

Insider

DAILY EDITION

Daily news from the SOHO 2026 Annual Meeting

Dr. Santini to lead society as SOHO president for 2026–2027 term

Her presidency will be followed by Selina Luger, MD, who will serve as president-elect in 2027 and president in 2028.



● **Valeria Santini, MD**, will assume the role of SOHO president today, Saturday, September 12, 2026, once the Fourteenth Annual Meeting has concluded.

Dr. Santini, who is an associate professor of hematology at the University of Florence Medical School in Italy, has been part of SOHO since its inception in 2012 and serves on the Education Committee, which develops the scientific and educational content of the annual meeting. In addition, Dr. Santini also serves on the Steering Committee and takes part in the Ambassador Program.

“I’m quite emotional about this presidency,” Dr. Santini said in a Pathways & Perspectives interview with SOHO Insider. “I’m incredibly honored. It’s truly amazing, especially as someone not based in the United States, because it makes the role even more meaningful.”

President-elect Selina Luger, MD

Dr. Santini’s presidency will be followed by **Selina Luger, MD**, who will serve as president-elect in 2027 and president in 2028.

Dr. Luger, a professor of medicine at the University of Pennsylvania, has been involved with SOHO for approximately a decade, first joining the society as an invited speaker when the annual meeting was significantly smaller, she explained. Over time, her role expanded to include the Education Committee, where she

●●● SEE LEADERSHIP ON PAGE 11

Selina Luger, MD, weighs the promise and challenges of modern ALL care

By Leah Sherwood



● **Selina Luger, MD**, sits down with SOHO Insider to discuss the next questions in acute lymphoblastic leukemia (ALL) and the barriers to treatment,

including toxicity to both the body and the wallet. She also reflects on her involvement with SOHO and the organization’s growth over the past dozen years.

What is SOHO’s role and contribution to the blood cancer community?

I’ve seen SOHO evolve over the dozen or so years since it was established. SOHO plays a unique role in bringing

cutting-edge advances in hematologic malignancies to the broader hematology-oncology community. The society is furthermore distinguished by its commitment to education throughout the year, not just during the annual meeting, and its ability to connect clinicians, investigators, and trainees in the US and beyond, around the questions that matter most for patient care.

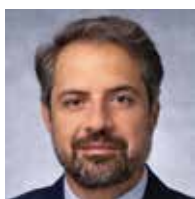
SOHO encourages people to think about the important questions that remain and helps them understand the questions being asked, in addition to the advances that have been made so far.

What are the remaining questions in ALL regarding the shift toward chemotherapy-free regimens?

●●● SEE SELINA LUGER, MD ON PAGE 8

Dr. Jabbour will speak during the Next Questions session on Saturday, September 12

Elias Jabbour, MD, previews the remaining clinical challenges and future directions in acute lymphoblastic leukemia (ALL).



● What are the next questions for ALL in 2026? At the SOHO Annual Meeting, we heard from leading experts about where we are today and where the field is going. But what remains unanswered?

First, in Philadelphia chromosome (Ph)-negative ALL, we are weighing whether it is time to move away from chemotherapy. The answer is possibly yes. Frontline trials are needed to determine whether chimeric

antigen receptor (CAR) T-cell therapy can reduce or potentially eliminate the need for chemotherapy. This approach holds tremendous promise.

The second question involves older adults with ALL. These patients are often frail and may have poor disease biology and other

●●● SEE DR. JABBOUR ON PAGE 7

SOHO ANNUAL MEETING
2026

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Insider

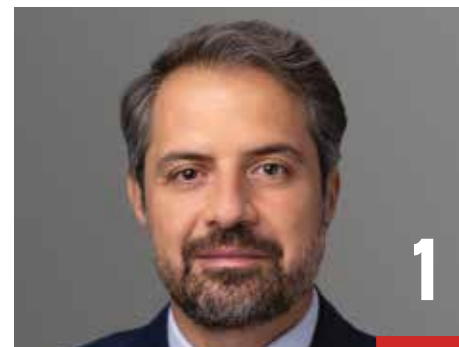
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Advertising Opportunities

Nick Luciano
Chief Media Sales Director
nluciano@sohoonline.org

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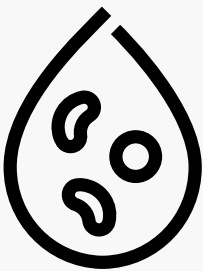


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SOHO ANNUAL MEETING
2026

Building on a history of innovation in **hematology**



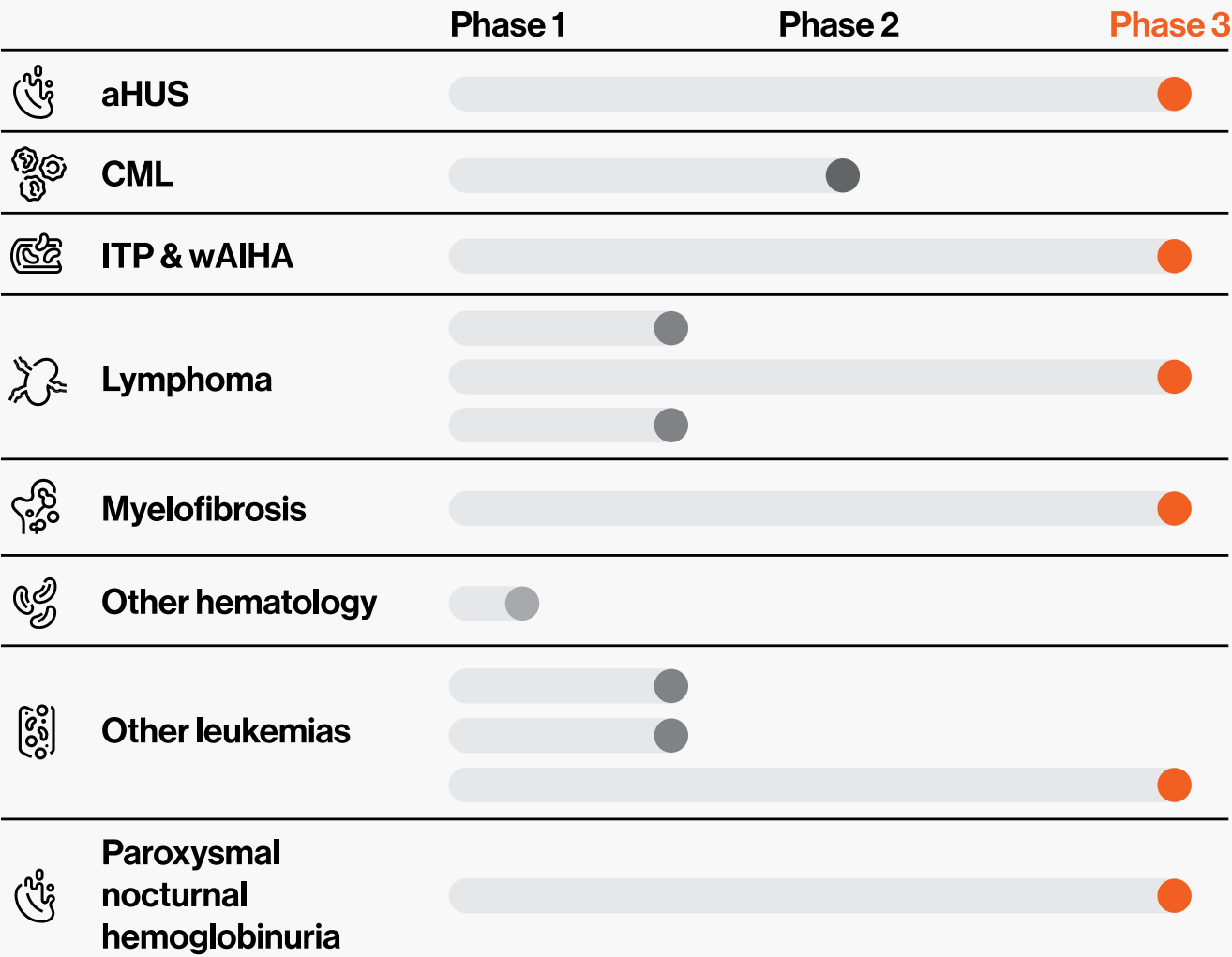
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7

Investigational compounds

17

Ongoing clinical trials



aHUS, atypical hemolytic uremic syndrome; CML, chronic myeloid leukemia; ITP, immune thrombocytopenia; wAIHA, warm autoimmune hemolytic anemia.



Scan to visit the pipeline navigator or speak to a medical representative to learn more at **#SOHO booth #175**

