



# HANSA

BIOPHARMA

## Investor Presentation

Økonomisk Ugebrev Life Science Conference  
Copenhagen, October 26, 2022

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*Head of Investor Relations*

# Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

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Successful track record...  
Strong momentum...  
Promising future...

## A validated technology

### VALIDATION ACROSS THREE AREAS

- ✓ Approval in kidney transplantations
- ✓ Proof of concept in autoimmune diseases
- ✓ Partnerships to explore gene therapy

## Idefirix® is our first approved drug in Europe\*

### EUROPE KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

## Broad pipeline in transplantation and autoimmunity

### PROGRAMS IN CLINICAL DEVELOPMENT

US kidney transplants  
Anti-GBM  
Guillain-Barré syndrome (GBS)  
Antibody mediated kidney transplant rejection (AMR)

## Established a high-performance organization

### NEW COMPETENCIES ADDED

145 employees September 2022 (~3x in 3 years)

Highly qualified team with 20 years on average in life science  
Purpose driven culture

## With current cash position Hansa is financed through 2024

### FINANCIALS

SEK 1.2bn in Cash and short term investments (USD ~120m) end of September 2022

SEK ~70m raised through NovaQuest financing transaction in July 2022

## Created shareholder value and diversified our ownership base

### MARKET CAPITALISATION (USD): ~300m

Listed on Nasdaq Stockholm  
18,000 shareholders

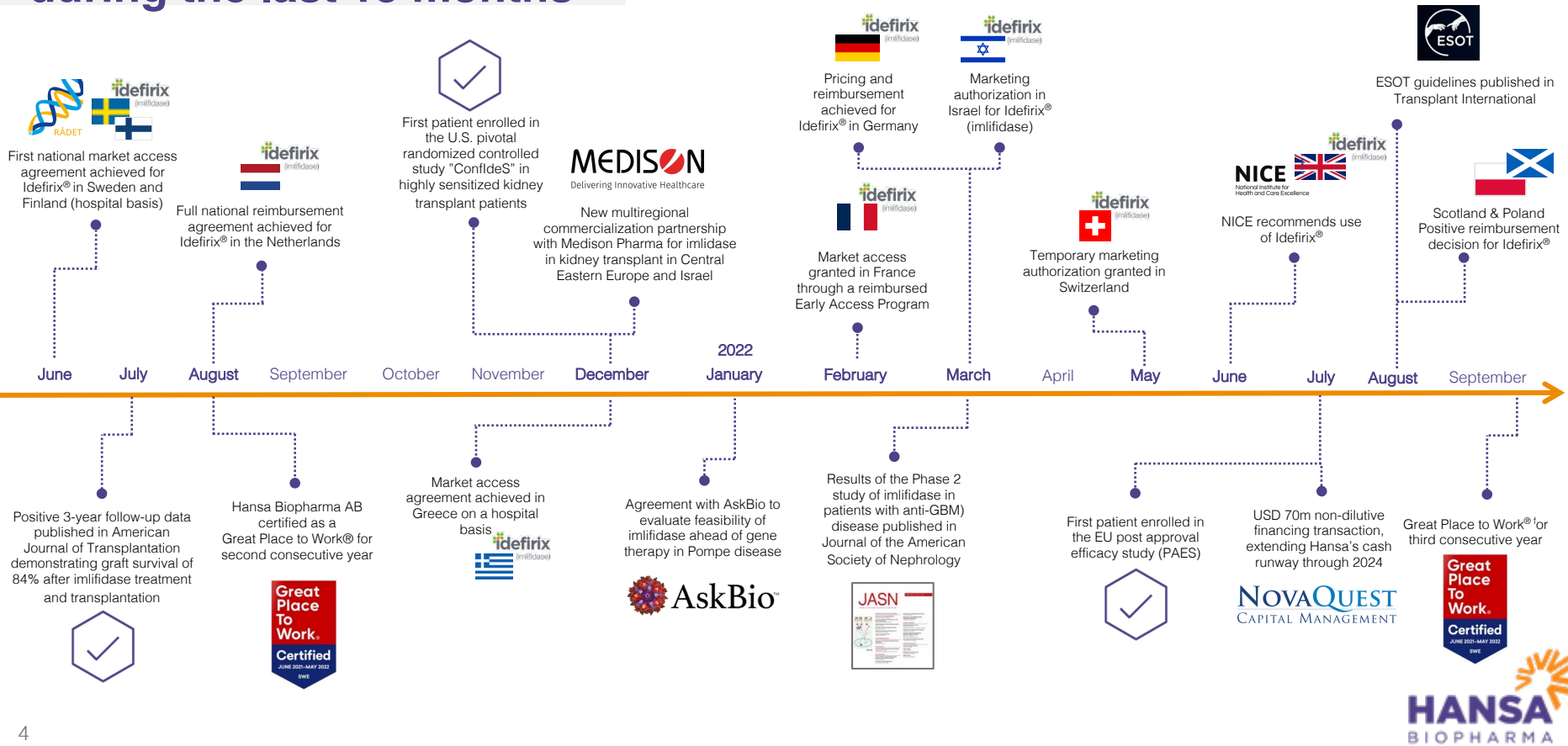
Foreign ownership make up ~40% through leading international life science specialist funds



