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Accelerating global research and education through scientific exchange

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FEATURED STORY

SPAIN'S POC MANUFACTURING MODEL REIMAGINES CAR-T DELIVERY

While the US relies on centralized, commercial CAR-T manufacturing, Spain is taking a different approach. At Hospital Clínic de Barcelona, POC delivers personalized cell therapies on-site, cutting delays, and expanding access.

Table of Contents

soho Insider

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Sagar Lonial, MD, FACP
Emory University
Winship Cancer Institute

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University of Texas MD Anderson Cancer Center

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University of California, Irvine

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THE FIRST WORD

Letter from the Executive Director

Dear Colleagues,

As the Society of Hematologic Oncology (SOHO) continues to expand and connect with a growing global community, we remain focused on supporting hematologic oncologists through targeted, high-impact programming around the world and at home. This includes our ongoing work with regional meetings and the continued delegation of local experts as SOHO ambassadors, an initiative that has strengthened our ability to share knowledge and foster collaboration globally.

We are also proud to invest in the future of our field through the SOHO Young Investigators Program (YIP). To support the next generation of clinicians and researchers and our SOHO Ambassadors, we have launched a fundraiser that will run through the end of the 2025 Annual Meeting, with all proceeds dedicated to expanding these unique SOHO initiatives.

This year for the first time, SOHO will be holding a preconference clinical success workshop on September 2, 2025, the day before the first day of our Annual Meeting in Houston. This four-hour, CME-certified session on anemia in MDS and MPNs will be led by Drs. Guillermo Garcia-Manero and John Mascarenhas. Together, they bring deep clinical expertise and complementary perspectives on anemia in MDS and MPNs, making them ideal co-chairs for this workshop. We hope you can join us for this new event and stay for the Thirteenth Annual Meeting.

Finally, I would like to share that Sagar Lonial, MD, FACP, has been appointed as the new Treasurer of the society, effective April 1, 2025. We thank Dr. Lonial for his continued service to SOHO as a member of the SOHO Board of Directors and leader of the Education Committee. As Treasurer, Dr. Lonial will be responsible for overseeing the society's financial health and management.

Thank you for your continued partnership and commitment to advancing care for patients with hematologic malignancies. We look forward to sharing more with you in the coming months and to welcoming you to Houston this September.

Sincerely,

Janet M. Cesak, MBA, BS
Executive Director

PS: Don't forget to register for SOHO 2025 or the anemia in MDS/MPN workshop by going to soho.click/2025.

EDITORIAL

The future of leukemia care requires investing in people, not just science

By: **Elias Jabbour, MD**

Professor, Department of Leukemia
The University of Texas MD Anderson Cancer Center

When I was growing up in Beirut during wartime, we faced constant adversity. But I was raised with a mindset that taught me never to take no for an answer. You keep pushing, you keep dreaming big, and you work hard until you get where you need to be. That determination is what drives me today, and it is why I believe we can cure leukemia in my lifetime.

I attended medical school in Lebanon, and after graduating, I completed a hematology and oncology fellowship in France, then moved to Houston in 2001 for further training in hematology and bone marrow transplantation. I had the privilege of being mentored by some of the greatest minds in the field. One of them was Hagop Kantarjian, who offered me a faculty position at the University of Texas MD Anderson Cancer Center in 2007. I loved it immediately. It felt like a dream come true.

Since then, I have worked hard and fully embraced the mission of MD Anderson: to make cancer history and work toward a cure. My work has focused on chronic myeloid leukemia and now acute lymphoblastic leukemia (ALL). I have been fortunate to help lead clinical trials that have transformed treatment. Today, someone diagnosed with ALL can expect a 10-year survival rate of 70%-90%. That was unimaginable when I began my training. We have gone from three years of intensive therapy to six to nine months, with many patients taking oral medication from home.

But our work cannot stop here. My goal is to take what we have built in Houston and bring it to patients everywhere. Not just in Texas, but across the world. I want to bring this model of care to underserved populations in the United States, the Middle East, Africa, Europe, and other regions. I want our trials to be confirmed in diverse settings so that all patients, no matter where they live or what resources they have, can access effective care.

I have been fortunate. I had a supportive family and the opportunity to study in France and the United States. But many brilliant people from my country have lost everything to war and instability. They may be just as capable as me, or even more so, but they have not had the same chances. I believe it is my responsibility not only to care for patients, but to help others walk the same path I did.

One day, someone who had supported me said, “You are one of the best investments I ever made.” That stayed with me.

I believe our greatest wealth is ourselves. Our ability to grow, to give, and to lift others up. That is why I have started a fundraising initiative to support students in Beirut. People can adopt a student, mentor them, and help them pursue the training and education they deserve. These students can become outstanding doctors and fulfill their purpose, just as I have been able to fulfill mine.

I love what I do. It is my passion and my life’s work, and I want to help the next generation fulfill their dreams too.

Learn more on how to mentor a student impacted by war

Upcoming 2025 Events

May 7–10
The American Society of Pediatric Hematology/Oncology
LOUISVILLE, KENTUCKY

May 8–10
SOHO Brazil
SÃO PAULO

May 15–16
3rd SOHO Israel Annual Meeting
TEL AVIV

May 30–June 3
American Society of Clinical Oncology
CHICAGO

June 12–15
The European Hematology Association
MILAN

June 17–21
International Conference on Malignant Lymphoma
LUGANO

July 20–25
ASCO/AACR Methods in Clinical Cancer Research Workshop
LA JOLLA, CALIFORNIA

July 24–27
Debates and Didactics in Hematology and Oncology
SEA ISLAND, CALIFORNIA

September 3–6
13th Annual Meeting of SOHO
HOUSTON, TEXAS

October 19–22
IDWeek2025
ATLANTA

November 10
SOHO Breakthroughs in Blood Cancers
VIRTUAL

December 6–9
67th American Society of Hematology Annual Meeting and Exposition
ORLANDO, FLORIDA

THE EVOLVING LANDSCAPE OF ANEMIA IN MDS & MPN:
CLINICAL UPDATES AND BEST PRACTICES

Half-day Presession Prior to the Society of Hematologic Oncology Annual Meeting (SOHO 2025)

Join us for this Clinical Success Workshop, Expert Roundtable, Open Mic Q+A, and Dinner

September 2, 2025

2:00 PM – 6:00 PM (US-Central Time)
Hilton Americas-Houston | Houston, TX

CO-CHAIRS

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Houston, TX, USA

John Mascarenhas, MD
Tisch Cancer Institute
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This activity is supported by educational grants from Bristol Myers Squibb and Geron.

PATHWAYS & PERSPECTIVES

Professor Charles Craddock

Meet Charles Craddock, CBE, FRCP (UK), FRCPath, DPhil, FMedSci, a professor of hemato-oncology at the University of Birmingham in the United Kingdom. A leader in transplant and cell therapy, Dr. Craddock has spent a lifetime building global clinical trial networks and advancing blood cancer research. Now, he's helping launch SOHO UK in 2026, an ambitious new chapter in international collaboration. With characteristic energy, he's working alongside colleagues to shape a program that reflects the depth and excellence of hemonc in the UK.

What drew you into the field of hematologic oncology?