pipelinenavigator.com/pipeline/

Saturday, September 12, 2026

TIME	TOPIC/SESSION	SPEAKER	AFFILIATION/ROOM
INDUSTRY EXPERT SESSION XI: BREAKFAST (Non-Accredited)			GRAND BALLROOM C, THEATER 3
6:45 AM	A 2L+ Combination Therapy for Adults With RRMM After a PI and an Immunomodulatory Agent	M. Yair Levy, MD	Baylor University Medical Center Dallas, Texas, USA
This activity is sponsored by Johnson & Johnson			
BREAKFAST WITH THE EXPERT III			LEVEL 3, GENERAL ASSEMBLY
6:45 AM	How to Use Fixed-Duration in the US	Nitin Jain, MD	MD Anderson Cancer Center Houston, Texas, USA
7:45 AM	BREAK		
SESSION XIII: CELLULAR THERAPY			LEVEL 3, GENERAL ASSEMBLY
Session Chairs: Rayne H. Rouse, MD and Betul Oran, MD			
8:15 AM	Debate: Should We Transplant TP53 Mutated AML – PRO	Betul Oran, MD	MD Anderson Cancer Center Houston, Texas, USA
8:30 AM	Debate: Should We Transplant TP53 Mutated AML – CON	Mariam Nawas, MD	University of Chicago Medicine Chicago, Illinois, USA
8:45 AM	Q&A		
8:51 AM	Debate: In Pediatric ALL Will There Still Be a Role for Allo SCT – PRO	Michael Pulsipher, MD	Huntsman Cancer Institute Salt Lake City, Utah, USA
9:06 AM	Debate: In Pediatric ALL Will There Still Be a Role for Allo SCT – CON	Rayne H. Rouse, MD	Baylor College of Medicine Houston, Texas, USA
9:21 AM	Q&A		
9:27 AM	Follicular Lymphoma Bispecific Antibodies vs CAR	Krish Patel, MD	Sarah Cannon Research Institute Nashville, Tennessee, USA
9:42 AM	Q&A		
9:45 AM	Oral Abstract CT-230: Outcomes of Lisocabtagene Maraleucel (Liso-Cel) in Patients With Relapsed or Refractory (R/R) Mantle Cell Lymphoma (MCL): First Real-World Data From the Center for International Blood and Marrow Transplant Research (CIBMTR)	Elise Chong, MD	Abramson Cancer Center University of Pennsylvania Philadelphia, Pennsylvania, USA
9:55 AM	BREAK		
Session XIV: NEXT QUESTIONS			LEVEL 3, GENERAL ASSEMBLY
Session Chairs: John DiPersio, MD, PhD and Valeria Santini, MD			
10:25 AM	Next Questions: Acute Lymphoblastic Leukemia	Elias Jabbour, MD	MD Anderson Cancer Center Houston, Texas, USA
10:35 AM	Next Questions: Acute Myeloid Leukemia	Tapan Kadia, MD	MD Anderson Cancer Center Houston, Texas, USA
10:45 AM	Next Questions: Cellular Therapy	Sairah Ahmed, MD	MD Anderson Cancer Center Houston, Texas, USA
10:55 AM	Next Questions: Chronic Lymphocytic Leukemia	Alessandra Ferrajoli, MD	MD Anderson Cancer Center Houston, Texas, USA
11:05 AM	Next Questions: Chronic Myeloid Leukemia	Jorge E. Cortés, MD	University of Alabama Birmingham, Alabama, USA
11:15 AM	Next Questions: Aggressive B-Cell Lymphoma	Jason R. Westin, MD, MS, FACP, FASCO	MD Anderson Cancer Center Houston, Texas, USA
11:25 AM	Next Questions: Indolent B-Cell Lymphoma	Brad Kahl, MD	Washington University St. Louis, Missouri, USA
11:35 AM	Next Questions: T-Cell Lymphoma	Mary Jo Lechowicz, MD	Emory University, Winship Cancer Institute Atlanta, Georgia, USA
11:45 AM	Next Questions: Mantle Cell Lymphoma	Krish Patel, MD	Sarah Cannon Research Institute Nashville, Tennessee, USA
11:55 AM	Next Questions: Hodgkin Lymphoma	Nancy L. Bartlett, MD	Washington University St. Louis, Missouri, USA
12:05 PM	Next Questions: Multiple Myeloma	Thomas G. Martin, MD	University of California San Francisco, California, USA
12:15 PM	Next Questions: Myelodysplastic Syndromes	Guillermo Garcia-Manero, MD	MD Anderson Cancer Center Houston, Texas, USA
12:25 PM	Next Questions: Myeloproliferative Neoplasms	Prithviraj Bose, MD	MD Anderson Cancer Center Houston, Texas, USA
12:35 PM	Closing Remarks	John DiPersio, MD, PhD	President Society of Hematologic Oncology



SESSION HIGHLIGHT

SESSION NAME:

In Pediatric ALL Will There Still Be a Role for Allo SCT?

WHEN:

September 12 at 8:51 AM

WHERE:

Level 3, General Assembly

To transplant or not to transplant in pediatric ALL?

During a debate series, Michael Pulsipher, MD, of Huntsman Cancer Institute, and Rayne H. Rouce, MD, of Baylor College of Medicine, offer their opinion on whether allogeneic hematopoietic cell transplant (HCT) is still necessary for pediatric patients with acute lymphoblastic leukemia (ALL).

Get a sneak preview of their point of view in this article.

PRO



Michael Pulsipher, MD

In the past decade, the introduction of highly effective immune and cell therapies has dramatically changed our ability to treat children with ALL. Blinatumomab has markedly improved outcomes in relapsed ALL and similarly improved survival when used up front in standard-risk ALL, leading to universal adoption of use in first remission for all but the lowest-risk ALL cohorts.

CD19-targeted chimeric antigen receptor (CAR) T cells have markedly improved remission rates in patients highly refractory to all forms of therapy, including blinatumomab, improving event-free and overall survival (OS) in relapsed/refractory ALL.

In spite of these advancements, the role of HCT in children with ALL has continued and, in some cases, increased. There is clear evidence that consolidation of CAR-T therapy with HCT improves survival, and patients losing B-cell aplasia early after CAR-T therapy strongly benefit from HCT. Monitoring of next-generation sequencing measurable residual disease (MRD) after CAR-T and prior to HCT had allowed careful planning of HCT to either maximize efficacy or minimize toxicity depending upon risk.

Patients previously unable to get into remission are achieving remissions through immunotherapy and are now eligible to receive a first and sometimes second chance at curative HCT. Until we develop universally available CAR T cells or bispecific/conjugated immunotherapies that target multiple antigens and have persistent effects, HCT will remain an important tool to treat and cure children with refractory or high-risk relapsed ALL.

CON



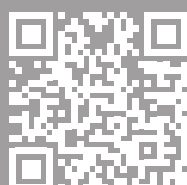
Rayne H. Rouce, MD

This is a simple yet loaded question—one that pediatric leukemia, transplantation, and cellular therapy specialists have continuously grappled with in light of the paradigm-shifting success of B-ALL targeted immunotherapies. The advent of new therapies, contemporary prognosticators, and sophisticated MRD monitoring have shifted this charged question from a one-size-fits-all inquiry (“Is there a role for allogeneic HCT in pediatric ALL?”) to one that warrants a more customized response: “For whom and when should we consider allogeneic HCT in pediatric ALL?”

Despite the curative potential and sophisticated risk mitigation of modern HCT approaches, clear evidence exists that consolidative HCT does not offer event-free or OS benefit in a subset of patients who achieve remission with CD19 CAR-T. Furthermore, while consolidative HCT remains common practice in many patients receiving cellular and non-cellular immunotherapies, whether we are transplanting some out of habit versus necessity remains less clear. We must continue to pursue clinical trials designed to answer this question, given the morbidity, mortality, and late effects that persist despite current HCT strategies.

Can contemporary prognostic algorithms accurately define patient subpopulations for whom we can confidently avoid HCT? Is there a subset of patients in whom post-immunotherapy remission can be maintained without HCT? Can we salvage patients who show signs of diminished efficacy, limited persistence, or residual disease post-CAR-T with non-HCT approaches? Could non-HCT consolidative regimens transform from a “salvage” to curative consideration, and how will they measure up to less toxic, more sophisticated modern HCT strategies designed to improve efficacy and reduce morbidity?

Thus, while HCT will continue to play a role, it will likely be for a smaller subset of patients for whom evidence continues to show benefit.



Who won?

Tell us your thoughts about the debate.

Tag us on X @SocietyofHemOnc

... DR. JABBOUR FROM PAGE 1

aggressive features, making chemotherapy a less suitable option. For these patients, the field is moving toward chemotherapy-free regimens that incorporate immunotherapy and potentially frontline CAR T-cell therapy. The coming years will show whether these approaches can improve outcomes.

The third question relates to central nervous system (CNS) relapses. Systemic chemotherapy is effective and immunotherapy has produced excellent results, but CNS relapse can still be a problem. We have seen this among patients with high white blood cell counts and Ph-positive ALL. Once a CNS relapse occurs, it can be difficult to eradicate.

CAR T-cell therapy is a promising option. Data have shown that CAR-T cells can penetrate the CNS, persist, and potentially prevent or control disease in this sanctuary site, further improving outcomes.

Another area to explore is T-cell ALL. Although we have several immunotherapies available for B-cell ALL, we have fewer options for T-cell ALL because of the nature of the disease and challenges such as fratricide and T-cell aplasia.

We are exploring CD7- and CD5-directed CAR T-cell therapies. These approaches are at the beginning of their development, but they hold promise for further improving patient outcomes.

To continue making progress, we need better classification and prognostic systems that can distinguish among disease subsets and help us tailor therapy accordingly. This work is already reflected in the research being presented.

Finally, we have many therapeutic options, but how should we sequence them? Should we use one treatment at a time or combine therapies sequentially? This is an important operational question.

We know that to achieve the best outcomes with CAR T-cell therapy, it should be administered when a patient has measurable residual disease (MRD). Following infusion, we must monitor CAR T-cell expansion and persistence. We must also monitor MRD negativity using next-generation sequencing to determine who may need a transplant and who may not.



SESSION HIGHLIGHT

SESSION NAME:

Next Questions: Acute Lymphoblastic Leukemia

WHEN:

September 12 at 10:25 AM

WHERE:

Level 3, General Assembly

The state-of-the-art question today is whether patients still need a transplant after CAR T-cell therapy. With the availability of newer therapies and models that can predict long-term outcomes, we may eventually reach a point at which CAR T-cell therapy is used as a finite consolidation approach rather than as a bridge to transplant.

Significant progress has been made, and the coming years will hopefully bring answers to these questions.

Elias Jabbour, MD, is an editor at SOHO Insider and a professor in the Department of Leukemia in the Division of Cancer Medicine at the University of Texas MD Anderson Cancer Center.

save

the date

AUGUST

25-28

SOHO

ANNUAL MEETING

2027

... **SELINA LUGER, MD** FROM PAGE 1

What we have learned over the last few years is that the role of immunotherapy in ALL has increased and improved our patients' outcomes. What we've seen in the Philadelphia chromosome (Ph)-negative population is that adding immunotherapy to chemotherapy enhances outcomes.

As we incorporate more immunotherapy into frontline treatment for Ph-negative ALL, one of the key questions is whether we can safely reduce chemotherapy exposure while maintaining excellent outcomes.

and CNS relapse need to be addressed if we're not using chemotherapy.

How are new therapies impacting treatment sequencing in ALL?

Multiagent chemotherapy has always been the hallmark of ALL therapy. But I think we're asking similar questions in ALL. With immunotherapy, do we need to start with chemotherapy and then move on to immunotherapy? Is immunotherapy best used only during consolidation or can it be added upfront?

chimeric antigen receptor T-cell therapy should primarily serve as a bridge to transplant or whether, for select patients, it may eventually function as definitive consolidation therapy.

