# HANSA BIOPHARMA

## Investor Presentation

Redeye lunch meeting
Stockholm, October 21, 2022


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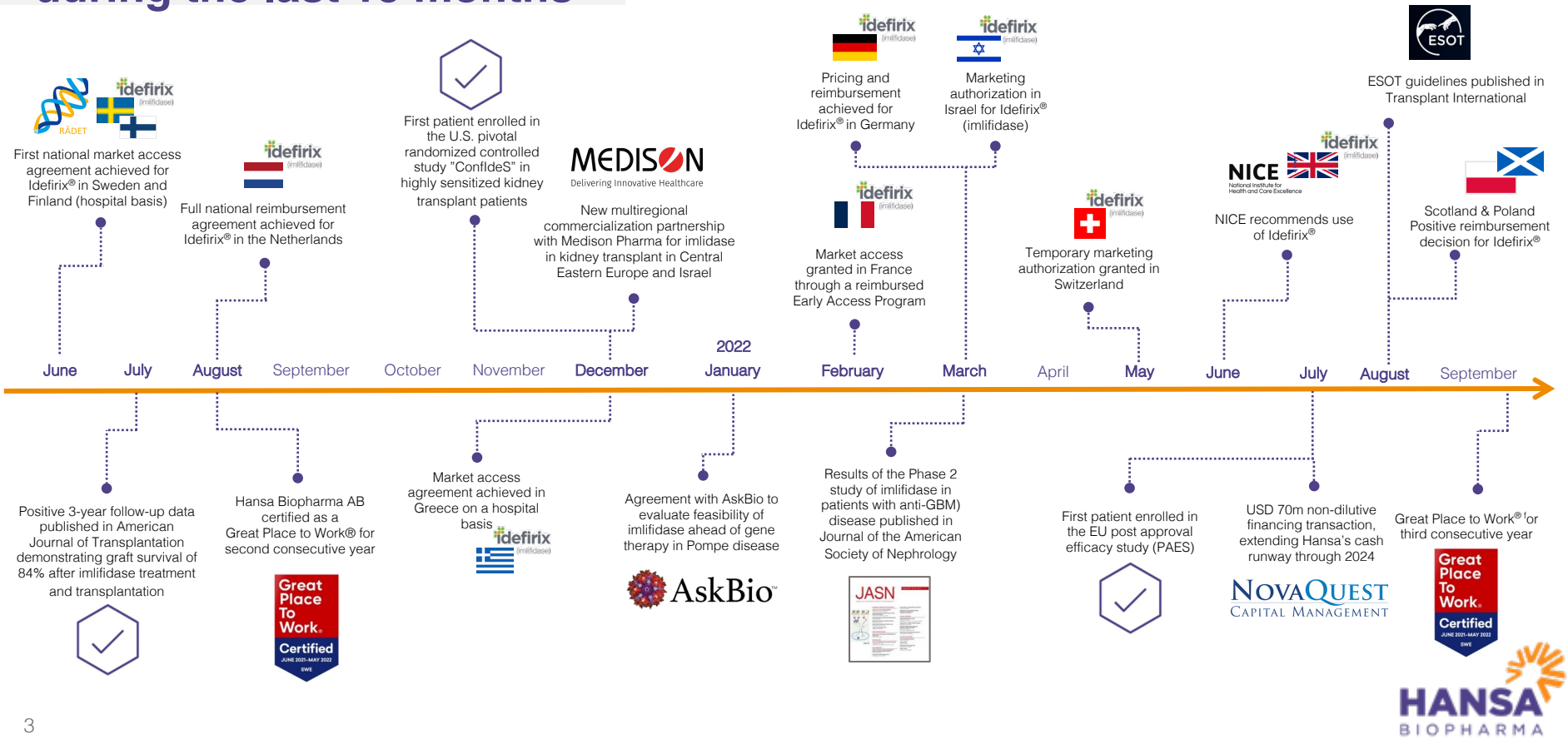
# Many milestones achieved during the last 15 months



# Positive reimbursement decisions received in Poland and Scotland; $70 million raised in non-dilutive financing; ESOT guidelines published in *Transplant International*

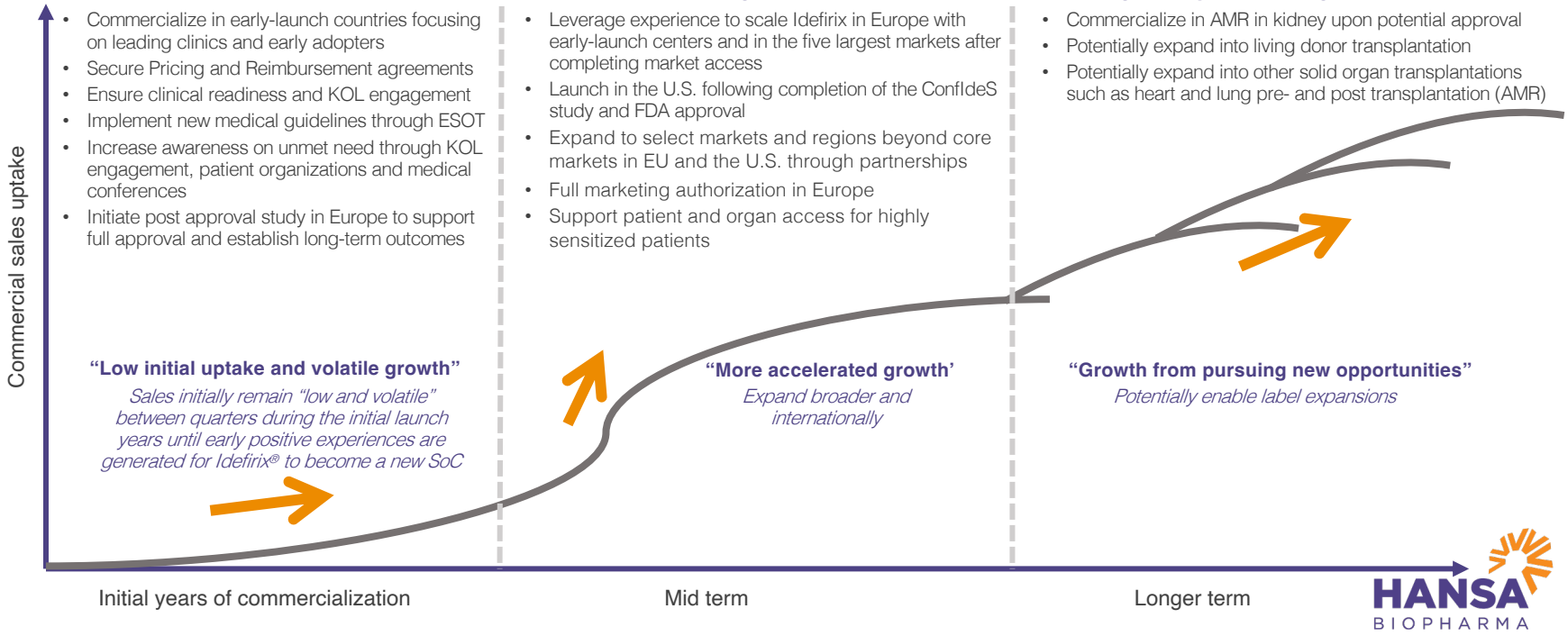
## Highlights for the third quarter of 2022

