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COVER STORY

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EDITORIAL

Facing 2026 with a mix of inspiration and trepidation

By: **Sagar Lonial, MD, FACP**
Editor in Chief, Emory University School of Medicine

"I was within and without, simultaneously enchanted and repelled, by the inexhaustible variety of life"

- F. Scott Fitzgerald

After ASH 2025, I was both excited and overwhelmed. The wealth of data across all hematologic malignancies was both inspirational and at the same time intimidating. How do we incorporate all this new information, all these new options, the multitude of immune and genomic markers into our daily practice, let alone provide access to these options for patients across many different geographic settings? How do we bring the full force of these new advances to bear on the challenges our patients experience? It is quite a contradiction, and one that needs to be sorted through as we adopt treatments that can have tangible impacts on so many people.

Then I got back into the "real world" and was confronted with the realities of a federal health machine bound to take us back to the medicine of the 1950s, a time when cancer therapy was nonexistent due to limited understanding of biology and limited tools. Time-tested public health guidance is seemingly a thing of the past, which relegates our push to cure and understand cancer into a much more challenging place. Failure to control diseases like measles, covid, influenza, and other common viruses have a significant impact on blood cancer patients who are highly susceptible to these illnesses as a consequence of our highly effective but significantly immunosuppressive treatment. Vaccinating patients isn't the solution; we need to be in a community where the prevalence of these preventable diseases is lower if we wish to limit the impact on our patients.

We have so much potential, so many lives dedicated to treatment and prevention of blood cancers, terabytes of data on immune function and genomic sequencing, yet basic science and the core principles of evidence, logic, and data are under attack. Our patients' trust in us has been undermined by disinformation. Never have we been so close to breakthrough, yet never has our training and expertise been viewed with such skepticism. But that is the difference: those who seek to relegate us to the past, to deny the simple logic and beauty of a well conducted trial in favor of anecdote, don't have that calling. They don't get to see the patient respond on a phase 1 trial, or hear 10 myeloma experts grapple with a tough case. We have the fortunate circumstance of curiosity and purpose that pushes us every day to make a difference. At ASH 2025 I saw that purpose on bright display among the 25,000 attendees and it was glorious. I saw people talking in a constructive and collaborative way to help make the world a better place, and it gave me hope, it energized me, and I came back with new ideas and excitement. So, if you were like me, inspired and overwhelmed, excited and anxious, fear not, for you are not alone. There is a worldwide community ready to take up the cause with you. If you are still confused about what to do and when, come to SOHO 2026 where my colleagues will help make sense of it all!

Sincerely,

Pathways & Perspectives with Valeria Santini, MD

2026-2027 SOHO President-elect Valeria Santini, MD, grew up in Florence, where she says the city's beauty, history, and art shaped her entire outlook on life. "My garden borders the medieval city walls," she says. "When I open my window, I see a medieval tower and a beautiful park. You feel that it belongs to you, it's part of you, and that beauty shapes your whole life."

What was your career path to medicine?

My family moved to Florence when I was six years old, and that's where I attended primary school, high school, and university. At the time of choosing my field, I was very uncertain. Growing up in Florence, I was drawn to philosophy or art history, but I decided to pursue something more scientific and humanity-focused, so I chose medicine.

Very early, in my second year of medical school, I asked to join a general pathology lab. I was studying for my regular exams but also doing a lot of lab work, and I just grew up with this combination of study and research.

After university, I moved to the Netherlands for three years during my post-graduation period, working in a lab on translational studies in acute myeloid leukemia under Professor Bob Levenberg.

After that, I returned to Italy, to the University of Florence, where I completed my post-graduate training. There, I became first an assistant professor and then an associate professor.

What first drew you to leukemia and MDS?

It started very early, during university. I was studying murine leukemias and murine erythroleukemias, and the biology was fascinating. Later, I met my mentor, who was a clinician, and I moved from experimental work to the clinic, but kept my interest in translational studies. The lectures we had were full of empathy and science; I knew I had to become a hematologist.

How has hematology changed since you began practicing?

When I started, there were very few treatment options. In chronic myeloid leukemia there were no active treatments yet; for AML, only a few; and for MDS, absolutely nothing — only the youngest could receive chemotherapy. Early on, I was very interested in CML, even before imatinib. I remember as a fellow, it was a nightmare to diagnosis CML. The hospital itself was different: less efficient, no ward chambers, and the conditions were basic.

Eventually, I became interested in CML and AML, which led me to spend time in Houston at MD Anderson. It was a beautiful and inspiring period. I was exposed to new drugs and an entirely new approach to disease. MD Anderson is different from anywhere else. The level of treatment, the organization, and the opportunity to work alongside so many skilled hematologists taught me so much.

What made you shift from AML to MDS, and what challenges do you see in treating MDS?

I moved to MDS because I thought the two diseases were similar and MDS somehow more challenging. In fact, MDS and AML are completely different diseases, with different biology; only some aspects overlap.

Many studies for high-risk MDS were designed in a similar way to the ones we have for AML, with the same endpoints, and sometimes that is really not the case. Another big problem is that several studies carried out recently for high-risk MDS have failed. This was partially because the study design was not strong and also because the treatment was not supported by strong biology. It was just empiric: you use a drug because you think it may work or it worked in another disease, but then it's not applicable to MDS.

MDS is also very heterogeneous. If you treat high-risk patients the same way, maybe you miss the subgroup that could respond to some agents more than to others. It is a big problem in treating this disease. Now the hopes and hypes are frustrating. We are left with only azacitidine or decitabine that have been used for a very long time. Only a few cases have the possibility of targeted therapy because of specific mutations, like IDH1 with ivosidenib or IDH2 with enasidenib. Let's say these are very rare cases for MDS; for the rest, unfortunately, it's a big problem.

With international collaboration, digital tools, and AI now aiding drug discovery, do you feel more hopeful about the future of MDS treatment?

Absolutely. What I think is important and will hopefully lead to solutions in our high-risk MDS fight is the fact that AI can help us put together the mechanisms of action that have been clarified in translational studies, agents that are available, and also define better MDS biological subgroups. MDS has been divided and stratified by type of mutations, cytopenias, and cytogenetics. There is so much heterogeneity that it is important to focus on all subgroups instead of just treating everybody the same way.

Has there been progress with consolidating the WHO and ICC classifications?

The WHO and ICC classifications are not so different, but there are some points that indeed differ. One major difference is related to the blast count and definition of MDS vs AML/

MDS, which in my view is not so crucial. Yes, there is progress. We are working very intensely to reach the final merging of the two groups and categories. Each group has raised issues—very important ones, actually, but this also highlights the heterogeneity and the difficulties in stratifying, classifying, and diagnosing MDS. It's a challenge, and I like it. It's very important.

It is becoming quite clear that blasts are not the problem and that what is called the continuum between MDS and AML is not always to be considered a continuum. They are two different diseases biologically. Some subtypes overlap, like the ones with TP53 mutations. These represent a separate category that brings together MDS and AML.

Will merging the WHO and ICC classifications immediately affect patients, or is it mainly an academic exercise?

Yes, it depends on which kind of classification you choose. A person who has acute leukemia might previously have been classified as high-risk MDS. In this sense, it may affect the patients, but only in this aspect. Otherwise, patients have their diagnosis, but they want to know their prognosis and risk.

Today, I saw a lot of patients. They asked me, "How long do I have to live? Is my life expectancy different from others my age? Will I develop a bad disease?" This is something they indeed ask for and we should be able to reply without being too pessimistic or too lighthearted.

How long have you been involved with the society?

I have been involved with SOHO since the beginning and have witnessed the incredible growth of the meeting. We started small, then it grew bigger, and now it's a huge event with many enthusiastic participants. The friendly atmosphere of the annual meeting has become a defining feature of the meeting; there's real exchange and opportunity for discussion. Every September, during this special month, we come together for this remarkable encounter.

"My garden borders the medieval city walls," Dr. Santini said. Photo courtesy of Dr. Santini.

I've been part of the Education Committee for many years, which has been a rewarding experience, and I've also frequently served on the faculty. I also learn a lot by attending sessions beyond my usual focus of MDS or AML.

Dr. Santini at SOHO 2024 holding the daily newspaper featuring her MDS plenary talk.

You were elected to be the 2026-2027 president of SOHO. How do you feel about taking over the presidency?

I'm quite emotional about this presidency. I'm very excited and a bit nervous because I hope to be a good president and create a strong program and agenda for the meeting. SOHO is more than a meeting, it's an experience. The level of science, medicine, and educational energy is outstanding.

