LEGN Earnings Call Transcript

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Quarter: 3

Operator: Ladies and gentlemen, thank you for standing by. Welcome to Legend Biotech's Third Quarter 2025 Earnings Call. [Operator Instructions] Please be advised that today's conference is being recorded. I would like now to turn the conference over to Jessie Yeung, Vice President of Investor Relations and Finance. Please go ahead.

Jessie Yeung: Good morning. This is Jessie Yeung, Vice President of Investor Relations and Finance at Legend Biotech. Thank you for joining our conference call today to review our third quarter of 2025 performance. Prior to this call, we issued a press release announcing our financing results for the quarter. You can find the press release on our IR website at legendbiotech.com. Joining me on today's call are Ying Huang, the company's Chief Executive Officer; Alan Bash, the company's President of CARVYKTI; and Carlos Santos, the company's Chief Financial Officer. Following the prepared remarks, we will open up the call for Q&A.; We have our President of R&D;, Guowei joining the Q&A; session. During today's call, we will be making forward-looking statements, which are subject to risks and uncertainties that may cause our actual results to differ materially from those expressed or implied here within. These forward-looking statements are discussed in greater detail in our SEC filings, which we encourage you to read and can be found under the Investors Section of our company website. In addition, adjusted net income or loss is a non-IFRS metric. This month, IFRS financial measures is in addition to and not a substitute for or superior to measures of financial performance prepared in accordance with IFRS. There are a number of new locations related to the use of these non-IFRS financial measures versus the closest IFRS equivalents. However, we believe that providing information concerning adjusted net income or loss and adjusted net income or loss per share enhances and investors' understanding of our financial performance. We use adjusted net income or loss as a performance metric that guides management in its operation and planning for the future of the business. We believe that adjusted net income or loss provides a useful measure of our operating performance from period to period. Our press release includes IFRS to non-IFRS reconciliation for these measures. With that, I will now turn the call over to Ying.

Ying Huang: Hello, everyone. Thank you for joining us today. The third quarter was marked by significant milestones that I will elaborate on momentarily. And we are looking forward to presenting new data at the Annual American Society of Hematology meeting in December. During the third quarter, CARVYKTI net trade sales were approximately $524 million, which is an 84% increase year-over-year. We have now treated over 9,000 patients with CARVYKTI, and our launch remains the strongest CAR-T launch to date. In the U.S., the majority of our utilization is in the earlier line setting. Additionally, we continue to see a lot of excitement about our long-term survival data presented at ASCO on CARTITUDE-1. As a reminder, 1/3 of patients with heavily pretreated relapsed/refractory multiple myeloma remain alive and progression-free for 5 years or more after being treated with CARVYKTI. This is especially impressive considering that today's bridging protocol did not exist at the time of the CARTITUDE-1 trial, and patients in the trial had received a median of 6.5 prior lines of therapy. Ever since our CARTITUDE-1 results were first presented in 2020, we have been setting new standards for efficacy in CAR-T for multiple myeloma. We're now changing that standard to curative potential. In fact, a recent article from Nature stated that 1/3 of the treated individuals had no evidence