\*Idefirix approved in EEA under conditional approval for kidney transplantation

\*\*Actual patient has given consent to provide images

# Many milestones achieved during the last 15 months



# Imlifidase

A novel approach to eliminate pathogenic IgG

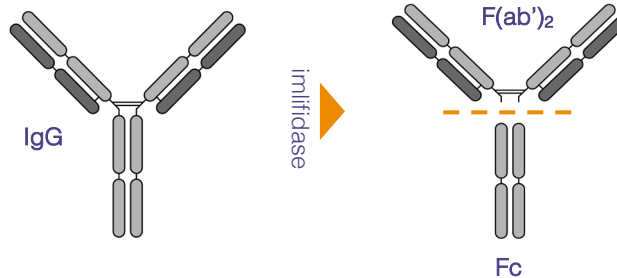
## Origins from a bacteria *Streptococcus pyogenes*

- Species of Gram-positive, spherical bacteria in the genus *Streptococcus*
- Usually known from causing a strep throat infection



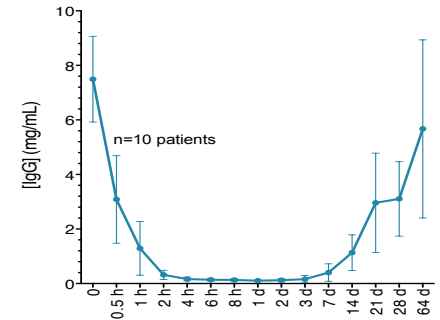
## A unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one F(ab')<sub>2</sub> fragment and one homo-dimeric Fc-fragment

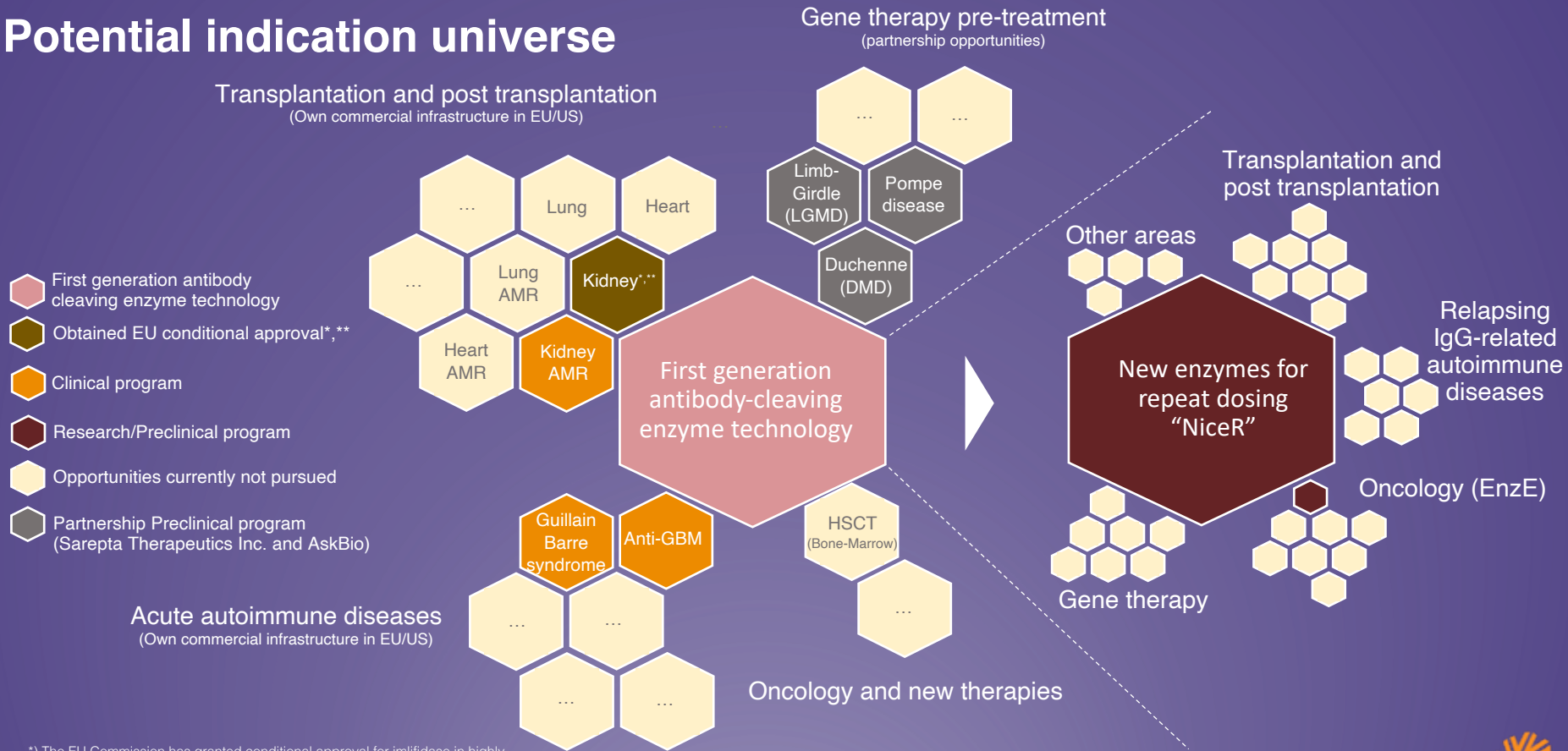


## Inactivates IgG in 2-6 hours

- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours
- IgG antibody-free window for approximately one week