I'm incredibly honored to become president-elect. It's truly amazing, especially as someone not based in the US, because it makes the role even more meaningful. SOHO's educational mission is global, reaching many countries through the Ambassador Program, which spreads learning and updates to hematologists worldwide, including those from developing countries who might not otherwise have access to this kind of education.

The Young Investigator Program scholarship is also unique. It has brought so many young investigators and hematologists to Houston who have been charmed by the atmosphere. I hope to continue that spirit. People come to listen and learn from the best experts in hematology.

How did growing up in Florence, surrounded by Italy's rich culture, inform you as a person?

Italy is a special place. Everywhere you go, even in a small town, you find amazing history and art. We are surrounded by beauty. My garden borders the medieval city walls. When I open my door or window, I see a medieval tower and a beautiful park. You feel that it belongs to you, that it's part of you, and that beauty shapes your entire life. Because you see beauty from morning to night, from the time you are a child, you get used to it, but at the same time, it educates your eyes and your way of thinking.

I don't have much time for hobbies, but I go to museums, or I take walks in the hills around Florence and discover incredible places. Recently, I took a walk near my home and met a guide who brought me to an abandoned church. He showed me the landscape and asked, "Do you recognize it?" It was the background from one of Leonardo's most famous paintings. This is the kind of experience you can have here, and I hope everyone who visits can understand and appreciate a little of this magic.

I also proudly belong to the Accademia delle Arti del Disegno, an academy founded in 1563 for art and design. It's an academy that brings together science, but mostly artists, writers, musicians, and sculptors. It's still active and lively after 450 years.

My inspiring, impossible companion for a special dinner is Matilde di Canossa. She was an incredible, strong and powerful woman who was born in 1046. She established the basis for the greatness of Florence, among other many political actions. I would like to hear her voice and ask how she could be so resilient, build her own fascinating personality in the middle-age era, surely difficult for independent women.

Valeria Santini, MD, is an associate professor of hematology at the University of Florence Medical School in Florence, Italy. She is SOHO president-elect and assumes the role of presidency in 2026.

YOUNG INVESTIGATOR SPOTLIGHT

Meet Maha Hameed, MD

As a resident physician who is fascinated by hematologic malignancies, Maha Hameed, MD, brings a distinctive combination of scientific intrigue and personal drive to her work in hematologic oncology.

Now in her third year of internal medicine residency and serving as an assistant chief resident at Florida State University (FSU) Sarasota, Dr. Hameed is a 2025 recipient of the SOHO Young Investigator Program (YIP) Award.

"Myeloma immediately drew my interest from the acuity standpoint" she told *SOHO Insider*. "People say it's the critical care of heme-onc. Things are quickly evolving. They're quick-paced and dynamic, and you're not necessarily reliant on other specialists."

At the 2025 SOHO Annual Meeting, Dr. Hameed was particularly struck by two myeloma-focused sessions. One was a presentation by Hans Lee, MD, on trispecific therapies.

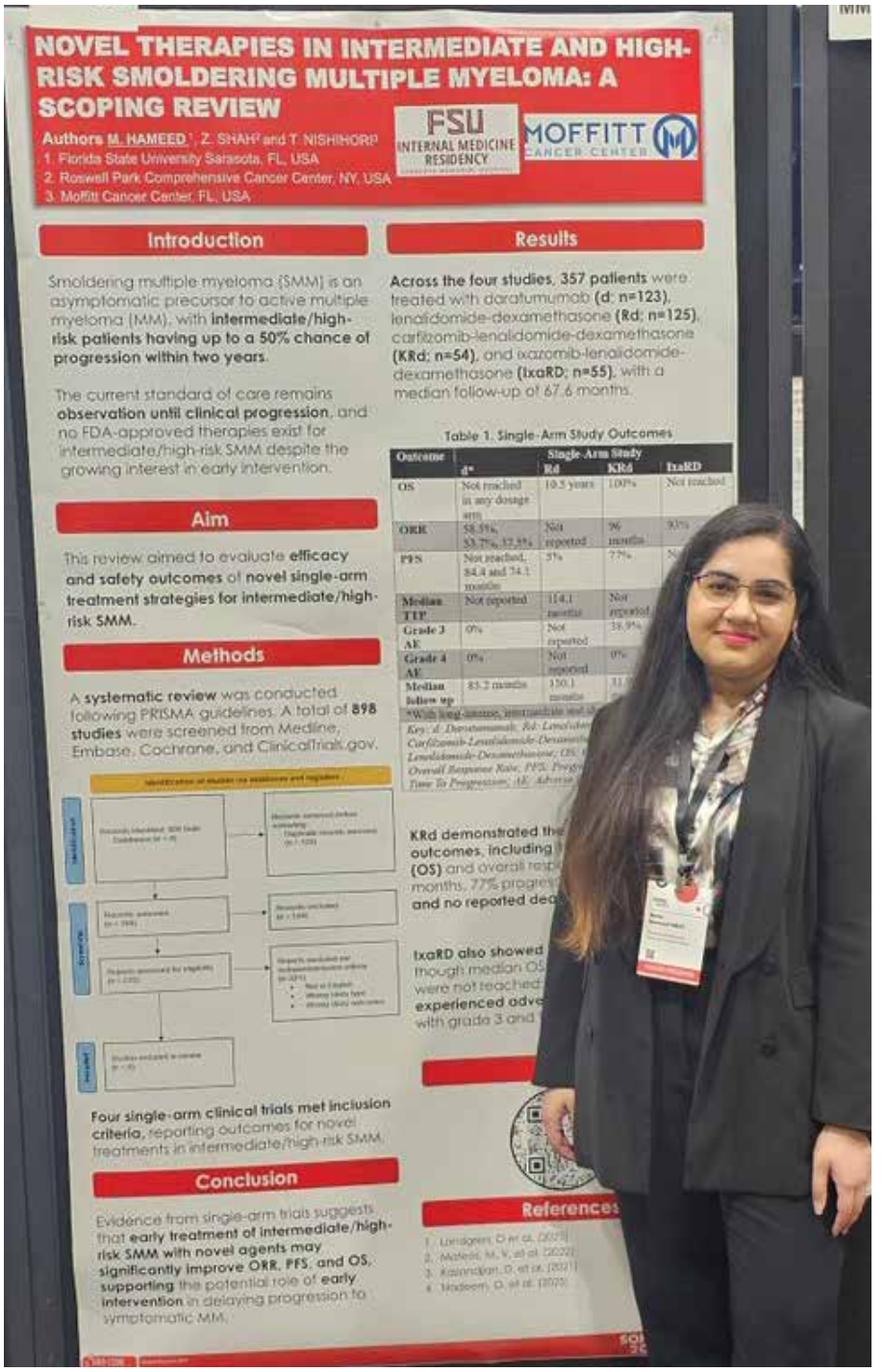
"I felt that was incredible … I was still trying to understand bispecifics… now we have trispecifics," she said.

The other standout session, she said, was given by Sundar Jagannath, MD, on whether it is time to use the word "cure" in myeloma.

"You're taught in [medical] school and residency, myeloma is incurable," she said. "It was fascinating to hear someone make the case for rethinking that."

She also spoke about the ongoing debate in the myeloma community between "cure" advocates and skeptics.

"Both sides definitely have very interesting points. I don't think I'm there from a clinical perspective to give an opinion, but as a trainee, it's interesting to see what's still considered controversial; those are the things I want to pay attention to," she said.



Dr. Hameed at SOHO 2025 with her poster. All photos courtesy of Dr. Hameed.

Dr. Hameed learned of the Young Investigator Program after first attending the SOHO meeting in 2024, where she presented a poster but wasn't aware of the opportunity. This year, she returned as a Young Investigator and presented two abstracts; one a systematic review of novel treatments for intermediate and high-risk smoldering myeloma, the other a retrospective study of four patients with hemophagocytic lymphohistiocytosis at Sarasota Memorial Hospital.

"The systematic review analyzed efficacy and safety outcomes from four single-arm clinical trials," she explained. "We found that the KRD regimen (carfilzomib, lenalidomide, and dexamethasone) had the best outcomes, with a 100% overall response rate and minimal severe adverse events."

She noted that it was especially interesting to see changes in clinical guidelines align with her research.

"It was about a week after SOHO that the International Myeloma Society decided to treat high-risk smoldering myeloma; that was exciting to witness," she said.

Her second study carried personal significance. It focused on four patients with HLH treated at her institution, and one patient in particular stayed with her throughout the process.

"I remember very vividly when I presented the consent form to the patient's wife," she said. "She told me that the only reason she was signing it was because she knew I would do a good job. That stuck with me."