In the ALL world, we talk about initial therapy, followed by post-remission therapy or consolidation therapy and, when appropriate, a transplant. The question is: What should that sequence be? In whom should we include all the different parts of that sequence? When can we use only some of them? Does everybody need maintenance? Can some people avoid maintenance? Those are all questions that come up in the ALL patient population.

One of the areas we can examine, perhaps more so in the ALL world than in the lymphoma world, is the use of our newer techniques for detecting measurable residual disease. There are different techniques for the various ALL subtypes, and they can help us make decisions about what the treatment sequence should be and which parts of therapy each patient should receive.

What are the main barriers and progress regarding patient access?

I think there are two or three issues related to access, and they're real issues. I think the simplest access issue is toxicity and the management of toxicity, as well as ensuring patients are aware of the toxicities, their characteristics, and when they should reach out to us.

But the other major access issue is a financial

“If you were to look at the cost of not using some of these agents and, for example, proceeding to an allogeneic transplant, it is probably less expensive in some cases to use these expensive agents than to undergo a transplant.”

That's one of the areas in which we're hoping to move forward. As we incorporate more immunotherapy into frontline treatment for patients with Ph-negative ALL, we're hoping to remove some of the chemotherapy.

In the Ph-positive population, we've already started moving in that direction. Some of the upfront regimens we are now looking at have no chemotherapy in them.

The questions are: What do we gain, and what do we have to worry about? A major concern in the Ph-positive population is how central nervous system (CNS) prophylaxis

When do we most want to use it? I think that's a question in terms of the toxicity we see when immunotherapy is given to patients with aggressive disease. Sometimes it's better to cytoreduce before giving immunotherapy. On the other hand, for patients who are not candidates for chemotherapy, including older patients, targeted therapies or immunotherapies may be the approach we want to use throughout their treatment.

We've also learned that immunotherapies can decrease the likelihood of needing a transplant. A key question is whether

What are the remaining questions for ALL heading into the SOHO Breakthroughs in Blood Cancers Virtual meeting on November 10?

What are the best approaches for older patients with ALL? One of the greatest unmet needs remains the treatment of older adults with ALL. While outcomes have improved dramatically overall, older patients have not always experienced the same degree of benefit. We need to continue developing regimens that are both highly effective and better tolerated and to continue to do correlative research studies to enhance our knowledge.

How can we optimize therapy for our older patient population, especially since they can't always tolerate some of the more aggressive therapies?

One of the major questions is: How can we begin decreasing the amount of treatment and treatment-related toxicity?

Registration is free, go to soho.click/sbbc.

Selina Luger, MD, is a professor of medicine at the University of Pennsylvania and has been involved with SOHO for approximately a decade, first joining the society as an invited speaker when the annual meeting was significantly smaller. Over time, her role expanded to include the Education Committee, where she served as the subcommittee chair for acute lymphoblastic leukemia until 2023. Currently, she serves on the Education and Steering Committees.

one. Many of these newer therapies are extremely expensive. Depending on the insurance a patient has available or the location, not just within the United States, but globally, many of these agents are not available in the way they have been studied as regimens and shown to be effective.

It brings up the question: How can you best use these agents? How can you minimize the financial impact? While many of these therapies carry significant upfront costs, it is important to consider the total cost of care.

In some situations, effective use of novel therapies may decrease the need for more expensive interventions such as allogeneic transplant, prolonged hospitalization for treatment, or treatment-related complications.

There are also challenges in terms of the way the agents are administered. Blinatumomab, which has been approved as consolidation therapy in ALL, has to be given as a continuous infusion for four weeks at a time. That is cumbersome for the patient.

Novel formulations and different ways of administering the agent are now being studied so that treatment will have less of an impact on patients and reduce the burden associated with receiving the therapy. Other similar agents with improved administration schedules are also being studied. These are all issues affecting patients that are being addressed through the development of novel agents and regimens.

Leah Sherwood is the editorial director of SOHO Insider.



13K

**SOHO has reached 13K members.
Thank you to all of our members
for making the society a success.**



SESSION HIGHLIGHT DEBATE

SESSION NAME:

Should we transplant TP53 mutated AML

WHEN:

September 12 at 8:30 AM

WHERE:

Level 3, General Assembly

Is limited survival benefit worth the rigors and perils of alloHCT in TP53-mutated AML?

On today's debate stage, Mariam Nawas, MD, will debate Betul Oran, MD, on whether transplant is appropriate in patients with TP53-mutated acute myeloid leukemia (AML). Dr. Nawas gives a preview of her position.



Mariam Nawas, MD
University of Chicago

In your opinion, why is this debate question still controversial?

TP53-mutated myeloid neoplasms are a vexing disease subset that have eluded medical progress. As transplanters, we are

optimists by nature as we offer our patients potential cures. It is tempting to gravitate toward the most optimistic interpretation of otherwise dismal outcome data and to resist the reality that there are subsets of disease we still cannot cure.

What is the biggest weakness in your own argument?

I am convinced that allogeneic hematopoietic cell transplant (alloHCT) rarely cures this disease subset, but I am willing to accept that it may prolong survival compared with alternative options (eg, chemotherapy alone).

Data from Versluis et al analyzing results from the BMT CTN 1102 study demonstrate this (JCO 2023). However, I think it is important to consider whether a limited survival benefit is worth the rigors and perils of alloHCT and whether those results are generalizable to the average patient with this disease. The patient in question faces a prohibitively high risk of

post-transplant morbidity and mortality and is not representative of patients on the 1102 study. I hope as transplant safety improves with time that gradually moves the needle on the risk/benefit analysis of transplant in this subgroup.

If we revisit this debate in three years, what do you think the answer will be?

I worry we will be having the same debate in 3+ years. Clearly, the graft-versus-leukemia effect alone is not enough to overcome this disease. I pray that within my career, we see a potential cure—perhaps a novel therapy that induces a deep response that alloHCT can effectively consolidate. It always seems impossible until it is done.

Dr. Jerald Radich highlights meaningful posters in chronic myeloid leukemia



CML-457: Artificial Intelligence in Chronic Myeloid Leukemia: Assessing the Accuracy and Clinical Utility of Large Language Model

"AI is everywhere. Is it useful in CML? This study tests three different AI engines in their ability to answer 25 clinically meaningful questions. Do they work? Is one better than the other? Come find out."

CML-731: Efficacy of Olverembatinib in Patients With Chronic-Phase Chronic Myeloid Leukemia With Prior Resistance

to Ponatinib or Asciminib and ASXL1 Mutations

"There are many TKIs. Are the new ones useful? This study looks at the use of olverembatinib in CML cases resistant to ponatinib and asciminib. The drug has notable activity in this setting, including patients who also harbor ASXL1 mutations."

CML-929: Validation of a Prognostic Score in Blast-Phase CML: A Cure CML Consortium Analysis

"Blast crisis remains a problem in CML. This study provides validation of a prognostic risk score for patients in blast crisis. The model

appears useful in categorizing patients into different risk groups with clinically meaningful different survival times."

CML-1050: ASC4FIRST Week 144 Analysis: Continued Superior Efficacy and Favorable Safety of Asciminib vs Investigator-Selected Tyrosine Kinase Inhibitors in Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase

"This is a week 144 analysis of newly diagnosed CML cases treated on the ASC4FIRST study. Do the earlier very encouraging early results hold up with longer follow up? Spoiler alert: Yes."

Member Spotlight: Valeria Santini, MD

By Mya Hughes

● The Board of Directors and the Steering Committee of the Society of Hematologic Oncology (SOHO) are pleased to announce that **Valeria Santini, MD**, will assume the position of SOHO president at the conclusion of the 2026 SOHO Annual Meeting. She will oversee the society during the 2026-2027 term and will chair the 15th Annual Meeting of SOHO in Houston, Texas.

Dr. Santini is an associate professor of hematology at the University of Florence Medical School in Italy, where she also earned her medical degree and a postgraduate diploma in hematology, cum laude. Her family moved to Florence when she was six, and she attended primary school, high school, and university there. Though drawn early on toward philosophy or art history, she chose medicine as a field that combined science with a focus on humanity, and by her second year of medical school, she had already joined a general pathology lab, balancing coursework with research.

Following her training in Italy, Dr. Santini spent three years in the Netherlands as an EORTC fellow in experimental hematology, from 1988 to 1991, at the Dr. den Hoed Kliniek at Erasmus University in Rotterdam, working on translational studies in acute myeloid leukemia. She then returned to the University of Florence where she rose from assistant to

associate professor. In 1999, she spent time in the Department of Leukemia at the University of Texas MD Anderson Cancer Center in Houston, an experience she has described as introducing her to new drugs, a different approach to disease, and a level of organization and collaboration unlike anywhere else.

Dr. Santini has been part of SOHO since the society's founding in 2012 and has served for many years on the Education Committee, shaping the scientific and educational content of the annual meeting, as well as on the Steering Committee. She is part of the Ambassador Program, which extends SOHO's educational mission to hematologic oncologists worldwide, including those in developing countries.

Dr. Santini has said she feels both honored and a little nervous to take on the presidency, hoping to build a strong program and agenda, and noting that leading SOHO as someone based outside the United States



makes the role feel especially meaningful. The chosen theme for SOHO 2027 will be announced separately.

Please join us in congratulating Dr. Santini!

Mya Hughes is the admin/communications assistant at SOHO Insider.

... LEADERSHIP FROM PAGE 1

served as the subcommittee chair for acute lymphoblastic leukemia until 2023. Currently, she serves on both the Education and Steering Committees.

Reflecting on her upcoming presidency, Dr. Luger discussed SOHO's global presence and how the meeting has evolved since its early days.

"The things we think about have to be relevant not just in North America, but also outside of North America," she said. "It's a great educational opportunity, but it's also become a place where people present preliminary

research and share new data that we haven't seen anywhere else."

Dr. Luger discussed the importance of SOHO's virtual and ancillary programs, noting that these programs allow clinicians worldwide to learn about the latest data and directly pose questions to leading experts.