I was fascinated as a child with being a doctor, having been inspired by my grandfather who worked in a mission hospital in central Africa. However, once I took my medical exams and rotated through the general medical disciplines, I became a little disillusioned because I found that in many of the disciplines such as chest medicine and cardiology—although scientifically fascinating—the interactions with patients were actually often quite brief. It wasn't until I was at the Hammersmith Hospital in London that I understood that hematology offers the best of both worlds. I was working with John Goldman, who was really a genius hematologist. He was pivotal in developing imatinib. He was the first person in the UK to perform a transplant for leukemia. His example gave me a profound insight into how science can be used to develop transformative new therapies. At the same time, I came to realise that hematology is a very special discipline because it gives you the opportunity to build long-term relationships with patients, which I have found to be one of the most fulfilling aspects of medicine.

Before I discovered hematology, I really was on the point of giving medicine up, either to be a lawyer or a crab fisherman. I think I probably would have been a very good crab fisherman. I certainly would have been a useless lawyer and so feel very lucky to be where I am at the moment.

Can you tell us about your current appointments?

I've been in Birmingham since 1999, working in stem cell transplantation. I came here because the opportunity arose to build a large transplant program on the basis of quite a small existing unit. I've spent my last 20 odd years working happily with colleagues to try to develop transplant and now cell therapy programs. In the last ten years, I've been absolutely fascinated by trying to build infrastructures allowing rapid recruitment for patients to clinical trials. We started initially with regional recruitment networks, but more recently we've established two national trial acceleration networks: the TAP (Trials Acceleration Program) and more recently, IMPACT, one of only two transplant and cell therapy trial networks in the world.

What are some of the challenges in implementing these multdisciplinary and multi-inter-agency programs?

I have learnt that the greatest source of inspiration comes from working with patients at the clinical coalface. It's only by looking after a lot of patients that one starts to understand what are the important clinical questions that are, as of yet, unanswered. In the last ten years, two key questions have emerged. First: what are the most important trials to allow us to rapidly assess the exciting tsunami of new drugs, cellular and transplant therapies? Second: Given that many critical clinical questions can only be answered through randomized, prospective trials, how do we build networks capable of conducting them? In this context the two national networks we have established, ACT and IMPACT, have been entirely transformational and together have resulted in more than 3,000 patients being randomized into prospective haemato-oncology and transplant trials.

Having identified what some of the important clinical questions are, and then having identified how you might answer them, the question is, how do you raise the money to do this? We've had two approaches there. In the first iteration, we were entirely dependent on philanthropic money to fund the TAP and IMPACT networks. We worked with charities across the UK, and persuaded these philanthropic organizations of the impact on patients that delivering high-quality clinical trials can bring. But bang, we were hit by COVID and lost most of our philanthropic funding, simply because during COVID, charities couldn't get people to run marathons or climb Everest. In response we have established an academically driven social enterprise trial delivery model, ACT—Accelerating Clinical Trials Limited (www.ACT4patients.com). ACT was established as a company limited by guarantee, which in

the UK means that whilst it's commercially nimble it's more like a foundation and re-invests any surplus funds it generates back into a clinical trials infrastructure. ACT therefore now funds the TAP and IMPACT networks and—because it is nimble and fast in trial delivery—is proving highly attractive to global pharmaceutical companies for the delivery of both industry sponsored and collaborative academic trials. Critically, ACT is able to generate clinical trial data of the quality required to support registration with a regulatory authority and so delivers a CRO function within the context of an academically directed trial network.

> *It's the team that not only shares the work, but also provides the support, encouragement, and laughter.*

It's increasingly clear that in 2025 there's a profound recognition of the importance of trial acceleration networks that are capable of delivering the quality of trial data, particularly pharmacovigilance, that's required for licensing by the FDA or EMA. There is also a recognition that academic clinical groupings, particularly with a large population base, are able to do this as well as, if not better than, conventional global CROs.

Finally, we must remember that we're really in a partnership in terms of improving patient outcomes with the global pharmaceutical sector. There are aspects of how global pharma operates that we may not wish to support, but at the core, our goals are aligned: to bring new treatments to patients whose outcomes with standard therapies are poor. I think there is also an increasing recognition that there is real value and impact to patients on delivering registration standard data, which means that you align your ambitions with a number of other partners. Government partners want to see that, but also the pharma partners want to see that. I think that creates a virtuous circle.

What have been some meaningful collaborations in your career?

One of my greatest pleasures has been building really good relationships with colleagues in the US and Europe. We've built strong links with MD Anderson and with many other fantastic colleagues throughout the US. I think particularly of collaborations with Naval Daver at MD Anderson, Gail Roboz in New York, and Steve Devine at CIBMTR. Because they work in the US, they often have access to these new agents quicker than we do, but perhaps our ability in the UK to deliver randomized trials is complementary to some of the groundbreaking work these colleagues do. I think the US has taught me quite a lot in terms of that clinical trial network approach. Mary Horowitz, who leads the Bone Marrow Transplant Clinical Trials Network, has been absolutely inspirational in helping us to understand that building a trial network across major transplant centers can deliver transformational studies. In terms of the clinical groupings in Europe, I also have been fortunate to have learnt from inspiring clinical triallists like Paresh Vyas, Bob Lowenberg, Hartmut Dohner and Andrew Wei who have been unbelievably generous with their time and taught me the value of academic CRO models such as HOVON and the ALLG.

How will emerging therapies reshape the future of treating blood cancers?

We can see it happening. We've already seen it with chronic myeloid leukemia (CML). I remember 25, 30 years ago, when I was at the Hammersmith, before the advent of imatinib, that half of our ward was filled with patients with blastic transformation of CML for whom there were no effective treatment options. Today, if you have CML and get promptly treated with a TKI like imatinib, your life expectancy is almost as good as a member of the general population. The principle that we will be able to find effective therapies that provide lifelong therapy and outstanding outcomes is now being proven in more and more diseases. I am optimistic about the future and believe that in 25 years time, I think it's reasonable to anticipate that we'll have effective treatments for everybody with blood cancer. These will increasingly be personalized, and much more gentle on the patient.

Are there any other any new updates that you want to share?

Like the rest of the global hemonc community, we've been enormously impressed with the way that the SOHO meeting has developed as a global brand. There's a freshness about the SOHO meeting, which I think now attracts more than 3,000 attendees, and particularly an emphasis on new ways of learning, new ways of delivering a broad hemonc curriculum, to not only fellows but also to practicing coalface clinicians. We were therefore absolutely delighted when Dr. Kantarjian and colleagues invited the UK to develop its iteration of a SOHO meeting, SOHO UK, which is going to launch in March 2026. We've had unbelievable interest and support from the UK hemonc community, and working with Tony Goldstone and many of my colleagues, I think we've now got a compelling program for 48 hours, which is not only going to cover the length and breadth of hemonc, but it's going to explore really important new areas such as the role of registries and translational medicine. We want to have it as a party to celebrate the excellence of UK hemonc, and to celebrate our partnership with MD Anderson and other major centers across the world working together to beat cancer to patient benefit.

What do you do in your downtime?