From an early age, Dr. Hameed knew she wanted to go into medicine. Born in Houston but raised in Canada and Saudi Arabia, she attended medical school directly after high school in Saudi Arabia, where her interest in hematologic malignancies solidified.

"In tenth or eleventh grade, we learned about the concept of stem cells and how they differentiate into red blood cells, platelets, and so on," she said. "One tiny change in that process can lead to different types of blood cancers. That fascination really drew me toward medicine."

Growing up and studying in multiple countries—notably at an international school in Saudi Arabia, where she made friends with students from all over the Middle East—gave Dr. Hameed a

versatile perspective that serves her well in clinical settings.

"All those interactions helped me keep a broad mind when it comes to adaptability and communication skills," she said. "Arab culture is very different from growing up in the US or Canada. I try to always consider someone's background when I interact with them."

Her mentors have also played a crucial role in her development, especially Faiz Anwer, MD, a hematologist-oncologist at the Cleveland Clinic, whom she has known since medical school.

"I've worked with him on many different research projects," she said. "One that I presented last year at ASH was through his mentorship."

For all her scientific focus, Dr. Hameed values balance in her life. Now that she is further along in residency, she has more time to enjoy comedy shows and taking outdoor excursions.

"We have a sunset boat tour here in Sarasota that I enjoy at least once a month," she said. "In the hospital, you're go, go, go. It's a great change of pace and helps me reset."

As for her future, she is interviewing for hematology-oncology fellowship programs, exploring interests that range from cellular therapies and CAR-T research to bone marrow transplantation.

"The way oncology is developing, most clinicians end up specializing in one disease because there's so much complexity," she said. "Right now, my plan is to focus on myeloma, but I'm definitely open to areas like lymphoma or cellular therapies."

When asked about emerging trends she finds exciting, she mentioned nanotechnology and its potential applications in medicine.

"There was an article about tiny chips that can deliver medicine and monitor doses inside the body," she said. "I don't have a biomedical background, but is fascinating to me."

Maha Hameed, MD, is an PGY-3 internal medicine resident and assistant chief resident at Florida State University (FSU) Sarasota, and 2025 SOHO Young Investigator awardee.

> *"You're taught in [medical] school and residency, myeloma is incurable," she said. "It was fascinating to hear someone make the case for rethinking that."*

COVER STORY

‘A stretch of normal life’ as myeloma patients enter uncharted era

By: **Leah Sherwood**

By the time Craig Chase, a father of two boys who lives in the San Francisco Bay Area, boarded a flight to China in 2017 to join a clinical trial testing an experimental therapy for his high-risk multiple myeloma, he had already exhausted nearly all treatment options.

“I was at the end of my rope,” he said.

Chase was diagnosed in 2014 at the age of 52 after failing to recover from injuries sustained in a fall during a bike ride on Mount Diablo, a well-known East Bay landmark. From the start, his disease was aggressive, and he was considered a very high-risk patient, with extramedullary disease, including plasmacytomas in his mouth. Having gone through multiple lines of therapy, he once again found himself on a waiting list for a clinical trial, this time at Stanford University in Palo Alto.

His chances were slim. As Chase recalled, the physician leading the trial told him he was “well down the list” and that “it was going to be a while.”

The 2010s ushered in the first wave of CAR-T cell therapies, but MM lagged behind other blood cancers.[1] While CAR-T treatments were beginning to show promise in leukemias and lymphomas, patients with myeloma still had no approved options.[2] Many faced a poor prognosis going through numerous regimens, sometimes more than a dozen, with no reprieve in sight.

“Other options back then were just different combinations of drugs a patient had already had before,” said Yi Lin, MD, PhD, a professor of medicine at in Rochester, Minnesota, in an interview with SOHO Insider.

Compelling out of China

As Chase searched for another treatment, he remembered seeing an email describing data from a small phase 1 study conducted in China. The findings had begun circulating on the conference circuit, but access was limited, and the therapy had not yet entered US trials. Investigators in the United States were still uncertain how to interpret the data.

“We were all somewhat skeptical about the data, especially since the patients were all from China, and perhaps there weren’t any heavily pretreated patients in the study,” said Thomas Martin, MD, a professor of medicine at the University of California, San Francisco, who helped Chase pursue treatment at UCSF and China.

With few options left, Chase asked his clinician at the time, Gabriel Mannis, MD, then a hematologist at UCSF, whether he could get in touch with the company behind the experimental therapy with the hopes of being enrolled.

“He seemed a bit perplexed, both of the data and my desire to go to China,” Chase recalled.

Dr. Mannis ultimately reached out to Dr. Martin, and conversations followed. Legend soon agreed to accept Chase into the study.

“They said they would take me,” Chase recalled. “But they wanted to know right away.”

Chase and his wife flew from San Francisco to Shanghai before traveling on to Nanjing, where the trial team was based. It was his first time in Asia and his first time pursuing treatment outside the United States.

“We were curious, excited, and hopeful,” he said.

Craig’s story would become a part of medical history. The product he received, then called LCAR-B38M, was later licensed to Janssen and became known as ciltacabtagene autoleucel (cilta-cel). It is one of the two BCMA-directed CAR T-cell therapies currently approved in the United States and, now eight years later, once again drew significant attention at ASCO 2025.

Legend Biotech

In 2014, a small biotechnology company called Legend Biotech was founded in Nanjing, one of China’s oldest cities. Now headquartered in the United States, with a large global base of operations in New Jersey, Legend began with little visibility; by the company’s own account, it was operating out of a space in Nanjing no larger than a freight elevator.[3]

At the time, Legend had no public profile or website, and no track record in drug development. That early anonymity would later fuel skepticism when the company's first clinical data began to circulate.

Legend's scientists were investigating a novel chimeric antigen receptor T-cell therapy targeting B-cell maturation antigen, or BCMA, a protein expressed on malignant plasma cells in MM. The approach involved collecting a patient's own T cells, genetically engineering them to recognize BCMA, and reinfusing them to attack the cancer.

Just about the time Chase was searching for treatment options, in June 2017, investigators on the study presented early results from a phase 1 study at the ASCO annual meeting. Among the first 35 heavily pretreated patients, the response rate was 100%, with a high proportion achieving complete response.

The reaction in the room was disbelief.

Ying Huang, CEO, Legend Biotech

"I was sitting in that same seminar room," said Ying Huang, PhD, who at the time was a biotech analyst and would later become Legend's CEO. "I think everyone had the same feeling. This is too good to be true."

Dr. Huang said the results immediately raised questions about the company itself.

"We had never heard about this company," he said. "After the seminar, I went back to my hotel room and did a Google search for Legend Biotech. There was nothing. The company didn't even have a website."

The skepticism was not limited to Legend's obscurity. Clinicians and scientists questioned whether the data could be replicated and whether the responses would hold up in a larger population.

"The first reaction was, is this real?" Dr. Huang said. "Is this really backed by good science, and can this data be reproduced in more patients?"

'You're not stopping it'

When Chase arrived at the clinic in China, he said the hospital felt full of humanity and care, even though the cultural differences were immediately apparent.

"It was culturally a big shift because we didn't speak the language," Chase said. "I was in waiting areas with patients who spoke no English. It was a little scary at first, but the experience was also thrilling."

By Chase's account, the treatment was challenging. After infusion, he developed cytokine release syndrome, a dangerous immune overreaction triggered by the therapy.

"At one point, things got pretty bad," he said. "I had a 106-degree fever. I could hardly breathe."

The medical team discussed administering a steroid to help control the immune reaction, a step that would have most likely stopped the treatment's effects altogether. Chase and his wife had already agreed that this would not be an option.

"We didn't go through all of this, separate from our family and travel halfway around the world, just to stop it," Chase said. "That would have meant coming home and dying."

His wife met with the physicians and made their position clear.

"She told them, 'You're not stopping it,'" Chase recalled. "He's either going to recover and let the medicine do what it's supposed to do, or he won't."

A few hours later, Chase said, his condition began to improve.

"I started to turn the corner," he said. "From there, I really went on to feeling pretty good, considering everything."

A long stretch of normal life

Chase began to recover in a way he had not experienced in years. He said the CAR-T therapy gave him a long stretch of normal life that had once seemed impossible.

"I was a year and a half without any treatment, and I had been blowing through treatments prior to that," he said. "I had a spell of great, normal life. We returned, and it was great to be free of the medication anchors that were in place at the time."

Returning home to his children after two months in China was an "incredibly emotional" moment, he recalled.

