rh blood type are not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX® and DARZALEX FASPRO®.

Type and screen patients prior to starting DARZALEX® and DARZALEX FASPRO®.

DARZALEX® and DARZALEX FASPRO®: Interference With Determination of Complete Response
Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

DARZALEX® and DARZALEX FASPRO®: Embryo-Fetal Toxicity
Based on the mechanism of action, DARZALEX® and DARZALEX FASPRO® can cause fetal harm when administered to a pregnant woman. DARZALEX® and DARZALEX FASPRO® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX® or DARZALEX FASPRO® and for 3 months after the last dose.

The combination of DARZALEX® or DARZALEX FASPRO® with lenalidomide, pomalidomide, or thalidomide is contraindicated in pregnant women because lenalidomide, pomalidomide, and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, pomalidomide, or thalidomide prescribing information on use during pregnancy.

DARZALEX®: ADVERSE REACTIONS
The most frequently reported adverse reactions (incidence ≥20%) were: upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX® are: neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

DARZALEX FASPRO®: ADVERSE REACTIONS
In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

INDICATIONS
DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI)
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihi) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Please see Brief Summary of full Prescribing Information for DARZALEX® and DARZALEX FASPRO® on adjacent pages.

References:
1. DARZALEX® (Prescribing Information). Horsham, PA: Janssen Biotech, Inc. 2021
CONTRAINDICATIONS
DARZALEX is contraindicated in patients with a history of severe hypersensitivity (e.g., anaphylactic reactions) to daratumumab or any of the components of the formulation [See Warnings and Precautions].

WARNINGS AND PRECAUTIONS
Infusion-Related Reactions
DARZALEX can cause severe and fatal infusion-related reactions including anaphylactic reactions. These reactions can cause life-threatening and fatal outcomes have been reported [See Adverse Reactions].

In clinical trials [monotherapy and combination: N=2,060], infusion-related reactions occurred in 37% of patients with the Week 1 (18 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had Grade 3/4 infusion-related reaction in Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 72 hours). The incidence of infusion modification following ASCT. Infusion-related reactions occurred in 21.3 months (range: 0.03 to 40.64 months) for

Serious severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as, asphyxia, congestion, wheeze, as well as cough, shortness of breath, and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension [See Adverse Reactions].

When DARZALEX dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.76 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX following ASCT were consistent in terms of symptoms and severity (Grade 3 or <1%) with those reported in previous studies at Week 2 or subsequent infusions.

In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days in 77.9% of patients. The incidence of any grade infusion-related reactions in Grade 4 reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion in patients with Grade 1 reaction from 100 mg/kg monotherapy. The median time to onset of a reaction was 1.8 hours (range: 0.5 to 14.8 hours). The incidence of infusion reactions due to reactions was 30%. Median durations of infusions were 4.2 hours for Week 1-Day 1, 4.2 hours for Week 1-Day 2, and 3.4 hours for the subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics and corticosteroids. Frequently monitor patients during the entire infusion [See Dosage and Administration (2.3) in Full Prescribing Information]. Interrupt DARZALEX infusion for reactions of any severity. If no evidence of any grade infusion-related reactions occurred, 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions. The median time to onset of a reaction was 1.8 hours (range: 0.5 to 14.8 hours). The incidence of infusion reactions due to reactions was 30%. Median durations of infusions were 4.2 hours for Week 1-Day 1, 4.2 hours for Week 1-Day 2, and 3.4 hours for the subsequent infusions.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX infusions [See Dosage and Administration (2.3) in Full Prescribing Information]. Patients with a history of severe anaphylactic disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with a history of chronic obstructive pulmonary disease [See Dosage and Administration (2.3) in Full Prescribing Information].

Interference with Serological Testing
Daratumumab binds to a non-reducing blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to matching antigens in the patient (typing of transfusion applicants). The determination of a patient’s ABO and Rh type blood are not impacted (See Drug Interactions).

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX. Type and screen patients prior to starting DARZALEX [See Dosage and Administration (2.1) in Full Prescribing Information].

Neutropenia
DARZALEX may increase neutropenia induced by background therapy [See Adverse Reactions]. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX until recovery of neutrophils.

Thrombocytopenia
DARZALEX may increase thrombocytopenia induced by background therapy [see Adverse Reactions]. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX until recovery of neutrophils.

Thrombocytopenia
DARZALEX may increase thrombocytopenia induced by background therapy [see Adverse Reactions]. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. Consider withholding DARZALEX until recovery of platelets.

Interference with Determination of Complete Response
Daratumumab is a human IgG1 kappa monoclonal antibody that can be detected on both, the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein [See Drug Interactions]. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Embryo-Fetal Toxicity
Based on the mechanism of action, DARZALEX can cause fetal harm when administered to a pregnant woman. DARZALEX is contraindicated in pregnant women. In a randomized clinical trial of 156 patients with multiple myeloma, 216 pregnant women received DARZALEX as monotherapy. In this pooled safety population, the most common adverse reactions (>20%) were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, cough, infection, and renal and respiratory symptoms. Of note, hypoxia, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthma.

Newly Diagnosed Multiple Myeloma Eligible for Autologous Stem Cell Transplant
Combination Treatment with Lenalidomide and Dexamethasone (DRd)

The safety of DARZALEX in combination with lenalidomide and dexamethasone was evaluated in EVAN [see Clinical Studies (14.1 in Full Prescribing Information)]. Adverse reactions described in Table 2 reflect exposure to DARZALEX for a median treatment duration of 13.1 months (range: 0 to 20.7 months) for daratumumab-lenalidomide-dexamethasone (DRd) and of 12.3 months (range: 0.2 to 20.1 months) for lenalidomide-dexamethasone (RD).

Serious adverse reactions occurred in 49% of patients in the DRd arm compared with 42% in the RD arm. Serious adverse reactions with at least a 2% greater incidence in the DRd arm compared to the RD arm were pneumonia (DRd 12% vs RD 10%), upper respiratory tract infection (DRd 7% vs RD 4%), influenza and pyrexia (DRd 3% vs RD 1% for each).

Adverse reactions resulted in discontinuations in 7% (n=19) of patients in the DRd arm versus 8% (n=22) in the RD arm.

Table 3: Adverse Reactions Reported in ≥10% of Patients and With at Least a 5% Greater Frequency in the DRd Arm in MAIA

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>DRd (n=364)</th>
<th>RD (n=362)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Reaction</strong></td>
<td>All Grades (%)</td>
<td>Grade 3 (%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>33 &lt;0.1&lt;1 6 4&lt;0</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>1 0 0 0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>32 1 2&lt;1 23 1 0</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>17 1 0 12 &lt;0.1&lt;1</td>
<td></td>
</tr>
<tr>
<td>Infusions</td>
<td>55 &lt;0.1&lt;1 36 2&lt;0</td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection*</td>
<td>95 1 0 94 1 0</td>
<td></td>
</tr>
<tr>
<td>Pneumonitis</td>
<td>28 1 0 27 1 0</td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>18 1 0 17 1 0</td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin reactions</td>
<td>41 2 0 39 2 0</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>20 1&lt;1 19 1&lt;1&lt;1</td>
<td></td>
</tr>
</tbody>
</table>
**Table 3: Adverse Reactions**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>DARZALEX (N=283)</th>
<th>Rd (N=281)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
<td></td>
<td></td>
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<tr>
<td>Cough</td>
<td>15</td>
<td>12</td>
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<td></td>
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</tr>
<tr>
<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Muscle spasms</strong></td>
<td>26</td>
<td>19</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
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<tr>
<td>Diplopia</td>
<td>13</td>
<td>7</td>
</tr>
</tbody>
</table>

**Key: D=daratumumab, Rd-lenalidomide-dexamethasone.**

- **Interference with Serum Protein Electrophoresis and Immunofixation Tests**


**Patient Counseling**

Advise patients to contact their healthcare provider if they have a fever (see Warnings and Precautions). Refer to lenalidomide, pomalidomide, or thalidomide prescribing information for additional recommendations for contraception.

**Pediatric Use**

Safety and effectiveness of DARZALEX in pediatric patients have not been established.

**Geriatric Use**

Of the 2,630 patients who received DARZALEX at the recommended dose, 38% were 75 years of age and 15% were 75 years of age or older. No overall differences in effectiveness were observed between these patients and younger patients. The incidence of serious adverse reactions was higher in older than in younger patients (see Adverse Reactions). Among patients with relapsed and refractory multiple myeloma (n=1,213), the serious adverse reactions that occurred more frequently in patients 65 years and older than in patients younger than 65 years were pneumonia and sepsis. Within the DKd group in CANDOR, fatal adverse reactions occurred in 14% of patients 65 years and older compared to 6% of patients less than 65 years. Among patients with newly diagnosed multiple myeloma who were ineligible for autologous stem cell transplant (n=710), the serious adverse reaction that occurred more frequently in patients 75 years older was pneumonia.