Well, I've suddenly discovered a passion for gardening. My dad used to garden, and I thought, how boring. But now we have a fruit cage housing gooseberries and blackcurrants in our little shack in Wales where we now grow unbelievably delicious potatoes and globe artichokes. That's fun and really interesting; you get an immediate response. I'm also learning to play the piano and am sitting my grade 6 exam, although I still really struggle with Scarlatti's piano sonatas. Although I can play them, it's perhaps not in a way that you or Scarlatti would have envisaged. So, it's the music and the garden that keep me sane.

Register today for SOHO 2025

FEATURED STORY

Spain's POC manufacturing model reimagines CAR-T delivery

While the US relies on centralized, commercial CAR-T manufacturing, Spain is taking a different approach. At Hospital Clínic de Barcelona, point of care manufacturing (POC) delivers personalized cell therapies on-site, cutting delays and expanding access.

By: **Leah Sherwood**

For the past several years, chimeric antigen receptor (CAR) therapies have been the go-to treatment for certain blood cancers, and rightly so. Where patients once had no viable options, there are now in many cases safe and effective therapies available.

Yet this clinical breakthrough brought new challenges, particularly in manufacturing.

Unlike traditional drugs, CAR-T cells must be made for each patient. In the United States, the process typically involves collecting the patient's cells, sending them to an FDA-approved specialized facility for modification, and shipping the final product back for infusion. Each step adds time, complexity, and cost.[1]

To address these challenges, investigators are exploring alternatives to centralized manufacturing to move CAR-T production closer to the patient, with the goal of lowering costs and reducing delays in treatment.[2]

One alternative is a decentralized model called point-of-care or place-of-care (POC) manufacturing, under which CAR-T cells are manufactured on-site at hospitals instead of at remote commercial facilities.[3,4]

"In simple terms, POC manufacturing is preparing the cellular therapy at the same institution where the patient is admitted for treatment," explained Magdi Elsallab, MD, PhD, the director of both the process development and the cellular therapy and transplantation laboratories at Massachusetts

General Hospital Cancer Center in Boston.

After being introduced to stem cell research during his residency at Mansoura University in Egypt, Dr. Elsallab became fascinated by how these therapies are translated into real products. Feeling that he needed a deeper understanding of both CAR-T cell theory and practice, he decided to go back and pursue his doctoral degree. That experience, and the gaps in care he saw firsthand, shaped how he views the field today.

Magdi Elsallab, MD, PhD

Faster production for faster patient treatment

The US manufacturing process is slow and fragmented, Dr. Elsallab explained, making it difficult for clinicians to treat patients.

"The current model for making quality cell therapies is limiting," he said. "It's not unlocking the full potential for cell therapy, and it limits access to these transformative therapies."

Wait times, logistical hurdles, and production constraints continue to delay treatment for patients who may not have time to wait. In some cases, disease progression or death occurs before CAR-T therapy can be delivered.[5]

"We can and should do better," Dr. Elsallab said, pointing to commercial manufacturing processes that still rely on outdated infrastructure.

On average, manufacturing takes four to six weeks, with little flexibility to shorten the timeline. Delays often begin even before cell collection.

"Patients can wait three weeks just to schedule apheresis," said Nirav Shah, MD, an associate professor at the Medical College of Wisconsin Cancer Center (MCW), where investigators are developing academic CAR-T programs and testing ways to bring production closer to the patient. "And that's before the cells are even modified."

Nirav Shah, MD

Pioneering POC manufacturing in the US

At MCW, Dr. Shah and his team are working on an early-stage POC program that focuses on manufacturing CAR-T cells on-site. The program aims to reduce the time from cell collection to infusion by eliminating the need to ship cells to third-party facilities. The cells are collected, modified, and administered within MCW, under FDA regulated and institutionally approved clinical protocols.[6]

Although still in development, the model is part of a growing effort in the US to incorporate decentralized manufacturing strategies that can improve access and responsiveness.

The program has managed to deliver vein-to-vein therapies in as little as eight days, according to Dr. Shah.

"We're able to manufacture the product on-site and administer it without delay," he said. "Patients receive a fresh product within eight days, which is critical for those with aggressive disease."

The MCW team has been working on POC manufacturing since 2017. By keeping the entire process under one roof, they can apherese patients on-site, immediately transport the cells to their manufacturing facility, and reinfuse the modified CAR-T cells without delay.

"In fact, we do it so quickly now that patients start lymphodepletion during the manufacturing process and actually receive a fresh product back," he said.

For patients with rapidly progressing lymphoma, this speed can make a significant difference.

"We're actually able to get a product to them as quickly as their clinical indication needs it," he said.

The POC model also enables faster innovation, according to Dr. Shah.

"We do this in the context of clinical trials," he said. "We can quickly test new manufacturing systems, new combinations of treatments, different doses of CAR-Ts, or entirely new CAR-T constructs."

Having on-site manufacturing capacity allows the team to design and launch trials more quickly and helps move the research forward, said Dr. Shah, noting that that several academic programs have gone on to partner with industry after initiating early CAR-T development, helping advance those therapies toward FDA approval.

As institutions begin to explore POC models at multiple sites, demonstrating consistency across locations for regulatory approval becomes paramount.

Dr. Shah gave the example of manufacturing CAR-T cells at different institutions, such as the Medical College of Wisconsin and the University of Texas MD Anderson Cancer Center. If one patient's cells are produced at one site and another's at the other, investigators must demonstrate that the resulting therapies are comparable.

"You have to be able to show comparability from site to site and show that no matter where it is made, you're making it in specification and the patients are getting a safe and effective cellular therapy product," Dr. Shah explained. "That is important. We do want to show that."

POC regulatory frameworks in Europe and the US

Europe might have a leg up in developing multiple POC sites given the US regulatory structure, according to Dr. Shah.

"From a regulatory standpoint, [Europe] might have a little bit more latitude in having a point of care system," Dr. Shah said. "That doesn't mean it won't happen in the US. I just think that it's going to take a lot of effort upfront to demonstrate that the [CAR-T] product is identical."

This level of validation might be unrealistic for most academic institutions, since it demands time and resources.

Dr. Elsallab noted that the current US regulatory framework "does not fully suit or fit the POC model," since it was built around centralized, industrial-scale manufacturing.

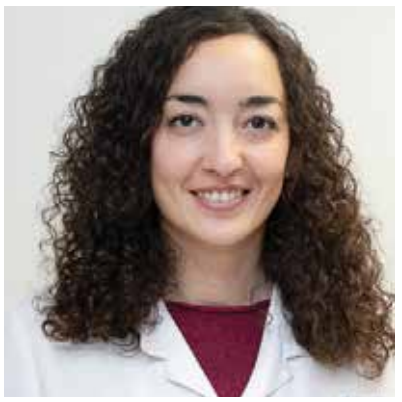
He explained that scaling such models across multiple sites would require "tedious" comparability studies and revalidation at each location, making widespread adoption difficult. As a result, expanding POC systems in the US remains a significant challenge.

In Spain, however, a nationally approved POC model is already in place.

Hospital Clínic de Barcelona

Hospital Clínic de Barcelona in Spain developed its own CAR-T products and received hospital exemption approval,[7] a regulatory designation under European law*.

