Alan Bash – Interim CEO, Legend Biotech

Legend is looking at all ways to bring CAR-T to more patients, including allogeneic, autologous, and in vivo approaches

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Alan Bash, Interim CEO of Legend Biotech speaks about achieving the milestone of treating 13,000 adult patients, with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, with their CAR-T therapy. Bash goes on to outline the therapy's clinical impact and the importance of bringing CAR-T into earlier approved lines of multiple myeloma treatment. He also shares Legend's focus on expanding access beyond academic centers into community oncology, the recent expansion of its Raritan, New Jersey manufacturing facility, and the company's pipeline to develop solid tumor and in vivo CAR-T therapies.

Could you introduce yourself and your scope of responsibility at Legend Biotech as the Interim CEO at Legend Biotech?

I have been at Legend for the last year and a half and am now the Interim CEO. The franchise is a significant part of the Legend story and encompasses all the key operations for our marketed CAR-T therapy, including commercial, medical affairs, manufacturing, and quality.

Prior to joining Legend, I had a long career in big pharma with twenty-three years at Bristol Myers Squibb in a variety of commercialization roles across oncology and the immune checkpoint inhibitors franchise. I also served as CEO of two small biotechs, one public and one private, both in the novel therapeutic and target space of oncology.

Legend's CAR-T therapy was first approved by the FDA in 2022, with an expanded approval in 2024. What does patient reach look like today?

Legend has been at the forefront of this novel space within cell and gene therapy. But beyond being at the forefront of science, we've also played an important role in broadening access and availability of CAR-T to more patients. Earlier this year we reached an incredible milestone, treating 13,000 patients with CARVYKTI.

When you consider everything that has to happen for a patient to receive CAR-T therapy, from having their cells manufactured, returned to them, and going through the full treatment journey, treating more than 13,000 patients is remarkable. We're also the top-selling CAR-T therapy by any measure, which reflects that we've advanced not only the science of CAR-T, but its commercialization, access, and availability as well.

CARVYKTI is currently approved and marketed in 19 countries, including the US. There has also been strong excitement for and adoption of CARVYKTI outside the US in major markets such as Germany, Spain, Denmark, and Belgium, as well as countries in the Middle East and Latin America. That speaks to a global demand and a significant unmet need for curative therapies in multiple myeloma (MM).

Based on our most recent earnings reports, the US represents about three quarters of CARVYK TI's revenue, with the remaining quarter coming from outside the US. Working alongside our partners at Johnson & Johnson (J&J), we believe the global portion of uptake will continue to grow.

Tell us about the clinical impact CARVYKTI has for multiple myeloma patients.

Most MM patients are told they'll be on a series of successive treatments. While those treatments might work and patients might go into remission, at some point the disease often re lapses. Then they need to rechallenge or move on to another class of therapies completely. MM has been described to patients as a chronic disease with no cure and clinical outcomes deteriorate over time as patients move through lines of therapy and efficacy lowers.

CARVYKTI has changed the game in that sense. We now offer a one-time infusion that enables patients to have a treatment-free interval and long-term remission. The data we presented at ASCO in 2025 looked at patients five years out on treatment in a late-line setting. From our CAR TITUDE-1 data set of a heavily pre-treated population, one in three were treatment-free, progression-free of their MM. That's an incredibly exciting milestone.

We still have more work to do before we can definitively call CAR-T a cure in myeloma, but we can confidently say there is potential for cure in a fraction of patients. The conversation is moving from thinking of MM as a disease we cannot cure to potentially being able to with treatments like CARVYKTI.

The 2024 approval expansion moved CARVYKTI into the second line of treatment for multiple myeloma patients. What's the significance of this for patient outcomes?

CARVYKTI was approved in 2024 for patients as early as the first relapse in MM. That means any patient who has relapsed after their initial treatment, whether that was a stem cell transplant and related maintenance or other therapies for those who didn't receive a transplant, is now eligible for CARVYKTI.

The five-year data we presented from CARTITUDE-1 represents later-line patients. But what clinicians will tell you, and what the data suggests, is that outcomes improve when treatment comes earlier. You get better efficacy, an improved side effect profile, and better overall management. Biologically, patients' T cells are in a fitter, healthier state earlier in the disease course, so they respond better to treatment.

We're excited to imagine what's possible if we're able to cure one in three patients in the late line setting. Bringing that same treatment to earlier lines, and following those patients over time, makes us excited about what more we might achieve.

In terms of awareness, where does CAR-T and cell therapy fit into today's treatment conversations in the clinical setting?