# Potential indication universe

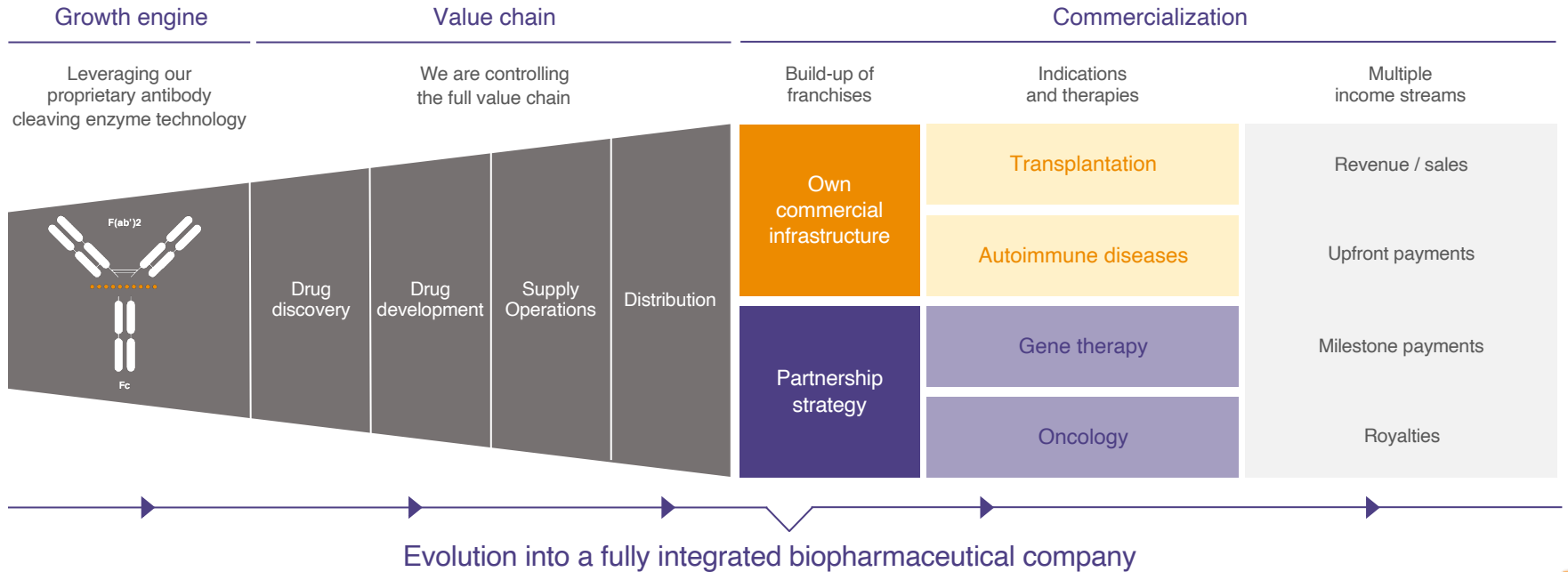


\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.

\*\*) In the US a new study has commenced targeting a BLA filing by H1 2024

# Our Business model

Leveraging our technology platform to develop new therapies targeting rare diseases with unmet medical need across a range of indications



# Idefix<sup>®</sup> (imlifidase) has received conditional approval in the European Union

Low complexity transplants ← → Higher complexity transplants

~70% of patients<sup>1,2</sup>

Non or less sensitized  
(cPRA < 20%)

15-20% of patients<sup>1,2</sup>

Moderately sensitized  
(20% < cPRA < 80%)

10-15% of patients<sup>1,2</sup>

Highly sensitized  
(cPRA > 80%)

Highly sensitized patients that are likely to be transplanted with a compatible donor

Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs

## Idefix<sup>®</sup> is indicated for

*desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.*

*The use of Idefix<sup>®</sup> should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients*

Potential patients

**idefix<sup>®</sup>**  
imlifidase

Actual patient has given consent to provide images

<sup>1</sup> EDQM. (2020). International figures on donation and Transplantation 2019  
<sup>2</sup> SRTR Database and individual assessments of allocation systems