of detectable myeloma after 5 years without further therapy, an outcome widely thought of as a prerequisite to consider using the term cure. This kind of efficacy for heavily pretreating patients is unprecedented in the field of multiple myeloma. On the regulatory front, the FDA recently approved an update to include CARVYKTI's overall survival benefit in this label. This was based on an analysis from the Phase III CARTITUDE-4 study showing a statistically significant improvement in overall survival for CARVYKTI compared to the standard of care therapy in patients with relapsed refractory multiple myeloma after 1 to 3 prior lines of therapy. Importantly, CARVYKTI is the only approved CAR-T in multi-myeloma with a demonstrated overall survival benefit in this label, which represents another step forward towards educating the physician community on CARVYKTI's unique profile as we work to bring CARVYKTI to more second-line patients in need across the United States. We expect label updates such as these and previous REMS updates will continue to improve the patient experience and enhance access in both community and academic settings. In fact, I want to share findings from a recent survey that was presented at the International Myeloma Society Meeting, where 237 patients and 267 physicians were represented across U.S., U.K., Spain, France, Germany, Italy, Japan and Brazil. In terms of what patients value when selecting a new line of treatment overall survival was clearly the most important attribute for patients. Also on the topic of survival, we are pleased that there will be two oral presentations on CARVYKTI at this year's upcoming ASH meeting. Before we dive deeper into this, I want to highlight that there will be an oral presentation at ASH on LCAR-G39D, our first-in-class allogeneic gamma delta T CAR-T cell therapy targeting both CD19 and CD20 in adults with relapsed/refractory B-cell non-Hodgkin's lymphoma. As you may have seen in the abstract, we are pleased that preliminary efficacy showed an encouraging response rate and sustained durability in patients. Turning to the CARVYKTI oral presentations. Based on the CARTITUDE-4 subgroup analysis, 80% of patients with standard risk cytogenetics were progression-free and off treatment at 2.5 years. In patients with standard risk disease who achieved MRD-negative CR at 1 year, this rate increased to 100% -- the low rate of progression events in CARVYKTI treated patients with standard risk cytogenetics shows the profound benefit of a single infusion in this population. z. In the second oral presentation on CARVYKTI, based on correlated biomarker data, longer PFS is associated with better immune fitness at baseline and stronger immune responses post CARVYKTI infusion. As observed in peripheral blood and within the tumor microenvironment of patients with relapsed refractory multiple myeloma in CARTITUDE-1 and CARTITUDE-4 studies. The peripheral immune fitness was more pronounced in patients with one and prior line of therapy versus three prior lines of therapy and beyond, where deterioration plateaued. Similarly on this topic, on the next slide, featuring data we presented at ASCO, you can see that while CARVYKTI has a favorable benefit risk profile across all different subgroups and lines of therapy, its PFS improvement diminishes with each line of therapy, which is why it's important to follow the latest International Myeloma Working Group guidelines on obtaining CAR-T therapy as early as first relapse. This slide also contextualizes the significance of our efficacy data from CARTITUDE-1, where there were 6.5 million prime lines of therapy and CARVYKTI still demonstrated a median PFS of 35 months. As we approach 10,000 annualized dose manufacturing capacity, we continue to extend our leadership in cell therapy through further advancing the field of CAR-T in multiple myeloma. We recently initiated another study called CARTITUDE-10, which is a Phase II multi-cohort trial to further characterize the efficacy and safety of cavity, which speaks to our commitment to investigating new product goals. Furthermore, a recent blood paper on effective bridging strategies across 20 centers found that among the 119 patients who proceeded to CAR-T therapy after receiving [indiscernible] including 98 patients receiving CARVYKTI. Not only were these deep responses, sustained soluble B-cell maturation energy decline and consistent CAR-T expansion. There were also no cases of peripheral neuropathy, parkinsonism, or colitis reported. As we focus on educating the physician community on our overall survival benefit based on the extensive CARVYKTI data that's been generated. We're also taking the opportunity to remind physicians about the latest research on bridging therapy and ALC monitoring as well as the most recent IMWG guidelines on CAR-T. In a few moments, you'll hear from Alan on how we and our partner, Johnson & Johnson, are bringing CARVYKTI to more multiple myeloma patients in need. In light of the demand, we continue to see across the U.S. and overseas we are moving full steam ahead on our capacity expansion plans. On a final note, on CARVYKTI before we turn to our pipeline, we continue to expect to complete

enrollment for CARTITUDE-5, 6 this year. We believe the CARTITUDE-5 and 6 trials are key to moving CARVYKTI into the frontline setting. Looking ahead at our long-term growth, in addition to looking forward moving carve into the frontline. We remain focused on solidifying our leadership in cell therapy more broadly. We are making progress in new indications such as solid tumor and NHL programs. as you have seen with the data at recent medical conferences. Additionally, we are looking forward to the ribbon-cutting ceremony tomorrow for our new research facility in Philadelphia, where in vivo delivery will be one of its key focuses, positioning us well to pursue this area of innovation. We remain excited about this new frontier of cell therapy. To sum up, Legend is the largest stand-alone cell therapy company with over 9,000 CARVYKTI patients treated as we forged the path to cure. With a cash position of nearly $1 billion, we are investing in our core differentiators in cell therapy and remain focused on delivering operational efficiency in order to ensure durable long-term growth. We continue to anticipate achieving profitability for CARVYKTI by the end of 2025 and company-wide profitability in 2026, excluding unrealized foreign exchange gains or losses. And with that, I'll pass it over to Alan to provide an update on CARVYKTI.