"I'll never forget pulling into the driveway," Chase said. "My two sons were at the house. I remember thinking at that time that no matter what the outcome, it was worth it because it was life affirming."

When Chase returned home, he was told he was in complete remission and had no measurable residual disease.

"It just blew me away," he said.

Chase's results helped draw the attention of the US pharmaceutical community to the experimental therapy, according to Dr. Martin.

"Many of us, including me, think that Craig is what prompted the US pharmaceutical industry to say, hey, let's try that CAR-T in the US," Dr. Martin said, adding that Chase was a heavily pretreated patient, meaning the kind of patient many doubted could achieve such a deep remission.

> *These amazing results are in patients who received cilta-cel after 6 prior therapies. When we start using these therapies as part of frontline or initial therapy or for early relapse, we are hoping this will translate into cure for many more patients. The expectation from the get-go will be cure—not for patients to have a chronic illness.*

Moving quickly

For Janssen's part, after seeing the early results from China, the company moved quickly, entering a collaboration and licensing agreement for the therapy from Legend in December 2017,4 just six months after the early data had become public.

In the spring of 2018, the company launched a new clinical program, later known as CARTITUDE-1, a phase 1b/2 trial that would go on to serve as the pivotal study to support the product registration in the United States.

Dr. Lin, an investigator on the CARTITUDE-1 trial, credits Janssen with "making the right call" to partner with Legend Biotech and bring the CAR T-cell therapy into trials in the United States.

The five-year results from the CARTITUDE-1 trial were published in the Journal of Clinical Oncology in 2025[5] and were presented at both the ASCO® Annual Meeting and the European Hematology Association Congress that same year.

The data were hard to ignore. At ASCO®, the investigators reported that the durability and depth of responses achieved without maintenance therapy were unprecedented in such a heavily pretreated patient population.

Of the 97 patients enrolled in the trial, investigators reported that 32 patients remained progression-free without additional therapy following a single infusion.

In its annual report, the American Association for Cancer Research described the results a "major milestone" and described the therapy as "potentially curative."[6]

"These are very, very exciting results," Dr. Lin said. "This is one-third of the patients treated on that clinical trial, and these are late-line patients. The median line was six prior therapies. Some had up to 18."

Five years without therapy for patients accustomed to frequent clinic visits and ongoing treatment can feel like a lifeline after years of constant care.

"Being five years out, not needing any antimyeloma treatment, still in remission, that's five years from a quality-of-life standpoint," Dr. Lin said. "Not being tied down to a clinic for a weekly injection. They can travel; they can do things. This is very powerful."

She said patients often describe the experience as emotional.

"After just a few months, I've had patients tell me, 'I'm finally remembering what my life was like before I had MM,'" she said. "They can simply enjoy life. That's what's so powerful about a treatment-free period."

It is time to say 'cure' in MM

"At EHA this year, I heard the word 'cure' more times in one talk than ever in my life," Dr. Martin said. "The talk was by this wonderful professor right here, and that's why we asked him to talk about 'cure' in myeloma at SOHO 2025."

Dr. Martin was referring to Sundar Jagannath, MBBS, a professor of medicine in hematology and medical oncology at the Icahn School of Medicine at Mount Sinai and the Tisch Cancer Institute.

It was September, a few months after the CARTITUDE-1 data were released, and Dr. Jagannath was about to take the stage at the Thirteenth Annual Meeting of the Society of Hematologic Oncology to talk about cure in myeloma.

"In the 1990s and early 2000s, we used the mantra 'treatable but not curable,'" Dr. Jagannath said. "Then more recently, it became 'a chronic disease that we can control with continuous maintenance therapy.' Those are all terminology we should get rid of. We can cure patients."

Language matters

Dr. Jagannath also argued that it is time to move past qualifiers such as "functional cure" or "operational cure."

A cure, he said, should mean a sustained complete remission lasting five years or longer without maintenance therapy.

For decades, that standard felt out of reach, particularly for patients with relapsed disease. But Dr. Jagannath said growing evidence now supports overtly using the word.

Data from CAR T-cell trials, including CARTITUDE-1, show that a subset of heavily pretreated patients can achieve deep remissions that persist for years after a single infusion, without ongoing therapy, according to Dr. Jagannath.

He added that similar patterns are beginning to emerge in other modern trials.

"This is a new kind of outcome for late-stage disease," Dr. Jagannath said.

He argued that language matters. Calling a disease incurable shapes how clinicians treat patients, how regulators evaluate therapies, and how patients imagine their futures.

"If you feel like you're going to cure the patient, it is a completely different approach," he said. "How you treat the patient, how you manage them, and how you talk to them."

Cure also provides patients with hope that they will not be afflicted forever with an incurable, fatal disease.

Pointing to the long-term follow-up from CARTITUDE-1, Dr.

Jagannath said the definition of cure can already be met in practice for some patients treated with cilta-cel.

"At my center, patients received a single infusion and went on to years without additional therapy," he said. "That meets the definition of cure."

Survivorship as part of the care plan

Eight years after Chase's flight to China, he remains on myeloma

treatment but is active, optimistic, and focused on the life he is able to live.

"I ski; I'm very active," he said. "I'm going to see my first grandchild born this December."

He also credits his wife for her long-term support.

"We celebrated our 40th this year and she has been an absolute rock, both in China and here at home," he said. "It's hard to imagine anyone taking this path without the inspiration and support of their person and she has been that for me."

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Clinicians do not fully understand why some patients experience long, treatment-free remissions after CAR T-cell therapy while others do not. Researchers have identified clues, Dr. Lin said, but there is no reliable way to predict outcomes in advance, and many patients fall somewhere between clear success and clear failure.

"I wish we had a crystal ball," Dr. Lin said. "We don't. That is why there are clinical trials trying to understand which patients have the benefit of the treatment-free period and whether we can predict who won't."

As myeloma experts continue to debate the meaning of "cure" in academic halls, Dr. Lin said it is time to start talking to patients more confidently about survivorship, given that some of them will experience five years or more free of myeloma.

The field, she added, needs to be "braver" in how it communicates success and to begin treating survivorship as part of the care plan, as is done in lymphoma.

"For myeloma, we don't have that because we're always telling them their disease could come back," she said. "But if they can have this remission period, isn't it important for them to be able to focus on life again?"

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SOHO names 2026 and 2027 presidents-elect

The Society of Hematologic Oncology has announced its next two presidents-elect. Valeria Santini, MD, will assume the president-elect position for 2026 and serve as president for the 2027 term, followed by Selina Luger, MD, who will serve as president-elect in 2027 and then president in 2028.

Dr. Santini, who is an associate professor of hematology at the University of Florence Medical School in Italy, has been part of SOHO since the society's inception in 2012 and serves on the Education Committee, which develops the scientific and educational content of the annual meeting. In addition to the education committee, Dr. Santini also serves on the Steering Committee and 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 to become president-elect. It's truly amazing, especially as someone not based in the US, because it makes the role even more meaningful."

Dr. Santini will assume the role of SOHO president on September 12, 2026, once the Fourteenth Annual Meeting has concluded. (SOHO 2026 is scheduled for September 9–12, 2026, in Houston at the George R. Brown Convention Center.)

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 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 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 to 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 about the availability of therapies and to "ensure treatment is feasible," she said.

"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.

REGULATORY ROUNDUP

Tracking regulatory news worldwide

DARZALEX FASPRO® gets FDA approval to treat HR-smoldering multiple myeloma

The US Food and Drug Administration has approved daratumumab co-formulated with hyaluronidase (DARZALEX FASPRO®), as a single-agent therapy for adults with high-risk smoldering multiple myeloma.

The approval was announced by Johnson & Johnson in a press release on November 6, 2025. The company said in the release that the therapy is the first and only approved treatment for HR-SMM.

The FDA approval is based on findings from the phase 3 AQUILA study, which showed that daratumumab monotherapy in patients with HR-SMM demonstrated "an opportunity to delay or even prevent end-organ damage and progression to MM while maintaining quality of life and improving survival," according to the investigators of that study.

The phase 3 AQUILA study is a randomized, multicenter study comparing treatment with DARZALEX FASPRO® to active monitoring in patients with SMM. Patients received single agent DARZALEX FASPRO® as a fixed-duration treatment for up to 36 months.

"Until now, patients diagnosed with smoldering multiple myeloma only have the option to watch and wait for any active signs of progression to active disease," Peter Voorhees, MD, director of outreach for hematologic malignancies, of Atrium Health/Levine Cancer Institute in Charlotte, North Carolina, said in the J&J release. "Results from AQUILA demonstrated DARZALEX FASPRO significantly delayed disease progression, underscoring the role of early disease intervention for patients with high-risk smoldering multiple myeloma."

