Hansa Biopharma Q3 2023 Conference Call Transcript

Company Participants

Søren Tulstrup - Chief Executive Officer

Matt Shaulis - Chief Commercial Officer and U.S. President

Donato Spota - Chief Financial Officer

Conference Call Participants

Gonzalo Artiach - ABG

Operator

Hi, everyone, and welcome to the Hansa Biopharma Third Quarter 2023 Earnings Results Conference Call. Today's call is being recorded. [Operator Instructions] Afterwards, there will be a question-and-answer session. [Operator Instructions] Speakers, please begin.

Søren Tulstrup

Thank you, operator. Good afternoon, good morning, and welcome to the Hansa Biopharma conference call to review third quarter 2023 results. I'm Søren Tulstrup, CEO of Hansa Biopharma. Joining me today is our Chief Commercial Officer and U.S. President, Matt Shaulis; and our Chief Financial Officer, Donato Spota.

Hansa's Head of Investor Relations, Klaus Sindahl, is also with us. Today, we'll discuss the highlights and progress we made during the third quarter of 2023 and review our near-term milestones. The presentation should take roughly 20 minutes, after which there will be an opportunity to ask questions during the Q&A session. Please turn to Slide 2. Please allow me to draw your attention to the fact that we will be making forward-looking statements during this presentation, and you should therefore apply appropriate caution. Please turn to Slide 3 and an overview of Q3 highlights. Our commitment to creating paradigm shifts in clinical care resulting in significantly better patient outcomes remain strong.

While the European launch of Idefirix in kidney transplant is still in its early phase where, as discussed on previous calls, sales and sales growth, as expected, remained limited and highly volatile quarter-on-quarter until market access has been fully secured and implemented to the level of individual hospitals, organ allocation systems have been adjusted to allow a sufficient flow of organ offers to highly sensitized patients, and leading centers have gained and evaluated first experiences in desensitizing and subsequently transplanting highly sensitized patients.

We're pleased with the programs, I guess key launch metrics, which suggest we are nearing the phase when market uptake of this transformative therapy will accelerate. Thus, as Matt will discuss later on this call, we continue to see steady growth both in the number of key transplant centers readied for utilization of Idefirix through implementation of new specific desensitization protocols and in patients identified and wait-listed for desensitization across Europe.

We're also encouraged by the fact that a growing number of transplant centers now have experience with Idefirix, and that positive first outcomes have led to repeat usage in several

hospitals, most notably in France, which as the only early launch country among the top 5 markets in Europe at this time is acting as a new uptake indicator. In addition, we continue to see strong and growing interest in Idefirix amongst the broader members of the European transplant community, thus the Hansa-sponsored symposium at the Annual Congress of the European Society of Transplantation in September entitled Crossing Donor-Specific Antibody Barriers to Transplant Today attracted more than 600 members of the European transplant community.

We heard some of their pioneer colleagues discuss their first experiences using Idefirix to enable kidney transplants in highly sensitized patients. Patient identification by the transplant clinics is ongoing and a growing number of patients are now included in specific Idefirix desensitization programs.

Transplantations are expected to take place as organs become available from allocation systems such as Eurotransplant, where the very first patients were selected in October for the new pilot program. Reflecting this, our efforts to grow supply arrangements with individual clinics is seeing good progress. During the third quarter, we secured several new agreements with leading transplant centers in Europe, and we expect this to translate into increased commercial sales in the coming period, supported by new markets such as the U.K., Germany and Belgium.

I do want to stress again, though, that as discussed since the very beginning of the launch, sales will remain highly volatile from quarter-to-quarter also into 2024. Our Q2 sales were the highest ever since the beginning of the launch, followed by lower sales this quarter. Idefirix is not only a transformative product that disrupts previous thinking about the eligibility of highly sensitized patients for kidney transplant necessitating significant market shaping efforts.

It's also a product that triggers a single high-value sales event when used in a patient, a sales that does not recur in subsequent quarters. This is very different from the sales uptake patterns seen in more traditional product launches where new patient initiations are added to an existing pool of [repeat use patients].Repeat sales of Idefirix occurs at the hospital level, which is why this criterion serves as a early growth indicator when added to progress on other key launch metrics such as funding center readiness to patient identification.