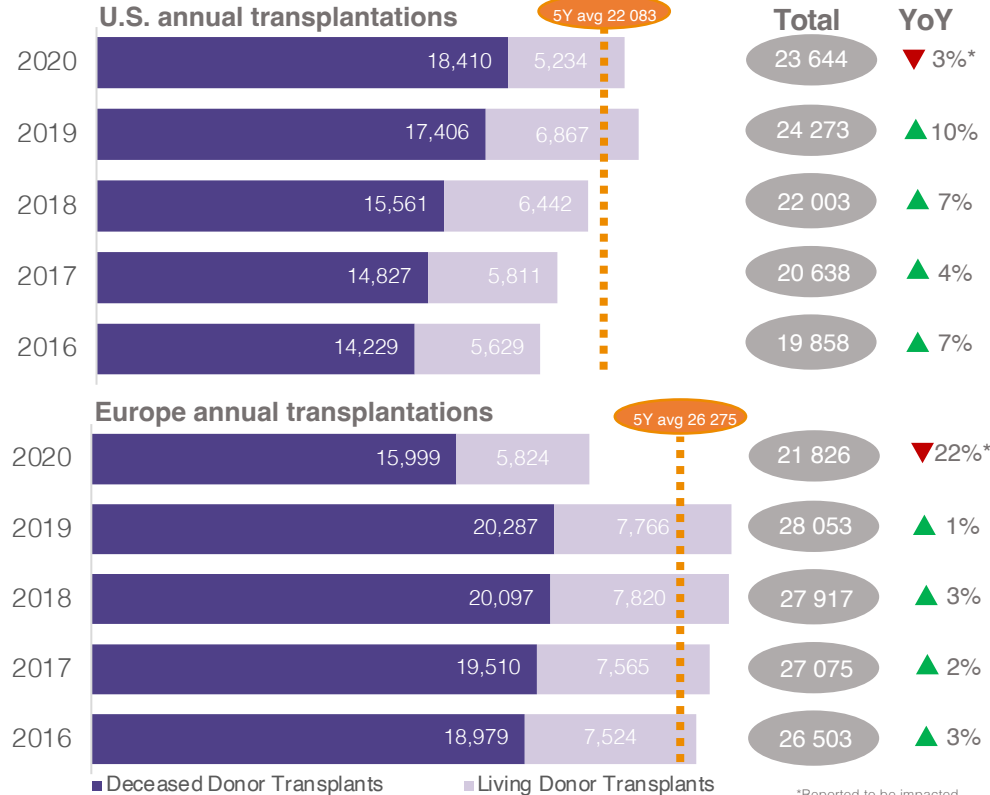
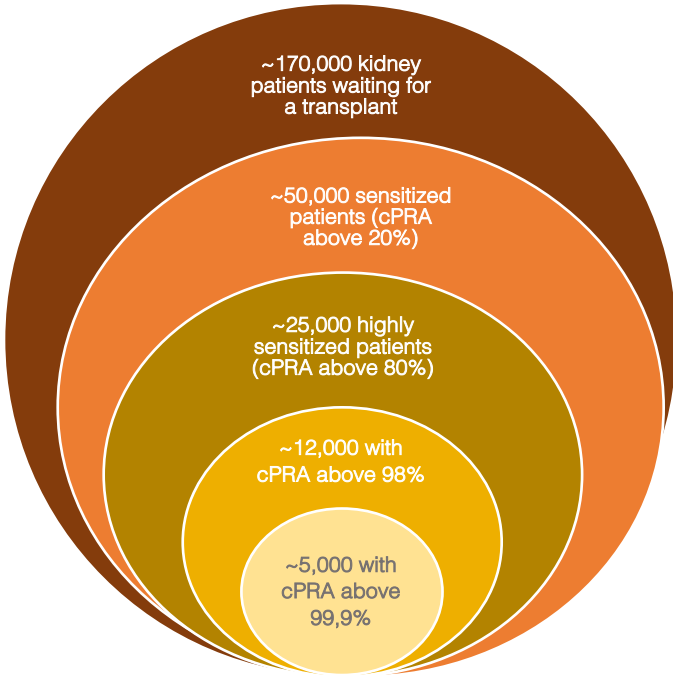