Novel AML product candidate granted orphan drug designation by FDA

Novel product candidate M2T-CD33 (LTI-214) was granted orphan drug designation by the FDA for the treatment of acute myeloid leukemia.

M2T-CD33, which is manufactured by Leukogene Therapeutics, a preclinical-stage biopharmaceutical company, is an immunotherapy that targets CD33. According to the company, preclinical studies have shown a favorable safety profile with minimal off-target toxicity.

"We are honored that the FDA has recognized the therapeutic promise of LTI-214 by granting orphan drug designation," Sandeep Gupta, CEO of Leukogene, said in a press release. "AML remains one of the most challenging hematologic cancers, and outcomes for relapsed or refractory patients remain poor. The LTI-214 program embodies our commitment to advancing new immunotherapy approaches that are both potent and safer for patients. This designation represents an important step toward our goal of transforming the treatment paradigm for AML."

FDA grants 510(k) clearance to MM diagnostic platform

The FDA granted 510(k) clearance to the EXENT® Analyser and Immunoglobulin Isotypes (GAM) Assay, a first-of-its-kind automated platform for detecting and isotyping M-proteins in patients with MM and related disorders.

The EXENT System offers increased sensitivity for low-concentration M-proteins by molecular weight, reducing subjective interpretation and flagging exogenous ones from therapeutic antibodies. It supports evaluation of MM, smoldering MM, Waldenström's macroglobulinemia, amyloid light chain amyloidosis, and monoclonal gammopathy of undetermined significance. The platform provides up to six hours of walkaway time per shift and requires no mass spectrometry, according to the press release from Thermo Fisher Scientific, the manufacturer.

"The clearance of the EXENT System represents a significant advancement in the tools available to aid in the diagnosis of multiple myeloma," said Noemi Puig, MD, of the department of hematology at the University Hospital Salamanca. "By combining increased sensitivity with ease of use and automated workflows, laboratories can achieve greater clarity and diagnostic confidence, ultimately supporting improved patient care."

The EXENT System is now available in the US and more than a dozen countries worldwide, including Australia, Belgium, Brazil, Canada, France, Germany, Italy, the Netherlands, New Zealand, Spain, Switzerland and the United Kingdom, according to the company.

"Our continued goal is to equip laboratories and clinicians with technologies that deliver greater accuracy, efficiency and clarity, enabling more informed clinical decisions and improving the patient journey," said Stephen Harding, vice president and general manager, protein diagnostics, at Thermo Fisher Scientific, in the release.

US FDA grants interchangeable designation for denosumab-bnht

The FDA granted interchangeable biosimilar designation to denosumab-bnht (Bomyntra) for patients with MM to prevent skeletal-related events, bone metastases from solid tumors, refractory hypercalcemia of malignancy, and unresectable giant cell tumor of bone, according to Fresenius Kabi, the manufacturer of denosumab-bnht.

The designation aligns with FDA draft guidance to simplify biosimilarity studies, reduce clinical testing, and ease interchangeability, allowing pharmacy substitution for biologics that drive 51% of drug spending in the United States despite 5% of prescriptions, according to a press release from the FDA.

Since the Biologics Price Competition and Innovation Act in 2010, the FDA has approved 76 biosimilars, including ones to treat various cancers.

Targeted immune CTCL therapy set for US launch in Q4 2025

Citius Oncology, Inc., a subsidiary of Citius Pharmaceuticals, has entered into an exclusive agreement with Eversana to lead the US commercialization of denileukin diftitox-cxdl, a novel immunotherapy for adults with relapsed or refractory stage 1 cutaneous T-cell lymphoma after at least one prior systemic therapy.

Under the partnership, Eversana will serve as Citius Oncology's sole commercialization partner, providing integrated services across market access, distribution, and patient support. The therapy is expected to launch in the United States in the fourth quarter of 2025.

Denileukin diftitox-cxdl was approved by the FDA in August of 2024, and is the only systemic treatment for CTCL that targets

the IL-2 receptor on malignant T-cells and T-regs, according to the press release announcing the agreement.

FDA approves ziftomenib for relapsed or refractory NMP1-mutated AML

The FDA has approved the menin inhibitor ziftomenib (KOMZIFTI) for the treatment of relapsed or refractory NMP1-mutated AML in adult patients who have no alternative treatment options.

The FDA approval is supported by the pivotal KOMET-001 trial, which evaluated the safety and efficacy of ziftomenib in 112 patients with relapsed or refractory NMP1-mutated AML. The rate of complete remission plus CR with partial hematologic recovery was 21.4% (95% CI, 14.2, 30.2). The median duration of CR+CRh was 5.0 months (95% CI, 1.9, 8.1) and the median time to first response in patients who achieved a CR or CRh was 2.7 months (range, 0.9 to 15 months), according to a press release from Kura Oncology.

"KOMZIFTI addresses a critical need for adult patients with R/R NPM1-m AML, many of whom are older and unable to tolerate intensive chemotherapy or transplant," said Eunice Wang, MD, chief of the leukemia service and professor of oncology at Roswell Park Comprehensive Cancer Center. "The clinical data demonstrate deep and durable responses with a manageable safety profile, including no drug-drug interactions and no Boxed Warnings for QTc prolongation or Torsades de Pointes — key advantages for patients on multiple concurrent medications. This approval equips physicians with a new oral therapy to integrate into care and improve outcomes for this vulnerable patient population."

The recommended ziftomenib dose is 600 mg taken orally once daily until disease progression or unacceptable toxicity, and the prescribing information includes warnings and precautions for differentiation syndrome, QTc interval prolongation, and embryo-fetal toxicity, according to an FDA press release.

FDA approves epcoritamab combo in R/R FL

The FDA has approved epcoritamab (EPKINLY®) in combination with rituximab and lenalidomide (EPKINLY + R2) for adult patients with relapsed or refractory follicular lymphoma.

This FDA approval marks the third indication for epcoritamab, according to Genmab, the manufacturer of the drug.

The FDA approval is based on the phase 3 EPCORE FL-1 trial, a randomized, open-label trial that enrolled 488 patients with relapsed or refractory FL. The prescribing information includes boxed warnings for cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, as well as warnings and precautions for infections and cytopenias, according to a press release from the FDA.

"Recurrent follicular lymphoma can be an incurable, complex, and persistent disease, creating a clear need for additional treatments that can change its course earlier in the treatment journey," said Lorenzo Falchi, MD, a lymphoma specialist at Memorial Sloan Kettering Cancer Center, in a press release from Genmab. "The results shown with EPKINLY + R2 in the EPCORE FL-1 study are incredibly meaningful, demonstrating durable responses compared to patients treated with R2 alone. These data, delivered by a regimen that's chemotherapy-free and can be administered in the outpatient setting, suggest that EPKINLY + R2 could potentially become a new standard of care."

Tafasitamab gets positive CHMP opinion in R/R FL

The trial showed that the treatment reached its primary endpoint and that the treatment was well tolerated, with a manageable safety profile.

EC approves tafasitamab combo in relapsed FL

The European Commission has approved tafasitamab (Minjuvi®) in combination with lenalidomide and rituximab for adult patients with relapsed or refractory FL grade 1-3a after at least one prior systemic therapy.

The approval is based on the phase 3 inMIND trial, which showed statistically significant improvement in progression-free survival with the combination versus lenalidomide and rituximab alone.

This is the second indication for tafasitamab in Europe.

FDA approves liso-cel in relapsed or refractory MZL

The FDA has approved lisocabtagene maraleucel (liso-cel; Breyanzi), a CD19-directed CAR T-cell therapy, for adult patients with relapsed or refractory marginal zone lymphoma after at least two prior lines of systemic therapy. Liso-cel is now the only CAR T-cell therapy approved for five different blood cancers, according to BMS, the drug's manufacturer.

In the MZL cohort of the phase 2 TRANSCEND FL study, patients with relapsed or refractory disease responded strongly to a single infusion of liso-cel. The overall response rate was 95.5% and the complete response rate was 62.1%. Median duration of response was not reached, with 90.1% of responders remaining in response at 24 months, according to a press release by BMS.

FDA grants traditional approval to pirtobrutinib in relapsed or refractory CLL/SLL

The FDA granted traditional approval to pirtobrutinib (Jaypirca), a noncovalent Bruton's tyrosine kinase inhibitor, for adults with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma who have previously received a covalent BTK inhibitor. This approval converts the 2023 accelerated approval for patients after at least two prior lines, including a BTK inhibitor and BCL-2 inhibitor.