Alan Bash: Thank you, Ying. CARVYKTI remains the undisputed leader of CAR-T sales in a single quarter with net trade sales of $524 million during the third quarter. In addition to being the highest selling CAR-T ever, CARVYKTI has also achieved a CAGR of 111% since launch, which is unmatched in this class. Despite these record-setting numbers, we continue to believe there is significant opportunity for further market penetration for CARVYKTI, given the magnitude of the addressable multiple myeloma market opportunity for CAR-T. While we are continuing to expand our footprint of authorized treatment centers in the U.S. The next frontiers of growth are also expected to come from expanding our presence in the community setting in the U.S. and expanding our market leadership outside the U.S. Diving deeper into our performance this quarter, CARVYKTI net trade sales grew 84% year-over-year and 19% from the second quarter. Our global growth was driven by continued share gains and site expansion. U.S. net trade sales of $396 million grew 53% year-over-year and 11% quarter-over-quarter. Quarter-over-quarter growth in the U.S. was primarily driven by continued strong demand with 60% utilization in earlier-line settings. Regarding our performance outside the U.S., we had sales of $128 million which is nearly 5x the amount over the same period a year ago and represents a 58% increase quarter-over-quarter. Our performance outside the U.S. was driven not only by continued growth in Germany, but by strong launches in Spain and Belgium. In terms of supply tailwinds to further build upon our CAR-T market leadership in multiple myeloma, I would like to provide some incremental updates since the second quarter. We are proud to announce that our manufacturing network growth and continued efficiencies mean that we are now able to fully supply the demand and there is no longer a wait for patients. We expect both supply and demand will continue to expand together to help ensure a seamless customer experience. In the U.S., we are currently in the final stages of the expansion of the Raritan facility that will significantly expand capacity to support continued U.S. market growth. As it relates to supporting growth outside the U.S. I am pleased to announce that our Tech Lane facility recently initiated commercial production. This is an important milestone for serving patients in Europe to meet the increasing demand. Turning to demand drivers. First, of course, is the recent unprecedented long-term survival data that we presented at ASCO on CARTITUDE-1, second is our demonstrated overall survival benefit, which has now been added to the U.S. label. We are focused on educating both treating and referring physicians in the academic and community settings on how CARVYKTI is the first and only multiple myeloma cell therapy via a single infusion to significantly extend overall survival versus standard therapies and on our long-term survival data. In the community setting, we continue to raise awareness, drive referrals and educate oncologists and nursing staff on managing patients once they transition back to their offices. And as Ying mentioned, we are also educating them on the IMWG guidelines and the importance of treating eligible patients as early as possible to take advantage of T cell fitness and potentially improve survival outcomes. Lastly, in the U.S., the number of authorized treatment centers now stands at 131 sites across the U.S., with about 1/3 of our sites being community and regional hospitals, which serve an important need in the community setting. We are also pleased with the discussions we've had with many stakeholders about the need to bring CAR-T even closer to the community and with adoption by community networks or

practices. Our early experience with Virginia Oncology associates indicates that this is an area of large need and opportunity. Currently, we estimate that 80% of myeloma patients live within 5 miles of a CARVYKTI authorized treatment center. While that is strong coverage, we think we can do even better over the next 1 to 2 years. And outside the U.S., we will continue to benefit from the new launches. And with reference to new markets, we are proud to say that we have currently launched in markets around the world. With the help of our partner, Johnson & Johnson, we have activated 246 treatment sites. We continue to be excited about bringing CARVYKTI to more eligible patients in Denmark, Sweden, Belgium, Luxembourg, Spain, Portugal Saudi Arabia and the private markets of Israel and the U.K. With the approval of commercial production at our Tech Lane facility, we are well on our way to being able to treat over 10,000 patients on an annualized basis around the world. Now it's time to take a closer look at the financials. So I'll turn the call over to Ying as we provide a warm welcome to Carlos.

Ying Huang: Thank you, Alan. As many of you already know, in August, we announced that Carlos Santos who's joining Legend as our new Chief Financial Officer. I'd like to extend my gratitude to Jessie Yeung for her outstanding leadership and significant contributions in guiding our finance organization prior to Carlos arrival. Carlos joins Legend from AstraZeneca where he held various positions over the last 10 years, including CFO for U.S. oncology, CFO of Latin America business and acting Aria VP of the Latin America Commercial unit. His extensive experience in the biotech sector and wealth of financial leadership expertise will be invaluable as we continue to execute on our commercial and clinical plans and seek to attain company-wide profitability in 2026. We are pleased to welcome Carlos to our executive team.