# The kidney transplantation landscape in Europe and the U.S.

Up to 15% of patients waiting for a new kidney are highly sensitized

~50,000 transplants done annually in the U.S. and Europe

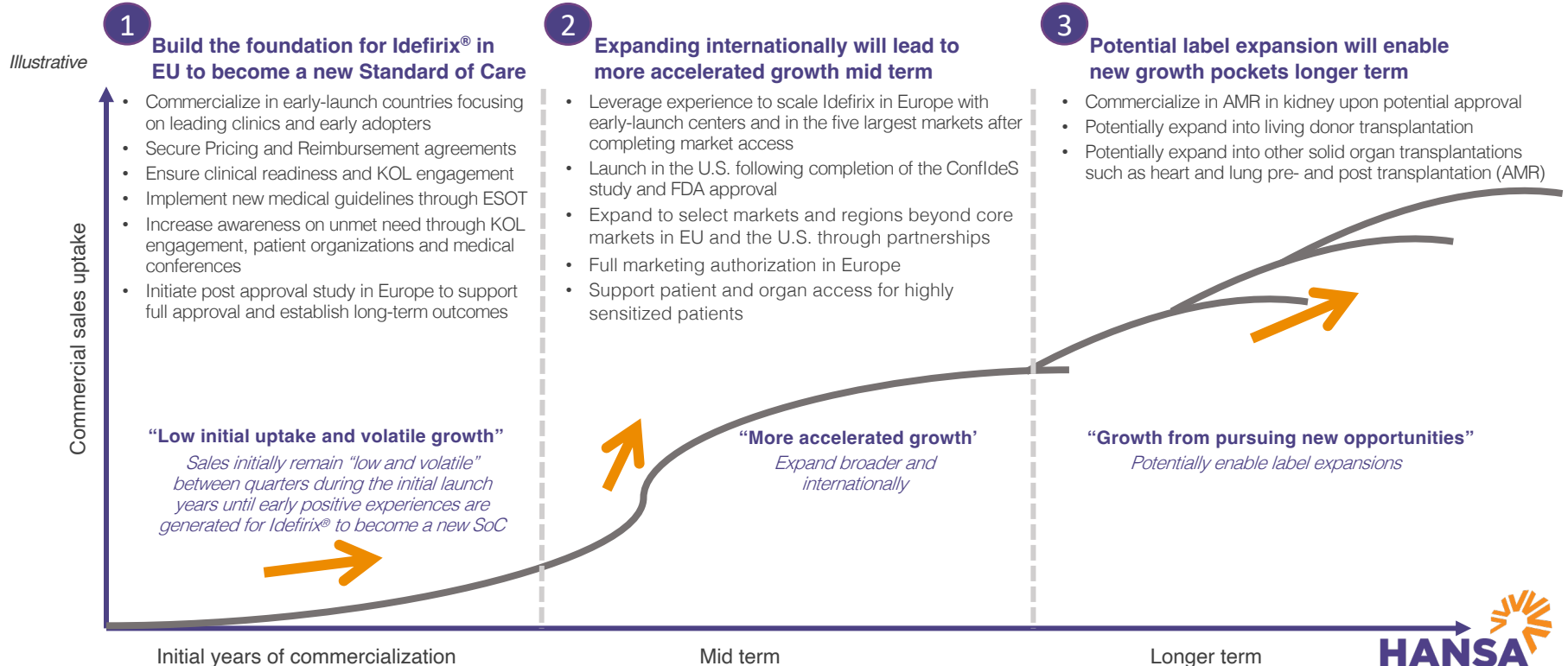
Breakdown of the kidney transplant waitlist in U.S. and EU



\*Reported to be impacted by the COVID-19 pandemic

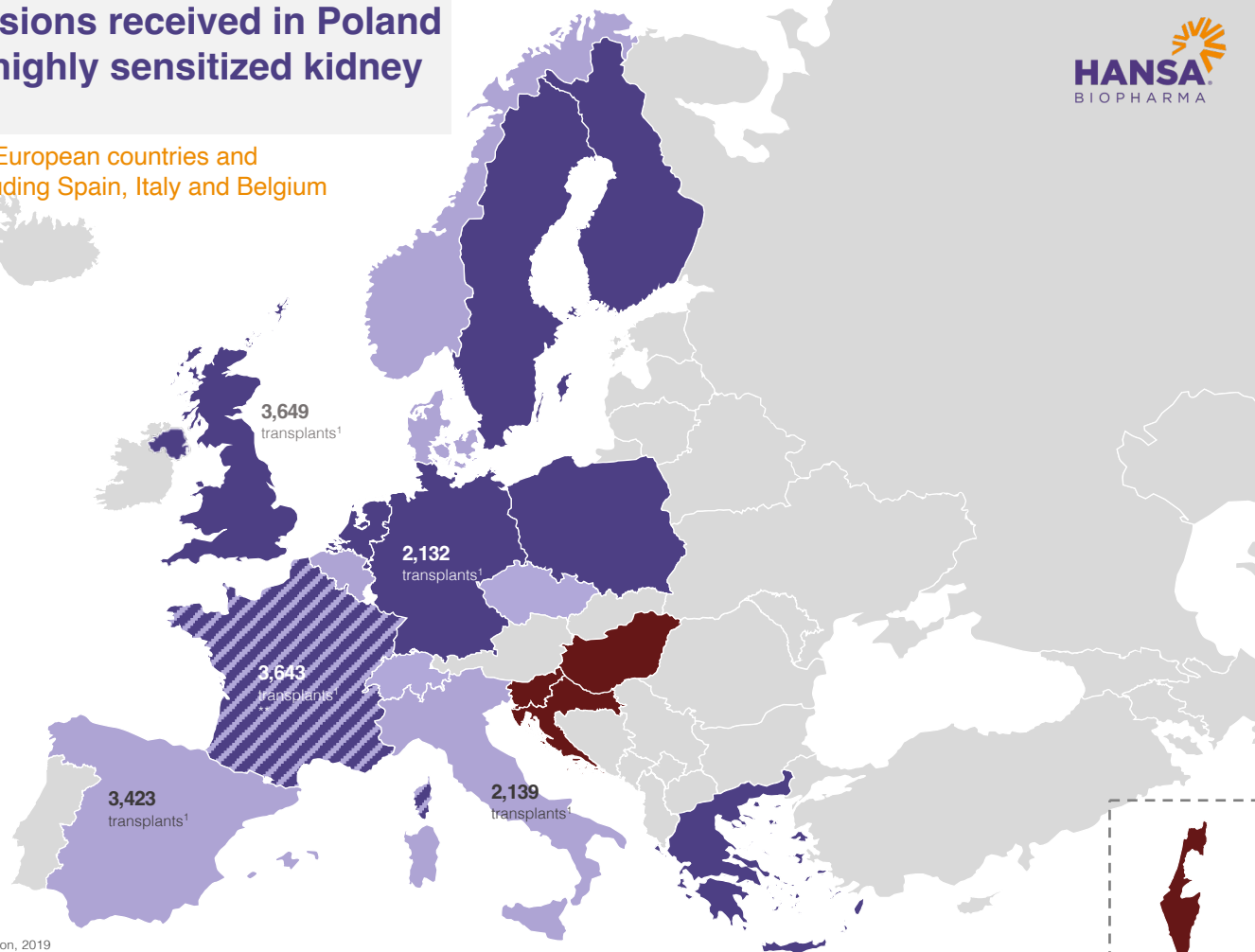
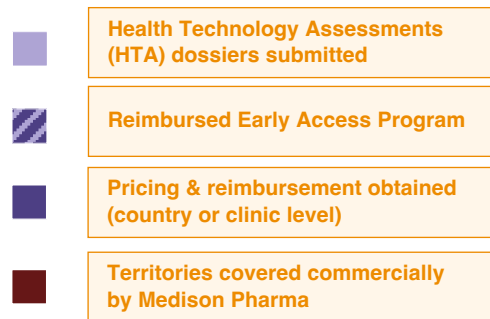
# Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