Leticia Alserawan, PhD, a pharmacist and immunologist in the hospital's immunotherapy unit, oversees the manufacturing of ARI-0001 and ARI0002h.[8] (The prefix ARI honors Ari Benedé, who died of ALL at the age of 19. The ARI Project, founded in her memory, provided the impetus and financial support to help develop these treatments.)[9]



Leticia Alserawan, PhD

"We started with ARI-0001, [varnimcabtagene autoleucel] an anti-CD19 CAR-T for acute lymphoblastic leukemia," Dr. Alserawan said. "After that, the IDIBAPS [the August Pi i Sunyer Biomedical Research Institute] research group developed ARI0002h [cesnicabtagene autoleucel], an anti-BCMA CAR-T for multiple myeloma." She added that a third CAR-T, ARI-0003, is now in clinical trials for lymphoma patients, and the investigators are working on including multiple manufacturing sites across Spain.

ARI-0001 is part of the European Medicines Agency's Pilot for Academic and Nonprofit Developers of Advanced Therapy Medicinal Products (ATMP),[10] which was launched to help institutions such as hospitals and universities bring their own treatments through the European Union-wide approval process. ARI-0001 was the first therapy accepted into the program, which offers additional regulatory guidance and flexibility to support noncommercial developers.

Under Spain's hospital exemption pathway, the Hospital Clínic de Barcelona, which is affiliated with the University of Barcelona and the IDIBAPS research institute, is approved to manufacture and administer ARI-0001 and ARI0002h at its treatment clinic.

"This means we can treat these patients here in our center," Dr. Alserawan said. "The patients are tested and come to our hospital for the entire process, so usually it is a bit faster." Dr. Alserawan described the typical timeline for ARI-0001 production as one month with some cases stretching to as long as two months.**

"From the moment the patient is selected to the moment they are treated, the process can take one to two months," Dr. Alserawan said. "Manufacturing usually lasts seven to 12 days, followed by another one to two weeks for quality control testing before the product is released."

ARI0002h is manufactured at two different centers, Hospital Clínic de Barcelona and Clinica Universidad de Navarra, and patients from seven centers across Spain, which participated in the clinical trial, are being treated. For ARI-0001, two manufacturing sites, Hospital Clinic Barcelona and Hospital Sant Joan de Deu, have also received approval after comparability data from both sites were submitted to the Spanish Regulatory Agency.

Dr. Elsallab said that the model in Spain demonstrates that the POC model can be successful in bringing treatments to patients, "not in a better or worse way, but in a different way."

Can multiple models coexist?

There is room for both centralized and POC manufacturing, depending on the disease context, infrastructure, and available support, according to Dr. Shah. He noted that some therapies may continue to rely on large-scale centralized production, while others would benefit from more localized, rapid delivery.

"There is the space where you can have some indications that can be targeted by the POC manufacturing and other indications where the centralized model will be the superior model," he said, adding that not all healthcare systems are equipped to support centralized manufacturing, particularly in resource-limited settings.

Embracing these alternatives could help lower costs and expand global access, according to Dr. Shah.

"This will help make things like cell therapy cheaper. It will also allow CAR-T to be globalized," Dr. Shah said. "Places like India or China will not be able to send their cells to the US or Europe for manufacturing. If we want to offer this therapy in an equitable fashion to people across the world, we're going to have to embrace these alternative manufacturing models."

Dr. Elsallab agreed, noting that flexible use of models tailored to different environments will be needed to expand global access to these much-needed therapies.

> *ARI-0001 treats patients faster with on-site CAR-T manufacturing.*
>
> *— Leticia Alserawan, PhD*

"I feel that the best approach is to support all the models equally and try to push innovation further," he said.

Leah Sherwood is a writer in Los Angeles.

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*Granted by Spanish national authorities, this exemption allows the hospital to produce the treatment on-site as long as it's used for a specific patient, led by a physician, and not for profit.
**Defined under European Regulation (EC) 1394/2007, Directive 2001/83/EC and Regulation (EC) 723/2004, provided by Leticia Alserawan.

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SOHO YOUNG INVESTIGATOR SPOTLIGHT

Shaping the future of hem/onc

The SOHO Young Investigator Program (YIP) supports aspiring hematologic oncologists to attend the Annual Meeting in Houston and the opportunity to meet with leaders in the field.

Meet Megan Melody, MD, an assistant professor at the University of South Florida (USF) and lymphoma and chimeric antigen receptor (CAR) T-cell therapy specialist at Tampa General Hospital Cancer Institute. In this YIP spotlight, Dr. Melody shares how the SOHO YIP award impacted her career growth and reveals how she balances her demanding role with a surprising passion for theater.

This interview has been edited for length and clarity.

How did you get started in medicine?

I am originally from New Hampshire, and I completed my undergrad at the College of the Holy Cross in Worcester, Massachusetts. I then worked in clinical research in cardiology for two years at Massachusetts General Hospital and completed a one-year master's program at USF, which shares a campus with the Moffitt Cancer Center. Here, I worked as a clinical research coordinator.

It was during my time at Moffitt that I was introduced to malignant hematologists in the department. I went onto medical school at USF, and it was because of these established relationships and my passion for malignant hematology that I was offered research roles to work on processing data for abstracts and publications.

When did you receive your first YIP award?

I think the first time I received a YIP award was in 2015. I was a second-year medical student when I applied to the program. It was my first time going to a large academic meeting, and I remember being intimidated; I brought multiple power suits to each meeting. We would go out for dinner, and I would be the only person dressed in a suit while everyone else wore jeans. I felt like such a nerd.

> *We go into medicine bright-eyed and bushy-tailed thinking, 'I like science, and I want to help people.' I think that that's a good motivating factor.*

How did the first SOHO meeting you attended spark your interest in malignant hematology research?

The YIP award and attending the SOHO Annual Meeting have been paramount to my career. I wound up continuing to do research and presenting at ASH and Tandem. Primarily, my research now focuses on lymphoma and CAR T-cell therapy.

After the first SOHO Annual Meeting I attended, I went on to finish medical school at USF, and then a residency at the Mayo Clinic in Jacksonville, where I did a lot of research in CAR T-cell therapy with Mohamed Kharfan-Dabaja. That's where I got my feet wet with CAR T-cell therapy, and when I first started presenting at Tandem. Then I went into a fellowship at Northwestern, where a lot of my research is with Jane Winter in lymphoma, and Reem Karmali who helped me grow my CAR T-cell experience there. And Leo Gordon.

How has participating in YIP helped you grow, and why do you think it's a valuable program for early-career clinicians?

I love the SOHO meeting because it's digestible. The same year I first attended SOHO, I also went to ASH for the first time. I remember struggling to figure out which sessions to attend and how to navigate everything—ASH and Tandem have so many different tracks. That's not to disparage those meetings; they're incredible.

But for a young investigator who is trying to understand the intricacies of hematology, SOHO is great because the meeting always has people who are leaders in the field who are presenting the research. Most of their oral presentations start with understanding of the disease, the treatment course, and then they go on to incorporate their views.

This past year there were a lot of interesting presentations on medical inequality and global health. Each session had non-

US-based clinicians present research on their experience giving treatment outside of the United States.