There's a growing belief that CAR-T can play a role earlier, but we have more work to do on that front. Right now, CAR-T is largely perceived as a treatment for later lines, and we're doing a lot of education, along with our partners at J&J, to help healthcare professionals, patients, and other stakeholders understand that earlier is better. It's not only indicated earlier now, but giving CAR-T earlier leads to better outcomes on both efficacy and safety, and a better patient experience overall.

As one physician described it to us, "I'd rather give a young, healthy patient in their 60s the opportunity for a treatment-free interval so they can go live their life, than wait for that opportunity

and not give it to them earlier.” Another physician joked, “You don’t want to wait until the fourth quarter to put Michael Jordan in the game.” This goes to show that there is a recognition of the important opportunity of bringing this incredible therapy to patients earlier in their treatment.

Legend has stated that expanding into community oncology settings is a key priority going forward. What does that transition require in terms of education, site readiness, and infrastructure to support CAR-T delivery safely outside of specialist academic centers?

Right now, treatment has to happen at what’s called an authorized treatment center. That center has gone through a rigorous amount of training and assessment to be able to do the apheresis, the cell collection, administer CARVYKTI, and monitor patients afterward. Today we have about 150 authorized treatment centers in the US, but that is still a fairly concentrated set of places where patients can access care. The next leg of the journey is bringing CARVYKTI into the community and closer to patients, which we do in a few ways.

The first is educating referring physicians and enabling referrals from the community to the authorized treatment centers. The second is that our authorized treatment center network isn’t just limited to top academic medical centers but also includes major community and regional hospitals. Roughly a third of our 150 authorized treatment centers are community and regional hospitals. The third, is having CARVYKTI administered directly in the community setting. We’ve been working on this closely with our partners at J&J and will continue to build out over the next year or two. We have a few community centers activated for CARVYKTI right now and we expect several more to come online over the next 12 months.

Legend recently completed the expansion of its Raritan, New Jersey manufacturing facility. What will this mean for increasing capacity and access in the long run?

Manufacturing scale has been another major achievement for CARVYKTI. We couldn’t have treated 13,000 patients without the manufacturing capacity to support it. It’s not just the number of slots available that matters either. Manufacturing reliability is just as important. Our turnaround time is now under 30 days, which fits well with how patients are managed once their cells are collected and clinicians are ready to give them their cells back. Nearly all orders are delivered on the day we promised customers without delay.

We now have four nodes in our manufacturing network. Two facilities supplying the US and two supplying our global demand. Outside the US, we have two facilities in Ghent, Belgium: Obelisc and Tech Lane. Our most recent achievement was securing Tech Lane's approval for commercialization in Europe at the end of last year, which has enabled the growth we're now seeing in ex-US markets.

The Raritan facility, which we have in partnership with J&J, is the largest cell therapy manufacturing facility in the world. This reflects the scale of the market it supplies. We also have a secondary site through a manufacturing contract with Novartis here in New Jersey, though Raritan is our main supply for the US.

Looking back at the early history of CAR-T, hospitals, physicians, and patients never really knew whether a product would be available when therapies were first launched. At this point, we can confidently say supply is not an issue, and we even have the capacity to meet growing demand in the future. The goal now is to broaden access and availability by making sure every eligible patient knows about the therapy and can get it.

What hurdles still exist in terms of access and uptake for CAR-T therapies like CARVYKTI?

Given CARVYKTI's clinical profile and the value it has demonstrated, payers have recognized that value. We now have broad payer coverage, including federal programs and commercial plans. So if we define access as payer coverage, that's largely available to patients.

The broader access question is still the biggest hurdle. A patient in their community might be 30, or even 50, miles from the nearest treatment center that offers CARVYKTI. How are they going to get there? How much time do they need to take off? Do they have a caregiver who can be with them, and how much work will that caregiver miss? These are the questions that make it harder for a patient to imagine leaving their local community oncologist to seek treatment elsewhere. That's the gap we're trying to bridge by helping patients understand where they can go, what treatment will be like when they get there, whether they need caregiver support, where they'll stay, and how long until they can get back to work.

We have several programs in place to address this. The MyCARVYKTI Patient Support Program, sponsored by Legend and J&J, offers eligible patients housing and lodging support since patients need to stay close to their treatment center for a period of time.

We've also worked to reduce how long that period needs to be. Last year, the FDA removed the risk evaluation and mitigation strategy (REMS) requirement for CARVYKTI. Instead of having to stay near an authorized treatment center for up to six weeks, patients now only need to stay near a center for at least two weeks and can do so closer to their home oncology practice. The driving restriction was also reduced from eight weeks down to two. That matters for patients who commute, drive for work, or otherwise depend on driving for their livelihood.