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



# 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



<sup>1</sup>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

# First patient experiences with Idefirix in highly sensitized kidney 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

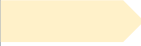

The first patient transplanted in the post-approval study was a 54-year-old man who had been on dialysis since 1984. After two failed transplantation attempts in the 90s, the patient’s immune system became sensitized, with very high antibody levels.

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](#)

# Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/Project	Indication	Research/Preclinical	Phase 1	Potentially Pivotal/Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>						EU: Additional agreements around reimbursement from H2'21	
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>						Completion of enrollment (64 patients) H2'22	
	Anti-GBM antibody disease <sup>3</sup>						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	

<sup>1</sup> Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)


<sup>2</sup> Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

<sup>3</sup> Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

 Completed

 Planned

 Ongoing

 Post approval study running in parallel with commercial launch

## 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 OBJECTIVES

- 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

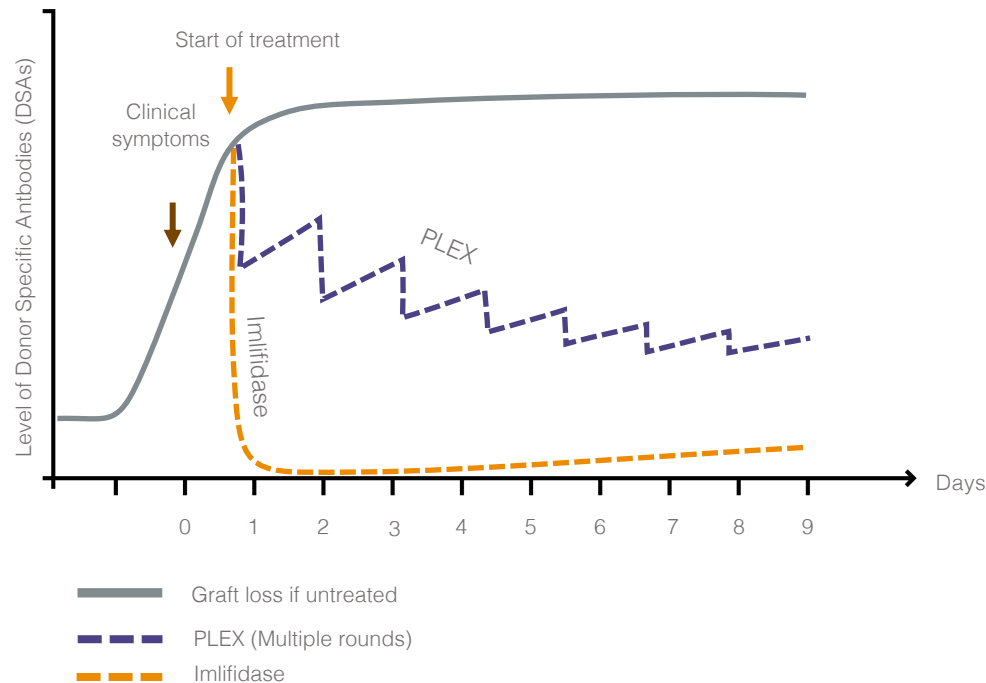
- Randomized, open-label multi-center active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

### STATUS

Completed enrollment awaiting first data read out H2 2022

## Potential of using imlifidase vs. PLEX in AMR

*Illustrative*



# 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  $\geq 99.9\%$  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