- ✓ Launch activities and market access efforts in EU progressing as planned
  - Total Q3 revenue of SEK 67m including SEK 23m in product sales and SEK 44m under our agreements with Sarepta and AskBio
  - Positive reimbursement decisions received in Poland and Scotland for Idefirix®
  - Market access has now been secured in nine European countries and procedures are ongoing in eight countries including Spain, Italy and Belgium
  - The European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized kidney transplant patients published in *Transplant International*.
  - First patient treated in the post-authorization efficacy study (PAES) of imlifidase in highly sensitized kidney transplant patients, at Vall d'Hebron Hospital, Barcelona.
- ✓ Clinical pipeline
  - U.S. ConfIdeS Study in kidney transplantation: 39/64 patients enrolled
  - Anti-GBM: Expect to commence Phase 3 study later this year, as previously guided
  - AMR: Patient enrollment completed; First data read-out expected in H2'22
  - GBS: 20/30 patients enrolled in the GBS phase 2 study; Higher infection rates are expected as the winter season approaches as well as additional measures will be implemented to accelerate recruitment in the coming months. Completion of enrollment in the GBS trail is anticipated H2 2022/H1 2023
- ✓ Great Place to Work® certification for the 3rd consecutive year
- ✓ $70 million raised in non-dilutive financing
  - Transaction supports the continued development of Hansa's antibody-cleaving enzyme technology platform while extending the cash runway through 2024

# Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

Idefirix® is the first and only approved treatment in Europe for desensitization treatment of highly sensitized kidney transplant patients. The long-term market uptake is highly dependent on successful early experiences in key early adopter centers

*Illustrative*




**1 Build the foundation for Idefirix® in EU to become a new Standard of Care**

- Commercialize in early-launch countries focusing on leading clinics and early adopters
- Secure Pricing and Reimbursement agreements
- Ensure clinical readiness and KOL engagement
- Implement new medical guidelines through ESOT
- Increase awareness on unmet need through KOL engagement, patient organizations and medical conferences
- Initiate post approval study in Europe to support full approval and establish long-term outcomes

**"Low initial uptake and volatile growth"**

*Sales initially remain "low and volatile" between quarters during the initial launch years until early positive experiences are generated for Idefirix® to become a new SoC*

**2 Expanding internationally will lead to more accelerated growth mid term**

- Leverage experience to scale Idefirix in Europe with early-launch centers and in the five largest markets after completing market access
- Launch in the U.S. following completion of the ConfIdeS study and FDA approval
- Expand to select markets and regions beyond core markets in EU and the U.S. through partnerships
- Full marketing authorization in Europe
- Support patient and organ access for highly sensitized patients

**"More accelerated growth'**

*Expand broader and internationally*

**3 Potential label expansion will enable new growth pockets longer term**

- Commercialize in AMR in kidney upon potential approval
- Potentially expand into living donor transplantation
- Potentially expand into other solid organ transplantations such as heart and lung pre- and post transplantation (AMR)

**"Growth from pursuing new opportunities"**

*Potentially enable label expansions*

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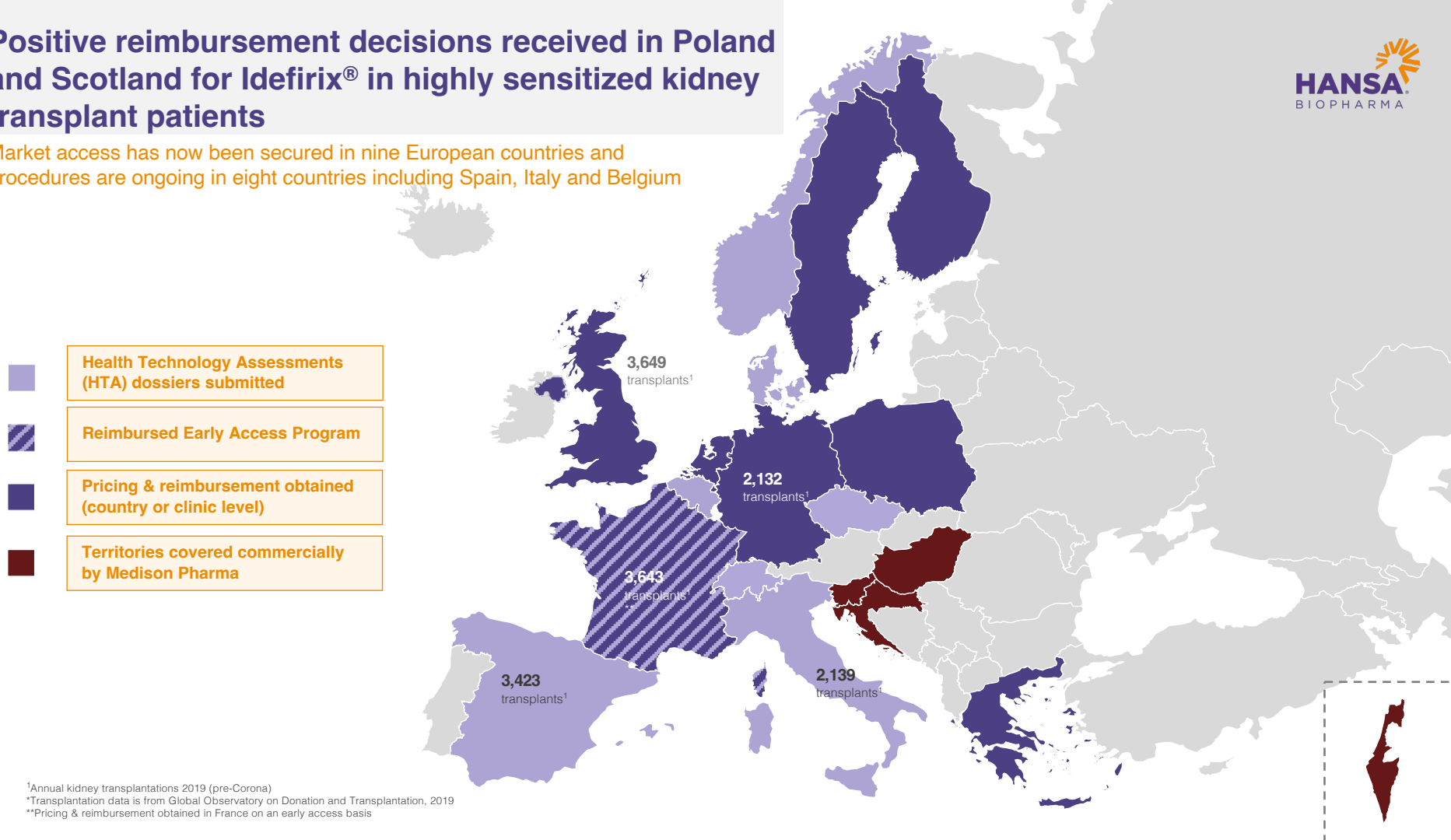
# Positive reimbursement decisions received in Poland and Scotland for Idefirix® in highly sensitized kidney transplant patients

Market access has now been secured in nine European countries and procedures are ongoing in eight countries including Spain, Italy and Belgium




[1]Annual kidney transplantations 2019 (pre-Corona)
*Transplantation data is from Global Observatory on Donation and Transplantation, 2019
**Pricing & reimbursement obtained in France on an early access basis

# The European Society for Organ Transplantation's (ESOT) guidelines for desensitization treatment of highly sensitized patients published in *Transplant International* in August 2022

## Guidelines represent first international consensus on a management pathway for highly sensitized patients

- The European guidelines document is a result of an expert working group, led by Professor Nizam Mamode M.D. Professor of Transplant Surgery, previously at Guys and St Thomas Hospital, London, and supported by other leading experts in the transplantation field.[1]
- Guidelines include imlifidase and provide a new clinical practice tool for healthcare professionals and represent the first international consensus on a management pathway for highly sensitized patients.
- Guidelines articulate the variability in definitions, approaches, outcomes as well as the perceived success of HLA-related transplantations
- Hansa Biopharma sponsors desensitization workstream as part of ESOT's educational programs, via an educational grant