The approval is based on the phase 3 BRUIN-CLL-321 trial, which randomized previously treated patients to pirtobrutinib or investigator's choice of idelalisib plus rituximab or bendamustine plus rituximab. Pirtobrutinib extended progression-free survival compared with the control arm; the median PFS was 11.2 months in the pirtobrutinib arm and 8.7 months in the investigator's choice of IR/BR arm, according to a press release from Eli Lilly, the manufacturer of the drug.

The review used the Assessment Aid, a voluntary submission from the applicant to facilitate FDA assessment.

Liso-cel receives expanded approval in R/R MCL by EC

The EC expanded approval of liso-cel in patients with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy.

The approval of the expanded indication is based on results from the TRANSCEND MCL trial, in which 82.7% of patients responded to liso-cel, with 71.6% of patients achieving complete response, according to BMS.

The expanded approval is applicable to all EU member states as well as the European Economic Area countries Iceland, Norway and Liechtenstein. Liso-cel is also approved in the EU for diffuse large B-cell lymphoma, high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma.

Latest from the conference floor

SOHO Insider *reports on the 1st SOHO Breakthroughs in Blood Cancers Meeting.*

Safer, more effective ALL therapies still needed

Novel agents have transformed outcomes for patients with relapsed or refractory acute lymphoblastic leukemia (ALL), said Selina Luger, MD, of the University of Pennsylvania, during her SOHO Breakthroughs in Blood Cancers session.

Even with these advances, relapse and treatment-related toxicities remain major challenges, according to Dr. Luger.

Dr. Luger explained that outcomes after transplant continue to vary widely by risk group. In several studies, she noted that "survival was primarily because of nonrelapsed mortality." In high-risk patients with a donor, two-year mortality reached 36%, compared with 14% in those without a donor and 20% in donor-positive patients with standard-risk disease. She added, "Patients who are MRD negative after induction are less likely to actually need a transplant, but those who are MRD positive are more likely to need a transplant."

Treating younger patients

"The next real advance that we made in ALL was understanding that we needed to treat younger patients differently," she said. She pointed to CALGB 10403, where younger adults treated with a pediatric-inspired regimen had far better outcomes than in prior adult trials.

"MRD remains very important," she said, noting the 85% three-year disease-free survival in patients who were MRD-negative at the end of induction.

Reshaping ALL treatment

"We have an unmet need for therapies that are more effective and less toxic," she said, describing the transition to the new agents now shaping ALL care.

She highlighted the three therapeutic classes reshaping relapsed or refractory ALL treatment: inotuzumab ozogamicin (Besponsa), a CD22-targeted antibody-drug conjugate; tisagenlecleucel (Kymriah), a CAR T-cell therapy; and blinatumomab (BLINCYTO®), a bispecific T-cell engager.

The pivotal phase 3 INO-VATE study evaluated inotuzumab ozogamicin against the standard intensive therapy in relapsed or refractory B-ALL, which showed higher remission rates than standard chemotherapy. That study showed that the rate of complete remission was higher with inotuzumab ozogamicin.

"The major toxicity, however, was hepatic toxicity, and this led to increased toxicity of transplant when done after inotuzumab, with an increased incidence of veno-occlusive disease," Dr. Luger said. "We have learned how to manage that more these days by spacing out the time between inotuzumab and transplant, decreasing the total number of cycles and dose, and by also using ursodiol."

The pivotal ELIANA trial evaluated tisagenlecleucel in patients ≥3 years at screening and ≤21 years at diagnosis. She reported that more than five years of follow-up showed an 82% overall response rate, 49% relapse-free survival, and 55% overall survival in patients, with durable efficacy and no late adverse effects.

"Tisagenlecleucel remains a potentially curative option," Dr. Luger said.

The other two CAR T-cell therapies she mentioned were brexucabtagene autoleucel and obecabtagene autoleucel, both of which show strong response rates across age groups.

The phase 3 TOWER trial showed that patients treated with blinatumomab had "significantly longer overall survival" compared with standard chemotherapy. Dr. Luger also noted that patients with high tumor burden respond less well, with lower complete remission and MRD response rates.

Dr. Luger also discussed promising chemotherapy-free approaches and reviewed recent ASH and EHA presentations, which included long-term follow-up from CALGB 10403 and updated results from E1910.

Rami Komrokji, MD, discusses current state of MDS treatment at SOHO breakthroughs meeting

At the SOHO Breakthroughs in Blood Cancers meeting, Dr. Komrokji of the Moffitt Cancer Center delivered an update on where the field of myelodysplastic syndromes is moving, including news on the molecular classification system and the role of anemia-directed therapies in patients.

Dr. Komrokji opened by noting that MDS is thought to be "the most common myeloid neoplasm" and that the field is finally seeing the molecular clarity needed to guide treatment. The WHO and ICC classifications, once distinct models, are now converging, with molecular groups taking priority over morphology. TP53-mutated MDS, del(5q), and SF3B1-mutated disease now anchor the main biologic categories.

Patients who become transfusion-dependent see survival decrease below five years. He said that is driven by marrow failure and cardiovascular complications linked to clonal hematopoiesis.

He also noted that lower-risk MDS is not purely palliative.

Updated data from the COMMANDS trial reinforce luspatercept's role across frontline lower-risk MDS, with doubling of response rates and durability compared with ESAs. Nearly one-third of patients achieved >18 months of transfusion independence, particularly those with high endogenous EPO levels (>200).

Early signals of overall-survival separation at three years hint at the long-term value of correcting anemia.

Early combination data, such as luspatercept plus ESA for secondary failures, show promise, with response rates at approximately 30%.

Dr. Komrokji also highlighted the IMerge study of the telomerase inhibitor imetelstat, now approved for ESA-refractory lower-risk disease. The agent delivered transfusion independence in 40% of patients, with durable responses approaching one year and meaningful hemoglobin improvements across RS-positive and RS-negative subsets.

Dr. Komrokji also pointed to new AI-supported modeling that integrates the molecular scoring systems to refine optimal timing for allogeneic transplant. In roughly one-third of patients, molecular restratification would shift transplant timing.

Login to your SOHO account to access all the SBBC sessions.

SOHO Insider *reports from the 2025 Society for Immunotherapy of Cancer (SITC)*

Natural killer T-cells show promise for 'off-the-shelf' cancer immunotherapy for NHL, ALL

Allogeneic natural killer T-cells (NKTs) expressing CD19-specific chimeric antigen receptors (CARs) are well tolerated and can mediate objective responses in non-Hodgkin lymphoma (NHL) and relapsed acute B-cell acute lymphoblastic leukemia (ALL) patients who relapsed following multiple salvage protocols, including commercial CAR-T products, according to a poster presentation presented at the 2025 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

The researchers generated a bank of healthy donor NKTs that co-express a CD19-specific CAR, IL-15, and shRNA targeting beta-2-microglobulin and CD74 to downregulate HLA class I and II expression, respectively. They then assessed the safety, persistence, and efficacy of these allogeneic CD19-CAR-NKTs in ANCHOR, a first-in-human phase 1 dose-escalation trial for patients with relapsed or refractory B-cell NHL and relapsed ALL.

No dose-limiting toxicities related to CAR-NKTs were observed. Two cases of grade 2 or lower CRS and one case of grade 3 neurotoxicity were observed, but in all instances resolved quickly. Four out of nine patients with NHL achieved an initial partial response four-to-six weeks after infusion that in two cases evolved into a complete response by three months post-infusion. Additionally, two out of three patients with ALL achieved an objective response.

The authors noted that whereas autologous cell products are costly and time-consuming to produce and demonstrate variability in potency and toxicity, monomorphic CD1d-restricted Vα24-invariant NKTs are not alloreactive like HLA-restricted T-cells and therefore can be made from allogeneic donors without risking graft-versus-host disease.

"Our data indicate that allogeneic CAR-NKTs are well tolerated and can mediate objective responses in NHL/ALL patients that relapsed following multiple salvage protocols, including commercial CAR-T products," the authors wrote. "Thus, NKTs represent a promising platform for 'off-the-shelf' cancer immunotherapy."

REFERENCE

Courtney AN, Ramos C, Steffin D. A phase I clinical trial of allogeneic NKT cells expressing a CD19-specific CAR in patients with relapsed or refractory B cell malignancies: an interim analysis. Abstract #553. Presented at the 2025 Society for Immunotherapy of Cancer (SITC) Annual Meeting. November 5–9; National Harbor, MD.