"We need to make it possible for patients and practitioners everywhere to think about how they diagnose patients, how they manage care, how they handle toxicities, and how they deliver treatment," Dr. Luger said. "I think SOHO, and the ancillary meetings, really

provide people with an opportunity to learn how to do that."

Finally, the field needs to give some thought to the availability of therapies and to "ensure treatment is feasible," she said, adding that the SOHO Annual Meeting allows for treatment discussions not found at meetings such as the American Society of Hematology (ASH).

"Not everyone has the same resources, and some patients may not have the ability to access the types of treatments discussed at meetings like ASH," Dr. Luger said.

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Real-world study shows infections are top driver of early mortality post-CAR-T

• A study presented by **Nanditha Karra, MD**, of the University of Maryland Capital Region Health, and colleagues at the 2026 SOHO Annual Meeting, showed that pooled non-relapse mortality (NRM) in a cohort of patients receiving chimeric antigen receptor (CAR) T-cell therapy was 6.8%, and infections accounted for the majority of these deaths, ranging from 50.9% to 56.0%.

NRM has emerged as a new challenge related to CAR-T therapy, limiting population-level survival gains and long-term therapeutic benefit despite the treatment's ability to improve relapse outcomes across disease subtypes, the authors noted.

Using population-level registries, national databases, and real-world data sets, they evaluated the incidence, temporal patterns, etiologic causes, and clinical, demographic, and socioeconomic determinants of early mortality and overall NRM following CAR-T use across hematologic malignancies.

They pooled data from the SEER-Medicare linkage, CIBMTR, French DESCAR-T registry, NRD, and global meta analyses through 2024 to evaluate mortality trends. The data set included more than 7600 adult and pediatric patients from 46 clinical trials and real-world studies in which patients received axicabtagene ciloleucel, tisagenlecleucel, lisocabtagene maraleucel, idecabtagene vicleucel, and ciltacabtagene autoleucel.

NRM was highest in patients with mantle cell lymphoma (10.6%) and multiple myeloma (8.0%).

Compared with NRM related to infections,

just 11.5% of deaths were caused by cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome. Thirty-day mortality ranged from 5.0% to 6.7%.

Older adults experienced higher rates of:

- Acute kidney infection
- Cardiovascular events
- Prolonged hospitalization
- Readmissions

Secondary malignancies and delayed infectious complications increasingly contributed to late NRM. Geographic

challenges reduced CAR-T utilization by up to 37.6% in underserved regions.

“Survivorship strategies should prioritize antimicrobial prophylaxis, CAR-HEMATOTOX risk stratification, longitudinal infection surveillance, and decentralized cellular therapy delivery models to reduce preventable deaths,” the authors concluded.

Reference

Karra N, Chorya H, Sangaraju SL, et al. Hematologic malignancies: a population-level study. Abstract CT-1048. Presented at the 2026 Society of Hematologic Oncology Annual Meeting; September 9-12, 2026; Houston.



POSTERS NOT TO MISS: Cellular therapy edition as reported by Krish Patel, MD

CT-1048: Early Mortality Following CAR-T Therapy in Hematologic Malignancies: A Population-Level Study

CT-227: Measurable Residual Disease by Circulating Tumor DNA in Patients With Third-Line or Later Relapsed or Refractory Follicular Lymphoma Treated With Lisocabtagene Maraleucel in TRANSCEND FL

CT-228: Outcomes of Lisocabtagene Maraleucel in Patients With Relapsed

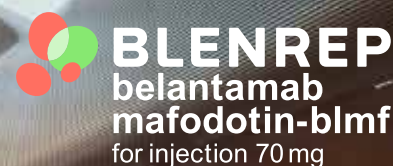
or Refractory Chronic Lymphocytic Leukemia: First Real-World Data From the Center for International Blood and Marrow Transplant Research

CT-594: Clinical Overview of Infection Events With Orca-T vs Conventional Allogeneic Hematopoietic Stem Cell Transplantation in the Precision-T Phase 3 Study

Krish Patel, MD, is the Director of Lymphoma Research at Sarah Cannon Research Institute in Nashville, Tennessee.

Miss any of these great sessions?
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For adults with relapsed or refractory multiple myeloma who have received at least 2 prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent

**Elevate the outcome.
Transform the journey.**

**Their ticket to
3x mPFS vs a daratumumab-based triplet
is within reach**

PFS (HR=0.31 [95% CI: 0.21-0.47]); mPFS was 31.3 months (95% CI: 23.5-NR) for BVd (N=108) vs 10.4 months (95% CI: 7-13.4) for DVd (N=109).¹

The data presented are based on a post hoc exploratory subgroup analysis (N=217) and not adjusted for multiplicity nor powered to detect a statistical difference.



Please scan for full Prescribing Information, including Boxed Warning, for BLENREP.

BVd, BLENREP (B) + bortezomib (V) + dexamethasone (d); CI, confidence interval; DVd, daratumumab (D) + bortezomib (V) + dexamethasone (d); HR, hazard ratio; mPFS, median progression-free survival; NR, not reached.

INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 2 prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

IMPORTANT SAFETY INFORMATION

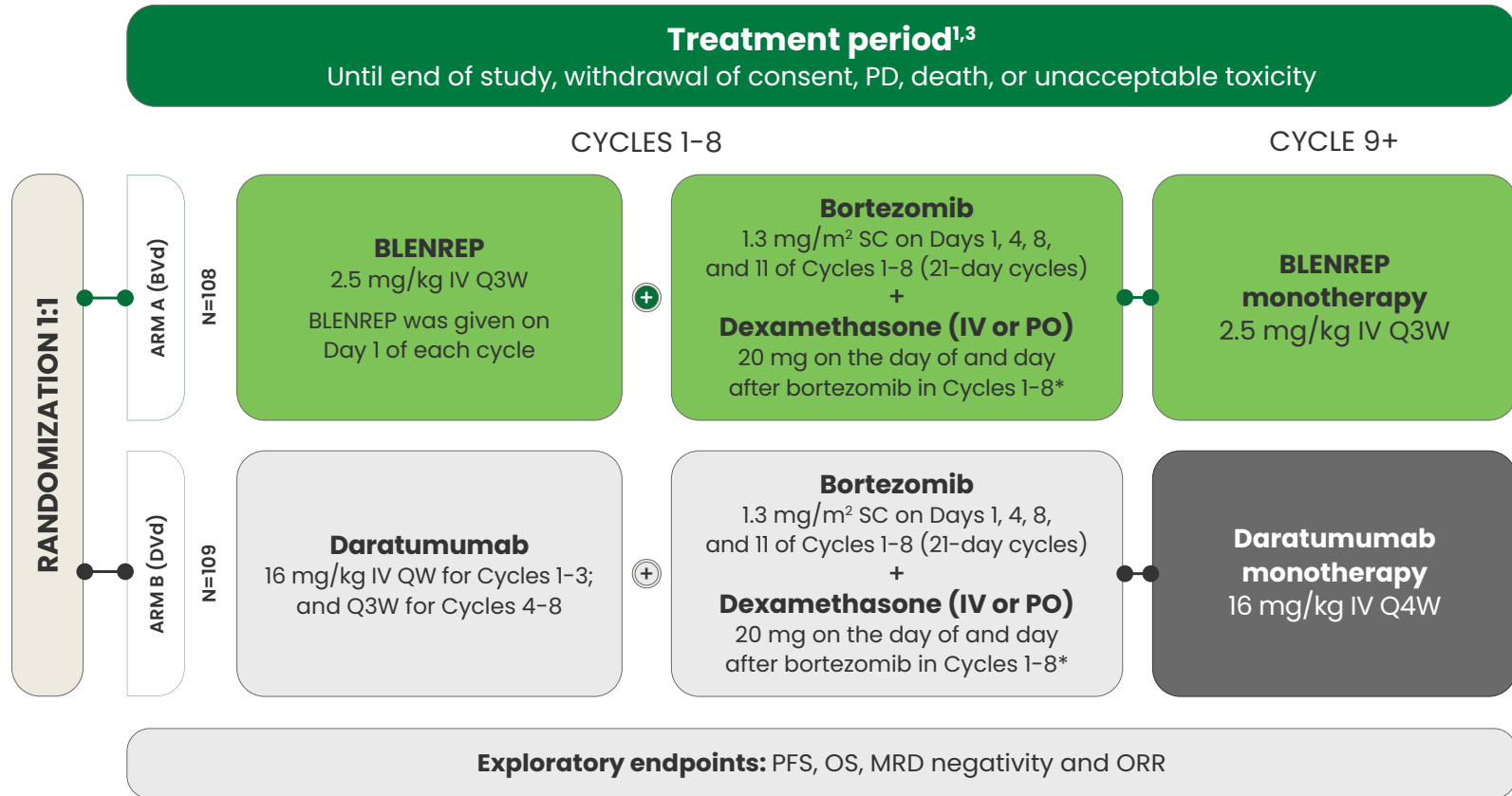
WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

Please see additional Important Safety Information, including Boxed Warning, and the Brief Summary of Prescribing Information for BLENREP on the following pages.

DREAMM-7 was a pivotal Phase 3 trial designed to study a triplet combination vs a daratumumab-based triplet^{1,2}

- FDA approval was based on a post hoc exploratory subgroup analysis of patients with at least 2 prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent
- DREAMM-7 was an open-label, randomized (1:1), multicenter study in adult patients with multiple myeloma who received at least 1 prior line of therapy¹



- **Follow-up period:** PFS Q3W.[†] Disease assessment Q3W. Follow-up for OS Q12W^{3,‡}

Select eligibility criteria for efficacy population^{1,3}

Inclusion criteria:

- Adults with RRMM
- 2 prior lines of MM therapy including a proteasome inhibitor and immunomodulatory agent
- Progressive disease during or after most recent therapy

Exclusion criteria:

- Prior treatment with anti-BCMA therapy
- Refractory to or intolerant of daratumumab or bortezomib
- Current corneal epithelial disease[§]

Patients were stratified by prior lines of treatment (1 vs 2 or 3 vs ≥4), R-ISS stage (I vs II/III), and prior bortezomib (yes vs no)³

*The dose of dexamethasone in each arm was reduced by half in patients aged ≥75 years.¹ [†]For patients who discontinue due to reasons other than PD.³ [‡]For patients who discontinue due to PD or other reasons.³ [§]Patients with current corneal disease, except for mild punctate keratopathy, were excluded.¹

BCMA, B-cell maturation agent; Bvd, BLENREP (B) + bortezomib (V) + dexamethasone (d); DVd, daratumumab (D) + bortezomib (V) + dexamethasone (d); FDA, US Food and Drug Administration; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PO, by mouth; QW, every week; Q3W, every 3 weeks; Q4W, every 4 weeks; Q12W, every 12 weeks; R-ISS, Revised International Staging System; RRMM, relapsed or refractory multiple myeloma; SC, subcutaneous; Vd, bortezomib (V) + dexamethasone (d).