Now that I'm an attending physician, obviously I find the presentations and oral abstracts at ASH very helpful, but for someone who's still just learning about CAR T-cell therapy, a 15-minute oral abstract on a niche or basic science aspect likely won't resonate with them. I had no idea what that was during medical school or residency.

Most medical students and residents can only go to an academic conference if they're presenting. Even still, that's often not funded. A lot of my friends have a budget during residency of $500 to $700. That's not going to cover a conference attendance. If you can only pick one conference to attend, sometimes that limits the smaller conferences, especially in 2015 when I first started going to meetings.

The last thing I would say about the YIP program is something I bring up with my residents and fellows. We never get any training on how to interact with pharmaceutical companies. I think watching my mentors model that behavior helped to shape my relationship with pharmaceutical companies, which is an essential part of academic medicine. Those are things that we are never taught in medical school. I know a lot of my colleagues felt a little lost when they graduated, and all of a sudden, all these people were reaching out to meet with them. Like, what do they want from you? Why do they want to meet with me?

It was great having the experience of going to SOHO and getting to see those discussions firsthand from very early in my career.

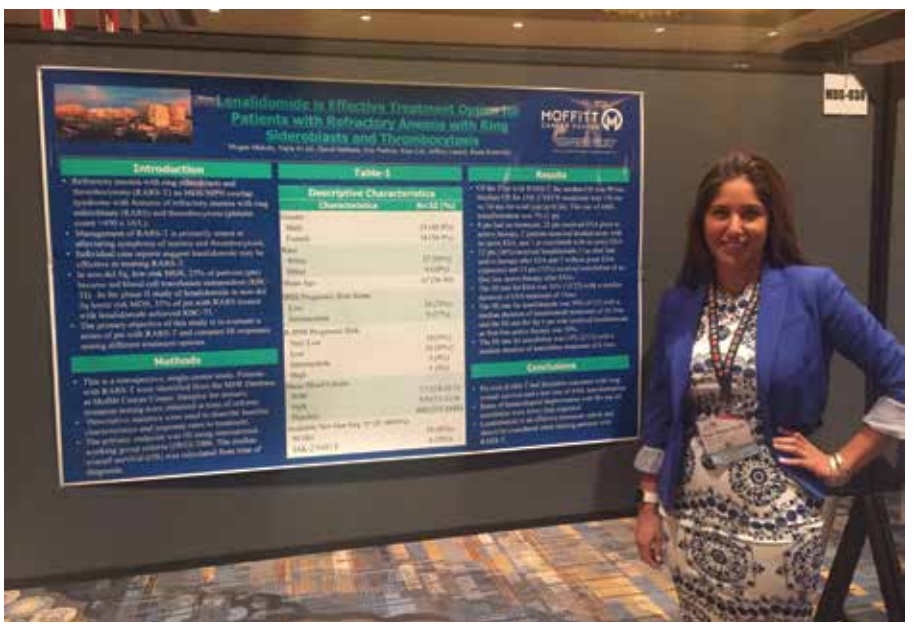
What misconceptions did you have when you started practicing medicine that have now changed?

We go into medicine bright-eyed and bushy-tailed thinking, "I like science, and I want to help people." I think that that's a good motivating factor. I think I didn't understand how much insurance dictates the care of my patients and how much I'd be interfacing with insurance companies.

> *The YIP award and attending the SOHO Annual Meeting have been paramount to my career.*

Who were your most impactful mentors?

In every phase of my career while I've been training, I have been lucky to be mentored by the major movers and shakers in the field.



Dr. Melody in the poster hall at a previous SOHO Meeting. All photos courtesy of Dr. Melody.

Dr. Melody in the poster hall at a previous SOHO Meeting. All photos courtesy of Dr. Melody.

At Moffitt, Julio Chavez, Eduardo Sotomayor, who's now my boss—he recruited me to the cancer center, and Rami Komrokji, who supported my career through research.

Then I went over to Mayo Clinic where Dr. Kharfan-Dabaja mentored me in CAR T-cell therapy. At Northwestern, Drs. Gordon, Winter, and Karmali—that whole group—they're all just amazing.

Truthfully, I could never pick only one of them that was most impactful. They're this powerhouse group that truly loves me as a person, a provider, and a friend.

What do you do when you're not working?

This year, my husband told me that I didn't have any hobbies, and the one thing you should never do is tell me I can't do something. I decided that I was going to audition for a play. I wound up getting cast as Little Red Riding Hood's grandmother and Cinderella's mother in Into the Woods.

What have you recently read?

I love Harry Potter, and there is a new fan fiction book that was all over my Instagram based on the premise of what would happen if Voldemort won rather than Harry Potter. Basically, it is about Hermione Granger, who is enrolled into a program (right out of The Handmaiden's Tale) because she's a Muggle-born. She winds up getting betrothed to Draco Malfoy—it's scandalous.

Support early-career clinicians by donating to the SOHO Young Investigator Program today!

MEETING NEWS

Latest from the conference floor

***SOHO Insider* reports from the 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR**

Deeper MRD response associated with better survival in obe-cel-treated patients with B-cell ALL

Measurable residual disease (MRD) negativity was associated with better response to treatment with the chimeric antigen receptor T-cell therapy obecabtagene autoleucel (obe-cel) in patients with B-cell acute lymphoblastic leukemia (ALL). Furthermore, deeper responses were associated with increased event-free survival (EFS) and overall survival (OS).

The study was presented at the 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR in Honolulu, Hawaii.

The phase 1b/2 FELIX study is assessing obe-cel in patients with relapsed or refractory B-cell ALL. At a median follow-up of 21.5 months, 12-month EFS was 50% and OS was 61%.

This study further evaluated the depth of MRD-negative remission and outcomes in obe-cel treated patients.

Bone marrow samples were collected at the following stages:

- **Screening**
- **≤1 week before lymphodepletion**
- **28 days after obe-cel infusion**
- **Months 3, 6, and 12**
- **Every 6 months thereafter until the end of the study**

Of the 127 patients in the study, 96 (76%) had samples for next-generation sequencing. About three-quarters (n=73; 76%) achieved complete remission (CR) or CR with incomplete count recovery. Most of these patients (n=68; 93%) had ≥1 post-infusion bone marrow samples available. Just 6% (n=4) of patients were MRD-positive after treatment, while the remaining 94% (n=64) achieved MRD <10^{-4} leukemic cells, including 10% with an MRD between 10^{-4} and 10^{-6} and 84% with an MRD <10^{-6}.

In evaluable responders, median time to best MRD response (<10^{-4} cells) was 1 month (range, 1-3). At a median of 21.5 months of follow-up (range, 8.6-41.4), median duration of response was noted as the following:

- **5 months for MRD ≥10^{-4}**
- **8 months for MRD between 10^{-4} and 10^{-6}**
- **1 month for MRD <10^{-6}**

Depth of response (MRD ≥10^{-4}, between 10^{-4} and 10^{-6}, and <10^{-6}) also impacted the following values:

RELAPSE RATE

- **100%, 100%, 48%, respectively**

MEDIAN EFS

- **0, 4.5, and 15.1 months, respectively**

MEDIAN OS

- **2, 8.9, and not estimable months, respectively**

At 12 months, EFS rates were 10%, 0%, and 61%, while OS rates were 20%, 27%, and 85%, for MRD ≥10^{-4}, between 10^{-4} and 10^{-6}, and <10^{-6}, respectively.