**REFERENCES**


**Embryo-Fetal Toxicity**

Advise pregnant women of the potential hazard to a fetus. Advise females of reproductive potential to inform their healthcare provider of a known or suspected pregnancy (see Warnings and Precautions, Use in Specific Populations).

**Hepatitis B Virus (HBV) Reactivation**

Advise patients to contact their healthcare provider if they have a fever (see Warnings and Precautions). Refer to lenalidomide, pomalidomide, or thalidomide prescribing information for additional recommendations for contraception.

**Partial Reproductive Potential**

DARZALEX can cause fetal harm when administered to a pregnant woman (see Use in Specific Populations). Pregnancy Testing

With the combination of DARZALEX with lenalidomide, pomalidomide, or thalidomide labeling for pregnancy testing requirements prior to initiating treatment in females of reproductive potential.

**Contraception**

Advise females of reproductive potential to use effective contraception during treatment with DARZALEX and for 3 months after the last dose. Additionally, refer to the lenalidomide, pomalidomide, or thalidomide labeling for additional recommendations for contraception.

**Other Clinical Trials Experience**

In clinical trials of patients with multiple myeloma treated with DARZALEX as monotherapy or as combination therapy, none of the 1,111 evaluable monotherapy patients, and 2 of the 1,386 evaluable combination therapy patients, tested positive for anti-daratumumab antibodies. One patient with newly diagnosed multiple myeloma (DKd) was positive for non-neutralizing antibody (using a neutralizing assay) that was cross-reactive with anti-lenalidomide antibodies.

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DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use

**INDICATIONS AND USAGE**

DARZALEX FASPRO® is indicated for the treatment of adult patients with multiple myeloma:

- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

**CONTRAINDICATIONS**

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase or any of the components of the formulation [see Warnings and Precautions and Adverse Reactions].

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity and Other Administration Reactions**

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO® [see Adverse Reactions].

**Systemic Reactions**

In a pooled safety population of 822 patients with multiple myeloma (N=439) or light chain (AL) amyloidosis (N=183) who received DARZALEX FASPRO® as monotherapy as a component of a combination therapy, 8% of patients experienced a systemic administration-related reaction (Grade 3 or 4). Systemic administration-related reactions occurred in 4% of patients with the first injection, 0.4% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 6.3 hours (range: 6 minutes to 3.5 days). Of the 129 systemic administration-related reactions that occurred in 74 patients, 110 (87%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritis, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen and corticosteroids [see Dose and Administration (2.5) in Full Prescribing Information]. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening Grade 4 administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions [see Dose and Administration (2.5) in Full Prescribing Information].

**Local Reactions**

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.8%. The most frequent (≥1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 6.5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management.

**Cardiac Toxicity in Patients with Light Chain (AL) Amyloidosis**

Serious or fatal cardiac adverse reactions occurred in patients with light chain (AL) amyloidosis who received DARZALEX FASPRO® in combination with bortezomib, cyclophosphamide and dexamethasone [see Adverse Reactions]. Serious cardiac disorders occurred in 16% and fatal cardiac disorders occurred in 10% of patients. Patients with NYHA Class III or Mayo Stage IIIA disease may be at greater risk. Patients with NYHA Class IIIB or IV disease were not studied.

Monitor patients with cardiac involvement of light chain (AL) amyloidosis more frequently for cardiac adverse reactions and administer supportive care as appropriate.

**Neutropenia**

Daratumumab may increase neutropenia induced by background therapy [see Adverse Reactions].

Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX FASPRO® until recovery of neutrophils. In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

**Thrombocytopenia**

Daratumumab may increase thrombocytopenia induced by background therapy [see Adverse Reactions].

Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX FASPRO® until recovery of platelets.

**Embryo-Fetal Toxicity**

Based on the mechanism of action, DARZALEX FASPRO can cause fetal harm when administered to a pregnant woman. DARZALEX FASPRO may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during pregnancy. Daratumumab bound to RBCs may cause detection of antibodies to minor antigens in the patient's serum [see References (15)]. The determination of a patient's ABO and Rh blood type are not impacted [see Drug Interactions]. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX FASPRO®. Type and screen patients prior to starting DARZALEX FASPRO® [see Dose and Administration (2.1) in Full Prescribing Information].

**Interference with Determination of Complete Blood Count**

Daratumumab is a human IgG kappa monospecific antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein [see Drug Interactions]. This interference can impact the determination of complete blood count and of disease progression in some DARZALEX FASPRO®-treated patients with IgG kappa myeloma protein.

**ADVERSE REACTIONS**

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity and Other Administration Reactions [see Warnings and Precautions].
- Cardiac Toxicity in Patients with Light Chain (AL) Amyloidosis [see Warnings and Precautions].
- Neutropenia [see Warnings and Precautions].
- Thrombocytopenia [see Warnings and Precautions].

**Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be indicative of the rates observed in practice.

**Released/Refractory Multiple Myeloma**

In Combination with Lenalidomide and Dexamethasone

The safety of DARZALEX FASPRO® with lenalidomide and dexamethasone was evaluated in a single-arm cohort of PLEIADES [see Clinical Studies (14.2) in Full Prescribing Information]. Patients received DARZALEX FASPRO® 1,800 mg/30,000 units administered subcutaneously once weekly from weeks 1 to 8, once every 2 weeks from weeks 1, 8, 15, 22 and 29.

**DARZALEX FASPRO® with Lenalidomide and Dexamethasone (N=65)**

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>All Grades (%)</th>
<th>Grades 3-4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased leucocytes</td>
<td>94 (94)</td>
<td>34 (34)</td>
</tr>
<tr>
<td>Decreased lymphocytes</td>
<td>62 (93)</td>
<td>58 (87)</td>
</tr>
<tr>
<td>Decreased platelets</td>
<td>86 (71)</td>
<td>9 (11)</td>
</tr>
<tr>
<td>Decreased neutrophils</td>
<td>89 (85)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Decreased hemoglobin</td>
<td>45 (69)</td>
<td>8 (12)</td>
</tr>
</tbody>
</table>

* Denominator is based on the safety population treated with DARZALEX FASPRO®-Rd (N=45).

**Immunogenicity**

As with all therapeutic proteins, there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with that of any other myeloma treatment may not be meaningful.
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) injection

In patients with multiple myeloma and light chain (AL) amyloidosis who received DARZALEX FASPRO as monotherapy or as part of a combination therapy, less than 1% of 796 patients developed treatment-emergent anti-daratumumab antibodies. In patients with multiple myeloma and light chain (AL) amyloidosis who received DARZALEX FASPRO as monotherapy or as part of a combination therapy, 1% of 796 patients developed treatment-emergent anti-HuR/PH20 antibodies. The anti-HuR/PH20 antibodies did not appear to affect daratumumab exposure. None of the reactions that were tested positive for anti-HuR/PH20 antibodies tested positive for neutralizing antibodies.

Postmarketing Experience

The following adverse reactions have been identified with post-approval use of daratumumab. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune System: Anaphylactic reaction; systemic administration reactions (including death)

Gastrointestinal: Pancreatitis

Infections: Cytomegalovirus, Listeriosis

DRUG INTERACTIONS

Effects of Daratumumab on Laboratory Tests

Interference with Indirect Antioglobulin Tests (Indirect Coombs Test)

Daratumumab binds to CD38 on RBCs and interferes with compatibility testing, including antibody screening and cross matching. Daratumumab interference mitigation methods include treating reagent RBCs with filter-aided leukocyte lysis (FALL) to disrupt daratumumab binding [see Reference(s)] or genotyping. Since the Kell blood group system is also sensitive to DTT treatment, supply K-negative units after ruling out or identifying allotransplants using DTT-treated RBCs.

If an emergency transfusion is required, administer non-cross-matched ABO/RhD compatible RBCs per local blood bank practices.