Carlos Santos: Thank you, Ying. And good morning, everyone. I am very excited to join Legend at this pivotal moment in its global development and growth. After my first 3 months here and visiting our Tech Lane facility, I can confidently say that there is a clear vision and path for Legend to be the global leader in cell therapy. I also see a strong path to profitability through our revenue growth and operational efficiency. First of all, CARVYKTI continues to grow at a strong rate with net sales up 84% year-over-year in the third quarter. And as Alan mentioned, we have a number of tailwinds that should continue to generate demand in the vast multiple myeloma market. I believe there's a significant opportunity for growth in the community setting, especially with our unique outpatient administration advantage, which provides physicians with flexibility. As Ying has mentioned previously, both CARTITUDE-5 and CARTITUDE-6 approvals have the potential to significantly expand the opportunity for our already proven commercial therapy, CARVYKTI. In terms of Legend's operational efficiency, our operating expenses as a percentage of revenue have significantly improved over the last 12 months due to our focus on disciplined expense management and increasing automation throughout our organization, and we continue to look at ways to further unlock efficiencies. Drilling deeper into our third quarter, we delivered solid financial results with CARVYKTI net sales up 84% year-over-year. Total revenues were $272 million, driven by collaboration revenue growth of 84% year-over-year. In Q3, we delivered a $40 million net loss, but was $19 million on an adjusted net loss basis, after excluding items that are not representative of the company's core business, such as $15 million in stock-based compensation. Importantly, our operating loss of $70 million in the same period 1 year ago was reduced by 38% to a $43 million operating loss during the third quarter. This meaningful improvement in operating results was driven by our operational efficiency and disciplined expense management. Even though we continue to invest in our robust pipeline and supporting the second-line indication launch and our manufacturing capacity. Our third quarter gross margin on net product sales remained consistent at 57%. As expected, R&D; expense on an IFRS basis grew slightly to $113 million or 42% of revenue, while SG&A; on an IFRS basis grew 10% from the prior year to $87 million in the third quarter or 32% of revenue. Overall, we have made significant progress on operating cash flow generation as evidenced by our $29 million in cash flow from operations this quarter and we are continuing to make strides towards profitability. Our adjusted diluted earnings per share was a negative $0.05 compared to a negative $0.11 for the same period last year. Now turning to capital allocation. We have maintained a strong balance sheet with approximately $1 billion in cash and equivalents and time deposits. We will continue to prioritize disciplined expense management as we fund our operating and

capital expenditures, including future innovation until we achieve company-wide profitability, excluding foreign exchange gains and losses, which we anticipate in 2026. In summary, our third quarter results demonstrate continued commercial execution supported by CARVYKTI's unique clinical outcomes along with increased operational efficiency. We are also pleased with our progress towards pioneering next-generation cell therapy treatments as we leverage our unique innovation model to maximize our cell therapy platform. And now it's time to take your questions. Operator, we're ready for the first question, please.

Operator: [Operator Instructions] The first question comes from Gena Wang with Barclays.

Huidong Wang: Carlos, congratulations on the new position. since you closed the remarks, maybe I will ask you. I know 2026, we should start to see positive cash flow and if given the robust revenue that CARVYKTI could generate. You actually in 2026, there could be very decent in full cash. So maybe I wanted to ask you with this increased cash in hand, what will be the best way to prioritize the cash and then in terms of the pipeline assets? And then I have a very quick question regarding the ASH abstract. I do know both J&J; and Legend actually withdraw a presentation of a comparison between IMAGINE-1 and CARTITUDE-1. So maybe, Ying if you can or Alan, if you can give a little bit more insight regarding the rationale behind it? And then lastly, very quickly regarding the Raritan site. I know you did say like a second half, that should be complete completion of expansion. And given we only have less than 2 months left. Should we expect everything is on track? Is the -- I know that the last step would need to be signed off by the FDA. And should we expect that should happen before year-end '25?

Carlos Santos: Okay. Thank you, Gena. This is Carlos. In terms of your inquiry about how we're going to allocate cash given our profitability expected in 2026. I would say that first and foremost, we want to maximize our CARVYKTI franchise. So this is our priority in terms of capital allocation. And as you know, we've been making significant capital investments in manufacturing and expanding our network. At the same time, we will also continue to significantly invest in our CAR-T platform. We're going to be looking into every opportunity to accelerate our existing programs that will strengthen our market leadership in CAR-T, including business development.

Alan Bash: And the yes, let me answer the other two questions. In terms of Raritan, the plan is very much on track to be able to have the facility expansion completed, and we've already started the submission process for that. So everything is on track for us to head into 2026 with the annualized doses for 10,000 doses, and that is complemented by, of course, as you know, the news we announced around the commercial production in Tech Lane. So now we have all four nodes operating on a commercial basis. I did want to just address your question on the abstract. So there was a poster from ASH that was withdrawn and due to the limited data available for ANIDA cell in the public domain at this point, the abstract was drawn in alignment with the authors, and we are looking forward to future opportunities to share the data.