IDP-023 demonstrates good safety, efficacy in relapsed or refractory myeloma

In a first-in-human study, IDP-023 demonstrated a promising safety and efficacy profile in patients with relapsed or refractory multiple myeloma, according to findings presented as a late-breaking poster by Krina Patel, MD, of the University of Texas MD Anderson Cancer Center at the 2025 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

The open-label, phase 1/2, dose-escalation and expansion study evaluated adult patients who received IDP-023 as a single agent or in combination with or without interleukin-2 (IL-2) and with or without a CD38 monoclonal antibody (isatuximab, daratumumab, or rituximab).

As of September 22, 2025, 22 patients (median age, 68 years; range, 56–77) had been treated across three dose cohorts: 5×10^9 (n=12), 10×10^9 (n=7), and 20×10^9 (n=3). The median number of prior therapies was six (range, 2–17), and half of patients had received a prior BCMA-targeted therapy, including CAR T-cell therapy.

ADVERSE EVENT	PATIENTS	FREQUENCY
Neutropenia	18	81.80%
Leukopenia	14	63.60%
Anemia	12	54.50%
Lymphopenia	12	54.50%
Thrombocytopenia	11	50%
Hypokalemia	9	40.90%
Diarrhea	8	36.40%
CRS	7	31.80%

Table 1. Treatment-emergent adverse events (≥30% of patients)

No dose-limiting toxicities were observed through the maximum administered dose. None of the patients experienced immune effector cell-associated neurotoxicity syndrome (ICANS), grade 3 or higher CRS, bleeding events or infections (see Table 1 for adverse events).

There were no treatment-related discontinuations or deaths. Investigators noted the safety profile of IDP-023 supports outpatient administration.

Overall, 18 patients (82%) experienced grade 3 or higher treatment-emergent adverse events, none of which led to treatment discontinuation. Deep responses, including very good partial responses or better, were reported across risk categories in this heavily pretreated population. Follow-up is ongoing, and updated efficacy data and the recommended phase 2 dose in combination with a CD38 monoclonal antibody will be reported, according to the researchers.

SOHO Insider *reports from the 67th American Society of Hematology Annual (ASH) Meeting and Exposition*

Updated phase 3 VERIFY results confirm rusfertide significantly improves PV outcomes over SOC

In patients with polycythemia vera receiving standard of care therapy, adding rusfertide to treatment continued to yield a statistically significant reduction in the mean number of phlebotomies and improved hematocrit control, as well as better patient-reported outcomes, according to updated (part 1b) results from VERIFY, a phase 3, double-blind, placebo-controlled study.

Earlier results from part 1a, which were reported in June 2025 at a plenary session at the 2025 ASCO® Annual Meeting in Chicago, demonstrated control of hemocrit <45% and a relative absence of phlebotomies up to week 32. The new part 1b results extend these results to week 52, demonstrating durable and sustained benefits across all subgroups, including age, PV risk category, and ongoing cytoreductive therapy. Similar findings were also observed after patients crossed over from placebo to rusfertide.

Rusfertide, which has received Breakthrough Therapy Designation, Orphan Drug Designation and Fast Track Designation from the US Food & Drug Administration, is a subcutaneous, self-injected, first-in-class peptide hepcidin mimetic that decreases erythrocytosis. The ongoing VERIFY trial is designed to assess rusfertide versus placebo in phlebotomy-dependent patients with PV receiving SOC.

The VERIFY trial, led by Andrew Kuykendall, MD, of Moffitt Cancer Center in Tampa, Florida, recruited patients requiring frequent phlebotomies with or without stable cytoreductive therapy to control hematocrit.

In the part 1b results, the proportion of patients who continued to have an absence of phlebotomy eligibility between weeks 0-52 (ie, patients initially randomized to rusfertide with durable response through the end of part 1b) was 61.9% (n=91/147).

In patients originally randomized to placebo who crossed over to rusfertide at week 32, the proportion of patients who achieved absence of phlebotomy eligibility was 32.9% (n=48/146) and 78.0% (n=110/141) in parts 1a (weeks 20-32) and 1b (weeks 40-52), respectively.

Mean hemocrit remained <43% throughout part 1b in patients who continued rusfertide and those who switched from PBO to rusfertide.

In terms of patient-reported outcomes, patients treated with rusfertide maintained a statistically significant improvement in the PROMIS Fatigue Short Form 8a total T-score and MFSAF v4.0 Total Symptom Score.

Rusfertide's safety profile in part 1b was consistent with prior observations, according to the researchers.

REFERENCE

Kuykendall A, Bankar A, Pettit K. Rusfertide or placebo plus current standard-of-care therapy for polycythemia vera: Durability of response and safety results through week 52 from the randomized controlled phase 3 VERIFY study. Abstract #81. Presented at the 67th American Society of Hematology Annual Meeting and Exposition; December 6-9, 2025; Orlando, Florida.

Epcoritamab triplet may set new standard in 2L follicular lymphoma

Epcoritamab in combination with rituximab and lenalidomide has the potential to be the new SOC in patients with second-line follicular lymphoma, according to results from the phase 3 EPCORE-FL-1 trial.

"E+R^2 [epcoritamab plus rituximab and lenalidomide] sets a new benchmark as a readily available treatment, is suitable for outpatient administration, and has the potential to become a new standard of care in 2L+ FL," the authors wrote in the abstract.

The phase 3 EPCORE-FL-1 trial evaluated the safety and efficacy of epcoritamab, a CD20xCD3 bispecific antibody, in combination with rituximab and lenalidomide compared to rituximab and lenalidomide alone in patients with relapsed or refractory follicular lymphoma.

To be enrolled, eligible patients had to be 18 years and older, have an ECOG performance status of 0–2, be eligible to be treated with rituximab plus lenalidomide, and have relapsed or refractory disease after ≥1 prior anti-CD20–based chemoimmunotherapy regimen, among other following characteristics.

In the presented abstract, the investigators reported that as of the data cut-off date, 488 patients who received the treatment had clear and clinically meaningful improvements over R^2 alone. Patients receiving the combination had higher response and complete response rates, more durable responses, and a longer progression-free survival, translating to an approximately 80% reduction in the risk of disease progression or death. These benefits were consistent across key high-risk subgroups. The safety profile was manageable, with mostly low-grade cytokine release syndrome and infrequent neurologic events, though higher rates of cytopenias and infections were observed with the combination, the investigators reported.

"[Epcoritamab] is the first CD20xCD3 bispecific antibody to demonstrate clinical benefit over standard of care in a randomized phase 3 trial in patients with FL, with statistically significant improvements in ORR, CR rate, and a 79% reduction in the risk of progression or death," the authors wrote.

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Pirtobrutinib significantly improves PFS in patients with treatment-naïve CLL/SLL

Data from a late-breaking abstract presented by Wojciech Jurczak, MD, PhD, of the Maria Sklodowska-Curie National Research Institute of Oncology in Poland, at the 67th ASH Annual Meeting and Exposition "suggest that pirtobrutinib may be considered a potential new standard-of-care treatment for patients with untreated" chronic lymphocytic leukemia/small lymphocytic lymphoma.

Pirtobrutinib is a highly selective noncovalent Bruton's tyrosine kinase inhibitor that has shown efficacy and safety in patients with relapsed/refractory CLL/SLL, though no previously released phase 3 data assessed the outcomes of a noncovalent BTKi in treatment-naïve patients.

The randomized, open-label, global, phase 3 BRUIN CLL-313 trial assessed the efficacy and safety of pirtobrutinib versus bendamustine plus rituximab (BR) in treatment-naïve patients with CLL/SLL.

Patients with del(17p) mutation, central nervous system involvement, Richter transformation, and significant cardiovascular disease were excluded.

Eligible patients (n=282) were stratified by IGHV mutation status (mutated vs unmutated) and Rai stage (low/intermediate vs high) and randomized 1:1 to receive monotherapy pirtobrutinib 200 mg once daily (n=141) or six cycles of BR (n=141).

After a median follow-up of 28.1 months, progression-free survival, as assessed by independent review committee, was significantly improved with pirtobrutinib (P<0.0001); the 24-month PFS rates were 93.4% with pirtobrutinib versus 70.7% with BR, indicating "one of the largest treatment effects ever observed for a single-agent BTKi against the comparator," the authors noted.

The PFS benefit observed with pirtobrutinib was sustained in clinically relevant patient subgroups, including those with mutated IGHV (HR, 0.293) and unmutated IGHV (HR, 0.172). PFS as assessed by the investigators was also consistent with IRC findings (HR, 0.186; P<0.0001).