Interference with Serum Protein Electrophoresis and Immunofixation Tests

Daratumumab may be detected on serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for monitoring disease monoclonal immunoglobulins (M protein). False positive SPE and IFE assay results may occur for patients with IgG kappa myeloma protein impacting initial assessment of complete responses by International Myeloma Working Group (IMWG) criteria. In DARZALEX FASPRO-treated patients with persistent very good partial response, where daratumumab interference is suspected, consider using a FDA-approved daratumumab-specific IFE assay to distinguish daratumumab from any remaining endogenous M protein in the patient’s serum, to facilitate determination of a complete response.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

DARZALEX FASPRO can cause fetal harm when administered to a pregnant woman. The assessment of associated risks with daratumumab products is based on the mechanism of action and data from target CD38 knockout animal models [see Data]. There are no available data on the use of DARZALEX FASPRO in pregnant women to evaluate drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

The combination of DARZALEX FASPRO and lenalidomide, thalidomide or pomalidomide is contraindicated in pregnant women, because lenalidomide, thalidomide or pomalidomide may cause birth defects and death of the unborn child. Lenalidomide, thalidomide and pomalidomide are only available through a REMS program. Refer to the lenalidomide, thalidomide or pomalidomide prescribing information for use during pregnancy.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Immunoglobulin G1 (IgG1) monoclonal antibodies are transferred across the placenta. Based on its mechanism of action, DARZALEX FASPRO may cause depletion of fetal CD38 positive immune cells and decreased bone density. Deferring administering live vaccines to neonates and infants exposed to daratumumab in utero until a hematology evaluation is completed.

Data

Animal Data

DARZALEX FASPRO for subcutaneous injection contains daratumumab and hyaluronidase. Mice that were genetically modified to eliminate all CD38 expression (CD38 knockout mice) had reduced bone density at birth and in later life when the integrity of CD38 was regulated in the regulation of humoral immune responses (mice), feto-maternal immune tolerance (mice), and early embryonic development (flogs).

No systemic exposure of hyaluronidase was detected in monkeys given 22,000 U/kg subcutaneously (12 times higher than the human dose) and there were no effects on embryo-fetal development in pregnant mice given 300,000 U/kg hyaluronidase subcutaneously during organogenesis, which is 45 times higher than the human dose.

There were no effects on pre- and post-natal development through sexual maturity in offspring of mice treated daily from implantation through lactation with 990,000 U/kg hyaluronidase subcutaneously, which is 134 times higher than the human doses.

Lactation

Risk Summary

There is no data on the presence of daratumumab and hyaluronidase in human milk, the effects on the breastfed child, or the effects on milk production. Maternal immunoglobulin G is known to be present in human milk. Published data suggest that antibodies in breast milk do not enter the neonatal and infant circulations in substantial amounts. Because of the potential for serious adverse reactions in the breastfed child when DARZALEX FASPRO is administered with lenalidomide, thalidomide or pomalidomide, advise women not to breastfeed during treatment with DARZALEX FASPRO. Refer to lenalidomide, thalidomide or pomalidomide prescribing information for additional information.

Data

Animal Data

No systemic exposure of hyaluronidase was detected in monkeys given 22,000 U/kg subcutaneously (12 times higher than the human dose) and there were no effects on post-natal development through sexual maturity in offspring of mice treated daily during lactation with 96,000 U/kg hyaluronidase subcutaneously, which is 134 times higher than the human doses.

Females and Males of Reproductive Potential

DARZALEX FASPRO can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations].

Prepregnancy Testing

When the combination of DARZALEX FASPRO with lenalidomide, thalidomide or pomalidomide, refer to the lenalidomide, thalidomide or pomalidomide labeling for pregnancy testing requirements prior to initiating treatment in females of reproductive potential.

Contraception

Advise females of reproductive potential to use effective contraception during treatment with DARZALEX FASPRO for 3 months after the last dose. Additionally, refer to the lenalidomide, thalidomide or pomalidomide labeling for additional recommendations for contraception.

Geriatric Use

Of the 211 patients who received DARZALEX FASPRO as monotherapy for relapsed and refractory multiple myeloma, 31% were 65 to <75 years of age, and 19% were 75 years of age or older. No overall differences in effectiveness of DARZALEX FASPRO have been observed between patients ≥65 years of age and younger patients. Adverse reactions that occurred at a higher frequency (≥5% difference) in patients ≥65 years of age included upper respiratory tract infection, urinary tract infection, diarrhea, nausea, asthenia, dyspepsia, cough, fatigue, and peripheral edema. Serious adverse reactions that occurred at a higher frequency (≥2% difference) in patients ≥65 years of age included pneumonia. Of the 214 patients who received DARZALEX FASPRO as part of a combination therapy for light chain (AL) amyloidosis, 35% were 65 to <75 years of age, and 10% were 75 years of age or older. Clinical studies of DARZALEX FASPRO as part of a combination therapy for patients with light chain (AL) amyloidosis did not include sufficient numbers of patients aged 65 and older to determine whether effectiveness differs from that of younger patients. Adverse reactions that occurred at a higher frequency in patients ≥65 years of age were peripheral edema, asthenia, pneumonia and hypotension.

No clinically meaningful differences in the pharmacokinetics of daratumumab were observed in geriatric patients compared to younger adult patients [see Clinical Pharmacology (12.3) in Full Prescribing Information].

REFERENCES


PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling [Patient Information].

Hypersensitivity and Other Administration Reactions

Advise patients to seek immediate medical attention for any of the following signs and symptoms of systemic administration-related reactions: tachy, runny or blocked nose; chills, nausea, throat irritation, cough, headache, shortness of breath or difficulty breathing [see Warnings and Precautions].

Cardiac Toxicity in Patients with Light Chain (AL) Amyloidosis

Advise patients to immediately contact their healthcare provider if they have signs or symptoms of cardiac adverse reactions [see Warnings and Precautions].

Neutropenia

Advise patients to contact their healthcare provider if they have a fever [see Warnings and Precautions].

Thrombocytopenia

Advise patients to contact their healthcare provider if they have bruising or bleeding [see Warnings and Precautions].

Hypersensitivity

Advise pregnant women of the potential hazard to a fetus. Advise females of reproductive potential to inform their healthcare provider of a known or suspected pregnancy [see Warnings and Precautions, Use in Specific Populations].

Advises females of reproductive potential to avoid becoming pregnant during treatment with DARZALEX FASPRO and for 3 months after the last dose [see Use in Specific Populations].

Advises patients to inform their healthcare provider, including personnel at blood transfusion centers, that they are taking DARZALEX FASPRO, in the event of a planned transfusion [see Warnings and Precautions].

Advises patients that lenalidomide, thalidomide and pomalidomide have the potential to cause fetal harm and have specific requirements regarding contraception, pregnancy testing, blood and sperm donation, and transmission in sperm. Lenalidomide, thalidomide and pomalidomide are only available through a REMS program [see Use in Specific Populations].

Interference with Laboratory Tests

Advise patients to inform their healthcare provider if they have ever had or might have a hepatitis B infection and that DARZALEX FASPRO could cause hepatitis B virus to become active again [see Adverse Reactions].

In patients with multiple myeloma and light chain (AL) amyloidosis who received DARZALEX FASPRO as monotherapy or as part of a combination therapy, less than 1% of 796 patients developed treatment-emergent anti-daratumumab antibodies. In patients with multiple myeloma and light chain (AL) amyloidosis who received DARZALEX FASPRO as monotherapy or as part of a combination therapy, 1% of 796 patients developed treatment-emergent anti-HuR/PH20 antibodies. The anti-HuR/PH20 antibodies did not appear to affect daratumumab exposure. None of the reactions that were tested positive for anti-HuR/PH20 antibodies tested positive for neutralizing antibodies.
Acalabrutinib Provides Long-Term Survival Benefits vs Standard of Care in Relapsed/Refractory CLL

Treatment with acalabrutinib (Calquence) for relapsed/refractory chronic lymphocytic leukemia was effective out to 3 years and demonstrated a progression-free survival (PFS) benefit over standard of care, according to a 3-year follow-up of the ASCEND study (NCT02970318). Long-term follow-up data from ASCEND, which were presented by Wojciech Jurczak, MD, PhD, head of the Department of Hematology at Maria Skłodowska-Curie National Research Institute of Oncology in Kraków, Poland, also demonstrated that acalabrutinib was well tolerated with no new safety findings.

During follow-up, patients treated with acalabrutinib monotherapy had significantly prolonged PFS compared with those treated with idelalisib/rituximab (Rituxan) or bendamustine (Bendeka)/rituximab (median, not reached [NR] vs 16.8 months; HR, 0.29; 95% CI, 0.21-0.41; P < .0001). More patients in the acalabrutinib group achieved 36-month PFS compared with those in the investigator–selected treatment group (63% vs 21%). When investigators assessed the groups separately, they observed similar benefits regarding PFS when comparing acalabrutinib with idelalisib/rituximab (median, 16.2 months; HR, 0.31; P < .0001) and with bendamustine/rituximab (median, 18.6 months; HR, 0.25; P < .0001).