Operator: And our next question will come from Terence Flynn with Morgan Stanley.

Terence Flynn: I just wondered -- I know you provided us with the ATC numbers, both in the U.S. and rest of world now. But as you look into 2026, where do you think those can go realistically? And then on the manufacturing capacity, again, great to hear all the progress there. You mentioned the 10,000 unit number now. Again, when you kind of complete all of these ongoing efforts, where should that number end up approximately?

Alan Bash: So regarding the ATC as you mentioned, we're at 131. Actually, we have an update. We have 132 sites in the U.S. So combine that with the OUS, we're past the 250 mark for total number of sites, and that's a recent update. We continue to update this every single day as we watch it. And to your question about where it could go in '26, we have our sights on continuing to expand, for example, making sure that we have full coverage in the 160-plus sites that some of the competition has. So as you hear from competitors around their network, we're very confident that in 2026 by the time they are launched that we'll be able to have coverage in the same vein. I will also add that as we look even

ahead, the total number of sites in the U.S. that have either started to do CAR-T or have seriously expressed interest and have started the process is something in the 180 number of sites, [Mark]. And we believe that we are well on track to be able to get there over time and then continue to expand further into the community setting. I will also address your question about the plan beyond 10,000. So with all four nodes in the network, that being in the U.S., obviously, Raritan, the expansion there, Novartis, which continues to ramp for us and deliver and of course, in Europe with the increasing demand in Europe, we have the Tech Lane facility now coming online with full commercial production and Obelisc continuing to drive production, as well and gaining efficiencies. This is a network that we believe will enable us to get eventually to 20,000 doses annualized. And that's through not only continued ramp in all four of the nodes but also continued efficiencies, lowering the out of stack, improving the manufacturing success rates.

Operator: And our next question will come from Eric Schmidt with Cantor.

Eric Schmidt: As you move from a supply-constrained environment to a demand-constrained environment, what do you think the most important things are that you need to do to mobilize demand to fulfill your new supply and how quickly do you think you can get to essentially near full utilization of the 10,000 doses? Thank you.

Alan Bash: This is Alan again. So in terms of accelerating demand, we have a number of plans in place to be able to do that. First of all, it's all about making sure that physicians around the U.S. and around the world, really fully appreciate the benefits of treating earlier. And that's something that we have certainly gotten traction on, whether that's data that's coming out in the real world or some of the app flow-throughs that you see in presentations. There's a broader and greater appreciation for the fact that efficacy is better when you treat in earlier lines the safety, the incidence of neurologic events and other adverse events is lower when you have patients treated in the earlier lines. You have improved T cell fitness, which is another aspect to have closer that's going to be at ASH. And as you see from the ASH posters, we also have data that clearly suggests that at the out spec rates are lower. So where everything is better earlier, and that's a key message that we'll continue to drive not only with the current authorized treatment centers, but also the referred in the community. Just to add one more point. We have a network as we talked about and the footprint today, but our community strategy is really based on not only continuing to leverage the 1/3 of sites that are in the community, the 1/3 of sites in our current network at our community and regional hospitals, but also driving referrals from the physician practices that are not in the network. And then ultimately, we're having conversations with some of the large practices such as the one you saw from our announcement earlier in the year in VOA to enable the community to actually start to administer CAR-T themselves.

Eric Schmidt: And any sense on when you get to full capacity?

Alan Bash: Well, I think as we said today, we are -- our capacity is now meeting the demand in the marketplace. And as we're going to be increasing capacity, we'll also be increasing the demand as well.

Eric Schmidt: I meant in terms of having almost 10,000 doses to dose in the near future. Do you think there's a time line to utilize that capacity?

Alan Bash: Well, I think we'll be able to achieve those goals in 2026, and that translates into the consensus revenues that we see in 2026 or that have been issued for 2026. So we're very much on track for that.

Ying Huang: Eric, this is Ying. Maybe I'll tell you that from where I sit, the latest data suggests that we're really running at nearly 100% capacity utilization at all four nodes right now. So we continue to expect that all four nodes will be utilized at very high capacity next year as well. Thank you.

Operator: And our next question will come from Jessica Fye with JPMorgan.

Unknown Analyst: This is [Dana] on for Jess. I really have just one question here. I wanted to ask you if you guys could throw some color on anything that would be watching out for at ASH from a competitive standpoint?