We're also educating community oncology practices on what conversations to have with the authorized treatment center once a patient returns to their care. These patients are off active treatment, but they still need monitoring and therapeutic support. Some receive monthly intra venous immunoglobulin (IVIG) treatment for a period of time, some need revaccinations, and most need regular lab work. The community oncologist plays an important role in that transition of care once a patient has received CARVYKTI at an authorized treatment center and is ready to return home.

Compared to the access channels you've seen globally, do you see the US as a front-runner in the uptake of CAR-T and cell therapies, or is there room to catch up?

I believe the US will continue to be the single largest market for CAR-T. This goes both for Leg end and for most companies in the space. This is driven by the size of the population and the large unmet need among patients relapsing off prior treatments or newly diagnosed. Given the demographics in the US like an aging population and a higher proportion of higher-risk patients, there's always going to be a high unmet need here.

We also have a system that rewards innovation and provides access to it. Whether on the payer side or the employer side, there's broad acceptance that a one-time infusion providing long term, durable remission is appealing not only for patients but for payers too.

The challenge we see in the US is the fragmented nature of the healthcare system. Incentives can keep some patients within their community practice rather than getting referred for the best available care. The geographic distances also make it harder for some patients to reach the novel treatments coming out of academic centers. Europe has an advantage in both of those areas since geographies are more compressed and incentives under a single reimbursement authority are better aligned to make sure every patient gets the same standard of treatment.

While Europe does have some positives on that front, there’s no question the US, given the size of the market, the unmet need, and the reward for innovation here, will continue to be our single largest market.

What can you say about the future of Legend’s CAR-T pipeline?

Legend is looking at all ways to bring CAR-T to more patients, including allogeneic approaches, autologous approaches, and in vivo approaches. We’re also expanding beyond hematology into solid tumors and autoimmune disease. All of these areas are in scope for where our research is going.

In the in vivo space specifically, we’ve announced three programs across lymphoma, myeloma targeting GPRC5D, and autoimmune disease. We also have other programs, including autolo gous CAR-T and other approaches targeting solid tumors.

Solid tumors have historically been a bigger challenge for CAR-T given tumor heterogeneity and the difficulty T cells face penetrating the tumor microenvironment. Our researchers are hard at work looking for ways to crack that code and bring CAR-T to solid tumors.

How much do you see in vivo as the next wave of CAR-T therapy, and where would that leave products like CARVYKTI? Is there space for both?

We’re excited about the promise of in vivo. We have a significant investment in this space and we were pleased to present the first data set from our clinical program recently at the European Hematology Association meeting, which showed the first clinical data for patients with non Hodgkin’s lymphoma. It’s still early in our in vivo journey but we have several exciting milestones ahead of us.

Speaking more broadly, the potential and promise of in vivo is being able to administer a one time treatment where the body itself is the manufacturing plant. There’s no need for apheresis or cell collection, no need for lymphodepletion, and no need for patients to travel somewhere else to get their cells processed. What’s exciting about in vivo is the opportunity to improve the overall patient experience and provide access to even more patients.

That said, it’s also early days for the space overall. We expect in vivo will still face a significant hurdle to beat autologous options like CARVYKTI on efficacy, safety, and patient experience. For

now, we’re comfortable that CARVYKTI will remain a mainstay in myeloma for many years to come.

What are your ambitions for CARVYKTI and for Legend’s cell therapy platform over the next three to five years?

We’re excited about a couple of important milestones. First, we’ll be reading out data in the frontline setting over the next few years. We now have two fully enrolled, fully dosed studies in the frontline. One in a patient population ineligible for stem cell transplant, and another in a population eligible for it as to compare against the standard of stem cell transplant. Moving CARVYKTI to the frontline is something we’re very excited about.

Another important milestone we’re working toward is to further establish the use of CARVYKTI in relapsed MM across the community oncology ecosystem. And of course, we’re excited about the next wave of innovation in CAR-T like in vivo. If we can deliver on that promise, we could take our ambition beyond the 13,000 patients we’ve treated so far and multiply that to bring CAR-T to far more patients.

Reflecting on your time at Legend Biotech over the past year and a half, what final thought would you like to share about what it has meant to be part of the Legend team?

Legend is an incredible place to work. It has the exciting culture of a smaller pharma company combined with the resources of a larger one. It’s a sweet spot of being very focused on patients while staying dedicated to the mission. Our team members work hard because they’re focused on what matters, which is bringing innovative therapies, and even potential cures, to patients.

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