MRD <10^{-6} was associated with more durable responses and higher EFS and OS rates, the authors concluded.

REFERENCE

Jabbour E, Park JH, Shaughnessy P, et al. Deep molecular remission predicts better clinical outcomes in adults with relapsed/refractory B-cell acute lymphoblastic leukemia (R/R B-ALL) treated with obecabtagene autoleucel (obe-cel). Abstract #292. Presented at the Tandem Meetings | 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR; February 12-15; Honolulu, Hawaii.

Earlier administration of CAR-T treatment may improve survival in LBCL

Axicabtagene ciloleucel (axi-cel) prolonged survival in large B-cell lymphoma (LBCL) compared with standard of care (SOC).

The ZUMA-7 trial also found that survival outcomes may differ in those with primary refractory versus early-relapse LBCL.

The study was presented at the 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR in Honolulu, Hawaii.

Patients were randomized 1:1 to receive axi-cel (n=180) or SOC (n=179; chemotherapy followed by high-dose chemotherapy with autologous hematopoietic cell transplant for those who responded). Most patients (n=133 and 131, respectively) had primary refractory LBCL; the remaining patients (n=47 and 48, respectively) had early relapse LBCL.

EFS (HR, 0.437), PFS (HR, 0.550), and OS (HR, 0.828) improved with axi-cel in primary refractory patients and in early-relapse patients (EFS, 0.401; PFS, 0.445; HR, 0.619).

Patients with early-relapse LBCL appeared to have longer OS and PFS compared with patients with primary refractory LBCL in both the axi-cel (OS median, not reached vs 29.4 months, respectively; PFS median, not reached vs 7.2 months) and the SOC (OS, 52.0 vs 19.8 months, respectively; PFS, 6.0 vs 2.9 months) arms.

Significantly higher infiltration of CD4 and CD8 T cells (P<0.05) and lower B-cell gene expression signature representative of hypoxia, glycolytic activity, and myeloid and stromal cells were observed in patients with early relapsed compared with primary refractory LBCL.

“These findings support early referral of [patients] with relapsed and refractory LBCL for axi-cel as a preferred [second-line] SOC,” the authors concluded.

REFERENCE

Westin JR, Oluwole OO, Kersten MJ, et al. Axicabtagene ciloleucel (axi-cel) versus standard of care (SOC) in patients with primary refractory or early relapsed large B-cell lymphoma (LBCL). Abstract #283. Presented at the Tandem Meetings | 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR; February 12-15; Honolulu, Hawaii.

Study questions clinical benefit of dexamethasone with axi-cel in LBCL patients

Prophylactic dexamethasone did not improve the safety or efficacy of axi-cel in patients with LBCL, according to a study presented at the 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR in Honolulu, Hawaii.

The study, which was led by Megan Melody, MD, MS, an assistant professor of medicine in the Department of Hematology, Oncology, and Cellular Therapy at the University of South

Megan Melody, MD, MS

Florida Tampa General Hospital Cancer Institute, suggests that prophylactic dexamethasone does not provide a clear clinical benefit to patients.

In the real-world setting, prophylactic dexamethasone is given to younger patients with a higher ECOG performance status at time of axi-cel infusion. A subgroup in the ZUMA-1 clinical trial showed an improved safety profile of axi-cel when used with prophylactic dexamethasone, according to Dr. Melody and colleagues.

In this study, investigators analyzed 233 patients from seven institutions treated with axi-cel between 2018 and 2024. Of these, 50 (21.5%) received 10 mg of prophylactic dexamethasone from day 0 to day 2 of infusion. Patients who received prophylactic dexamethasone were younger (median 58 vs 63 years, *P*=0.04) and had a higher ECOG performance status (20.4% ECOG 2-3 vs 4.6%, *P*=0.001) at the time of infusion compared to those who did not.

Patients who received prophylactic dexamethasone had no significant reduction in cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) compared to those who did not. The incidence, severity, and duration of CRS were similar between both groups (*P*=0.03), but patients who received dexamethasone had a higher rate of severe grade 4) ICANS (*P*=0.001). There was also no improvement in treatment outcomes, including complete response rates (30% vs 42.6%, *P*=0.63), PFS (248 vs 345 days, *P*=0.62), or OS (537 vs 656 days, *P*=0.61).

"The use of [prophylactic dexamethasone] did not significantly impact incidence or duration of treatment related toxicities; the use of [prophylactic dexamethasone] was associated with a higher incidence of grade 4 ICANS and the majority of [patients] who received [prophylactic dexamethasone] experienced CRS during the time of [dexamethasone] administration," the investigators wrote. "[Prophylactic dexamethasone] did not impact response rates or survival with axi-cel."

REFERENCE

Melody M, Herr M, Grover N. No impact of prophylactic corticosteroid use in patients receiving axicabtagene ciloleucel for large B-cell lymphoma. Abstract #18. Presented at the Tandem Meetings | 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR; February 12-15; Honolulu, Hawaii

ACROBAT interim results support AlloHeme for relapse prediction in AML, MDS

Interim results of the ACROBAT study suggest that increasing microchimerism and loss of complete chimerism may indicate relapse risk in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). The findings were presented in an oral abstract[1] at the 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR in Honolulu, Hawaii.

Monzr Al Malki, MD

The ACROBAT study is a prospective, multicenter, observational cohort study that enrolled patients 18 years and older who were eligible for allogeneic hematopoietic stem cell transplantation (HSCT) with AML, acute lymphoblastic leukemia (ALL), and MDS.[2]

To measure microchimerism for relapse prediction, the investigators analyzed blood or bone marrow samples using the AlloHeme® microchimerism test,

a next-generation sequencing technology, which measures single nucleotide polymorphisms to assess donor and recipient cell proportions after HCT.

The AlloHeme® microchimerism test has a limit of detection of 0.04% for unrelated donors and 0.07% for related donors, according to the study's investigators. Increasing microchimerism was defined as ≥0.2% increase in recipient chimerism between two consecutive time points. Complete chimerism was defined as donor chimerism ≥99.8% at three months after transplantation, and relapses were defined using CIBMTR criteria.

In this interim analysis, the researchers report on CD33 increasing microchimerism in 235 patients with AML and MDS at a median follow-up of 14 months. The researchers reported 7% relapse and 23% nonrelapse mortality in this patient subgroup.

Analyses at three and six months showed that patients with increasing microchimerism had a significantly higher risk of relapse compared with those without increasing microchimerism (*P*=0.016 and *P*=0.001). A time-varying effects model found that patients with increasing microchimerism had a 35.2 times higher risk of relapse (CI, 15.5-80.3; *P*<0.001).

An increasing microchimerism threshold of ≥0.2% had 93% sensitivity, 76% specificity, a 98% negative predictive value and a 47% positive predictive value for relapse prediction.

The median time from increasing microchimerism detection to relapse was 50 days in 63% of relapsing patients (n=25).