“Overall, these data support the use of acalabrutinib in patients with relapsed/refractory chronic lymphocytic leukemia, including those with high-risk features,” Jurczak said during the presentation.

Ibrutinib Plus FCR Shows Encouraging Activity as Time-Limited Option for Younger Patients With CLL

The addition of ibrutinib (Imbruvica) to fludarabine, cyclophosphamide, and rituximab (Rituxan; IFCR) resulted in a higher rate of complete responses (CRs) with bone marrow undetectable minimal residual disease (BM-uMRD) in younger, fit patients with chronic lymphocytic leukemia (CLL), according to long-term data from a phase 2 study (NCT02251548). Moreover, these results included patients with unmutated IGHV, a population who rarely has durable responses, according to Matthew S. Davids, MD, MMSc, director of clinical research in the Division of Lymphoma at Dana-Farber Cancer Institute and an associate professor of medicine at Harvard Medical School.

“Other studies have suggested that patients treated with ibrutinib-based therapy have variable benefits, even with IGHV-unmutated disease. However, we have not seen larger data yet for the combination of ibrutinib with FCR,” said Davids during a presentation of the data. “We hypothesized that combining ibrutinib with FCR as initial therapy would lead to a high rate of CR with BM-uMRD in a broad population of younger, fit patients [with CLL].”

The median number of ibrutinib maintenance cycles was 24 (range, 0-81). In the intent-to-treat (ITT) population, the rate of CR with BM-uMRD improved to 55% (n = 47) and the best rate of BM-uMRD remained at 84% (n = 71). The CR rate deepened with ibrutinib maintenance therapy, from 34% to 81% as the best rate. This was similar among the IGHV-mutated and -unmutated patients, up from 41% to 88% and up from 28% to 76%, respectively, as the best rates. Lastly, the BM MRD-negative rates in the ITT population were 91% in the 81 patients with the TP53 mutation.

With the time-limited novel agent plus chemoimmunotherapy, 3-year progression-free and overall survival rates were 97% and 99%, respectively. Thirteen patients (21.3%) who discontinued ibrutinib have had recurrent BM-MRD, including 5 patients with clinical progression of CLL. Seven patients restarted treatment with ibrutinib, all of whom have experienced partial responses. The median time on retreatment is 12.8 months (range, 4.2-26.2).

For a full list of references, see the article on OncNursingNews.com

Ciltacabtagene autoleucel (cilta-cel) elicited a 97.9% objective response rate (ORR) and an 82.5% stringent complete response (sCR) rate in patients with relapsed/refractory multiple myeloma at a median of approximately 2 years of follow-up, according to updated findings from the phase 1b/2 CARTITUDE-1 trial (NCT03548207). Additionally, the 2-year progression-free and overall survival (OS) rates were 60.5% and 74.0% in all patients, respectively, and minimal residual disease (MRD) negativity was achieved in 92% of evaluable patients for MRD (n = 61). The 2-year progression-free survival (PFS) rates were improved in those who had MRD negativity sustained for at least 6 and 12 months, at 91% and 100%, respectively, as well as the 2-year OS rates at 100% and 100%.

“These data are encouraging, and they suggest that cilta-cel will be an important treatment option for patients with...
multiple myeloma," said lead study author Thomas Martin, MD, a clinical professor of medicine in the Adult Leukemia and Bone Marrow Transplantation Program, and associate director of the Myeloma Program at the University of California, San Francisco, in a presentation on the data.

Ciltacel is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell therapy with 2 BCMA-targeting single-domain antibodies that are designed to confer avidity. A biologics license application seeking approval for the agent is currently under priority review with the FDA for its use in adult patients with relapsed and/or refractory multiple myeloma.2

In November 2021, the FDA extended the Prescription Drug User Fee Act target date for the application to review recently submitted data linked with an updated analytical method following the agency’s request for information request that was issued by the agency.3 The new action date is February 28, 2022.

For a full list of references, see the article on OncNursingNews.com

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**CLINICAL INSIGHTS**

**Liso-Cel Outperforms Standard Therapy in Improving QoL in Relapsed/Refractory LBCL**

Lisocabtagene maraleucel (liso-cel; Breyanzi) fostered a better quality of life (QoL) in patients with relapsed/refractory large B-cell lymphoma (LBCL) compared with current standard of care (SOC), according to data from a comparative analysis of the phase 3 TRANSFORM trial (NCT03575351).1

- **Overall QoL was either improved or maintained from baseline in patients with relapsed/refractory LBCL who received liso-cel as second-line treatment,”** presenting study author Jeremy Abramson, MD, director, Jon and Jo Ann Hagler Center for Lymphoma, associate professor of medicine, Massachusetts General Hospital Cancer Center, said during a presentation of the data. “These findings corroborated with previously reported health-related QoL associated with liso-cel treatment.”

For a full list of references, see the article on OncNursingNews.com

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**SABCS 2021 Highlights & Conclusions**

Combination therapy, selective estrogen receptor degraders, and more were covered at the 2021 San Antonio Breast Cancer Symposium.

by Oncology Nursing News® Staff

**Immunotherapy, Oral SERDS, and Breast Cancer–Related Lymphedema**

Immunotherapy May Represent New Standard of Care in Metastatic TNBC

Pembrolizumab (Keytruda) plus chemotherapy demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) and overall survival (OS) vs chemotherapy alone in patients with previously untreated, locally recurrent, inoperable, or metastatic triple-negative breast cancer (TNBC) with a PD-L1 combined positive score (CPS) of 10 or higher, according to updated data from the phase 3 KEYNOTE-355 trial (NCT02819518).1

Furthermore, a PD-L1 CPS of at least 10 was found to be a reasonable cutoff to define the population of patients expected to derive the most benefit from this regimen. Results showed that the combination of pembrolizumab and chemotherapy yielded a median OS of 23.0 months vs 16.1 months with chemotherapy alone in patients with a CPS of 10 or higher (HR, 0.73; 95% CI, 0.55-0.95; P = .0093). The 18-month OS rates were 58.3% with pembrolizumab vs 44.7% with placebo or chemotherapy.

Moreover, the median PFS elicited by the combination was 9.7 months vs 5.6 months in patients with a CPS of at least 10 (HR, 0.66; 95% CI, 0.50-0.88). The 12-month PFS rate was 39.1% with pembrolizumab and 23.0% with placebo or chemotherapy.

“These results provide further support for pembrolizumab in combination with chemotherapy as the new standard-of-care treatment regimen for patients with locally recurrent, unresectable, or metastatic TNBC whose tumors express a PD-L1 CPS of 10 or more,” said lead study author Javier Cortés, MD, PhD, head of breast cancer and gynecological cancers at Hospital Universitario Ramón y Cajal in Madrid, Spain, in a presentation of the data.

For a full list of references, see the article on OncNursingNews.com

Do Oral SERDs Hold Potential to Change Outpatient Practices?

The selective estrogen receptor degrader (SERD) elacestrant (RAD1901) led to a 30%
The aim of our study was to assess the incidence of lymphedema in a prospective cohort of patients treated with ALND to identify risk factors associated with lymphedema development.”

Andrea V. Barrio, MD, FACS

Oncology Nursing News

Breast Cancer–Related Lymphedema Rate Is Higher in Black Women Than White Women

Data presented at the 2021 San Antonio Breast Cancer symposium revealed that in patients with breast cancer treated with axillary lymph node dissection (ALND) and radiotherapy there is a 3.5-fold increased incidence of lymphedema among Black women compared with non-Black women.1 The results also indicated that Hispanic women have a 3-fold increased incidence of breast cancer–related lymphedema compared with White women. However, after a sentinel lymph node biopsy to be eligible for inclusion in the analysis.

At a median follow-up of 22.6 months, 56 patients had developed lymphedema. The results demonstrated that the 12-month lymphedema rate was 8.8% (95% CI, 5.9%-13%) and that the 24-month rate was 24.7% (95% CI, 19.2%-31.5%). The highest incidence of lymphedema observed was among Black women, with a 24-month lymphedema rate of 39.4%. That rate was 27.7% in Hispanic women, 23.4% in Asian women, and 20.5% in White women.

The results also showed that receipt of neoadjuvant chemotherapy was associated with a higher 24-month lymphedema rate compared with upfront surgery at 30.9% vs 11.1% (P = .0066). Of note, among women with lymphedema, disease severity did not vary across racial and ethnic groups with similar relative volume changes observed.