As I said earlier, looking at the progress of the Idefirix launch against the totality of these key launch metrics, we remain confident that the Idefirix launch is on track. Having said this, we would obviously like to see faster uptake and showing the patient we encounter not least amongst the desensitization pioneers in the transplant community, who have invested much effort into making their clinics ready to initiate a highly innovative, potentially life-saving therapy and are experiencing significant lead times due to the complexities of the organ allocation and transplant systems.

Given the strong Idefirix data from the clinical development program that led to the product's conditional approval in Europe, and the long-term data that have appeared since most recently, the 5-year data announced last week confirming that patient and graft survival outcomes in highly sensitized patients desensitized using Idefirix continue to mirror what is seen in the broader transplant base.

It is, of course, somewhat frustrating to see the relatively slow initial uptake of the UT sensitization procedures enabled by Idefirix. But this is unfortunately not unexpected, and we continue to see significant commercial potential in this indication and more importantly, a unique opportunity to prolong and improve human lives. While we're excited about the opportunity to bring Idefirix to end-stage renal disease patients waiting for a potentially

lifesaving kidney transplant, we're equally excited about the progress we are making in advancing the pipeline of drug candidates for patients suffering from serious autoimmune diseases and genetic disorders enabled by our unique IgG-cleaving enzyme platform.

In autoimmune diseases, we see good momentum in our pivotal Phase III program in anti-GBM, where we have now enrolled almost [20%] of the patients targeted since we commenced the study earlier this year, and also in the investigator-initiated Phase II program in ANCA-associated vasculitis, where we already have seen 3 out of 10 targeted patients treated following initiation back in July. Earlier this month, we also reported encouraging high-level data from the first-in-human trial of HNSA-5487, the lead candidate from our NiceR program focused on developing next-generation IgG-cleaving enzymes, a program that we see as a very important potential company value driver.

We will cover the specifics on this program in more detail later during the presentation. As far as our clinical development activities within kidney transplant are concerned, last week, as previously said, we could announce positive data from our 5-year follow-up study, which further supports the clinical benefit of imlifidase in kidney transplantation with graft survival of 82% 5 years out, consistent with the outcomes seen at 3 years post transplant. In the U.S., we continue to carry out initiatives to accelerate randomization in the pivotal Phase III ConfIdeS trial in kidney transplantation.

Despite several new centers being activated in the last 4 months to 6 months and an acceleration in the number of patients being randomized over the summer, with more than half of the targeted 64 patients randomized, we are now expecting randomization to complete by mid-2024 with a subsequent BLA submission expected in 2025.

Matt will cover our U.S. ConfIdeS trial in more detail later during this presentation. Finally, I'm happy to welcome Dr. Hitto Kaufmann as Hansa's new Chief Scientific Officer. Hitto joins us on December 1 and brings more than 20 years of experience in R&D from both large pharma and small biotech. With this overview, I will now hand over the call to Matt Shaulis, who will walk us through our commercial and U.S. related progress in more detail.

Matt, please.

Matt Shaulis

Thank you, Soren, and please turn to Slide 4. As mentioned, we're committed to creating paradigm shifts in kidney transplant clinical care, resulting in significantly better patient outcomes. We're not simply launching a product for an established use, but rather enabling the treatment of cross-match positive patients that previously had no viable options to enable transplantation. For decades, the medical training and practice of transplantation has been predicated on compatibility only in cross-match negative patients. This is because the modalities considered to enable transplant patients each have some limitations.

PLEX removes antibodies from circulation, IVIg replaces pathogenic antibody. And B-cell depletion lowers antibody levels through B-cell depletion, but none of these approaches completely eliminate IgG antibody in both the blood circulation and tissue. As such, none of these has meaningful outcomes in kidney transplantation with highly sensitized patients are considered standard of care or are regulatory approved. As a result, highly sensitized patients have suffered the inequity of going untreated in many cases. Our challenge is to change the paradigm, such that these patients are treated equitably by enabling a cross-

match positive transplant. Fortunately, Idefirix addresses the limitations of these other modalities from a mechanistic outcomes and regulatory standpoint.

Idefirix provides a completely IgG-free window of clinically suitable duration by cleaving the Fc region of IgG pre and postoperatively and as part of an overall treatment approach that includes immunosuppression. Idefirix has demonstrated critical outcomes such as engraftment, long-term and high functional eGFR levels, and most importantly, patient survival. As a result of this, and our safety data, Idefirix has regulatory approval in Europe, providing the opportunity for greater equity for the cross-match positive patients. But only if the compatibility paradigm can be changed to treat this patient with Idefirix.