## *Transplant International*

https://www.frontierspartnerships.org/articles/10.3389/ti.2022.10511/full


GUIDELINES
published: 10 August 2022
doi: 10.3389/ti.2022.10511

ESOT | Transplant International

**European Guideline for the Management of Kidney Transplant Patients With HLA Antibodies: By the European Society for Organ Transplantation Working Group**

Nizam Mamode[1]*, Oriol Bestard[2], Frans Claas[3,4], Lucrezia Furian[5], Siân Griffin[6], Christophe Legendre[7], Liset Pengel[8] and Maarten Naesens[9]

[1]Department of Transplantation, Guys Hospital, London, United Kingdom, [2]Department of Nephrology and Kidney Transplantation, Vall d'Hebron University Hospital, Barcelona, Spain, [3]Department of Immunology, Leiden University Medical Center, Leiden, Netherlands, [4]Department of Surgical Gastroenterological and Oncological Sciences, University Hospital of Padua, Padua, Italy, [5]Department of Nephrology, University Hospital of Wales, Cardiff, United Kingdom, [6]Centre for Evidence in Transplantation, University of Oxford, Oxford, United Kingdom, [7]Department of Microbiology, Immunology and Transplantation, KU Leuven, Leuven, Belgium

This guideline, from a European Society of Organ Transplantation (ESOT) working group, concerns the management of kidney transplant patients with HLA antibodies. Sensitization should be defined using a virtual parameter such as calculated Reaction Frequency (cRF), which assesses HLA antibodies derived from the actual organ donor population. Highly sensitized patients should be prioritized in kidney allocation schemes and linking allocation schemes may increase opportunities. The use of the ENGAGE 5 ((Bestard et al., Transpl Int, 2021, 34: 1005–1018) system and online calculators for assessing risk is recommended. The Eurotransplant Mismatch program should be considered. If strategies for finding a compatible kidney are very unlikely to yield a extended. desensitization may be considered and should be performed with plasma ...adsorption, supplemented with MG and/or anti-CD20 antibody. ...idase, may offer alternatives. Few studies compare HLA ...on the waiting list, and comparisons of ...change programs (KEP) should ...donors, as well as highly

OPEN ACCESS

*Correspondence: Nizam Mamode

[1]Mamode N, Bestard O, Claas F, Furian L, Griffin S, Legendre C, Pengel L and Naesens M (2022) European Guideline for the Management of Kidney Transplant Patients With HLA Antibodies: By the European Society for Organ Transplantation Working Group. Transpl Int 35:10511. doi: 10.3389/ti.2022.10511

# Continuous progress in our ongoing clinical programs

Enrollment status
Oct 19, 2022


## Antibody Mediated Rejection Phase 2 study

- 30/30 patients enrolled in the AMR phase 2 study
- Enrollment completed May 2022
- First data read out expected toward the end of 2022*
- Data from the Phase 2 program will determine the path forward for imlifidase in patients with active AMR episodes


## Guillain-Barré Syndrome Phase 2 study

- 20/30 patients enrolled in the GBS program
- Ten centers are active and open for recruitment; Additional measures will be implemented to accelerate recruitment in the coming months.
- Aim to complete enrollment of GBS patients H2'22/H1'23
- Enrollment expected to be boosted from higher infection rates during winter season, while increased capacity at the enrollment sites is also expected to support a faster enrollment
- Aim to communicate first high-level data read out in H2 2023

Enrollment status
Oct 19, 2022


## Anti-GBM Phase 3 study

- FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a pivotal global Phase 3 study
- Aim to commence the planned anti-GBM study later this year, as previously guided. Study will target 50 patients*


## U.S. ConfIdeS Phase 3 study

**Randomized, controlled trial in highly sensitized kidney transplant patients across up to 15 centers**

- 39/64 patients enrolled for randomization
- Aim to complete of enrollment expected toward end of 2022
- Aim to complete randomization n the first half 2023
- BLA submission is expected in 2024 under the accelerated approval path

*Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.*



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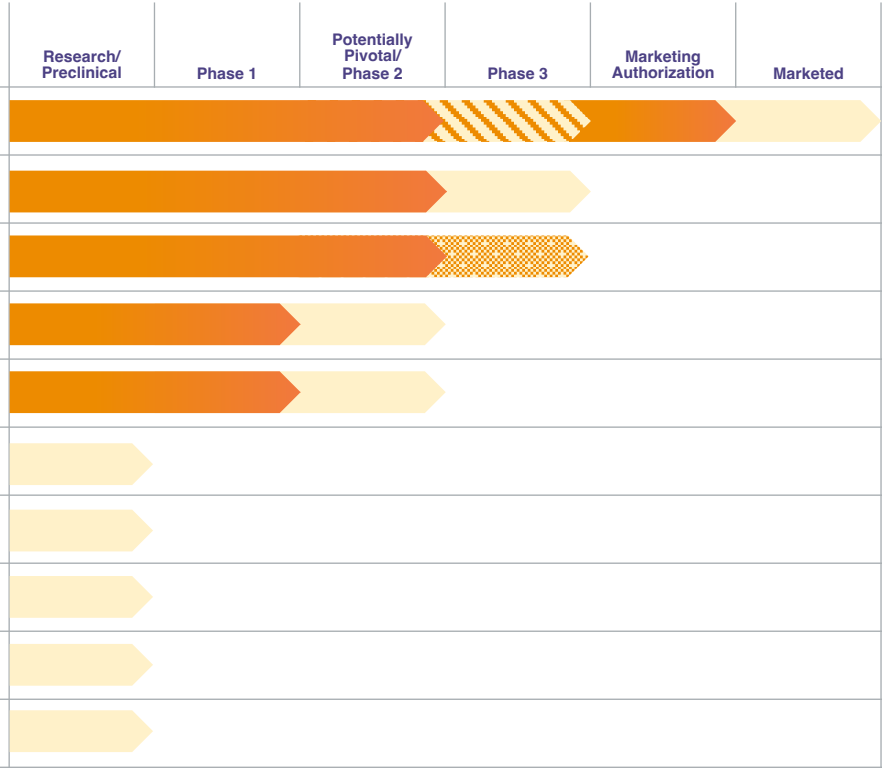
# Broad clinical pipeline in transplantation and auto-immune diseases

| Candidate/ Project | Indication | Next Anticipated Milestone |
|---|---|---|
| Imlifidase | EU: Kidney transplantation in highly sensitized patients[1,2] | EU: Additional agreements around reimbursement from H2'21 |
| | US: Kidney transplantation in highly sensitized patients[1,2] | Completion of enrollment (64 patients) H2'22 |
| | Anti-GBM antibody disease[3] | Pivotal Phase 3 study expected to commence in 2022 (50 patients) |
| | Antibody mediated kidney transplant rejection (AMR) | First data read-out H2 2022 |
| | Guillain-Barré syndrome (GBS) | Completion of enrollment (30 patients) H2'22/H1'23 |
| | Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta) | Preclinical research |
| | Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta) | Preclinical research |
| | Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio) | Preclinical research |
| NiceR | Recurring treatment in autoimmune disease, transplantation and oncology | Completion of GLP toxicology studies in 2022 |
| EnzE | Cancer immunotherapy | Research |