Alan Bash: I think in the absence of information -- sorry, it's Alan here. It might be the absence of information that is most relevant. We're fully ready and prepared to compete with a potential [BC] of a CAR-T that's coming out potentially next year. But I will say that we haven't seen the Kaplan-Meier curve from ANIDA Cell yet. So it's quite hard to know what that data is going to look like. But I will say that we're going to continue to be raising the bar on efficacy we have a significant advantage in terms of the efficacy that we've seen in the CARTITUDE-4 population in the subgroups in the earlier lines in CART-4 and over the next year, we're going to be also demonstrating the fact that just as we did in CAR-T. CARTITUDE-1 that CARTITUDE-4 has the long-term durability that physicians and patients are asking for. So we're very comfortable with the data that we're going to be presenting in terms of efficacy, and it's really just a question of when we might see that data from competition.

Guowei Fang: Yes. And this is what -- on the pipeline side, we are also going to release early clinical data for our internal [indiscernible] platform. And this is a product with a unique design and unique CMC process. We see a highly manageable safety profile and good expansion in oncology patients. The preliminary efficacy show encouraging response rate and also importantly, sustained durability.

Operator: And our next question will come from Jon Miller with Evercore.

Jonathan Miller: I'd love to dial in more on the community progress that you've made -- specifically in the VOA network, have you been treating patients there already? How has the uptake been going in that patient network? Do you have plans to expand beyond the Virginia network near term? And when you say that 1/3 of your sites are regional or community centers, I mean, I assume most of that is regional centers. Can you talk a little bit more about adoption expectations in the communities specifically as we head into '26?

Alan Bash: Sure. Yes. So let me unpack that a little bit. We think about the community strategy on a number of paradigm. The first is the fact that we have in our current network, as you mentioned, sites that are already community and regional hospitals. And it's a mix because sometimes a large regional hospital will be servicing a community, and that's what we mean by that group. It's about 1/3 of the 130 or so space that we currently have. And we see that, that segment of our network is already contributing about past the growth that we see. So it's a very healthy, robust part of our network. It's going to continue to grow and it's going to continue to serve the community at large. The second part of the strategy is around engaging community physicians who are referred and we've been doing that over the last many months with our partner, J&J;, we have sales teams and medical teams who are engaging fully with the referring network. We're building a lot of good information there for them. We're communicating on the profile we're communicating on the fact that referring earlier is better, and we're gaining traction there as well. The third leg of the journey, if you will, is then going to the community networks, and you mentioned VOA. So just to answer your question, yes, we have started to treat patients at VOA. The feedback has been positive so far. We're also learning a number of things about just how these community networks will need to be supported throughout their experience of coming online, but there is definitely plans to engage not only with VOA and continue to grow that network but also to engage with other practices throughout the next several months and into 2026.

Jonathan Miller: And when you think about the community-specific practices here, I mean, I guess I'm asking about your ability to dose in settings where your potential competitors absolutely would not be able to dose at least not first, not just referring to academic centers, but folks getting treated in the community where competitors don't have reach. Can you talk about how that will evolve in '26?

Alan Bash: Well, I think we're laying the groundwork for having that -- having all that presence in the community, but also to your point, we have about half of our current patients are treated in the outpatient setting. And by virtue of the fact that we have a median onset of the CRS in the clinical

studies at 7 days. That means that increasingly, practices are comfortable with making sure that physicians can dose patients in the outpatient setting, they can be monitored. And then if they need to be readmitted for one reason or the other, they're able to do that afterwards. And in addition, as we've discussed before, the removal of the REMS is also an important tailwind because it's been enabling patients to have only 2 weeks of local modeling before they're able to go back home. And then also it removes the driving description of 8 weeks, and that's now down to 2 weeks. So that's another important factor for patients being able to get dosed get infused and then be able to be monitored more close to home and get back with their lives.

Operator: And the next question will come from Yaron Werber with TD Cowen.

Unknown Analyst: This is [Dana] on for Yaron. n an amazing quarter. I have a question on the ASH abstracts. I think there were two abstracts from Mayo and Moffitt suggesting that prophylactic dex doesn't seem to reduce the risk of delayed neurotox with CARVYKTI. And given those results, how are you thinking about adjusting your strategy for mitigating delayed neurotox? Are you considering any alternative regimens or thinking about amending any Phase III protocols?