“We observed a higher incidence of lymphedema in Black women treated with ALND and radiotherapy after adjustment for other variables. Similar findings were observed in Hispanic women, but confirmation in a larger data set is needed,” Barrio concluded.

For a full list of references, see the article on OncNursingNews.com

Oral Elacestrant Requires Patient Education in Metastatic ER+ Breast Cancer

“Elacestrant is an oral agent, meaning there is no need for intramuscular shots, compared with other SERDS, such as fulvestrant, for use in select patients with advanced breast cancer. However, nausea and upper GI discomfort are frequently linked with its use.”

Scan the QR code or visit OncNursingNews.com

Anditya Bardia, MD, MPH

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The Rise of e-Cigarettes—What Nurses Should Know

Awareness of the e-cigarette epidemic among youth could help drive primary prevention.

by Leah Lawrence

In 2018, the US surgeon general issued an advisory calling for immediate action against the epidemic of youth electronic cigarette use. For the past 7 years, e-cigarettes have been the most commonly used tobacco product among US youth with an estimated 1 in 5 high school students and 1 in 20 middle school students using them. Nurses are on the front lines and are a direct touch point in the effort to curb e-cigarette use among children and teenagers, according to Joelle Fathi, DNP, RN, ARNP, CTTS, FAAN, chief healthcare delivery officer at the GO2 Foundation for Lung Cancer and deputy chair of the Tobacco Control and Smoking Cessation Committee at the International Association for the Study of Lung Cancer.

“Nurses [belong to] the No. 1 most trusted profession. If more nurses understand how these products hijack the brain and neurohormones, they can use this information to educate children and have [repeated] conversations about the harms before they are ever exposed,” Fathi said.

Defining the Problem

Conventional or combustible tobacco includes tobacco products designed to be burned and smoked, such as cigars or cigarettes. In contrast, e-cigarettes work by heating the tobacco product.

The FDA defines these products as electronic nicotine delivery systems (ENDS), which include vapes, vaporizers, vape pens, hookah pens, e-cigarettes, and e-pipes. To best educate their patients, it is important that all nurses understand the mechanism of addiction for nicotine.

“When someone inhales vapors from ENDS, those gases go into the depths of the lungs; they permeate across the very fine lining of the lung and into the arterial bloodstream,” Fathi noted. “From the time of inhalation it takes only about 7 seconds for any substance in that tobacco to reach the brain and other organs via the arterial blood stream.”

“There are other things that cause these surges, but nothing can touch the surge that nicotine causes. It takes only as few as 3 repetitive exposures to develop nicotine dependence,” she said. “When people use nicotine, even for a short duration, their neurocircuity never goes back to normal.”

E-Cigarette Rates, Risks

The good news, according to Mary Rezk-Hanna, PhD, FAHA, an assistant professor at UCLA School of Nursing, is that there has been a clear reduction in the use of combustible cigarettes among adolescents. Unfortunately, the use of e-cigarettes and other alternative tobacco and nicotine products is offsetting that decline. Data show that from 2011 to 2018, the use of e-cigarettes increased among high school students from 1.5% in 2011 to 20.8% in 2018.

Nurses can raise awareness among adolescents about the amount of nicotine in e-cigarettes. For example, 1 combustible cigarette contains about 1 mg of nicotine. Smoking a pack of 20 cigarettes a day would equal 20 mg of nicotine. In comparison, one 3% JUULpod contains 35 mg of nicotine per mL, or about 23 mg of total nicotine at the time of manufacture. The 5% JUULpod contains 40 mg of nicotine.

E-cigarettes have not been around long enough to fully understand the long-term associated health risks. However, as of 2020, more than 2800 hospitalized cases or deaths from e-cigarette or vaping product use–associated lung injury (EVALI) had been reported to the Centers for Disease Control and Prevention (CDC). Symptoms of EVALI include respiratory symptoms, gastrointestinal symptoms, and constitutional symptoms such as fever, chills, and weight loss.

Role of the Nurse

“Nurses have a critical role in controlling the smoking epidemic,” Rezk-Hanna said. Research findings have indicated that compared with smokers who receive usual care, smokers who receive assistance from a nurse have a 29% greater probability of successfully quitting for 5 or more months. This emphasizes the importance of nurses in efforts to curb tobacco use.

According to Rezk-Hanna, the 5 A’s framework for promoting smoking cessation (ask, advise, assess, assist, and arrange) is highly effective and nurses should be encouraged to use it with their patients. This means that nurses should identify tobacco use status for every patient at every visit (ask). They should urge tobacco cessation (advise) and determine whether the user is willing to attempt to quit (assess). For those who are willing, nurses should provide counseling and pharmacotherapy to help (assist), and schedule a follow-up (arrange). “Assisting patients to achieve permanent [smoking] cessation is one of the most important services we can offer them to protect their health now and in the future,” Rezk-Hanna said.

Some excellent cessation resources are available, including 1-800-QUIT-NOW, a national portal to a network of state quit lines. The Truth Initiative has launched an e-cigarette quit program to address the increase in youth vaping. To access the new program, users must text “DITCHJUUL” to 88709 to enroll. The American Lung Association’s Not On Tobacco is a voluntary quit program for young people aged 14 to 19.

Treatment combined with behavioral counseling is the best way to help patients quit, Fathi said. Nurses have to be familiar with and know how to access local behavioral counseling resources and pharmaceutical treatments. For example, Yale Tobacco Center of Regulatory Science has launched a vaping cessation program for young people aged 14 to 19 years in Connecticut.

“The biggest bang for our buck will always be to prevent youth from ever picking these products up,” Fathi said. “There is clear science that demonstrates that 90% of people who have used tobacco lifelong started before the age of 18.”

“If we can change that…smoking will be obliterated.”

For a full list of references, see the article on OncNursingNews.com
Access-Focused Care: The 4-1-1 on Oncology Phone Triage Programs

For this episode of The Vitals, we spoke with Nikki Urban, RN, a practice manager at Allegheny Health Network, about implementing a successful phone triage program at the oncology institution.

by Oncology Nursing News® Staff

Q: Oncology Nursing News®: How did getting this system in place come about?

Urban: Phone triage is always a challenge in any specialty office. Oftentimes, what ends up happening is that calls come in and they end up going to a voicemail. [Staff] triage the calls one by one and try to get back to patients in a timely fashion. Unfortunately, that could mean that a patient with significant symptoms might be leaving a message about those symptoms on a voicemail line. [When] the staff are busy in clinic, they can’t get back [to patients] until the end of the day, so we couldn’t really address symptoms on the same day. We started to have a dialogue surrounding that—we saw these things coming up and patients sometimes needing to go to the emergency department at the end of the day because we just couldn’t address their concerns.

Q: Since implementing this project, what successes has your institution seen?

Well, it has been very exciting. I know sometimes patients will call and say, “Oh my goodness, I have a real person that I’m speaking to!” Patients have been excited about it. The oncology triage team can immediately address symptoms, assess patients, and decide whether a patient needs a same-day visit or whether they need to come into our infusion office for supportive care. They can schedule those appointments right at the point of the call and get a patient scheduled to see a provider or maybe have some hydration if the orders are already in the chart. Systematically, we have seen an increase in those same-day visit opportunities.

Q: How might training differ for phone triage nursing compared with traditional oncology nursing? Assessing a patient’s well-being and needs over the phone can be quite different than in person; how do you standardize that training?

As we considered how we were going to implement the project, we determined that nurses needed to have oncology experience. We don’t even consider anyone unless they have had at least a year of oncology infusion clinic experience, as that skill set is very, very important. Because we’re on an electronic health record system, our staff are able to assess all the assessment tools that would be available in person in the office. And, in general, when you’re talking to somebody on the phone and you’re in the comfort of your own home, there’s a lot of dialogue that occurs; patients are very comfortable going through those assessments and talking about what their concern is. Because it isn’t a terribly rushed situation and the patients are comfortable in their own environment, nurses can really get to the bottom of what the issue is and address their concerns.

Education is really “hands-on.” We have shared files that the nurses can access for each of the offices. They know who the providers are, who the support staff are, and how to direct calls. A lot of [training] is just learning how to obtain resources, how to get the information that’s required, and who to give it to.

We get them on the phones right away. [Because] they already had the clinical experience, they just have to learn how to handle the calls and start the telephone encounters. We also created standardized-format clinical notes. Even as the office teams are getting our messages, they’re very standardized and nurses have the necessary information to really get the answer back to the patient as quickly as possible.

Q: In your opinion, what is the value of a phone triage program? How can it improve patient outcomes at various institutions?