With this novel therapy, we're paid in the way forward in changing the desensitization treatment ecosystem in transplantation requiring significant changes in both transplant protocols and organ allocation systems to be able to identify the right patient and then manage the immunological complexity, but there's a huge leap in modernizing transplantation care for highly sensitized patients.

Generating successful early experiences in key early adopter clinics is highly critical for the long-term market uptake of this innovative product. As Soren said in his introduction, adoption of a new desensitization approach will take time as this is an entirely new way of thinking for clinicians and patients.

While everyone acknowledges the significant unmet need and we're frustrated and impatient to see faster uptake of new treatments and resulting sales numbers, sales have long been expected to follow an SH -- S-shaped curve with high quarter-on-quarter volatility. Please turn to the next slide. So ultimately, we must win the acceptance battle both for treatment of the patient type and the subsequent adoption of the product. To measure our progress, we are using a set of key launch metrics, which will directly impact future adoption and sales of Idefirix as a new transformative therapy. And today, we will review progress year-to-date as compared to last year. We'll revisit these key metrics on a regular basis.

They include market building and market access activities, patient identification and transplant center readiness and use. First, market building activities such as creation of new guideline for the long-term uptake of Idefirix have been marked by steady progress at both a pan-European and country level. Following the publication of the first guidelines in Transplant International by the European Society of Organ Transplantation in August last year, ESOT has published a mid-'23 a consensus paper supporting the treatment of highly sensitized patients and the use of Idefirix.

Moreover, Idefirix-specific guidelines have now been implemented on a national level in several countries, including the U.K., France, Finland, Belgium and the Netherlands.These guidelines provide a new clinical practice framework for health care professionals on a management pathway for highly sensitized patients, and our medical teams are supporting further country-level guideline development in additional European countries. Beyond guidelines, we've been highly engaged in peer-to-peer activities within the transplantation community, supporting the identification and treatment of highly sensitized patients with Idefirix, as demonstrated by our significant presence at the European Society of Organ Transplantation Congress, which was held in Athens in September.

A Hansa-sponsored symposium, *Crossing DSA Barriers to Transplant Today* was attended by more than 600 members of the transplantation clinical community. The symposium featured KOLs from multiple centers with clinical experience, utilizing Idefirix and kidney transplant patients.

In addition to the symposium, Hansa hosted expert meetings at [ESOT] with 22 regional transplanters. These 4 allows new adopters to engage with experts, physicians with experience identifying and treating highly sensitized patients with Idefirix. Such significant interest validates Idefirix as a transformative desensitization therapy for patients who previously were regarded as incompatible. Second, securing market access is another key component of Idefirix launch in Europe. During the past 10 months, we have secured pricing and reimbursement in such important markets as Spain, Italy, Belgium and Czech Republic, increasing the number of countries with full market access to a total of 13, including all the top 5 in volume.

Securing reimbursement at the national level is in some countries only a necessary first step before the regional and sometimes even local level.

This is the case in Spain and Italy, where we're currently also making good progress at the regional level and expect this to translate into sales in the near future. In addition, HTA processes continue to run in several other markets such as Portugal and Switzerland, while we recently received provisional approval in Australia in both living in deceased donor situations and are driving progress on pricing and reimbursement. Third, let's look at patient identification mix. Another factor not to forget is that Hansa is running a mandatory post-approval study in Europe in parallel with commercialization.

We're roughly 1/3 into completion of this post-approval study, which has set out to complete in 50 patients by the end of 2025. The post-approval study helps clinicians generate valuable experience in treating and managing patients as we build the foundation for Idefirix to become a new standard of care in desensitization.

While in the short-term, this study may affect commercial sales and patient uptake, the experiences from the study will benefit sales growth in the longer term. Ongoing patient identification through organ allocation systems such as Eurotransplant is another critical factor for sales development since increased access to organs is critical for equity for highly sensitized patients. During October, the first patients have been identified for Eurotransplant new desensitization program, which initially is set up as a pilot program, targeting 20 patients, starting with the longest on the wait list.

We'll cover the dynamics of the program in the following slide. Fourth, scaling up the base of transplant centers with clinical experience is our key commercial metric. And while we're frustrated that despite our great product, we currently see slow sales growth and volatility in sales, we are pleased with continued progress in establishing new centers that use Idefirix. Indeed, our most important metrics relate to this clinical readiness and use.