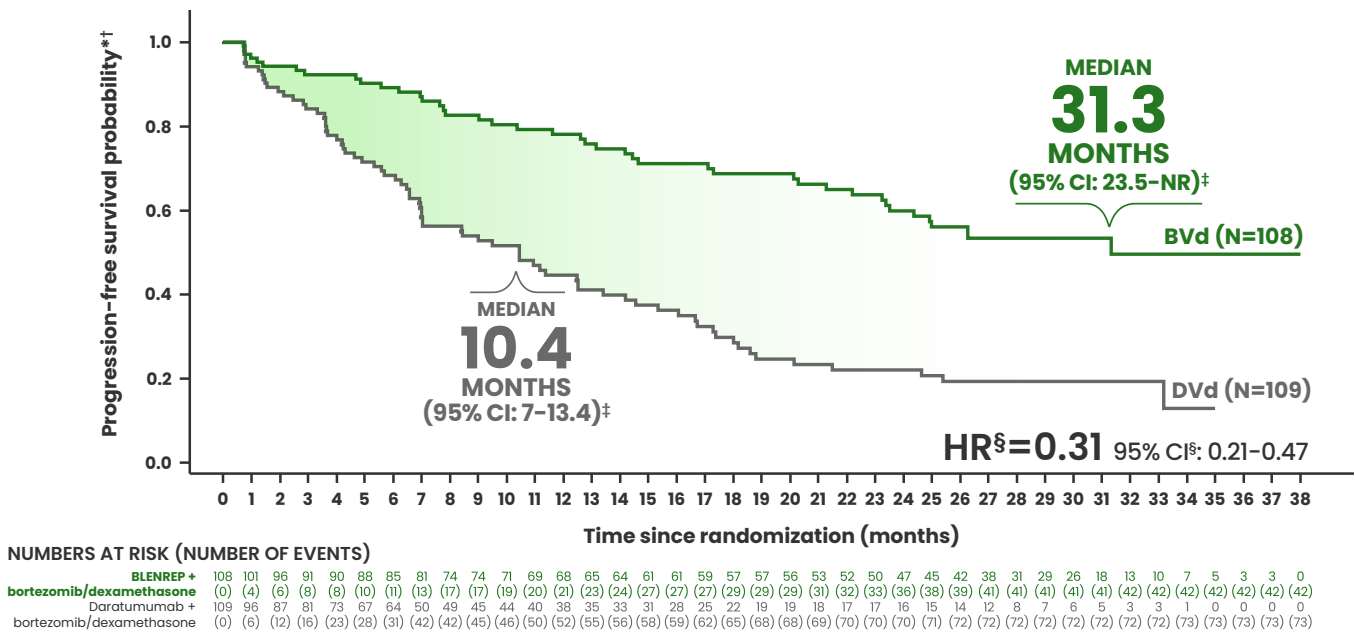
FDA approval was based on a post hoc exploratory subgroup analysis of patients with at least 2 prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent.



The data presented are based on a post hoc exploratory subgroup analysis (N=217) and not adjusted for multiplicity nor powered to detect a statistical difference.

BLENREP triplet combination (BVd) delivered 3x mPFS vs a daratumumab-based triplet (DVd)¹

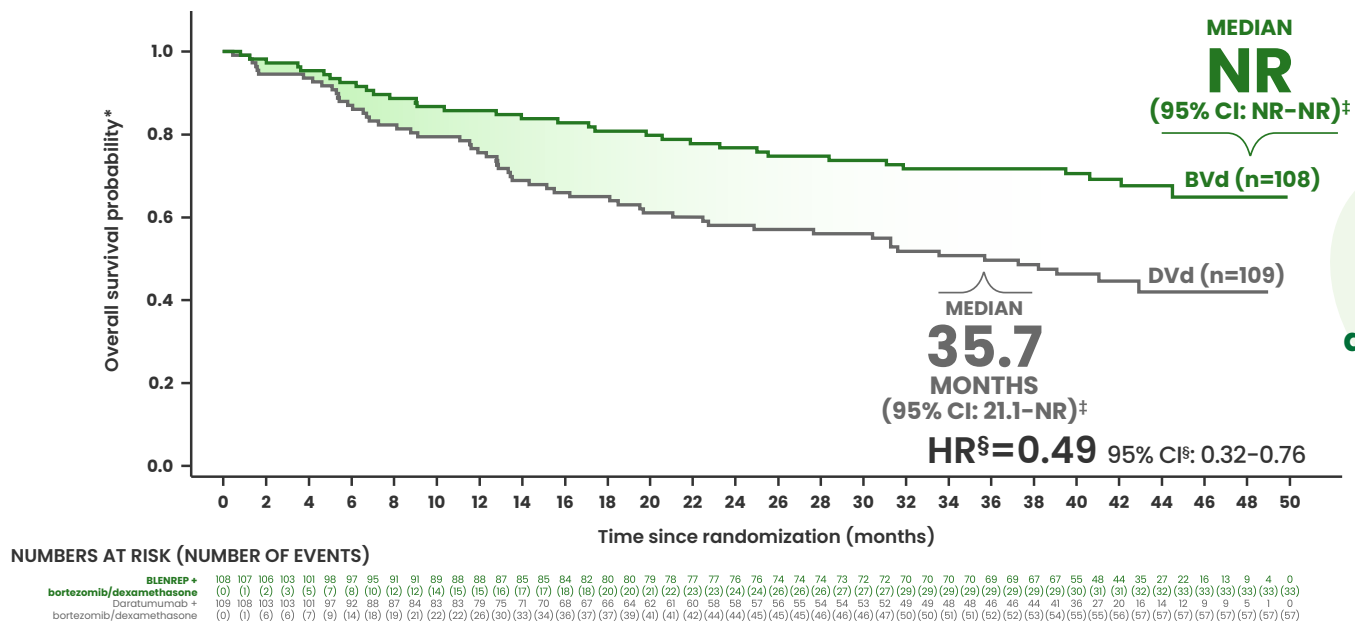
BVd is the first and only triplet that improved median PFS vs a daratumumab-based triplet, with durable benefit observed¹



Response was based on Independent Review Committee per International Myeloma Working Group criteria.¹

- PFS data had a median follow-up of 27.9 months¹

BVd improved overall survival benefit vs DVd¹



51% reduction in risk of death with BVd vs a daratumumab-based triplet¹

- mOS for BVd was not reached. At the time of the interim analysis data cutoff, fewer patients on BVd (33; 31%) had an event vs DVd (57; 52%)¹
- OS data had a median follow-up of 38.7 months¹

*Based on all randomized patients who had received at least 2 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent.¹ [†]Median follow-up of 27.9 months.¹ [‡]By Brookmeyer and Crowley method.¹ [§]Based on stratified Cox regression model.¹

BVd, BLENREP (B) + bortezomib (V) + dexamethasone (d); CI, confidence interval; DVd, daratumumab (D) + bortezomib (V) + dexamethasone (d); HR, hazard ratio; mOS, median OS; mPFS, median progression-free survival; NR, not reached; OS, overall survival.

BLENREP has a well-characterized safety profile¹

In DREAMM-7, the safety of BLENREP with bortezomib and dexamethasone (n=242) compared to daratumumab with bortezomib and dexamethasone (n=246) was assessed in patients who received at least 1 prior line of therapy. Safety of BLENREP in combination with bortezomib and dexamethasone in patients who have received only 1 prior line of therapy (n=125) has not been established.

Adverse reactions (≥20%) in patients with relapsed or refractory multiple myeloma who received BLENREP in DREAMM-7¹

Adverse Reaction*	BLENREP + Vd N=242		Daratumumab + Vd N=246	
	All Grades (%)	Grades 3+4 (%)	All Grades (%)	Grades 3+4 (%)
Eye Disorders				
Reduction in BCVA [†]	89	57	44	9
Corneal exam findings [†]	86	72	19	3
Blurred vision	66	22	11	0.8
Dry eye [‡]	51	7	7	0
Photophobia	47	2	2	0
Foreign body sensation in eyes [‡]	44	3	4	0
Eye irritation	43	5	5	0
Eye pain [‡]	33	0.8	4	0.4
Cataract [‡]	24	8	14	3
Gastrointestinal Disorders				
Diarrhea	32	4	31	4
Infections				
Upper respiratory tract infection ^{‡§}	38	2	36	2
Pneumonia ^{‡§}	26	16	17	5
COVID-19 [§]	24	5	20	2
Hepatobiliary Disorders				
Hepatotoxicity [‡]	33	14	16	2
General Disorders and Administration Site Conditions				
Fatigue [‡]	26	6	27	4

- Serious adverse reactions** occurred in 50% of patients who received BVd. Serious adverse reactions in ≥2% of patients included pneumonia (18%), pyrexia (5%), thrombocytopenia (5%), COVID-19 (5%), upper respiratory tract infection (4%), sepsis (4%), second primary malignancy (3%), and anemia (2%)¹
- Fatal adverse reactions** occurred in 10% of patients who received BVd. Fatal adverse reactions which occurred in >1 patient included pneumonia (4%), sepsis (2%), COVID-19 (1%), respiratory failure (<1%), and intracranial hemorrhage (<1%)¹
- Permanent discontinuation** of BLENREP due to an adverse reaction occurred in 17% of patients. Adverse reactions which resulted in permanent discontinuation of BLENREP in ≥3% of patients included ocular toxicity (9%) and pneumonia (4%)¹

*Adverse reactions, except ophthalmic exam findings, were graded according to CTCAE v5.0.¹ [†]Based on ophthalmic exam findings.¹ [‡]Grouped term includes other related terms.¹ [§]Includes the following fatal adverse reactions: BVd: pneumonia (n=10), COVID-19 (n=3), upper respiratory tract infection (n=1); DVd: pneumonia (n=7), COVID-19 (n=5), pyrexia (n=1).¹

BCVA, Best-Corrected Visual Acuity; BVd, BLENREP (B) + bortezomib (V) + dexamethasone (d); CTCAE, Common Terminology Criteria for Adverse Events; Vd, bortezomib (V) + dexamethasone (d).