Truly the best value is the patients’ being satisfied, patients’ having access to care. As we have patients reaching out to us, we can identify more urgent situations for oncology. If we can bring those patients in, assess any toxicities or any issues that they’re having, we can potentially adjust treatments. As we adjust treatments, we can improve adherence, keep patients on track for treatment, and ultimately improve their outcomes based on the adherence and completion of treatment.

It has been very exciting. I know sometimes patients will call and say, ‘Oh my goodness, I have a real person that I’m speaking to!’ Patients have been excited about it. The oncology triage team are able to immediately address symptoms, assess patients, and decide whether a patient needs a same-day visit.”

Nikki Urban, RN
Help Patients Manage Cancer-Related Fatigue

Andrew Kass, MSN, RN, AGNP-C, AOCNP, discusses the impact fatigue can have on patients with cancer and how oncology nurses and APPs can help their patients address this common adverse event.

by Oncology Nursing News® Staff

Most patients with cancer experience some degree of fatigue throughout treatment. Appropriately managing it is an important component of advanced practice supportive care, because fatigue can affect whether patients are able to meet the everyday demands of family, friends, or work, explained Andrew Kass, MSN, RN, AGNP-C, AOCNP, an advanced practice nurse at Rutgers Cancer Institute of New Jersey.

In an interview with Oncology Nursing News®, Kass discussed the impact fatigue can have on patients with cancer, best ways to assess fatigue as an advanced practice provider (APP), and best fatigue management practices for patients.

Q. Oncology Nursing News®: Why is addressing fatigue so important in improving overall patient outcomes?

Kass: Fatigue affects so many aspects of a patient’s quality of life. There is a direct connection between how somebody feels when they’re tired, and how well they can manage their pain, how well they can heal after surgery, and even their ability to take in information. If somebody is super fatigued, it’s very hard to give them proper education on self-management. If somebody is too tired, they might not eat or drink adequately and that might affect their ability to heal. Therefore, it is important to address it. When it comes to treating cancer, 80% to 90% of patients will complain of fatigue at some point during their journey.

When patients come to the center to receive chemotherapy, fatigue and pain are part of their initial assessment and we get a number scale from 0 to 10. We ask what their [current] activities of daily living [are]…because there are performance scales that are used to determine whether it’s safe to give chemotherapy to a patient. There are 2 of them—the ECOG score and the Karnofsky score—that we use for performance status. If the patient is not out of bed more than 50% of the time, they will not get chemotherapy (unless it’s critical). That shows how important it is to get fatigue under control. This is because if a patient is not able to get out of bed, they will not receive their chemotherapy. If they don’t get their chemotherapy, they will not get better. Therefore, it becomes super important to take care of fatigue.

Q. Which questions do you hear most frequently from your patients about fatigue?

Patients will also often ask us, “Does the fatigue ever go away?” or “What can I do to eat or drink to feel better?” because they want [answers].

What I try to tell patients is that they need to exercise more to have more energy. This is well established; it is well documented. The idea [is,] presumably, that when I’m a healthy person and when I feel tired, I will tend to nap for 20 minutes; I will restore energy and I’ll feel much better for the rest of the day. However, people who have cancer are going through therapy. Sometimes no amount of rest will make them feel better. [But] energy creates energy. Patients need to be taught how to exercise to tolerance and to safety for 30 minutes a day, 3 times a week—something of that extent.

Right now, we are in winter. We talk with patients [about] walking in the mall to stretch their legs and get some activity. Recently, people also [have been] talking about doing yoga to build strength, but in a very controlled and safe manner to help to feel stronger and replenish fatigue.

What we’re talking about is an integrative kind of discussion. It’s not just one thing that can help a patient with fatigue; you can’t just give somebody epoetin alfa and hope things feel better. Transfusions certainly will help, but that’s not the big picture. We need to integrate all aspects of things that can make patients feel better.

We talk about yoga [and] simple things such as drinking plenty of fluids to be well hydrated and consuming an adequate number of calories; we usually have dietitians help us with patients that are starting to lose weight. If you lose weight, if you’re not drinking enough, it will cause more fatigue. We need to have all those aspects together to help the patient and to support them during this really stressful time.
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A Primer on the Rising Use of Medical Cannabis in Oncology

by Eloise Theisen, MSN, AGPCNP-BC

Unsurprisingly, the use of cannabis in patients with cancer appears to be increasing as more and more states are adopting cannabis legislation, both for medical and adult use. As of February 2022, 37 states along with the District of Columbia have legalized medical cannabis, and 19 states plus the District of Columbia have legalized adult-use cannabis.1

Furthermore, 7 states are expected to have adult-use cannabis legislation on the ballot in 2021, which could mean more than half of the United States supports adult use. Moreover, in addition to increased cannabis legalization, there has been an explosion of cannabidiol and other nonimpairing cannabinoids that hit the market—thanks to the 2018 Farm Bill, which descheduled hemp.

With nearly two-thirds of the states allowing for medical cannabis use and the legalization of hemp, accessing cannabinoids has become much easier, especially for patients with cancer, which is a qualifying condition in almost every state. The increased access to cannabinoids has led to patients’ curiosity. Many of these patients are seeking symptom relief with cannabis and are turning to their oncology care team for further guidance.

Yet, many oncology professionals have had little to no education on cannabis.

In survey findings published in the Journal of Clinical Oncology in 2018, 70% of medical oncologists felt unequipped to make clinical cannabis recommendations, and 46% of oncologists are recommending cannabis for symptom relief even though they have had no formal training.2 Additionally, an estimated 20% to 40% of patients with cancer are consuming some form of cannabis either during or after treatment—and that number may be underreported in states where cannabis is not legal.3

Cannabis Research in Oncology

Uncertainty exists among the different types of cannabis and whether clinical evidence supports cannabis use in certain medical conditions. Research is limited due to the federal designation of cannabis as a Schedule I drug.

Despite this restriction, there is sufficient evidence in some areas to demonstrate that cannabinoids may have a therapeutic effect. In 2017, the National Academy of Sciences, Engineering, and Medicine released The Health Effects of Cannabis and Cannabinoids report, which followed a review of more than 10,000 peer-reviewed journals. The authors concluded the following:4

1 Conclusive evidence suggests that cannabis or cannabinoids are effective at treating chronic pain in adults with chemotherapy-induced nausea and vomiting.

2 Moderate evidence suggests that cannabis or cannabinoids are effective at improving short-term sleep disturbances, and limited evidence suggests effectiveness at improving appetite and decreasing weight loss.

3 There is insufficient evidence to demonstrate whether cannabis or cannabinoids are effective or ineffective in treating patients with gliomas or cancer-associated anorexia-cachexia.

Despite the comprehensive review of the literature, generalized anxiety disorder and chemotherapy-induced peripheral neuropathy were not addressed. However, the report highlighted the need for more clinical research to better understand the therapeutic effects of cannabinoids in certain diseases.

Even though limited data support the use of cannabis as a first-line treatment in cancer-related symptoms, many patients are using it to relieve anxiety, pain, nausea, vomiting, and insomnia. In a recent Cancer study, 42% of 612 patients with breast cancer reported using cannabis for symptom relief.5 Seventy-eight percent used it to help with pain, 70% for sleep, 57% for anxiety, and 46% for nausea and vomiting relief.

Data also found that 39% of participants discussed their cannabis use with their physicians and that when they did, it was initiated by the patient 76% of the time. Moreover, only 4% of respondents listed their physician as the most helpful source of information on cannabis, instead listing the internet (22%), family members (18%), and dispensary staff (12%) as more helpful sources of information. This trend is concerning, considering that the internet is not always an accurate or reliable source of information and that dispensary staff often have no medical background and little cannabis education.

Oncology professionals can start to address patient questions and concerns by educating themselves on the endocannabinoid system, cannabinoids, routes of administration, dosages, potential drug-drug interactions, adverse effects, and common cancer-related uses and considerations.

Unfortunately, this information is not widely taught in medical or nursing schools, and without standardized cannabis education, clinicians are self-selecting sources to decrease their knowledge gap. Foundational knowledge of key concepts can allow oncology professionals to better guide patients to safe and effective use.
The Endocannabinoid System
Discovery of the first cannabinoid receptor in 1988 led to detection of the endocannabinoid system (ECS). The ECS, of which the main function is to maintain homeostasis, is a molecular signaling system that consists of 2 cannabinoid receptors (most commonly CB1 and CB2), ligands, and enzymes that normalize sleep, pain perception, memory, mood, and appetite. These receptors can be stimulated by human endogenous cannabinoids as well as plant-derived cannabinoids (phytocannabinoids) and synthetic cannabinoids. CB1 and CB2 are known as G protein–coupled receptors, and CB1 receptors are found predominantly in the adrenal glands, heart, kidneys, prostate, pancreas, colon, liver, central and peripheral nervous systems, lungs, testes, and ovaries. Upon CB1 receptor activation, the CB1 receptors assist in relief from depression, anxiety and stress, pain and inflammation, neurodegenerative disorders, posttraumatic stress, and multiple sclerosis–related symptoms.