Ying Huang: This is Ying. I'll answer this question. So obviously, if you look at both the presentations asset, you see that ALC remains a very predictive marker. However, the dexamethasone prophylaxis may not be sufficient. And in fact, recently, you have seen publications from real-world studies, including the blood paper that was published in August, right? So we think that the most important factor is you need to treat those patients with high tumor burden with effective bridging regimen. And you will see actually quite a few assets coming out in the ASH next month, that various centers are using different recipes or different regimens. But again, all the commonality suggests that you have to use an effective bridging therapy. In fact, one of the PIs from Mayo, right, Dr. Lin recently said at IMS that you have to switch to a different effective regimen if the first one does not work. So the critical factor here is we have to bring the tumor burden down. And once you do that, you will not see adverse events such as neurotox colitis or CRS. So that is actually a trend we're seeing. Like I said, you will see more real-world data and also more presentations at ASH about this.

Operator: And the next question will come from James Shin with DB.

James Shin: I got a couple on CARTITUDE-10. I see fludarabine is being removed, but is there any change to cyclophosphamide dosing? And assuming this looks, I guess, to Legend standards, will this be somehow added to the label or formally, I guess, approved by the FDA and can be adopted broadly?

Ying Huang: James, this is Ying. So you're right. We and our partner, Johnson & Johnson, recently initiated a Phase II study called CARTITUDE-10. And the first cohort would evaluate the fludarabine-free regimen for lymphodepletion. The reason being that we know fludarabine has been established as a neurotox factor here. So we'd like to see whether we can actually achieve similar level of lymphodepletion without using fludarabine. So that is already up and running. We're enrolling and dosing patients now. Now on your second question, we have to generate the data first. And of course, if the data is positive, we would potentially take that to the FDA to see if that could be included in the label. But right now, it's premature to say anything about the label inclusion.

James Shin: Can I ask one more on the primary being MRD? Was that any insight from the FDA? And do you have any insight on MRD becoming formally a surrogate?

Ying Huang: Yes. So James, regarding MRD as a potential registrational endpoint, we're continuing our discussion with the FDA. And also, we'd like to see under which setting in which line potentially can margin activity be an endpoint. But you have to stay tuned. And when we have more to say, we'll disclose about that.

Operator: Thank you. the next question is going come from Justin Zelin with BTIG.

Justin Zelin: I was curious if you could give us an update on outpatient administration, what percentage of patients are you seeing dose in the outpatient setting? And any update on the contribution of revenue from earlier lines versus later lines?

Alan Bash: Yes. So I think I mentioned this earlier, outpacing based on claims data is about 50% of the patients currently and we continue to expect that will be growing over time. Although as we onboard new sites, sometimes they tend to start with patients in the inpatient. So the growth of the site network is also a little bit of a drag on the outpatient overall mix, but those sites that have converted into outpatient are doing so with good success, and it's enabling additional capacity at each site and efficiency. To answer your second question, we see about 60% of our overall scripts coming from the second through fourth line population. That does continue to grow, albeit a little bit more slowly than we had anticipated, but we see that evolution continue, and in fact, the fastest-growing part of that mix is in the third line. So what that tells us is that increasingly, there is adoption, there is acceptance and there's enthusiasm for bringing CAR-T and CARVYKTI specifically into the earlier line setting based on the CARTITUDE-4 data.

Operator: And the next question will come from Mitchell Kapoor with H.C. Wainwright.

Unknown Analyst: This is Katie on for Mitchell. Regarding your guidance for profitability by 2026, what milestones and roadblocks are kind of underpinning that? And what should we be keeping an eye on to understand if you're on track to hit that goal?

Carlos Santos: Yes. Thank you, Katie. Our view on profitability has not changed. We actually expect to have profitability for CARVYKTI this year in 2025 and enterprise-wise or for Legend as a company in 2026. This is underpinned by our significant growth for the [factor] for CARVYKTI, and our management of operating expenses resulting in positive free cash flow in the year of 2026. Again, as we've mentioned, we have significant tailwinds in our revenue growth, and this should serve us well for profitability next year.

Operator: And the next question will come from Ash Verma with UBS.

Ashwani Verma: So just maybe like I'm trying to understand if I mix between the second to fourth line that you commented on third line you said there's a post comment. Can you give us a sense of how much is that? And just secondly, on the Majestic III data, like top line is available now, but just curious how that can start to impact the second line opportunity for you in any way?