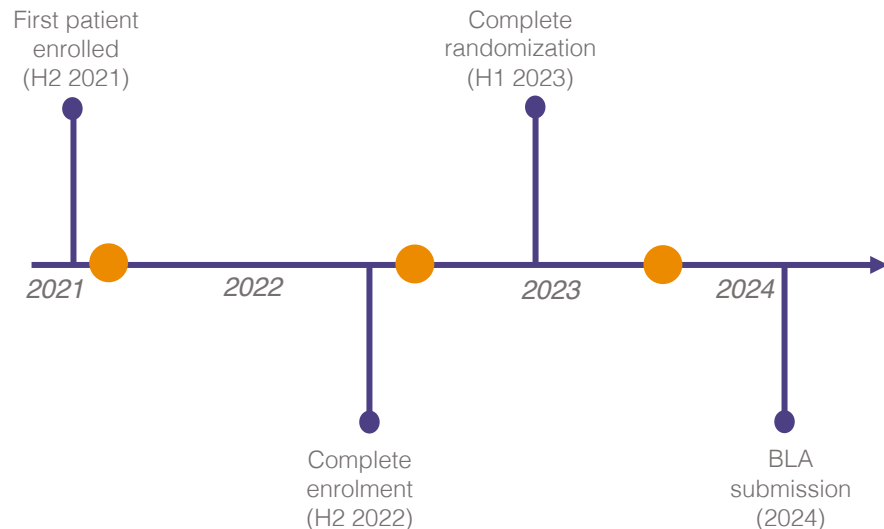
## Secondary endpoint

- 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

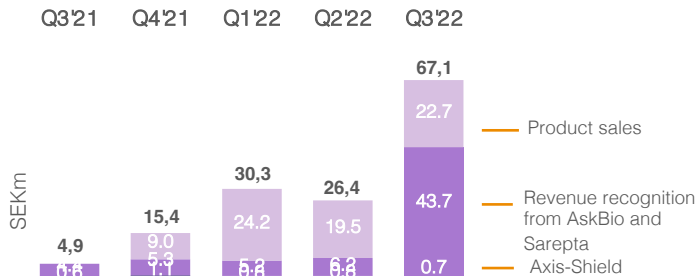
## Timeline



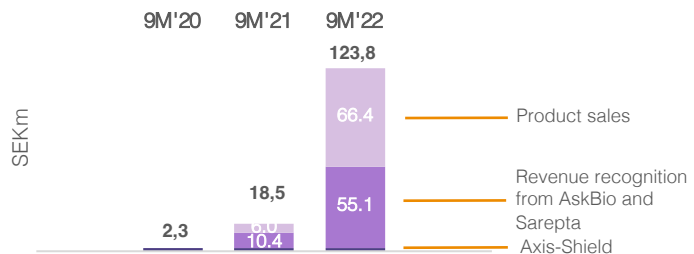
\*Experimental desensitization treatment can include any combination of plasma exchange (PLEX), intravenous IVIg, anti-CD20 antibody, and eculizumab. Link to the full protocol at [ClinicalTrials.gov](https://clinicaltrials.gov)

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

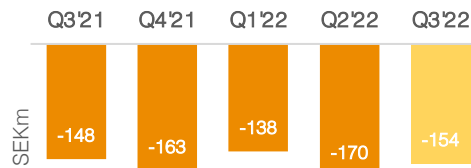
### Revenue (Q/Q)



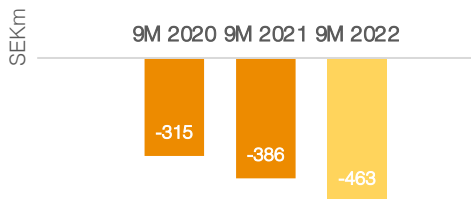
### Revenue (9M/9M)



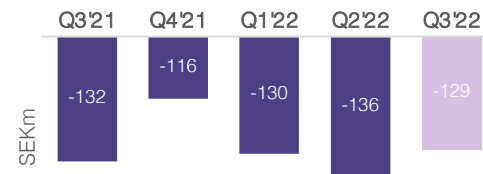
### Net loss (Q/Q)



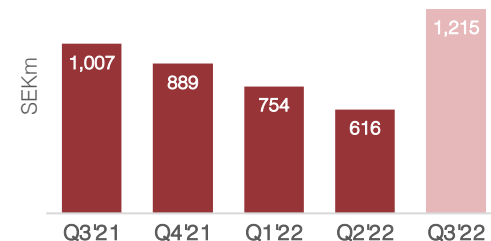
### Net loss (9M/9M)