It all starts with the transplant centers' ability to incorporate Idefirix into their treatment protocols for highly sensitized patients. We call this readiness and it includes 24 -- 24-hour access to pathology labs, immunology labs and T-cell and B-cell depletion as part of an overall immunosuppression approach. Today, approximately 50 clinics qualifies Idefirix ready to treat patients. We're very pleased that this number has doubled since a year ago.

More importantly, the number of clinics who have treated patients commercially or through our post-approval study has grown to more than 20 centers, representing 120% growth this year, with 9 centers having experience with repeated usage across clinical studies and commercial. From a commercial standpoint, the clinics in France have contributed most to our sales growth so far through the Early Access Program established in 2022.

Going forward, we expect other major markets such as U.K. and Germany to start contributing more meaningful in the periods to come as we secured several new agreements in the last few quarters. We're very pleased to see our commercial and medical efforts support the steady increase in treating centers over time, but also recognize that as the space of centers grows, we'll continue to see volatility and the timing and number of organs allocated as well as the rate of [organ assessment], particularly from month-to-month and at times from quarter-to-quarter.

We've previously guided that 2023 would be back-loaded and while third quarter sales have been soft at SEK 16.5 million, early indications from patient identification and sales in the beginning of the fourth quarter affirm that this final quarter of 2023 will be stronger than the third quarter. Please turn to Slide 6. Now let's further discuss Eurotransplant.

As we mentioned in July during our second quarter earnings call, Eurotransplant has initiated a new desensitization program among its member states from imlifidase-eligible patients as part of a pilot in the Acceptable Mismatch Program. These member states include Germany, Belgium, the Netherlands, Luxembourg, Austria, Croatia, Hungary and Slovenia and represent a combined population of approximately 137 million.

Patients will be included based on certain criteria, such as a minimal wait time of 3 years in the Acceptable Mismatch Program, donors below 65 years of age and preferably negative T-cell cross-match towards acceptable antigens for the desensitization program. The first screen by Eurotransplant took place recently to identify more than 150 eligible patients for further consideration. Starting with the patients would have been the wait list the longest, earlier this month, an initial group was assessed for inclusion as the first patients selected for prioritization.

The program is intended to significantly increase the likelihood of an organ being made available for highly sensitized patients by allowing access to an expanded pool of organs, which normally would not be possible due to their complex immunologic profile. Moreover, the Acceptable Mismatch and highly sensitized programs are allocated to organs before organs are released to the broader Eurotransplant allocation network.

The progress of the Eurotransplant program is obviously very important for future uptake in the associated market as the program will provide opportunities for generating critically important clinical experiences using Idefirix to treat highly sensitive patients and in due course, improve outcomes for hundreds of Idefirix-eligible patients in the Eurotransplant zone. Please turn to Slide 7. With regard to our pivotal U.S. ConfIdeS trial in kidney transplantation, we'll continue to enroll additional patients as previously guided.

The ConfIdeS study is set up to evaluate imlifidase as a potential disruptive therapy for highly sensitized patients waiting for a deceased donor kidney through the U.S. Kidney Allocation System.

Approximately 2,500 highly sensitized patients in the U.S. with a cPRA score of 99.9% and above fit into this category and are not transplanted today despite prioritization points on the wait list. We've learned that identifying and screening patients for this trial can take anywhere from weeks to several months. Unlike other trials that can progress once patients meet certain criteria, this trial is dependent on allocation of suitable organs to consented patients, a process that within the U.S. is managed by an independent third-party. Additionally, we see variability in the acceptance of those organs that are allocated based on the immunologic profile book at donor and the recipient.

However, we've acted on these learnings to accelerate ConfIdeS. Comparing October 2023 year-to-date versus the full year of 2022, ConfIdeS has accelerated across key metrics, including approximately 30% higher consented patients, approximately 60% higher patients consented and waiting for organ allocation and randomization and approximately 20% higher patient randomization. Furthermore, we have implemented measures to continue to accelerate ConfIdeS.

First, we're increasing the study sites with 9 additional centers initiated to bring our total to 25 centers geographically dispersed across the U.S. for coverage of key population tenants.

Second, we have implemented a protocol amendment that will allow a greater proportion of waiting recipients to be allocated and accept organs. This is achieved by a degree of antigen delisting that would otherwise preclude organ allocation and acceptance. And finally, we have made operational improvements in the study that provide for great -- suitable patient identification, more support and guidance on treatment protocol implementation at study centers and faster conversion of study centers from initial identification to site activation.