Patients who never achieved CD33 complete chimerism (n=30) had a 12.2 times higher relapse risk than those who achieved complete chimerism (n=199). Those who achieved complete chimerism but later lost it (n=60) had a 27.5 times higher relapse risk than those who maintained CC (n=139). The median time from loss of complete chimerism to relapse was 153 days (n=27, 68% of relapses).

"Microchimerism using AlloHeme is an accurate and sensitive test for monitoring relapse in post-allo HCT AML and MDS patients with a clinically meaningful lead time to relapse prediction," the investigators, led by Monzr Al Malki, MD, of the Department of Hematology and HCT at the City of Hope National Medical Center in Duarte, California, wrote in the oral abstract.

REFERENCE

1. Al Malki MM, Sobecks R, Cutler Cory. Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR. CD33 Microchimerism Assessment By Alloheme Predicts Early Relapse in Patients with AML/MDS—Interim Results from the Acrobat Multicenter Study. Abstract #7. Tandem Meetings | 2025 Transportation and Cellular Therapy Tandem Meetings of ASTCT and CIBMTR; February 12-15; Honolulu, Hawaii

2. ClinicalTrials.gov. Study of microchimerism and relapse in post-transplant patients (ACROBAT). Identifier 35384. Updated January 23, 2024. Accessed February 12, 2025.

REGULATORY ROUNDUP

Tracking regulatory news worldwide

EC expands use of liso-cel CAR T-cell therapy for relapsed or refractory follicular lymphoma

The European Commission (EC) has granted approval to lisocabtagene maraleucel (liso-cel), a CD19-directed chimeric antigen receptor (CAR) T-cell therapy, for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

The decision is based on results from the global phase 2 TRANSCEND FL study. Among patients treated in the third-line-plus setting, liso-cel demonstrated a high overall response rate of 97.1% (95% CI, 91.7–99.4) and complete response rate of 94.2% (95% CI, 87.8–97.8), the study's primary and key secondary endpoints, respectively. The median time to first response was 0.95 months (range, 0.6–3.3 months) with 75.7% (95% CI, 66.0–83.0) of patients still in response at 18 months.

Safety results were consistent with the safety profile of liso-cel observed across clinical trials and approved indications, with no new safety signals observed in FL. In all patients treated in the TRANSCEND FL study (second-line-plus), any grade cytokine release syndrome (CRS) occurred in 58% of patients, with 0.8% of patients experiencing grade 3 CRS. The median time to onset was six days (range, 1–17 days). Any grade neurologic toxicities occurred in 16% of patients, including grade 3 in 3% of patients. The median time to onset of the first event was eight days (range, 4–16 days).

Liso-cel is also approved in the European Union for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma (PMBCL), and FL grade 3B (FL3B), who relapsed within 12 months from completion of, or are refractory to, first-line chemoimmunotherapy, and for the treatment of adult patients with relapsed or refractory DLBCL, PMBCL, and FL3B after two or more lines of systemic therapy.

ANVISA approves ropeginterferon alfa-2b for polycythemia vera

The Brazilian Health Regulatory Agency (ANVISA) has approved ropeginterferon alfa-2b (BESREMi) for the treatment of adult patients with polycythemia vera (PV). This approval was announced on March 20, 2025.

Ropeginterferon alfa-2b offers prolonged activity and is administered every two weeks, or every four weeks if hematological stability is maintained, according to the therapy's manufacturers, Pint Pharma and PharmaEssentia.

In Brazil, DataSUS, the IT department of the Brazilian Unified Health System, recorded 1,843 cases of PV between 2016

EC approves imetelstat for transfusion-dependent anemia in lower-risk MDS

The EC has approved the marketing authorization for imetelstat (RYTELO), a first-in-class telomerase inhibitor, as a monotherapy for the treatment of adult patients with transfusion-dependent anemia due to lower-risk myelodysplastic syndromes (MDS) in patients without a non-del 5q abnormality who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy. This approval was announced on March 11, 2025.

The approval is based on the phase 3 IMerge clinical trial, which demonstrated the therapy reduced the need for red blood cell transfusions for enrolled patients in the first 24 weeks of treatment compared with placebo, according to the press release from Geron Corporation, the manufacturer of the therapy.

"I am thrilled that the European Commission has approved RYTELO in LR-MDS. The long-term and durable responses observed in the phase 3 IMerge study reinforce the practice-changing potential of telomerase inhibition as a clinically meaningful and differentiated option for the treatment of lower-risk MDS," said Uwe Platzbecker, MD, an investigator on the IMerge trial and CMO at the University Hospital Carl Gustav Carus Dresden in Germany. "Physicians and patients in Europe are now one step closer to accessing a novel treatment that, in addition to having a generally manageable safety profile, has the potential to provide extended and continuous red blood cell transfusion independence."

China NMPA approves IND for KPG-818 in relapsed or refractory MM

The Center for Drug Evaluation of the China National Medical Products Administration (NMPA) has approved the Investigational New Drug (IND) application for KPG-818, a novel oral molecular glue modulator of CRL4-CRBN, for the treatment of relapsed or refractory multiple myeloma (MM) in patients who have received prior therapies. This approval was announced on February 25, 2025.

The phase I clinical trial of KPG-818 in the United States for various hematological tumors has been completed. Preliminary results indicate that in relapsed or refractory MM patients who have previously received two immunomodulatory drugs (lenalidomide and pomalidomide), at least one proteasome inhibitor (bortezomib, ixazomib, or carfilzomib), and a CD38 monoclonal antibody (daratumumab or isatuximab), KPG-818 demonstrated good safety, tolerability, pharmacokinetic characteristics, and encouraging therapeutic effects, according to the press release from Kangpu Biopharmaceuticals, the manufacturer of the therapy.

EC approves blinatumomab for Ph-negative CD19-positive B-ALL in the consolidation phase

The EC has approved blinatumomab (Blincyto) as a consolidation therapy for adult patients newly diagnosed with Philadelphia chromosome-negative, CD19-positive B-cell precursor acute lymphoblastic leukemia (B-ALL).

The approval follows the phase 3 E1910 study, which demonstrated that blinatumomab significantly improved overall survival when added to chemotherapy compared to chemotherapy alone.

Blinatumomab, a bispecific T-cell engager (BiTE®) immuno-oncology therapy, is designed to target CD19 surface antigens on B cells, according to Amgen, the manufacturer of the treatment.

"While there has been some treatment progress, many patients with newly diagnosed Philadelphia chromosome-negative B-ALL remain at high risk of relapse," said Robin Foà, MD, an emeritus professor of hematology at the Sapienza University of Rome. "The E1910 study results highlight that Blincyto has the potential to advance frontline consolidation treatment, including patients who are minimal residual disease (MRD)-negative, offering a crucial new option to achieve deeper remissions and improve long-term survival."

FDA clears Ventana hematopathology test for diagnosing BCL

The US Food and Drug Administration (FDA) has granted clearance to the Ventana Kappa and Lambda Dual ISH mRNA Probe Cocktail, an ISH test sensitive enough to cover the full spectrum of B-cell lymphoma subtypes. The FDA clearance follows the assay's CE Mark approval in June 2024.

The test helps in distinguishing a B-cell cancer from a normal, reactive immune response, providing diagnostic certainty for healthcare providers, according to Roche, the manufacturer of Ventana.