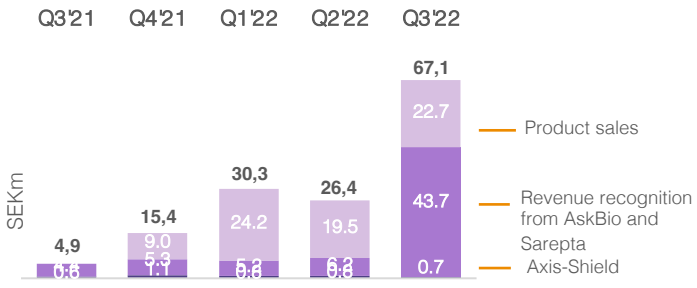



[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

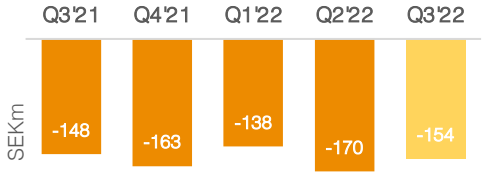
Completed
Ongoing
Planned
Post approval study running in parallel with commercial launch

# Total Revenue amounted to SEK 67m in the third quarter including SEK 23m in product sales

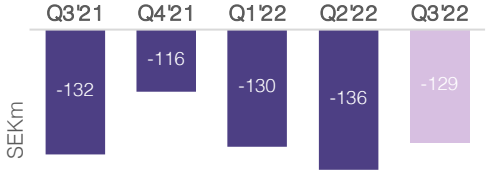
## Revenue (Q/Q)



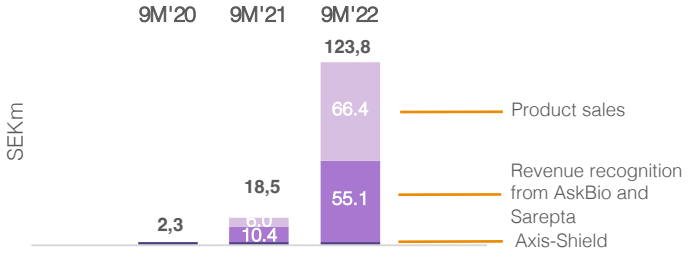

## Net loss (Q/Q)



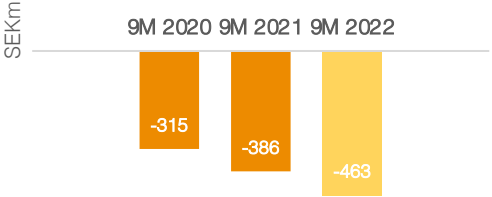

## Operating cash flow (Q/Q)



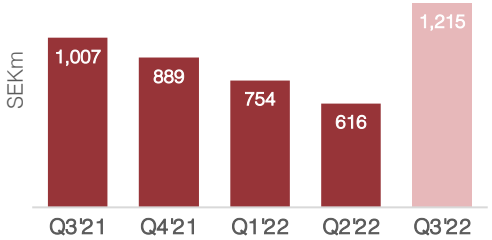

## Revenue (9M/9M)




## Net loss (9M/9M)

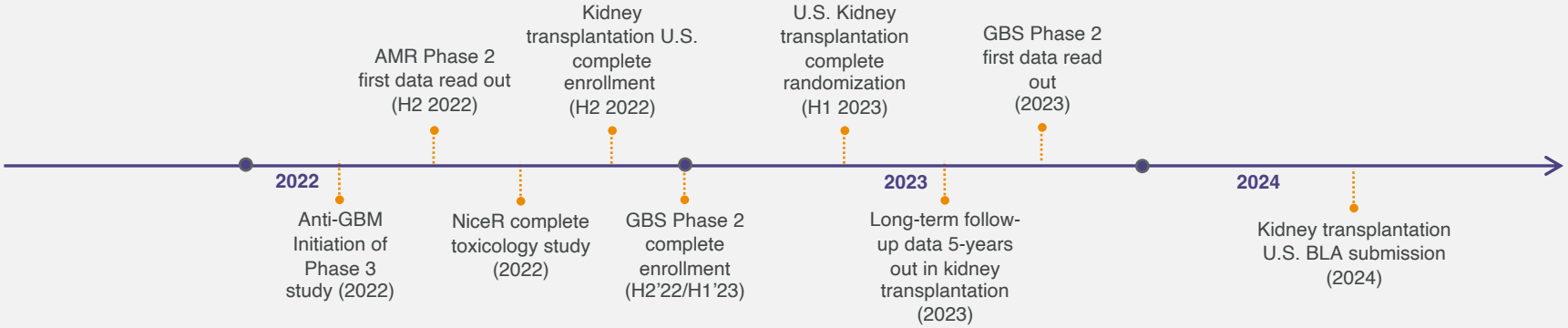



## Cash & short-term investments (Q/Q)



# Upcoming milestones

## Milestones subject to potential COVID-19 impact




*Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.*

# Antibody Mediated Rejection

## Long term graft survival is challenged by AMR post transplantation

### There is no approved treatment for AMR

- Active antibody mediated rejection after transplantation occurs in 5-7% of kidney transplants[1] annually[4] and is a significant challenge to long term graft survival
- Today's standard of care include plasma exchange, and treatment with steroid and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist
- The AMR Phase 2 study is a randomized, open-label, multi-center, active control study designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute and chronic acute AMR in kidney transplant patients
- Completion of enrollment in 30 patient at 14 centers across the US, Europe and Australia was done May 2022
- First data read out expected in H2 2022



[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.
[2] Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

AMR Phase 2

# AMR Phase 2 study

Aim of the study is test imlifidase ability to reduce the amount of donor specific antibodies in AMR patients post transplantation

## CLINICALTRIALS.GOV ID

NCT03897205 (2019)

## SUBJECTS

30 patients targeted (20 patients will be treated with imlifidase and 10 with Plasma exchange). Recruitment from 11 sites in the U.S., EU and Australia.

## DOSES/FOLLOW UP TIME

1 dose of imlifidase (0.25 mg/kg) or 5-10 sessions of plasma exchange

## MAIN OBJECTTIVES

- Imlifidase ability to reduce the amount of DSA in comparison with plasma exchange in patients who have an active AMR post transplantation
- Ensure safety for patients

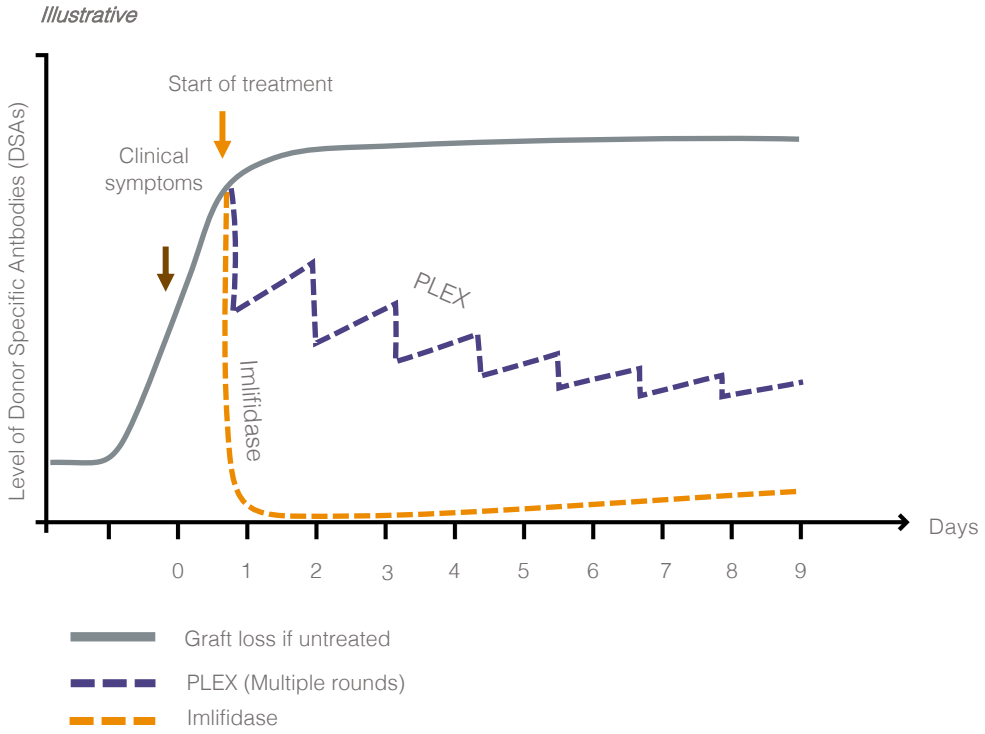
## STUDY DESIGN

- Randomized, open-label multi-center active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