Despite these improvements, the allocation of organs to patients in the study and the acceptance of those organs based on immunologic patient and donor factors remain highly variable and difficult to predict. The total of 64 highly sensitized patients will be randomized in the trial. And as of today, we've enrolled 87 patients and have achieved more than half of the randomization target.

We expect to complete randomization by mid-'24 and target submission of the BLA in 2025 as per our recently updated guidance. Importantly, increasing the number of centers in the pivotal ConfIdeS trial will also help build valuable patient identification and clinical utilization experiences in desensitization among KOLs and key transplant centers in preparation for our planned launch in the U.S. market. Please turn to Slide 8. On October 17, we reported positive data from our 5-year follow-up study, an extended pooled analysis using data from the international long-term follow-up study.

After 5 years, the patient's survival rate was 90%, while graft survival death censored was 82%, in line with outcomes seen at a 3-year post transplantation follow-up.

Kidney function measured through the mean estimated glomerular filtration rate, eGFR was [50], in line with what you can expect in the normal transplantation population. The results are extremely encouraging, and we're pleased to see the consistency with the 3-year data that was published in 2021.

Despite the high-risk immunological profile of these patients, we see stable long-term outcomes, both on graft survival and patient survival, not different, again, from what we see in compatible kidney transplantation. With this, I will hand it back to Soren for continuing the update on our clinical programs.

Søren Tulstrup

Thanks, Matt. Now please turn to Slide 9. Earlier this month, we're very pleased to report encouraging high-level data from the first-in-human trial of HNSA-5487, lead candidate from our NiceR program focused on developing next-generation IgG-cleaving enzymes. HNSA-5487 is being developed with the goal of potentially opening new innovative treatment approaches in a broad range of indications, including IgG-driven autoimmune diseases, gene therapy and oncology. The Phase I study included 36 healthy volunteers and is designed as a double-blind randomized placebo-controlled trial evaluating safety, PK and PD

of single ascending doses of HNSA-5487.Results demonstrated that the molecule was safe and well tolerated and fast and complete depletion of immunoglobulin G antibodies observed at increasing doses in all subjects.

Pharmacokinetics were in line with expectations and pharmacodynamics expressed through efficacy on IgG cleavage showed a fast and complete cleavage of IgG to [Fab2 and Fc-fragments with increasing doses. These data are highly encouraging as we continue to explore the potential of our next-generation enzymes and better understand how this powerful new drug candidate and the broader NiceR program can benefit patients with diseases where a prolonged IgG-free window is needed and where repeat dosing would be beneficial.

The trial also included exploratory endpoints focused on achieving a deeper understanding of the immunogenicity profile with follow-up on all subjects for 12 months, and this part is currently ongoing. This analysis will give us key input in determining the future clinical development program, including selection of first indication in 2024.Please turn to Slide 10. As we discussed at our last quarterly earnings call, Hansa has expanded its pipeline of valuable drug candidates to 7 clinical programs with the recent addition of the [indiscernible] sponsored Phase II study in ANCA-associated vasculitis.

The ANCA study is off to a good start with 3 patients currently enrolled out of a target of 10 patients with severe ANCA-associated vasculitis and acute respiratory distress syndrome due to pulmonary hemorrhage.

In this study, patients will be treated with imlifidase on top of standard of care consisting of standard immunosuppression as per standard protocol and intensive support care. In anti-GBM, we have recently seen good uptake in patient enrollment in the global pivotal Phase III study with 5 patients enrolled during the third quarter, while the number of access sites has expanded from 12 to 25 in the past 3 months. In total, 9 patients have now been enrolled out of a target of 50 patients across centers in the U.S., U.K. and EU. The primary objective of the study is to assess the superior efficacy of imlifidase in combination with standard of care versus standard of care alone consisting of a combination of immunosuppressors, steroids and plasma exchange with a 6-month follow-up on renal function. Earlier this year, we announced completion of enrollment in our GBS Phase II program.

GBS is an acute autoimmune attack on the peripheral nervous system, which affects approximately 1 to 2 patients per 100,000 people annually. Top line data on safety, tolerability and potentially the early effect in imlifidase-treated GBS patients is expected to be announced in Q3 -- Q4 of this year as per previous guidance. Further, we plan to publish the full data set from the AMR study in the fourth quarter, as previously announced, following the positive top line data on the primary endpoint announced in November of last year. Last, in our partner, gene therapy program with Sarepta, we expect small European Phase Ib study in Duchenne muscular dystrophy will be initiated in Q4 of this year.