The HR for overall survival for pirtobrutinib versus BR was 0.257 (P=0.0261), "despite an effective crossover rate of 52.9% (n=18/34 patients with investigator-assessed progressive disease)," the authors noted. The median treatment duration was 32.3 months for 140 patients receiving pirtobrutinib and 5.6 months for 132 patients receiving BR.

Grade ≥3 treatment-related adverse events were reported in 40.0% of the pirtobrutinib group and 67.4% of the BR group. Grade 5 treatment-related AEs were reported in one and four patients, respectively.

Treatment-related treatment discontinuations occurred in six (4.3%) pirtobrutinib-treated patients and 20 (15.2%) BR-treated patients. In the pirtobrutinib group, two patients (1.4%) experienced atrial fibrillation/flutter, occurring in just one of 20 patients aged ≥75 years, indicating that this could be a potential treatment consideration in "older patients who may receive only one line of therapy," the authors noted.

REFERENCE

Jurczak W, Kwiatek M, Czyz, et al. Pirtobrutinib vs bendamustine plus rituximab (BR) in patients with CLL/SLL: first results from a randomized phase III study examining a non-covalent BTK inhibitor in untreated patients. Abstract LBA-3. Presented at the 67th American Society of Hematology Annual Meeting and Exposition; December 6-9, 2025; Orlando, Florida.

'Promising' early-phase results seen with KLN-1010, an off-the-shelf in vivo CAR-T for myeloma

Preliminary phase 1 results of the inMMyCAR trial showed "promising clinical activity and manageable toxicities" associated with the investigative chimeric antigen receptor T-cell therapy KLN-1010 in patients with multiple myeloma.

Results were presented by Phoebe Joy Ho, MBBS, DPhil, FRACP, FRCPA, of Royal Prince Alfred Hospital in Australia, as a late-breaking abstract at the 67th ASH Annual Meeting and Exposition.

KLN-1010 is a novel in vivo gene therapy that generates anti-BCMA CAR-T cells and eliminates the need for apheresis, bespoke ex vivo cell manufacturing, or lymphodepleting chemotherapy, which "may broaden access to CAR-T therapies," according to the authors.

The results presented show the outcomes of the first three patients (aged 61–72 years) dosed with KLN-1010. All patients had adequate end-organ and bone marrow function and received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody. All patients had high-risk cytogenetics, were BCMA therapy-naïve, and did not have extramedullary involvement.

All patients experienced treatment-emergent adverse events; two patients developed an infusion-related reaction that occurred 30 to 60 minutes postinfusion and resolved within six to 48 hours.

Two patients experienced grade 2 CRS during CAR-T expansion, which the authors said was "consistent" with what is seen with ex vivo CAR-T therapies. No immune effector cell-associated neurotoxicity syndrome or delayed neurotoxicity were reported.

Cytopenias were "notably limited," according to the researchers.

No grade ≥3 thrombocytopenia, grade ≥3 hematologic toxicity, or treatment-emergent infections were reported at month one. T-cell expansion occurred despite no preparative chemotherapy, with peak absolute lymphocyte counts between days 13 to 18 at 2.3, 7.37, and 43.1×109/L. CAR-positive cells comprised 35%, 22%, and 72% of CD3+ lymphocytes on day 15.

CAR-T cells were detected in the bone marrow and peripheral blood through month three and were comprised predominantly of memory-phenotype T cells.

All patients were measurable residual disease-negative (at 10-5 or 10-6 sensitivity) one-month post-treatment, and MRD was sustained for more than three months in the patient with the longest follow-up.

All patients achieved a partial response at month one, which deepened over time. The best observed response was a very-good partial response at three months post-treatment. No patients experienced disease progression at the time of reporting.

The study is ongoing, and the researchers are expected to report additional follow-up.

REFERENCE

Harrison S, Ho PJ, Lim SL, et al. Minimal residual disease (MRD)-negative outcomes following a novel, in vivo gene therapy generating anti–B-cell maturation antigen (BCMA) chimeric antigen receptor (CAR)-T cells in patients with relapsed and refractory multiple myeloma (RRMM): preliminary results from inMMyCAR, the first-in-human phase 1 study of KLN-1010. Abstract LBA-1. Presented at the 67th American Society of Hematology Annual Meeting and Exposition; December 6-9, 2025; Orlando, Florida.

REGISTRATION IS NOW OPEN!

SOHO 2026

Fourteenth Annual Meeting of the Society Hematologic Oncology

September 9-12, 2026

George R. Brown Convention Center | **Houston, Texas**

SOHO Egypt 2025 debuts with 2-day meeting in Cairo

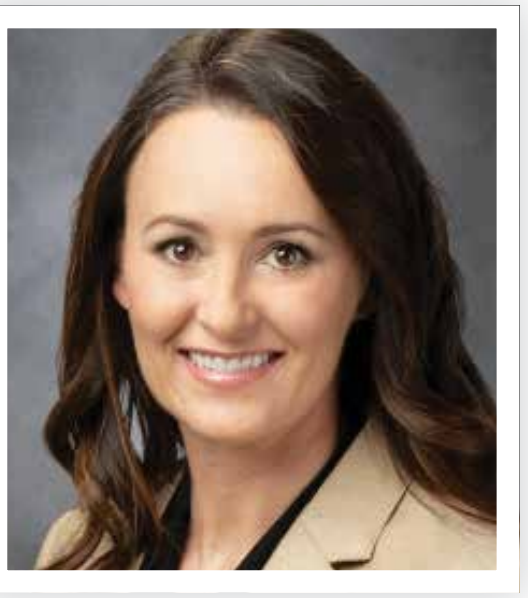
The inaugural SOHO Egypt regional meeting was held November 5–6, 2025, in Cairo at the Intercontinental Cairo Citystars Hotel. The presidents of the meeting were Mohamed Abdel Mooti Samra, MD, dean of the National Cancer Institute at Cairo University, and Hagop Kantarjian, MD, professor in the Department of Leukemia at the University of MD Anderson Cancer Center.

The SOHO Egypt regional meeting was held in conjunction with the Annual Congress of the National Cancer Institute (BGO 2025). That meeting is held annually and covers cancers outside of blood cancers. Its 2025 theme was "Bridging Gaps in Oncology" and it overlapped SOHO Egypt by one day. (BGO 2025 was held November 5-7, 2025.)

Over the two-day period, SOHO Egypt covered such topics as nilotinib in chronic myeloid leukemia, chemotherapy-free management in chronic lymphocytic leukemia, and updates in diagnosing acute myeloid leukemia. The organizers said they hoped to extend the 2026 meeting from two days to three days.

soho Insider

Virtual Community Oncology Brown Bag SERIES



Join *SOHO Insider*, the official media platform of the Society of Hematologic Oncology, for the inaugural **VIRTUAL COMMUNITY ONCOLOGY BROWN BAG SERIES**, an informal lunchtime discussion featuring community oncologists sharing real-world experiences from practice.

The program is led and developed by

LORETTA J. NASTOUPIL, MD.

Community Oncology Brown Bag Series list of events

soho society of hematologic oncology

JANUARY 20, 2026
2:30 – 3:00 PM PST (4:30–5 PM CT)
Expanding access to CAR T-cell therapy outside academic centers
Manali Kamdar
CU Anschutz Medical Campus

FEBRUARY 11, 2026
2 – 2:30 PM CST
Implementing bispecific antibodies in community practice
Tara Graff
Mission Cancer + Blood

MARCH 18, 2026
12:30 – 1 PM CST
Managing access to novel agents in the community setting
Jeffrey Matous
Colorado Blood Cancer Institute

APRIL 2026
TBD
Addressing workforce shortages in oncology
TBD

MAY 15, 2026
9:30 – 10:00 AM PST (11:30 – NOON CT)
Exploration of barriers and solutions for activating and sustaining research programs in nonacademic environments
Jeff Sharman | US Oncology

JULY 2026
TBD
Building partnerships between community and academic centers
TBD

AUGUST 11, 2026
TBD
Integrating new evidence into everyday practice
Xavier Marin
Scripps Clinic Medical Group

SEPTEMBER 2, 2026
12:30 – 1 PM CST
Increasing US representation in global clinical trials
Hans Lee
Sarah Cannon Research Institute

OCTOBER 13, 2026
1– 1:30 PM CST
AI impacting pathology and treatment decisions
Shakira Grant
CROSS Global Research & Strategy, LLC

NOVEMBER 10 2026
NOON-12:30 PST (2 PM-2:30 PST)
How can pharma engage with community oncologists
Nina Shah
AstraZeneca

SCAN THE QR CODE TO REGISTER FOR FREE NOW.