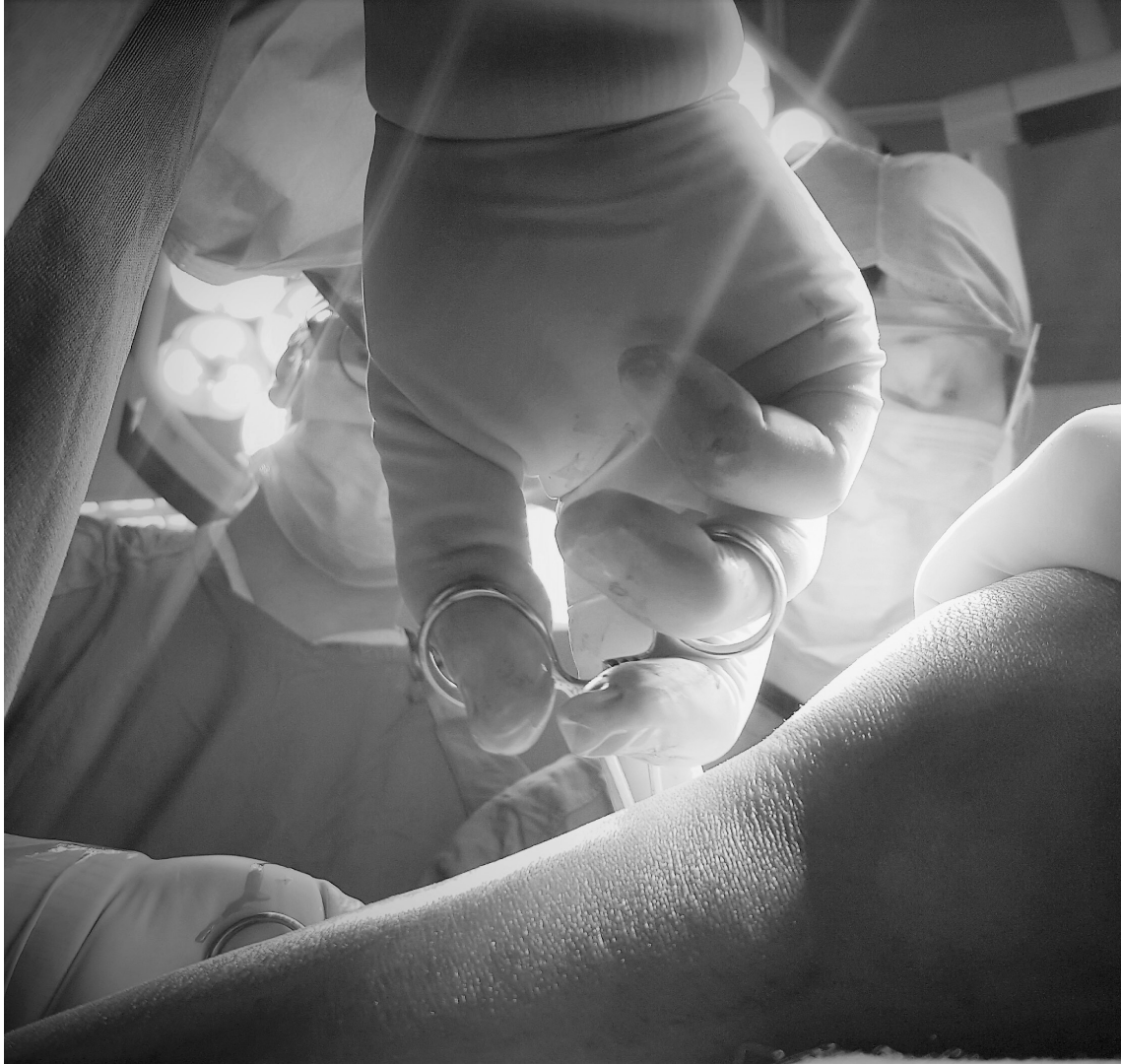
## STATUS

Completed enrollment awaiting first data read out H2 2022

## Potential of using imlifidase vs. PLEX in AMR



# Imlifidase in kidney transplantation



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# U.S. ConfIdeS study: Completion of enrollment expected H2 2022; BLA submission expected 2024

## U.S. trial design

64 highly sensitized kidney patients with the highest unmet medical need

- Patients with a cPRA score of ≥99.9% will be enrolled
- First patients enrolled at Columbia University, NYC
- 39 patients enrolled across ten sites October 19, 2022

1:1 Randomization

- When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase or to a control arm, where patients either remain waitlisted for a match or receive experimental desensitization treatment*

Primary endpoint

- Mean estimated glomerular filtration rate (eGFR) “kidney function” at 12 months.
- For randomized patients who do not undergo transplantation, lose their graft or die before 12 months, eGFR will be set to zero, consistent with kidney failure

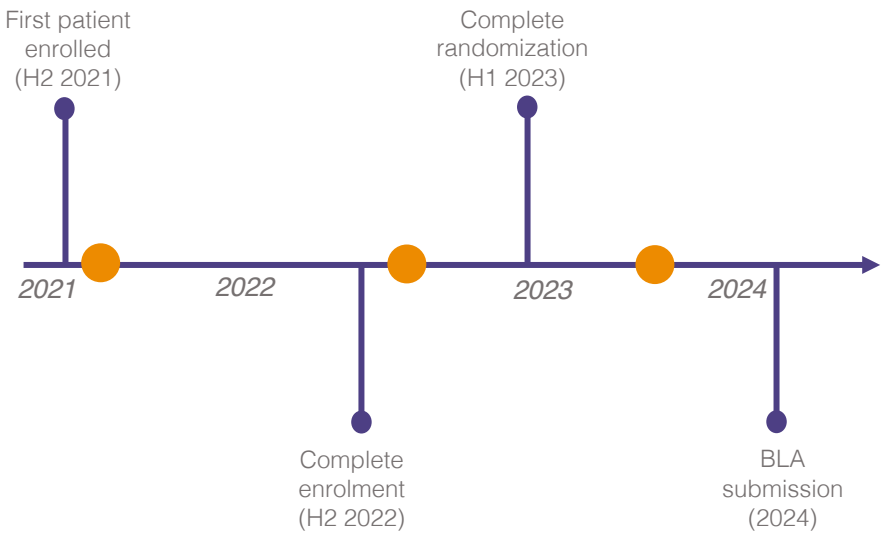
Secondary endpoint

- Patient survival at 12 months

Up to 15 leading transplantation centers in the U.S. will be engaged in the study

- Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, NYC is appointed to be the principal investigator

Timeline




*Experimental desensitization treatment can include any combination of plasma exchange (PLEX), intravenous IVIg, anti-CD20 antibody, and eculizumab. Link to the full protocol at ClincalTrials.gov

# U.S. kidney transplantation landscape

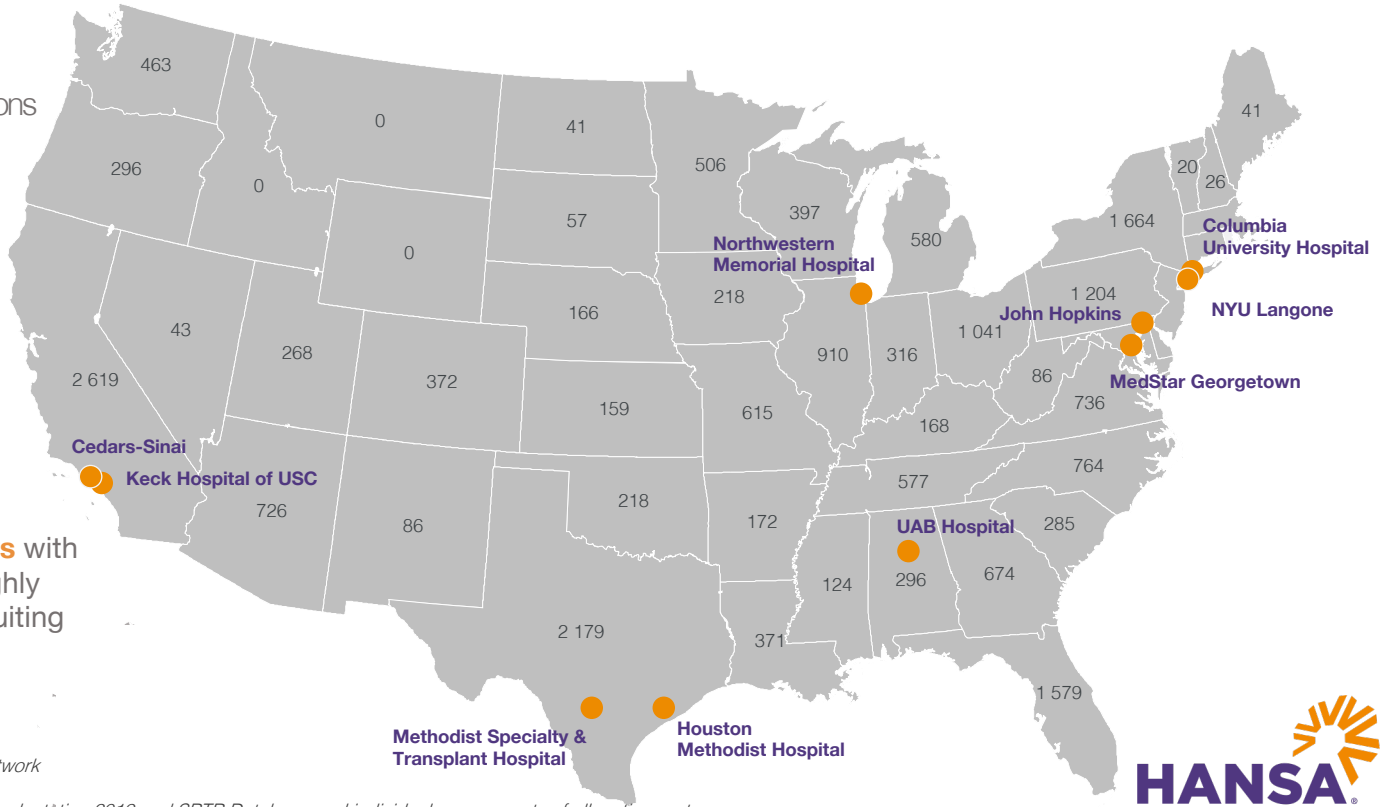
Our ConfIdeS study is currently enrolling patients across ten leading transplantation centers across seven states covering ~10% of annual kidney transplants in the U.S.; Aim to have up to 15 centers recruiting patients

**>23,000**[1] annual kidney transplantations

**~71%**[1] deceased donor

**~90,000**[2] waiting for a kidney transplant

**10-15%**[3] of waitlisted patients are highly sensitized




**Ten leading transplantation centers** with experience in desensitization and highly sensitized patients are currently recruiting

**2,542**[1] combined annual kidney transplants

**334**[1] highly sensitized (>80% cPRA)

*[1]2019 data from Organ Procurement & Transplantation Network*
*[2]United Network for Organ Sharing*
*[3]EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems*

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# First patient experiences with Idefirix (imlifidase) in highly sensitized kidney transplant patients post approval published

## 29-year-old woman transplanted with Idefirix at Erasmus Medical Center, Rotterdam

The woman has had kidney disease since childhood and has been dialysis dependent since 2016, after previously having had two transplantations where the organs were rejected.

Due to high levels of antibodies, it was virtually impossible for her to find a match through Eurotransplant but in March 2022, the 29-year-old was transplanted using Idefirix and is since doing well.

*"She gained new perspective on a good life through transplantation"* says nephrologist Annelies de Weerd

Link article in Amazing Erasmus from July 7, 2022

## 54-year-old man successfully transplanted at Vall d'Hebron, Barcelona after being on dialysis since 1984

The first patient transplanted in the post-approval study was a 54-year-old man who had been on dialysis since 1984. After two failed transplantation attempts in the 90s, the patient's immune system became sensitized, with very high antibody levels.

In May 2022, the patient received imlifidase treatment followed by a kidney transplant. After three months, he continues to be followed up on and does not require dialysis.

*"This drug may open the door to transplantation for a group of highly sensitized individuals with virtually no option for a compatible transplant."* says Dr. Francesc Moreso