Please see additional Important Safety Information, including Boxed Warning, and the Brief Summary of Prescribing Information for BLENREP on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Ocular Toxicity

BLNREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLNREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLNREP dosing as possible. Withhold BLNREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

BLNREP Risk Evaluation and Mitigation Strategy (REMS)

BLNREP is available only through a restricted program called the BLNREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLNREPREMS.com and 1-855-690-9572.



IMPORTANT SAFETY INFORMATION (cont'd)

Thrombocytopenia

Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥ 2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

Embryo-fetal Toxicity

Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.

The most common Grade 3 or 4 ($\geq 10\%$) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

Please see accompanying full Prescribing Information, including BOXED WARNING, for BLENREP. For more information, please visit www.BLENREPhcp.com

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

References:

1. BLENREP. Prescribing information. GSK; 2025.
2. Hungria V, et al. *N Engl J Med*. 2024;391(5):393-407.
3. Hungria V, et al. *N Engl J Med*. 2024;391(5)(suppl):1-31.

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Please see additional Important Safety Information, including Boxed Warning, on this spread and the Brief Summary of Prescribing Information for BLENREP on the following pages.

BRIEF SUMMARY

BLENREP (belantamab mafodotin-blmf) for injection, for intravenous use

The following is a brief summary; see full Prescribing Information for additional product information

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred [see Warnings and Precautions (5.1)].**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity [see Dosage and Administration (2.3), Warnings and Precautions (5.1)].**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS) [see Warnings and Precautions (5.2)].**

1 INDICATIONS AND USAGE

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Ocular Toxicity

BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE [see Adverse Reactions (6.1)].

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%) [see Adverse Reactions (6.1)].

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional [see Adverse Reactions (6.1)].

(continued on next page)

5.1 Ocular Toxicity (cont'd)

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity [see *Dosage and Administration (2.1, 2.3) of the full Prescribing Information*].

Counsel patients to inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional [see *Dosage and Administration (2.1) of the full Prescribing Information*].

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

5.2 BLENREP Risk Evaluation and Mitigation Strategy (REMS)

BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity [see *Warnings and Precautions (5.1)*]. Notable requirements of the BLENREP REMS include the following:

- Prescribers must be certified in the BLENREP REMS by enrolling and completing training.
- Prescribers must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic exams before each dose, and provide patients with the BLENREP REMS Patient Guide.
- Patients must be enrolled in the BLENREP REMS and adhere to monitoring.
- Healthcare settings that dispense BLENREP must be certified in the BLENREP REMS by enrolling and must obtain authorization prior to dispensing.
- Wholesalers and distributors must distribute BLENREP only to certified healthcare settings.

Further information is available at www.BLENPREMS.com and 1-855-690-9572.

5.3 Thrombocytopenia

Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7 [see *Adverse Reactions (6.1)*].

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥ 2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity [see *Dosage and Administration (2.3) of the full Prescribing Information*].

5.4 Embryo-fetal Toxicity

Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

5.4 Embryo-fetal Toxicity (cont'd)

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose [see *Use in Specific Populations* (8.1, 8.3)].

6 ADVERSE REACTIONS

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

- Ocular Toxicity [see *Warnings and Precautions* (5.1)]
- Thrombocytopenia [see *Warnings and Precautions* (5.3)]

6.1 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 with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Relapsed or Refractory Multiple Myeloma in Combination with Bortezomib and Dexamethasone

The safety of BLENREP with bortezomib and dexamethasone (n = 242) compared with daratumumab with bortezomib and dexamethasone (n = 246) was evaluated in DREAMM-7 in patients with relapsed or refractory multiple myeloma who received at least one prior line of therapy [see *Clinical Studies* (14) of the full Prescribing Information]. Patients received BLENREP 2.5 mg/kg of actual body weight once every 3 weeks in combination with bortezomib and dexamethasone (BVd) for the first 8 cycles, followed by BLENREP as a single agent or daratumumab in combination with bortezomib and dexamethasone (DVd) for the first 8 cycles, followed by daratumumab as a single agent. Among patients who received BLENREP, 69% were exposed for 6 months or longer and 55% were exposed for greater than one year. The safety of BLENREP in combination with bortezomib and dexamethasone in patients who received only one prior line of therapy (n = 125) has not been established.

Serious adverse reactions occurred in 50% of patients who received BVd. Serious adverse reactions in $\geq 2\%$ of patients included pneumonia (18%), pyrexia (5%), thrombocytopenia (5%), COVID-19 (5%), upper respiratory tract infection (4%), sepsis (4%), second primary malignancy (3%), and anemia (2%). Fatal adverse reactions occurred in 10% of patients who received BVd. Fatal adverse reactions which occurred in >1 patient included pneumonia (4%), sepsis (2%), COVID-19 (1%), respiratory failure ($<1\%$), and intracranial hemorrhage ($<1\%$).

Permanent discontinuation of BLENREP due to an adverse reaction occurred in 17% of patients. Adverse reactions which resulted in permanent discontinuation of BLENREP in $\geq 3\%$ of patients included ocular toxicity (9%) and pneumonia (4%).

Dosage interruptions of BLENREP due to an adverse reaction occurred in 78% of patients. Adverse reactions which required dosage interruption of BLENREP in $\geq 3\%$ of patients included ocular toxicity based on ophthalmic exam findings (74%), blurred vision (32%), upper respiratory tract infection (20%), dry eye (14%), photophobia (14%), pneumonia (14%), eye irritation (13%), COVID-19 (12%), foreign body sensation in eyes (12%), eye pain (10%), thrombocytopenia (9%), visual impairment (7%), cataract (5%), diarrhea (4%), and neutropenia (4%).

Dosage reductions of BLENREP due to an adverse reaction occurred in 36% of patients. Adverse reactions which required dosage reductions for BLENREP in $\geq 3\%$ of patients included ocular toxicity based on ophthalmic exam findings (30%), thrombocytopenia (14%), and blurred vision (10%).

The most common adverse reactions ($\geq 20\%$) were reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract, and COVID-19. The most common Grade 3 or 4 laboratory abnormalities ($\geq 10\%$) were decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma glutamyltransferase, decreased white blood cells, and decreased hemoglobin.

Table 4 summarizes the adverse reactions in DREAMM-7.

(continued on next page)

6.1 Clinical Trials Experience (cont'd)

Table 4. Adverse Reactions (≥10%) in Patients with Relapsed or Refractory Multiple Myeloma Who Received BLENREP in DREAMM-7

Adverse Reaction ^a	BLENREP + Bortezomib and Dexamethasone N = 242		Daratumumab + Bortezomib and Dexamethasone N = 246	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Eye disorders				
Reduction in BCVA ^b	89	57	44	9
Corneal exam findings ^b	86	72	19	3
Blurred vision	66	22	11	0.8
Dry eye ^c	51	7	7	0
Photophobia	47	2	2	0
Foreign body sensation in eyes ^c	44	3	4	0
Eye irritation	43	5	5	0
Eye pain ^c	33	0.8	4	0.4
Cataract ^c	24	8	14	3
Visual impairment	11	5	2	0.4
Gastrointestinal disorders				
Diarrhea	32	4	31	4
Nausea	16	0.8	12	0
Infections				
Upper respiratory tract infection ^{c,d}	38	2	36	2
Pneumonia ^{c,d}	26	16	17	5
COVID-19 ^d	24	5	20	2
Hepatobiliary disorders				
Hepatotoxicity ^c	33	14	16	2
General disorders and administration site conditions				
Fatigue ^c	26	6	27	4
Pyrexia ^{c,d}	19	0.4	11	2

BCVA = best-corrected visual acuity; BVd = BLENREP + bortezomib and dexamethasone; DVd = daratumumab + bortezomib and dexamethasone.

^a Adverse reactions, except ophthalmic exam findings, were graded according to Common Terminology Criteria for Adverse Events v5.0.

^b Based on ophthalmic exam findings.

^c Grouped term includes other related terms.

^d Includes the following fatal adverse reactions: BVd: pneumonia (n = 10), COVID-19 (n = 3), upper respiratory tract infection (n = 1); DVd: pneumonia (n = 7), COVID-19 (n = 5), pyrexia (n = 1).

Clinically relevant adverse reactions in <10% of patients who received BVd included: increased lacrimation, vomiting, diplopia, albuminuria, sepsis, eye pruritus, infusion-related reactions, corneal ulcer (including cases with infection), and pneumonitis.

(continued on next page)

6.1 Clinical Trials Experience (cont'd)

Table 5 summarizes the laboratory abnormalities in DREAMM-7.

Table 5. Select Laboratory Abnormalities (>10%) That Worsened from Baseline in Patients with Relapsed or Refractory Multiple Myeloma Who Received BLENREP in DREAMM-7

Laboratory Abnormality	BLENREP + Bortezomib and Dexamethasone ^a		Daratumumab + Bortezomib and Dexamethasone ^a	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Hematology				
Platelets decreased	100	74	88	48
Lymphocytes decreased	90	53	92	56
Leukocytes decreased	59	11	67	17
Neutrophils decreased	52	17	53	13
Hemoglobin decreased	51	10	60	12
Chemistry				
Aspartate aminotransferase increased	88	5	40	0
Gamma glutamyltransferase increased	73	15	44	3
Alanine aminotransferase increased	71	5	54	1
Creatinine increased	51	2	53	<1
Creatine phosphokinase increased	48	3	31	3

BVd = BLENREP + bortezomib and dexamethasone; DVd = daratumumab + bortezomib and dexamethasone.