Earlier this year, Sarepta's gene therapy, Elevidys, received U.S. FDA approval as a onetime treatment in ambulatory pediatric patients [indiscernible] through 5 years suffering from Duchenne muscular dystrophy.

In combination with imlifidase, additional treatment may potentially be enabled and up to 14% of patients who are currently suffering from too high titers of neutralizing antibodies against AAVrh74.With this overview, I will now hand over the call to Donato, who will walk us through a review of the financials for the third quarter and first 9 months of 2023. Donato?

Donato Spota

Thank you, Soren. Please turn to Slide 11. Total revenue for the third quarter of 2023 amounted to SEK 22.8 million, including SEK 16.5 million in product sales and SEK 6.3 million in contract revenue, mainly from our agreement with Sarepta. For the 9 months of 2023, total revenue was SEK 83.7 million, including approximately SEK 60 million in product sales. Product sales in the third quarter came in softer compared to the second quarter since sales from new markets, such as the U.K., Spain, Germany and Italy are yet to contribute as identified patients are waiting for organs to become available with the different allocation systems.

However, we do continue to expect to see an acceleration in sales in the fourth quarter and the quarters to come with quarter-on-quarter volatility to remain high though. Please turn to Slide 12. Total SG&A expenses for the third quarter of 2023 amounted to SEK 112 million compared to SEK 83 million for the third quarter of 2022. The increase in expenses reflects Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix in Europe.

Further, inflation and devaluation to Swedish krona against the euro and the U.S. dollar are negatively impacting costs relative to the same period last year. For the first 9 months, SG&A expenses increased to SEK 345 million versus SEK 254 million in the same period last year to the reasons just mentioned as well as certain one-off costs incurred this year.

Investments in R&D amounted to SEK 96 million for the third quarter 2023, which is approximately on par with the third quarter in 2022. For the first 3 quarters in 2023, R&D expenses amounted to SEK 303 million compared to SEK 254 million for the same period last year.

The increase is mainly driven by the initiation of the clinical program for HNSA-5487 and the ongoing ConfIdeS U.S. studies.Net loss amounted to SEK 251 million for the third quarter 2023 compared to SEK 154 million for the same period last year. For the first 9 months of 2023, net loss was SEK 707 million versus SEK 462 million for the same period in 2022.

The increase in net loss versus last year period is driven by increased investments in our operations, revenue recognized under our agreement with AskBio in the third quarter of last year and imputed interest expenses related to our long-term loan. Notably, these interest expenses are noncash expenses. Please turn to Slide 13. Cash flow from operating activities amounted to minus SEK 193 million for the third quarter of 2023 compared to minus SEK 129 million for the third quarter a year ago. For the first 9 months of 2023, operating cash flow was minus SEK 583 million versus minus SEK 393 million in the first 9 months of 2022, which at the time included a SEK 50 million upfront payment received under our agreement with AskBio.

The increase over last year is mainly driven by the increase in operating expenses.

On September 30, 2023, our cash position stood at SEK 908 million, which is expected to provide a cash runway into 2025 as previously guided.

I'll now hand back the call to Soren for his final remarks.

Søren Tulstrup

Thanks, Donato. Please turn to Slide 14. As communicated earlier this month, it's been necessary to revise time lines for our pivotal U.S. ConfIdeS study as we now expect randomization to complete mid-2024 and the subsequent BLA submission in 2025 following the 12-month follow-up assessment of patients' eGFR level in the 2 study arms. As discussed, what we learned in our assessment is that identifying and screening patients for this trial can take anywhere from 1 week to 7 months based on patient, donor and site-specific factors, including overall patient health and proximity to the site.

Organ allocation in the U.S. is managed by an independent third-party. And unlike other trials, I can progress once patients meet certain criteria, this trial is largely dependent on allocation of suitable organs to consenting patients. With this in mind, we're committed to advancing this important clinical trial as fast as possible and see a significant commercial opportunity for Idefirix in the U.S. market. As communicated early on this call, we plan to announce a full data readout from the AMR Phase II trial in Q4 as well as the first high-level data readout from the Phase II program in Guillain-Barre Syndrome.