Link article from Vall d'Hebron news forum August 25, 2022

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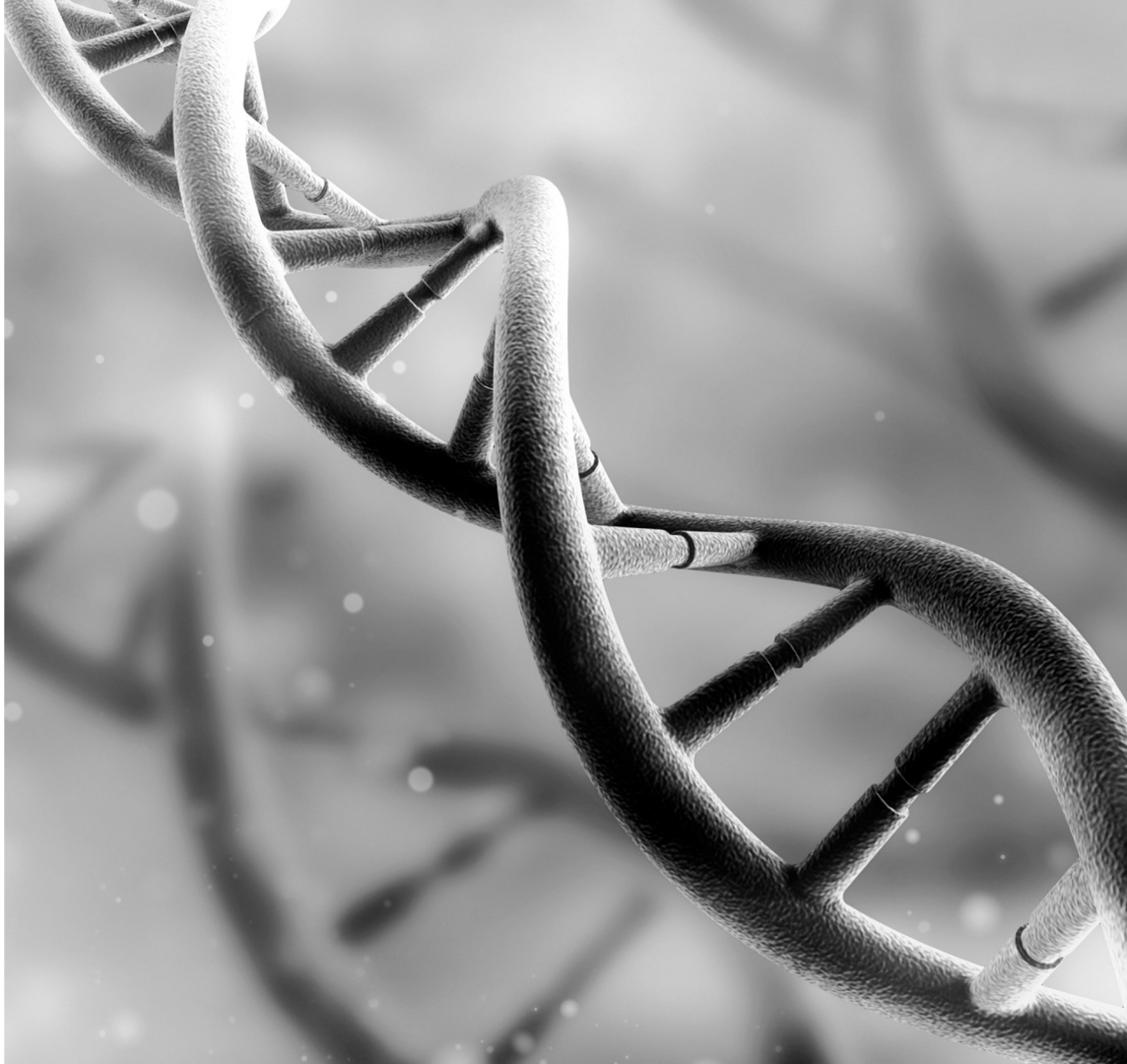
# Gene Therapy



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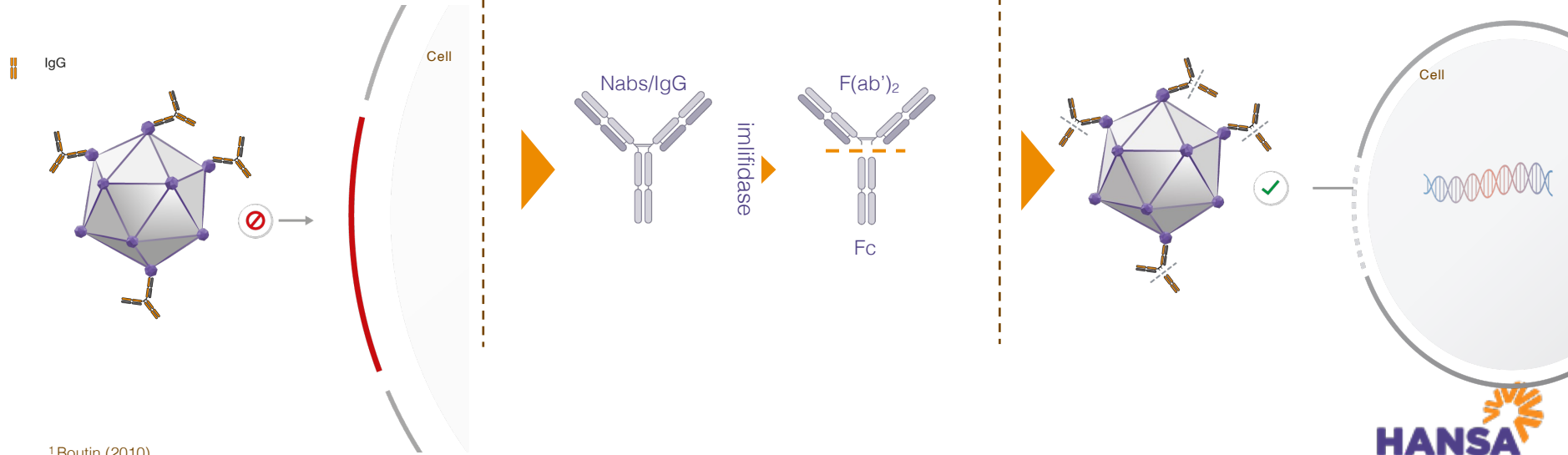
# Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

Between approximately 5% and 70%[1,2] of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

**1** Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern

**2** Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity

**3** The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy




[1] Boutin (2010)
[2] Kruzik (2019)



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# Global and exclusive agreement with Sarepta Therapeutics

to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

**Indication exclusivity:**

- Duchenne Muscular Dystrophy (DMD)
- Limb-Girdle Muscular Dystrophy (LGMD)

## Hansa's key resources

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval
- Positive preclinical data published in *Nature*
- Clear path to U.S. approval (kidney transplant)

+

## Sarepta's key resources

- World leader within gene therapy targeted at muscular dystrophies
- Pre-clinical plan: PoC and IND-tox
- Clinical / Regulatory
- Promotion

## Collaborative research, development and commercialization – working together at every stage

| Antibody cleaving enzyme technology | Preclinical Development | Clinical Development | Regulatory Approvals | Commercialization |
|---|---|---|---|---|
| HANSA BIOPHARMA | SAREPTA THERAPEUTICS / HANSA BIOPHARMA | SAREPTA THERAPEUTICS / HANSA BIOPHARMA | SAREPTA THERAPEUTICS / HANSA BIOPHARMA | SAREPTA THERAPEUTICS / HANSA BIOPHARMA |

**Upfront payment**
USD 10 million upfront

**Milestones**
Hansa is eligible for up to USD 397.5 million in development, regulatory and sales milestones

**Royalties & Sales**
Hansa to receive high single-digit to mid-teens royalties on Sarepta's gene therapy sales enabled with imlifidase in Nabs positive patients and also book all sales of imlifidase

# Duchenne Muscular Dystrophy (DMD) SRP-9001

## About Duchenne Muscular Dystrophy (DMD)[1]

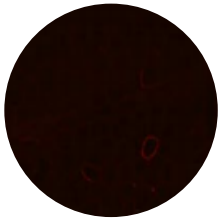
- Rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3 to 5, and most patients use a wheelchair by the time they are 11
- Cardiac and respiratory muscle deterioration becomes life-threatening
- 1/3,500 to 5,000 male births (worldwide)
- Approximately 15% of patients have pre-existing IgG antibodies to rh74

## SRP-9001 micro-dystrophin gene therapy for treatment of DMD

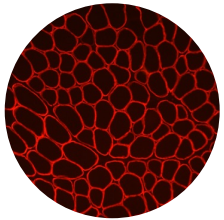
- AAVrh74 vector with micro-dystrophin transgene
- Broad patient experience
- 4 ongoing clinical trials – including recently initiated pivotal study
- Robust micro-dystrophin protein expression with commercially representative process material
- Functional benefits sustained up to 3 years after administration
- Observed safety profile is consistent
- On September 29, 2022, Sarepta announced that it had submitted a Biologics License Application (BLA) to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD.