^a The denominator used to calculate the rate varied from 238 to 241 (BVd) and 243 to 246 (DVd) based on the number of patients with a baseline value and at least one post-treatment value.

Patient-reported ocular symptoms were assessed using the Patient-Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE) and Ocular Surface Disease Index (OSDI).

PRO-CTCAE assessments were collected at baseline and then every 3 weeks until treatment discontinuation. Completion rates in both arms were ≥90% at baseline and ≥81% at subsequent timepoints where >50% of patients remained on treatment. OSDI assessments were collected every 3 weeks until Dose 6 and then every 6 weeks thereafter until treatment discontinuation for BVd and every 3 weeks until Cycle 6 and then every 12 weeks thereafter until treatment discontinuation for DVd. Completion rates in both arms were ≥90% at baseline and ≥52% at subsequent timepoints where >50% of patients remained on treatment.

Table 6 summarizes the patient-reported symptom of blurred vision as assessed by PRO-CTCAE.

Table 6. Patient-Reported Symptom of Blurred Vision Assessed by PRO-CTCAE in Patients with Relapsed or Refractory Multiple Myeloma in DREAMM-7

Symptom (Attribute) ^a	Any Symptom Before Treatment ^b		Score 3 or 4 Before Treatment ^c		Any Symptom on Treatment ^{d,e}		Score 3 or 4 on Treatment ^{d,f}	
	BVd (%) n = 232	DVd (%) n = 227	BVd (%) n = 232	DVd (%) n = 227	BVd (%) n = 238	DVd (%) n = 239	BVd (%) n = 238	DVd (%) n = 239
Blurred vision (severity)	28	24	<1	2	93	74	55	15

BVd = BLENREP + bortezomib and dexamethasone; DVd = daratumumab + bortezomib and dexamethasone; PRO-CTCAE = patient-reported outcomes common terminology criteria for adverse events.

(continued on next page)

6.1 Clinical Trials Experience (cont'd)

- ^a Symptom attribute scoring defined as severity with a score of 0 = 'none'; 1 = 'mild'; 2 = 'moderate'; 3 = 'severe'; 4 = 'very severe'.
- ^b Percentage of patients whose symptom score before treatment was 1 to 4.
- ^c Percentage of patients whose symptom score before treatment was 3 or 4.
- ^d Number of patients who provided at least one on-treatment score.
- ^e Percentage of patients whose maximum post-baseline score was 1 to 4 on treatment.
- ^f Percentage of patients whose maximum post-baseline score was 3 or 4 on treatment.

Driving at night was assessed using the OSDI. At baseline, the proportion of patients who reported limitations with driving at night "all of the time" or "most of the time" during the last week was 9% in the BVd arm and 4% in the DVd arm. The proportion of patients who reported limitations with driving at night "all of the time" or "most of the time" during the last week was highest in the BVd arm at 47% at Week 13 and in the DVd arm at 12% at Week 76.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman, because it contains a genotoxic compound (the microtubule inhibitor, MMAF) and it targets actively dividing cells [see *Clinical Pharmacology (12.1)*, *Nonclinical Toxicology (13.1)* of the full Prescribing Information]. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, belantamab mafodotin-blmf has the potential to be transmitted from the mother to the developing fetus. There are no available data on the use of BLENREP in pregnant women to evaluate for drug-associated risk. No animal reproduction studies were conducted with BLENREP. Advise pregnant women of the potential risk to a fetus.

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.

8.2 Lactation

Risk Summary

There are no data on the presence of belantamab mafodotin-blmf in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with BLENREP and for 3 months after the last dose.

8.3 Females and Males of Reproductive Potential

BLENREP can cause fetal harm when administered to pregnant women [see *Use in Specific Populations (8.1)*].

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating BLENREP.

Contraception

Females: Advise females of reproductive potential to use effective contraception during BLENREP treatment and for 4 months after the last dose.

Males: Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose [see *Nonclinical Toxicology (13.1)* of the full Prescribing Information].

8.3 Females and Males of Reproductive Potential (cont'd)

Infertility

Based on findings in animal studies, BLENREP may impair fertility in females and males. The effects were not reversible in male rats but were reversible in female rats [see *Nonclinical Toxicology (13.1) of the full Prescribing Information*].

8.5 Geriatric Use

Of 242 patients who received BLENREP in DREAMM-7, 121 patients (50%) were aged 65 years or older and 37 patients (15%) were 75 years or older. No overall differences in the safety of BLENREP were observed between patients 65 years of age and older and younger adult patients.

Of the 108 patients who received BLENREP and were evaluated for efficacy in the DREAMM-7 study, there was an insufficient number of older adult patients to determine if the effectiveness in patients 65 years of age and older is different than in younger adult patients.

8.6 Hepatic Impairment

No dose adjustment is recommended for patients with mild hepatic impairment (total bilirubin > upper limit of normal [ULN] to $\leq 1.5 \times$ ULN and any aspartate aminotransferase [AST] or total bilirubin $\leq$ ULN with AST > ULN).

The recommended dose of BLENREP has not been established in patients with moderate or severe hepatic impairment [see *Clinical Pharmacology (12.3) of the full Prescribing Information*].



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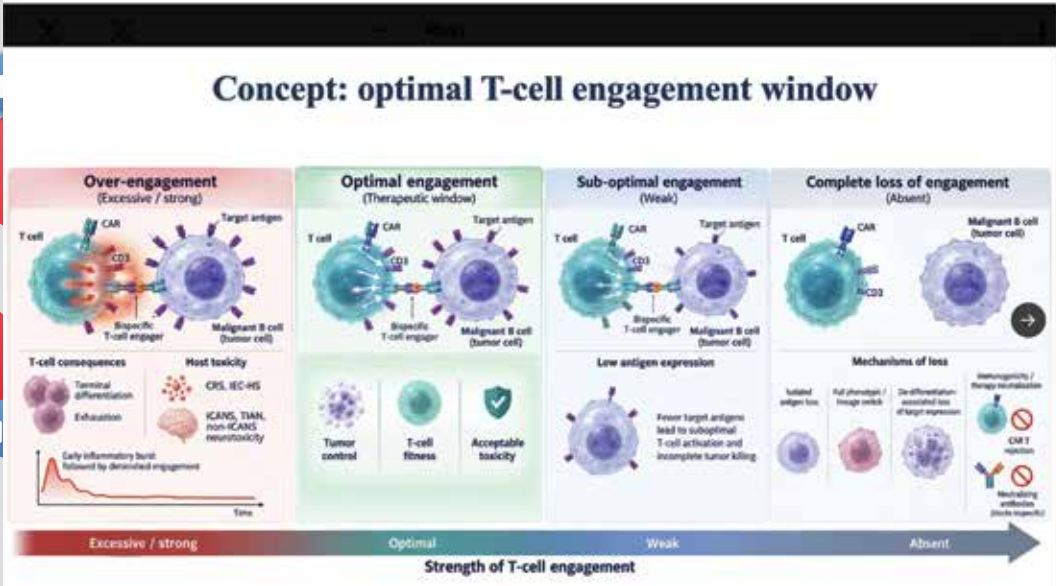
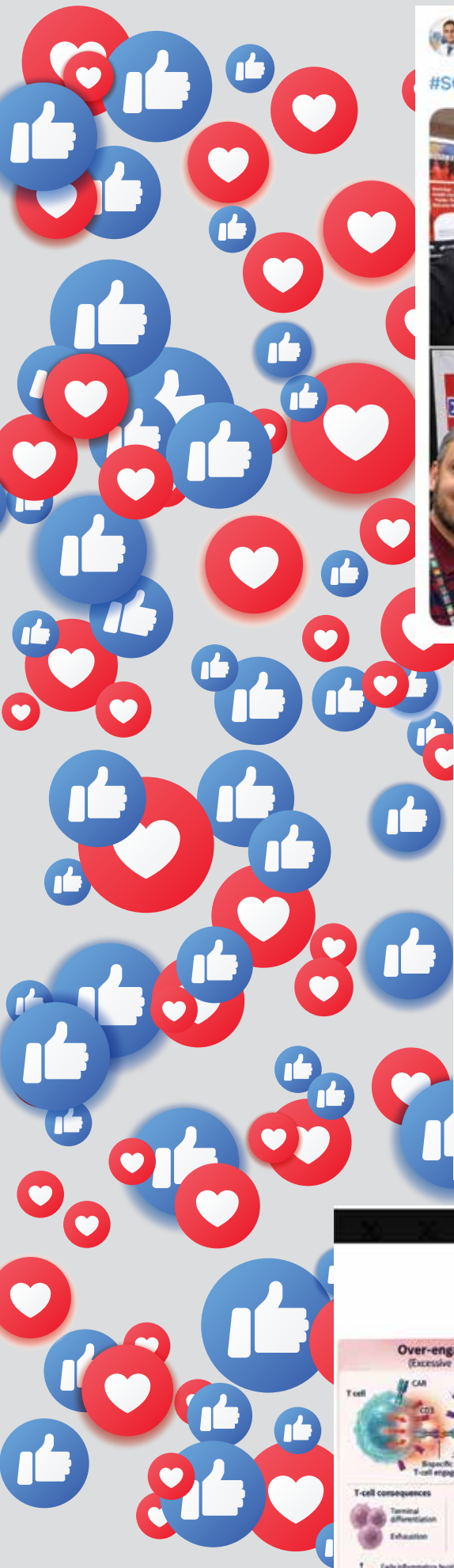
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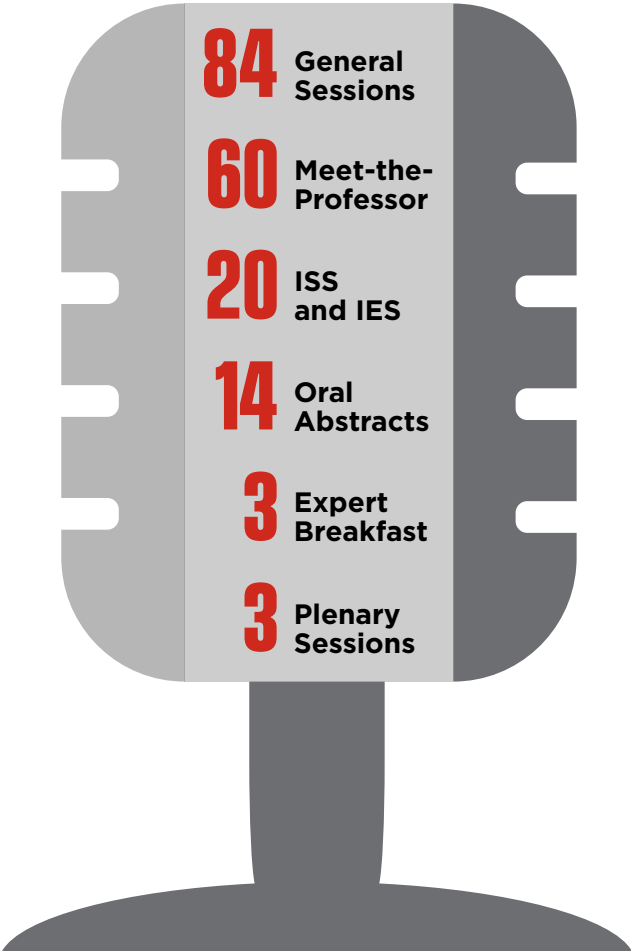
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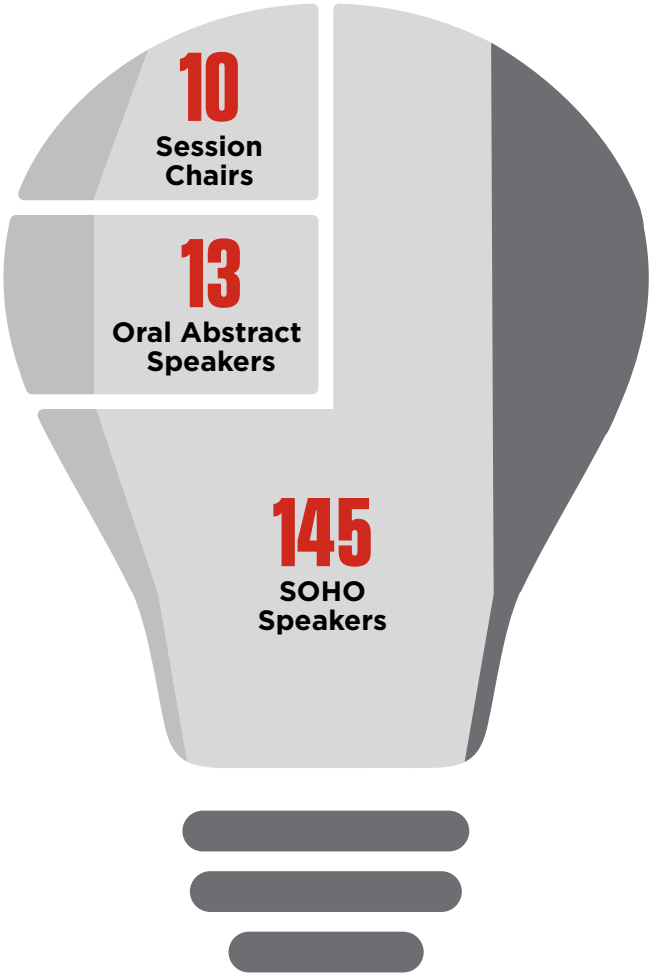