CB2 receptors are also detected in the brain and peripheral nervous systems. However, these are mostly contained in the peripheral immune cells. These receptors are found in the brain-stem neurons, lungs, microglia, and uterus. Upon activation, CB2 receptors are known to reduce inflammation and treat mental health disorders and neurologic diseases such as Alzheimer, Parkinson, Huntington, and multiple sclerosis.

Cannabinoids
Cannabinoids are defined as chemical compounds, which can be plant-derived (phytocannabinoids), synthetic, or endogenous, with the ability to influence the cannabinoid receptors while promoting neurotransmitter release. D-9 tetrahydrocannabinol (THC) and cannabidiol (CBD) are the 2 most commonly known cannabinoids, the first of which is primarily responsible for the euphoric effects of cannabis. Behavior, consciousness, mood, and perception are all altered by Δ-9 THC, which binds to CB1 receptors in the brain and causes a change to the function of the binding cell. Studies have suggested efficacy when using Δ-9 THC to treat the following conditions:

- Nausea
- Pain
- Appetite loss
- Insomnia
- Sleep apnea
- Anxiety
- Inflammation
- Posttraumatic stress disorder

CBD is typically the second most abundant cannabinoid in cannabis. It is psychoactive but not in the same manner as THC. It can alter mood, perception, and decrease anxiety. Studies have suggested that CBD can also treat patients with the following conditions:

- Nausea and vomiting
- Seizure disorders
- Psychosis disorders
- Inflammatory disorders
- Neurodegenerative disorders
- Depression

THC and CBD can be found in the cannabis plant along with more than 100 other cannabinoids and can often be purchased through licensed dispensaries in legal states or through hemp retailers (online and in store). Phytocannabinoids are not standardized, and states can set their own limits on potency and testing. FDA pharmaceutical-grade THC is available via dronabinol, which is synthetic and has been approved as an antiemetic and appetite stimulant. Cannabidiol (Epidiolex) is a medication that is derived from the cannabis plant and approved by the FDA as an anticonvulsant. In
states where cannabis is legal for medical or adult use, patients can explore cannabinoids for a variety of health conditions without FDA approval.

**Cannabis Routes of Administration**
Cannabis products offer various routes of administration, including topical, transdermal, inhalation, sublingual, and ingestion. Understanding the onset and duration of action can be helpful in determining which route will effectively treat patient symptoms. Unfortunately, products’ availability to patients depends on an individual state’s cannabis laws, and many state cannabis programs severely limit the product and formulary options.

**Topical**
Topical administration can provide localized relief within 15 minutes and often has little to no adverse effects (AEs). Upon activation, CB1 receptors on the skin assist in redness and inflammation reduction linked with conditions such as atopic dermatitis and psoriasis. Evidence also suggests that topical cannabis can reduce arthritis-related pain and inflammation. There is little risk involved with this administration method.

**Transdermal**
Transdermal cannabis products—which are most commonly patches—are intended to penetrate the skin and reach the bloodstream and can provide between 6 and 12 hours of relief while avoiding first-pass metabolism. Transdermal products may be the optimal administration choice in patients whom drug interactions or medication adherence is a concern.

**Inhalation**
Inhalation provides relief quickly by reaching the bloodstream within minutes; this method is also found to be the most predictable while having the most control. It also provides a benefit for those who are unable to ingest other forms of medications. Chronic use has been associated with bronchitis and airway inflammation, so the benefit must outweigh the risk. Additionally, most indications for inhalation are short term.

**Ingestion**
Ingesting cannabis is a go-to choice for patients who suffer from chronic pain, inflammation, nausea, and insomnia because it can provide more durable and dependable relief. However, it does have variability in onset of action and is dependent on a patient’s metabolism, genetics, gender, and food intake. Taking these factors into consideration, the onset of action can range from 30 minutes to 2 hours or more.

That being said, the effects of ingesting cannabis can last for at least 5 hours. Because of this factor, patients can overconsume and experience AEs, such as tachycardia, paranoia, hypotension, vomiting, and hallucinations. AEs associated with cannabis use are often from ingestible products. The use of the “go low and slow” method can help avoid some unwanted AEs associated with cannabis overconsumption.

**Drug Interactions**
Although drug interactions with cannabis are rarely hazardous, there is still potential for interactions to occur, especially with ingested cannabinoids.

When taken orally, cannabinoids are metabolized by the cytochrome P450 (CYP) family of enzymes. THC is often metabolized by the CYP2C9, CYP2C19, and CYP3A4 enzymes, which convert THC into 11-hydroxy-THC. CBD, however, is commonly metabolized by the CYP2C19 and CYP3A4 enzymes, which convert CBD into 7-hydroxy-cannabidiol. Because most medications are metabolized by CYP3A4, CBD and THC can inhibit or induce other medications metabolized through that same enzyme. Warfarin, among other medications, can inhibit or induce THC and CBD, which increases or decreases cannabinoid plasma levels. Cannabis should be used with caution with other central nervous system depressants, including alcohol, since it can generate sedative effects.

**Dosing**
Cannabis dosing remains one of the most challenging components of providing care. Very few clinical trials have established dosing protocols with cannabinoids for specific conditions. As it stands, most dosing protocols have been developed from real-world evidence rather than evidence-based trials. The go-low-and-slow method is most applicable with cannabis. Because cannabinoids can have biphasic effects, a low dose is often sufficient for symptom relief.

**Considerations for Patients With Cancer**
With cannabis accessibility on the rise, many patients with cancer will be seeking guidance on the safe and effective use for symptom management. As cannabis research evolves and the industry matures, oncology professionals can look to cannabinoids as a potential supportive medicine. With proper guidance, cannabis can have a high safety profile with adverse effects that are generally well tolerated when administered at low doses. Patients are using it. Therefore, oncology professionals must be ready to meet the needs of their patients.

Eloise Theisen, MSN, AGPCNP-BC, is a board-certified adult geriatric nurse practitioner who specializes in cannabis therapy and is co-founder and chief executive officer of Radicle Health and the Radicle Health Clinician Network.

For a full list of references, see the article on OncNursingNews.com.
Power of Palliative Care: How Oncology Nurses Can Increase Referrals

A nurse-driven palliative care referral intervention demonstrated preliminary success in increasing the number of patients who received this form of supportive care.

by Nicole Feraco, MSN, RN, OCN

Palliative care (PC) is fundamental to high-quality cancer care, particularly in the advanced setting. The incorporation of this specialty has been shown to improve quality of life (QOL), reduce physical and psychological burden, and improve overall survival in some cases of advanced cancer. Notably, health care organizations such as the American Society of Clinical Oncology (ASCO), the Institute of Medicine, and the National Comprehensive Cancer Network all support the integration of PC into standard oncology care. However, despite its substantial value, PC continues to be underused throughout the country.

Our outpatient cancer center in Southwestern Pennsylvania is not immune to this trend. While the majority (>94%) of patients treated in our clinical trial unit in 2018 had distant metastasis, only 17.3% had a PC referral. These numbers are in sharp contrast to ASCO guidelines, which recommend that all patients with advanced disease be followed by specialized PC providers while receiving cancer treatment.

Quality Improvement Initiative
To combat this discrepancy, a nurse-driven PC referral intervention was evaluated in our outpatient clinical trial unit. This intervention included development and delivery of nurse and patient education, creation of an evidenced-based PC screening tool, and establishment of a formal procedure for nurse-led PC referrals.

The procedure for nurse-driven PC referrals included all patients visiting the unit for oncologic treatment. Treatment nurses determined if the patient was already supported by a PC specialist. If a nurse identified a patient who was not receiving PC, they would consequently fill out the PC screening tool (Figure 1). Patients who screened positively on the tool received verbal and written PC education from the nurse, and if they demonstrated interest in PC, they were connected with the PC clinic located in the cancer center.

Education for treatment nurses was delivered by the author during a 30-minute in-service on the nursing unit. The education included:

- Is the patient experiencing uncontrolled physical symptoms such as pain, nausea/vomiting, shortness of breath, severe fatigue, diarrhea or constipation?
- Is the patient experiencing uncontrolled emotional symptoms such as anxiety or depression?
- Does the patient require assistance with decision making or care planning?
- Does the patient have an ECOG performance status of 2 or greater?
- Has the patient experienced 2 or more unplanned hospital admissions or emergency department visits in the past 3 months?