*For further information regarding Sarepta's gene therapy programs, please refer to www.sarepta.com*

Pre-treatment



Post-treatment



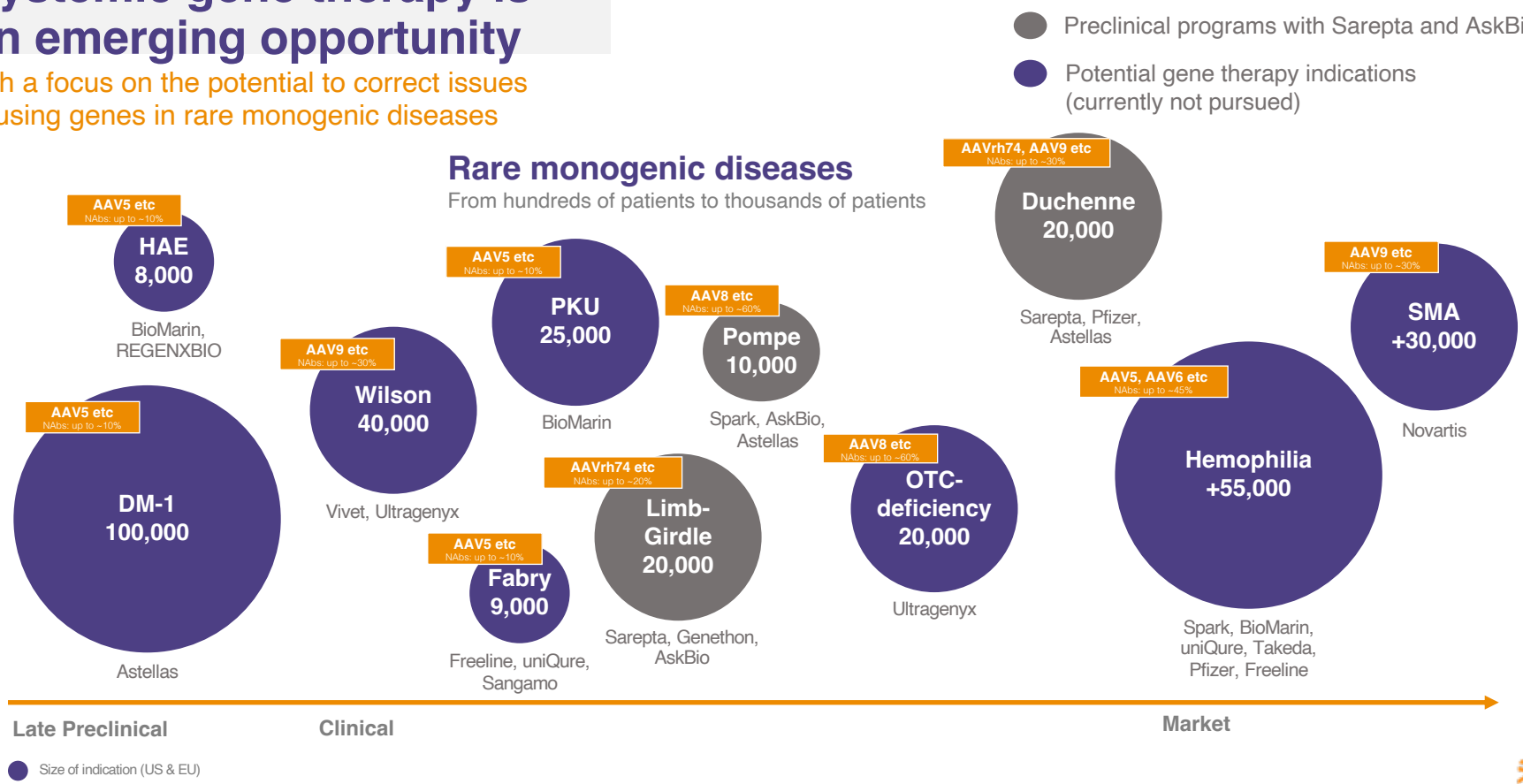
Source:
[1] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad71
[2] National Institutes of Health. Genetics Home Reference. Duchenne and Becker muscular dystrophy. https://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular-dystrophy. Accessed Jan 2020.
[3] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad7



HANSA BIOPHARMA

# Systemic gene therapy is an emerging opportunity

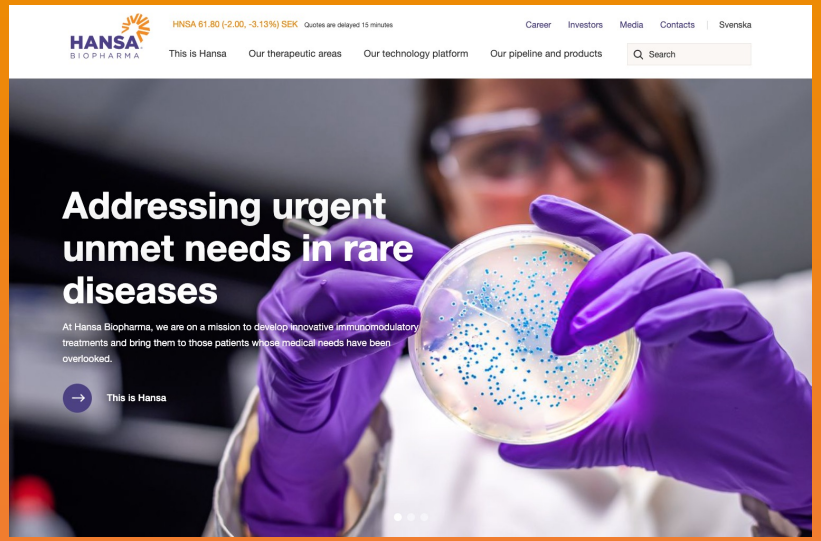
with a focus on the potential to correct issues causing genes in rare monogenic diseases



# Q&A

… at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives…

Visit our new web site
www.hansabiopharma.com





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# Investor Relations

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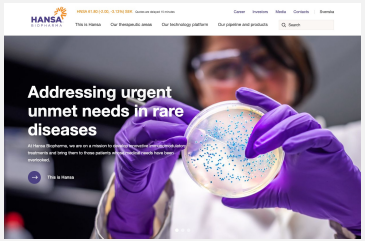


Visit our new web site
www.hansabiopharma.com

## Calendar and events

| | |
|---|---|
| Oct 20, 2022 | Redeye After Work presentation, Gothenburg |
| Oct 21, 2022 | Redeye Lunch presentation, Stockholm |
| Oct 26, 2022 | Økonomisk Ugebrev Life Science Conference, Copenhagen |
| Oct 27, 2022 | HCA Capital Expert call on the commercial progress and launch strategy |
| Nov 22, 2022 | Bryan Garnier KOL Expert call on kidney transplantation (virtual) |
| Nov 23, 2022 | SEB Healthcare Seminar 2022, Stockholm |
| Nov 24, 2022 | Redeye Life Science Day, Stockholm |
| Dec 1, 2022 | Erik Penser Banks Temadag - Health Care, Stockholm |
| Dec 2, 2022 | Geneva Corporate Access Midcap Event, Geneva |
| Dec 15, 2022 | DNB Nordic Healthcare Conference, Oslo |
| Jan 9, 2023 | JPM Week, San Francisco |
| Feb 2, 2023 | Interim Report for January-December 2022 |
| Mar 14, 2023 | Carnegie Nordic Healthcare Seminar 2023 |
| Mar 30, 2023 | 2022 Annual Report |
| April 20, 2023 | Interim Report for January-March 2023 |
| June 14, 2023 | 2023 Annual General Meeting |
| July 20, 2023 | Half-year Report for January-June 2023 |
| Oct 19, 2023 | Interim Report for January-September 2023 |