### Operating cash flow (Q/Q)



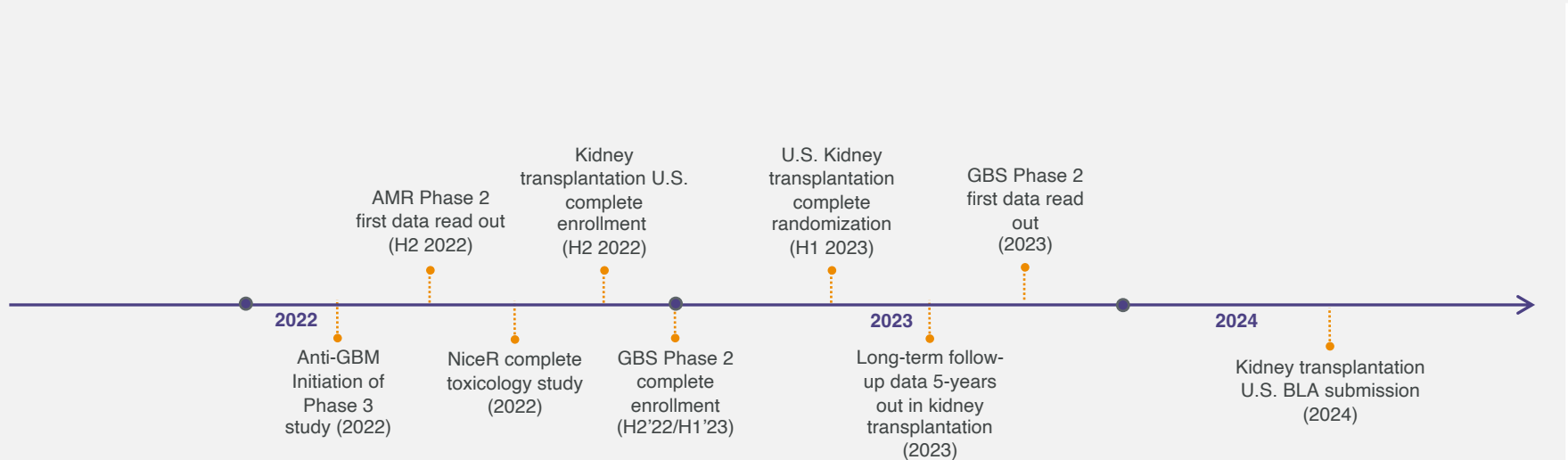
### Cash & short-term investments (Q/Q)





# 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.*

# Our unique antibody cleaving enzyme technology may have relevance across a range of indications

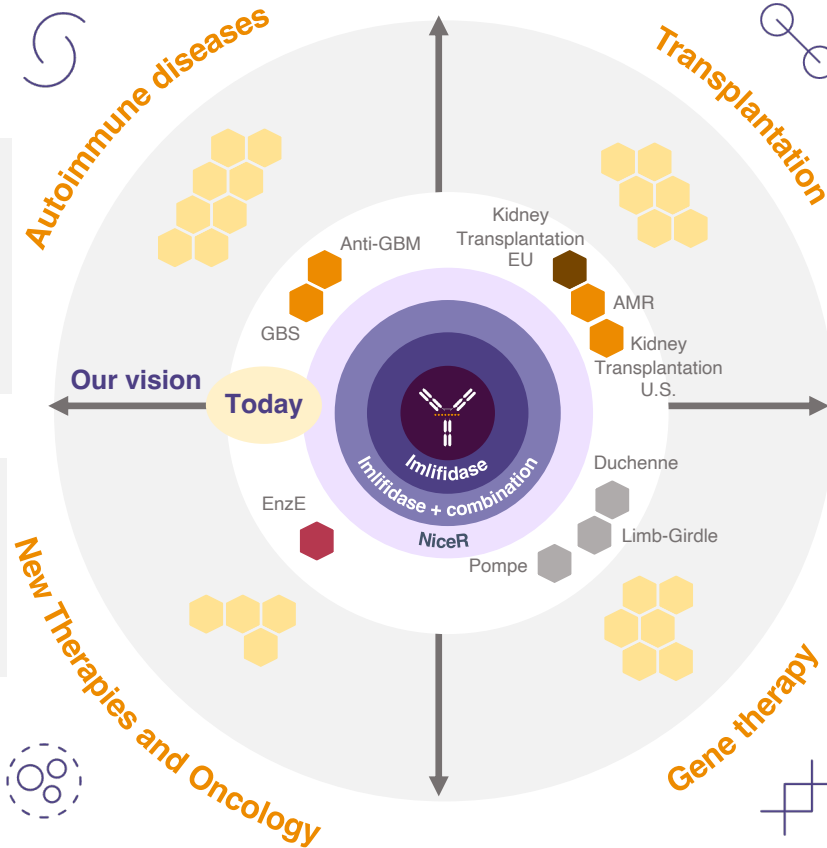
Targeting rare IgG mediated diseases

## Anti-GBM paves the way for development in other autoimmune diseases

- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders

## IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic stem cell (bone marrow) transplantation (HSCT)
- Enzyme-based antibody Enhancement (EnzE)



## Expanding our commercial franchises

- Regulatory approval (conditional)
- Clinical development
- Partnership (preclinical development)
- Preclinical development
- Potential indications (currently not pursued)

## Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

## Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta and AskBio
- Wide indication landscape beyond



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# Investor Relations

## Contact

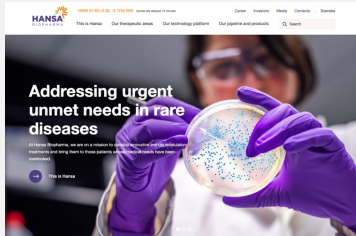


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## Calendar and events

- 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