The implementation of this intervention led to an increase in PC referrals, as seen in Figure 2. Project initiation

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Figure 1. Palliative Care Screening Tool

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<tr>
<th>Palliative Care Screening Tool</th>
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<th>No</th>
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<tr>
<td>Is the patient experiencing uncontrolled emotional symptoms such as anxiety or depression?</td>
<td></td>
<td></td>
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<tr>
<td>Does the patient require assistance with decision making or care planning?</td>
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<tr>
<td>Does the patient have an ECOG performance status of 2 or greater?</td>
<td></td>
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<tr>
<td>Has the patient experienced 2 or more unplanned hospital admissions or emergency department visits in the past 3 months?</td>
<td></td>
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</tbody>
</table>

Figure 2. Palliative Care Use

- Mean (baseline)
- LCL
- UCL
- PC Use
focused on the purpose and benefits of PC; potential patient, clinician, and institutional barriers; strategies for effectively discussing the specialty; and introduction to the procedure for nurse-driven PC referrals. This information was provided verbally and reinforced with written materials. Reeducation and one-on-one coaching were periodically provided throughout the quality improvement study period. The education provided to the nursing staff served to improve the verbal education they provide to patients. Patient education was also improved through the distribution of a flyer discussing PC and highlighting resources available at the outpatient cancer center.

The final component to this intervention was the development of a tool to assist treatment nurses with the identification of oncology patients in urgent need of PC. The screening tool was developed by the author with assistance from a PC nurse practitioner. The tool consisted of ‘yes’ or ‘no’ questions. An answer of ‘yes’ to any of the questions indicated the patient was especially likely to benefit from a PC referral. The criteria for these screening questions were extracted from a systematic review and international consensus panel of oncology and PC providers. Special attention was taken to select screening criteria that were readily evaluable and within the nursing scope of practice to assess.

In addition to support from literature, the last 2 screening criteria were also found to be relevant to our population based on local-level data. In previous logistics regressions, ECOG Performance Status of 2 or greater—and 2 or more hospital admissions or emergency department visits—were shown to predict which patients within our unit were at high risk for dying within the next 90 days.

**Intervention Results**

The nurse-driven PC referral project was trialed over a 2-month period. At the end of the trial period, the average percentage of patients followed by PC in the unit increased from 16.4% to 37.6%. During this time, there were 62 unique patients treated, of which 50 were not currently followed by PC and thus eligible for screening. Of these 50 patients, 11 (22%) screened positively on the PC screening tool and were subsequently provided PC education. Six of these patients (54.4%) were interested in PC services and scheduled with the PC clinic. A weekly breakdown of PC use is provided on the previous page (Figure 2).

Overall, the nurse-driven PC referral project was well received by patients and nursing staff. Nurses found the education helpful in making their PC conversations with patients more effective. In addition, they found the process of connecting patients with PC services to be a rewarding experience.

Patients also appreciated the chance to learn about resources available to them, even if they did not ultimately choose to pursue PC at the time. One particularly grateful patient who opted to begin PC services stated, “I am so glad you mentioned this. I am so relieved to know that I don’t have to continue suffering every day.”

**Future Implications**

After the preliminary success during the trial period of this nurse-driven PC referral project, the PC screening tool and procedures were implemented as a permanent process for this unit. Leadership also plans to implement these changes throughout other units in the cancer center. To facilitate this change in process, the PC screening tool was also integrated into the electronic medical record.

**REFERENCES**

Care Management Tools Can Mitigate Clinician Burnout

Health care staffing shortages exacerbated by the COVID-19 pandemic have intensified an already serious problem in health care: clinician burnout.

by Jessica Scruton, BSN, RN, CCM

Findings from an American Medical Association (AMA) national survey of nearly 21,000 health care professionals show that nearly half (49%) reported at least 1 symptom of burnout, and 43% said they suffered from work overload.1 The costs of clinician burnout are steep; a 2019 study estimated that physician burnout costs the US health care industry $4.6 billion annually, mostly through clinician turnover and a reduction of clinical hours.2 Subsequently, there are personal and professional costs. Clinicians with burnout may exhibit multiple symptoms, including low energy, exhaustion, compassion fatigue, insomnia, irritability, alcohol and drug abuse, and a lack of purpose in their jobs.3 Clinician burnout also can affect quality of care because physicians under physical and emotional duress are more prone to making mistakes, leading to poorer outcomes and increasing the risk of malpractice exposure.

The time crunch resulting from high patient demand for services and a severe shortage of clinical professionals is also of concern, neither of which shows signs of abating soon. Data from a study from the early 2000s showed that the average patient visit with a primary care clinician lasted just over 15 minutes and often covered up to a half-dozen health issues.4 Worse, clinicians may spend large chunks of that valuable time attempting to find or enter data on a digital screen.

Today, clinicians are trying to implement new models of digital care delivery during a once-in-a-century pandemic. Clinicians and care managers are overburdened with data, alert fatigue, and Best Practice Advisories that, in an effort to streamline care management, only make their work more difficult. Often they lack the basic clinical supplies and resources necessary to safely do their jobs. Furthermore, the trauma of working through the fear surrounding COVID-19 leaves little wonder as to why nurses are leaving their careers and years of training at alarming rates as they respond to mentally and physically draining shifts and unsafe patient loads.

To add to the disruption, other clinicians are quitting their jobs in opposition to vaccine mandates by their states or employers. Health care organizations are struggling with chronic staffing shortages that limit how many patients can be seen and the quality of care that can be delivered. Ironically, staffing shortages can lead to increased spending because a hospital or health system might hire nurses on a contract basis at a higher rate than they would pay a full-time nurse.

On the patient side, staffing shortages will inevitably affect not only the quality of care they receive, but whether they receive care at all. This is particularly so for patients with debilitating but not fatal conditions, such as deteriorating joints or other conditions requiring elective procedures. Care will always be provided for the most urgent cases, such as patients in an intensive care unit (ICU), but a woman who needs a knee replacement may not be able to schedule her procedure because clinicians are being deployed to higher-priority patients. These are both medical and quality-of-life issues, the latter yet another cost of clinician burnout and staffing shortages.

Burnout Solutions

There is no magic bullet for reducing clinician burnout; rather, targeted solutions can be applied to each of the major causes. On the most basic level, giving clinicians the supplies and resources they need to effectively (and safely) provide care helps them to better manage the stress of their jobs. Health care organizations should communicate with clinicians to determine where there are supply and resource shortages and take steps to eliminate them. A review of the supply chain and inventory supply could also result in opportunities for cost savings.

Reasonable patient loads would also go a long way toward easing clinician burnout. However, given the demand for care, shortage of clinical staff, and ongoing impact of the pandemic, clinicians aren’t likely to see relief in the form of full staffing levels any time soon.

Fortunately, the right technology can address this major cause of burnout by making it far easier for clinicians to access the right patient data before and during an encounter, during which every minute is valuable. A technology platform that streamlines and organizes data for clinicians at the point of care also helps provider organizations offset the burden of staff shortages by dramatically increasing efficiency. Additionally, a platform with analytics capabilities supports care coordination and ensures that clinicians can track the most at-risk patients and provide outreach support if necessary. This type of preventive approach can help health care organizations avoid unnecessary costs and improve patient outcomes. Analytics-based prevention is especially valuable in cases where patients may be nonadherent with medication. Identifying and proactively reaching out to those patients can help counter possible adverse health events and prevent future unnecessary costs.

A fully integrated care management platform can enable care managers to coordinate care and easily access relevant, actionable, and organized patient data when it is needed, promoting fast, evidence-based action at the point of care. Although technology alone can’t solve clinician burnout, it can provide the means for organizations to provide better care while increasing efficiency and alleviating stress. A comprehensive approach employing technology solutions, better resource allocation, and direct feedback from clinicians will be key to easing burnout across the industry.

Jessica Scruton, BSN, RN, CCM, is vice president of clinical transformation at Lightbeam Health Solutions.

For a full list of references, see the article on OncNursingNews.com
IS MYELOFIBROSIS TREATMENT ILL-FITTED TO PATIENT NEEDS?

Not all treatments are sufficient for all patients — which leaves them with less than optimal outcomes.¹ New approaches must be pursued to manage a fuller range of signs and symptoms in myelofibrosis.

TO LEARN MORE, VISIT MYELOFIBROSISINSIGHTS.COM

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