"With this new test, clinicians can have confidence in their diagnosis, while the test reduces the need for multiple samples and time-consuming follow-up tests, giving patients certainty sooner, and enabling faster access to the right treatment," Jill German, the head of the Pathology Lab at Roche Diagnostics, said in a press release from Roche.

The Ventana Kappa and Lambda Dual ISH mRNA Probe Cocktail can assess small biopsies and formalin-fixed tissue, reducing the need for a fresh tissue sample, which may result in fewer additional patient biopsies and allow for quicker pathology interpretations, according to the company.

FDA accepts BLA review for Blenrep combo in relapsed or refractory MM

The FDA has accepted for review a Biologics License Application for belantamab mafodotin (Blenrep) in combination with bortezomib plus dexamethasone and pomalidomide plus dexamethasone for patients who have undergone at least one prior therapy for MM.

The FDA's decision is based on data from the phase III DREAMM-7 and DREAMM-8 trials, which showed statistically significant improvements in progression-free survival compared with the standard of care. The DREAMM-7 trial also demonstrated a significant benefit in overall survival for patients, according to a press release from GSK, the manufacturer of Blenrep.

If approved, these combinations could redefine treatment options for MM at or after first relapse, according to GSK.
The FDA has set a decision date of July 23, 2025.

"Relapsed/refractory multiple myeloma treatment could be transformed by additional, efficacious treatment options with manageable side effects and community-based administration," Hesham Abdullah, the senior vice president of Global Head Oncology, R&D at GSK, said in the press release.

FDA grants Orphan Drug Designation for small-molecule MM therapy

The FDA has granted Orphan Drug Designation for OPN-6602, an oral small-molecule EP300/CBP inhibitor, for patients with MM who have undergone at least one prior therapy.

OPN-6602 targets the EP300 and CBP proteins, which are involved in the proliferation and survival of MM cells, according to Opna Bio, the manufacturer of the drug. The therapy is currently being tested in a phase 1 clinical trial.

Recent data presented at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2024 highlighted the promising results of OPN-6602 in preclinical studies, showing significant reduction in MM cell growth and survival, thus supporting its potential as a novel treatment option, the company wrote in a press release.

If approved, OPN-6602 could become a pivotal new option for patients with MM, according to Opna Bio.

FDA clears IND for novel relapsed or refractory NHL therapy

The FDA has cleared the Investigational New Drug (IND) application for LTZ-301, a first-in-class bispecific myeloid engager immunotherapy, for patients with relapsed or refractory non-Hodgkin lymphoma (NHL).

Preclinical studies showed robust activity and a favorable safety profile. The drug manufacturer, LTZ, expects to initiate its phase 1, open-label, multicenter study in quarter two of 2025.

LTZ-301 selectively depletes CD79b-positive B-cells by enhancing phagocytosis. It targets CD79b, a tumor-associated antigen highly expressed in B-cell malignancies, including those resistant to CD19- or CD20-directed therapies, by recruiting monocytes and macrophages to remove malignant B-cells via an Fc-gamma receptor-independent mechanism, according to LTZ Therapeutics.

"The FDA's clearance for our phase 1 study of LTZ-301 marks a significant milestone, and we aim to evaluate its potential as an effective therapy for [relapsed or refractory] NHL and other indications," Robert Li, PhD, the founder and CEO of LTZ, said in the press release.

If successful, LTZ-301 could offer a novel immunotherapy approach for patients with limited treatment options, according to LTZ Therapeutics.

Japan regulatory body approves epcoritamab for relapsed or refractory FL

The Japan Ministry of Health, Labour and Welfare has approved epcoritamab (Epkinly) as a treatment for adult patients with relapsed or refractory FL who have undergone at least two prior therapies. This approval was announced on February 20, 2025.

According to data from the phase I/II EPCORE NHL-1 and EPCORE NHL-3 trials, epcoritamab demonstrated significant responses and tolerability in patients with relapsed or refractory FL. This immunoglobulin-1-bispecific antibody targets CD3 on T-cells and CD20 on B-cells to induce cancer cell death, according to Genmab, the manufacturer of the therapy.

"The responses and tolerability demonstrated in this trial support epcoritamab's potential as an important option for relapsed or refractory FL," said Koji Izutsu, head of the department of hematology at the National Cancer Center Hospital in Tokyo and principal investigator of the Japanese phase 1/2 EPCORE NHL-3 trials.

1st SOHO Spain debuts in Madrid, bringing together global hematologists

By: **Guillermo Garcia-Manero, MD**
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The first meeting of SOHO Spain was held in Madrid on February 27 and 28, 2025. The setting was the Rafael del Pino Auditorium in the center of Madrid, and the event was a total success. Around 400 international colleagues registered for the meeting of which 362 attended in person. The audience consisted not only of Spanish hematologists but also an international audience including researchers and industry. The meeting was directed by Dr. Adolfo de la Fuente, chief of hematology at MD Anderson Cancer Center Madrid, and Dr. Guillermo Garcia-Manero from the University of Texas MD Anderson Cancer Center in Houston.

An important aspect of this initiative is that the event was fully coordinated with the Spanish Society of Hematology led by Dr. Maria Victoria Mateos who also served as honorary president of the society together with Dr. Hagop Kantarjian. In addition, Dr. Phil Scheinberg, president of SOHO, was present at the meeting and welcomed and closed the two days of activities in Madrid. The meeting was a real tour de force of all aspects of malignant hematology, covering treatment of multiple myeloma, chronic myeloid leukemia, myelodysplastic syndromes (MDS), T cell lymphomas, acute myeloid leukemia, lymphoma, chronic lymphocytic leukemia, myeloproliferative neoplasms, stem cell transplantation, and cell therapy.

Because Spain has one of the most active hematology programs in the world, with leading cooperative programs in myeloma, leukemia, MDS and others, all sessions included leading Spanish hematologists and international speakers, allowing a very fruitful exchange of information from local real-world experience to the latest advances in each disease. Indeed, the scientific committee was formed by Drs. Sureda (Barcelona), Fernandez de Larrea (Barcelona), Panizo (Pamplona), Martin Moro (Madrid), Bosch (Barcelona), Diez Campelo (Salamanca), Montesinos (Valencia), Garcia-Sanz (Madrid), Garcia Gutierrez (Madrid), Isidori (Italy), Cerchione (Italy), Jabbour (USA), and Daver (USA).

As past president of SOHO and as an American hematologist from Spain, it was amazing for me to see this meeting take place in Madrid. The level of Spanish hematology is incredible and together with leading international experts, I strongly believe that the two days of lectures and interaction were very positive and educational. The atmosphere of the meeting was collegial and a constructive experience. I want to congratulate Dr. De la Fuente for organizing an amazing meeting. The plan is to repeat SOHO Spain in 2027. I hope to see everyone in Spain then.

Guillermo Garcia-Manero, MD, co-director of SOHO Spain 2025, served as the 2024-2025 president of SOHO and is a professor in the Department of Leukemia at the University of Texas MD Anderson Cancer Center in Houston.

SOHO Spain is part of the SOHO Ambassador Program, which appoints experts from around the world to represent the society in their geographic regions. Ambassadors share local developments in hematologic oncology with SOHO and promote its educational resources within their communities.

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