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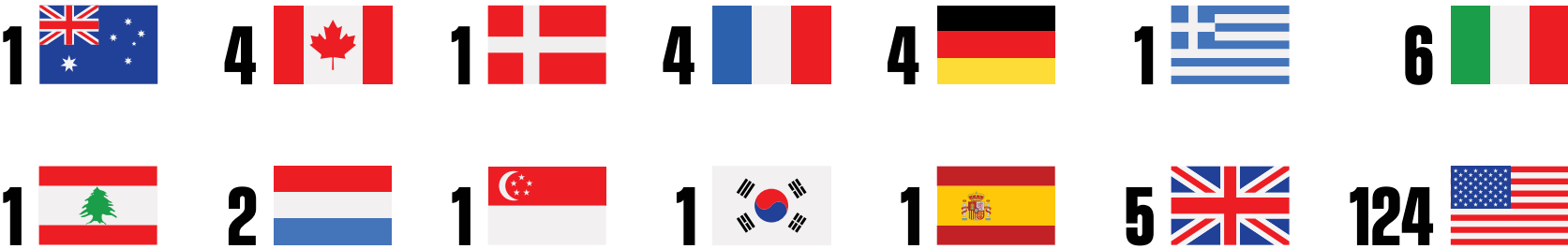
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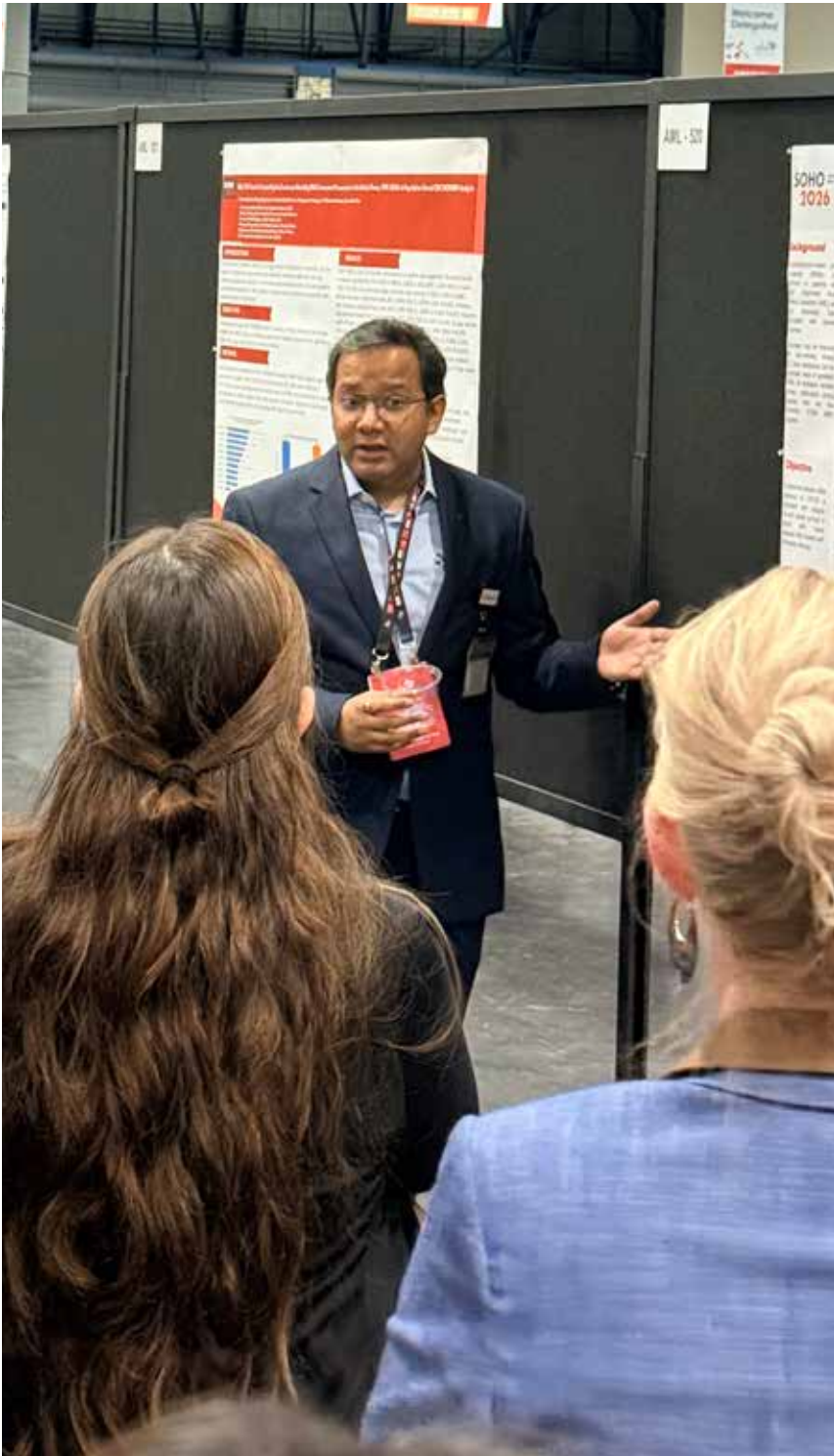
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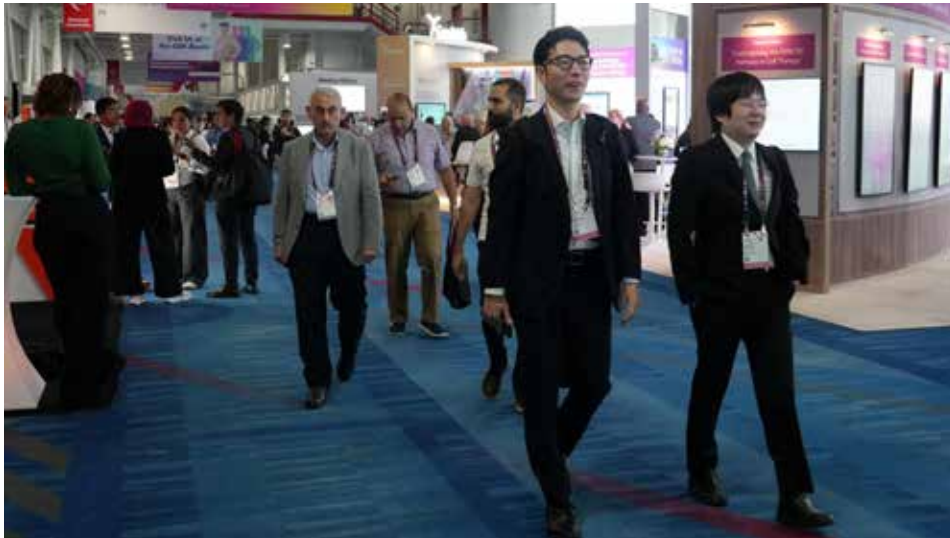


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