Finally, we're excited about the upcoming clinical trial with imlifidase as part of Sarepta's Duchenne muscular dystrophy program.

The trial, which is expected to be commenced in Q4 will be the first time imlifidase is used as a pre-treatment in gene therapy patients and will be conducted in a small patient population with pre-existing IgG antibodies to Sarepta's newly approved gene therapy, Elevidys.

Following treatment with imlifidase and Elevidys, a 12-week follow-up will take place. Now please turn to Slide 16. So this concludes our presentation, and we would now like to open the call for questions. Operator, please begin.

Question-and-Answer Session

Operator

[Operator Instructions] The first question will be from the line of Gonzalo Artiach from ABG.

Gonzalo Artiach

The first one is on your transplant. From what you say, things have started moving a bit now in October, but has any of the 20 patients being transplanted so far? And what are the reasons for the pilot program going that slow, let's say, since it was launched in June? I don't know if you could give or provide us some guidance on realistically how long it's going to take to get the 20 transplants there?

Søren Tulstrup

Well, thank you very much, Gonzalo, for that question. So essentially, as we said, a high number of patients have been identified and then we've been taking through a funnel. And then 23 patients have been prioritized. And of those, the first patients have now been made

ready, if you will, and essentially ready to be transplanted. And it is, of course, an overall slow-moving process.

You're right, started in June. There are various steps that this process has to go through. I'll let Matt make some further comments on this. But the good thing is that now we have this program running. And obviously, this will be a very, very important generator of patients that are eligible and selected for transplant going forward in key countries in Europe.

But Matt, maybe you have some further comments.

Matt Shaulis

Sure. Yes. Soren, I'll just add that you've absolutely identified the process here. It's a funnel. And I guess one of the reasons for it being a little bit slower initially is that the patients need to have been on the wait list in this status for over 3 years.

But at the very initial phases, Eurotransplant is starting with the patients that have been on the wait list, the very longest. And in some cases, those are patients that have been on the wait list well over the 3-year time frame. So they're working through contacting the centers, understanding more specifics about those patients. And in some cases, because these are the patients that have been on the wait list the longest, they're finding not all of them are sort of suitable or eligible, but it's just taking a little bit more time to really assess those individual patients.

So we think that they'll continue to work through the list. We do anticipate seeing some treatment in the near-term here and then things will probably accelerate as they get down on the wait list for the patients that meet the criteria, but it hasn't been on the wait list the longest.

Søren Tulstrup

Just to [add], so none of the patients have been transplanted yet, right, so they've been put on the selected patients, now prioritized patients have been put on the list and they're just waiting for an organ to allocate it, but none of them have actually been transplanted yet. Now the system is really up and running for real, right, and we expect this to obviously be a key generator of transplanted patients going forward as you said.

Gonzalo Artiach

Great. And second question on the AMR program. One of the milestones for the -- for Hansa is the top line data from the -- from this study, the AMR study. And do you have a clear strategy for this program once the data is released, assuming positive long-term data? And how should we see the program moving forward?

Søren Tulstrup

Well, I think, first of all, it was very reassuring and encouraging to see the excellent data on the primary endpoint, right, which is the donor-specific antibodies are reduced and also how

fast that goes, right, because that provides lots of confidence that actually in the early days, you have a therapy that works better than plasma exchange, it's much more predictable. So I think this per se will be really important input to the clinicians as they make their choices when they have a patient that is in danger of losing his or her kidney.

Then in terms of going forward, obviously, we'll look at the data when we get the data. As we've discussed on previous calls, it's very, very tricky to get very clear data in the AMR study. This is what we've seen in those trials in the past because of the, let's say, the variability between not just the patients, but also the centers, right, in standard of care and so on. And typically, we need studies with large patients, large numbers of patients enrolled and taking place for a long period before you can really generate hard endpoint data that are satisfactory. So I think that's the overall expectation.

We'll get additional data from the final readout here. And once we have that, obviously, we will engage in dialogue with the regulatory authorities and broader clinical community to determine the path forward. But certainly, we're very encouraged by what we've already seen in the data of our assisted primary endpoint.

Operator

[Operator Instructions] As there are no more questions, I will hand it over to the speakers for any closing remarks.

Søren Tulstrup

Well, thank you so much, operator, and thank you, everyone, for calling into today's call. We look very much forward to keeping you updated on progress as we move forward. Many things are happening at this time. And as I said, we look forward to keeping you updated. So thanks so much.