Alan Bash: Yes. So we wouldn't break down -- we're not going to break down the split between how much is coming from each line. But I think it is important that all of the lines of therapy on an absolute basis are growing. We're getting more and more patients in the second line, more and more patients than third, et cetera, et cetera. We also happen to be getting more patients in the later lines. That's just by virtue of the demand for CARVYKTI across all lines, and that's why the mix continues to be about a 60-40 split between the earlier lines of CARTITUDE-4 and the CARTITUDE-1 populations. But again, the -- where the growth we're seeing most pronounced is in the third line, and that's because, again, physicians are recognizing that they want to try to get patients with -- into CARVYKTI treatment as quickly as possible post first relapse or perhaps second relapse.

Ying Huang: Ash, I do want to answer a question about Majestic III. First of all, we're really pleased that there could be potentially another regimen for patients in second line with multiple myeloma. And secondly, I want to point out that the commercial opportunity for this addressable market is very large. You're looking at about 80,000 to 100,000 patients in that segment. And thirdly, I think we are targeting potentially a different segment here, right? Because if you look at CARVYKTI, we want to emphasize that CARVYKTI has unmatched unprecedented survival data and also with durability. It's also a onetime treatment. So there is a certain patient population who really prefer that kind of a convenience, right, brought by a onetime infusion without further need for any other medication for myeloma. So that is how I view this market, and we don't really expect MAJESTIC III. Data will really impact the uptake for CARVYKTI in second line.

Operator: And our next question comes from Clara Dong with Jefferies.

Unknown Analyst: This is [Jenna] on for Clara. Could you give us some comments on your strong international growth? Maybe elaborate on -- where are you seeing the strongest demand and uptake now versus where do you see higher growth potential after Tech Lane comes on? And going into '26 and beyond, how do you foresee the Tech Lane capacity impact market share?

Alan Bash: Yes. Outside of the U.S., which is obviously led by our partner, J&J;, there's been strong uptake in Germany, Spain and Belgium, in particular, as well as the other markets that have launched. Many of the European markets to really see the value here of a onetime infusion, the durability that you get with the PFS and OS benefit as truly providing a strong value not only to patients but also to the health system. So there's a lot of support for using CARVYKTI earlier in the treatment paradigm, and that's encouraging. We continue to advance the launches that we've already had in the 14 markets around the world, which we listed in the presentation. And we're very excited to have Tech Lane now online from a commercial standpoint to enable the supply both between Tech Lane and Obelisc together, we'll be able to meet the capacity demand for the growing European launches.

Operator: And our next question will come from Sean McCutcheon with Raymond James.

Sean McCutcheon: A couple of quick ones from us. You noted improving out of spec rates. Can you speak to the trend as you see more real-world patients in the earlier line setting and ongoing efforts to push that out of spec lower? And any commentary on what you think is a feasible kind of minimum steady state there? And then secondarily, can you speak to any early impact of loosening REMS requirements through auto CAR-T and whether you're seeing an uptick in referrals for earlier line patients?

Alan Bash: Yes. There is an abstract at ASH that's reviewing about 3,000 patient records for out of spec. And the out-of-spec rate is somewhere in the 6% to 9% accorded abstract and in fact, it's lower in the earlier lines. So it's very consistent with what we're hearing around earlier is better. is very consistent with the fact that the T cell is stronger in the earlier patients, and that's enabling a better dose and better viability and lower out of spec. And we'll continue to drive that down over time across all the nodes in the network, and we believe that, that's going to be very competitive with other products on the market. In terms of the REM, it's a little bit early. We're hearing sort of a mix of reactions from sites. One is that this is great news for patients and that it is enabling patients to get back home more quickly. Other sites are taking a little bit more of a wait-and-see approach in saying they're going to decide on a patient-by-patient basis. which patients were able to go back and which patients they want to keep more close to home. But it's going to be a consultation. The bottom line is it's a burden lifted and it's one that is enabling a more robust conversation about the fact that we can extend the benefit and the efficacy we see with CARVYKTI to more and more patients.

Operator: I show no further questions at this time. I would now like to turn the call back over to Ying for closing remarks.

Ying Huang: Thanks, everyone, for joining today's call. As you can see, we had a really strong quarter, and we continue to expect another strong quarter in the fourth quarter, as well as a very strong year in the next year, 2026. So I just want to say that we look forward to seeing everyone here at ASH because we and James are very confident about the efficacy of CARVYKTI and in fact, we will publish the data in an oral presentation of some data. That's not including the ASH abstracts. And we strongly believe that the data at ASH will raise the bar even further for efficacy. So we look forward to seeing everyone in Orlando. Thank you.

Operator: Thank you. That does conclude today's conference call. Thank you for participating, and you may now disconnect.