



## Investor Presentation

SEB Nordic Healthcare Seminar  
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*...at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...*

# 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.

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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
- ✓ Partnership 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

133 employees December 2021  
(~3x in 3 years)

Highly qualified team with 20 years on average in life science

Purpose driven culture

## With recent capital injection Hansa is financed into 2023

### FINANCIALS

SEK 889m in Cash (USD ~98m)  
December 2021

## Created shareholder value and diversified our ownership base

### MARKET CAPITALISATION (USD): ~0.4bn

Listed on Nasdaq Stockholm  
18,000 shareholders

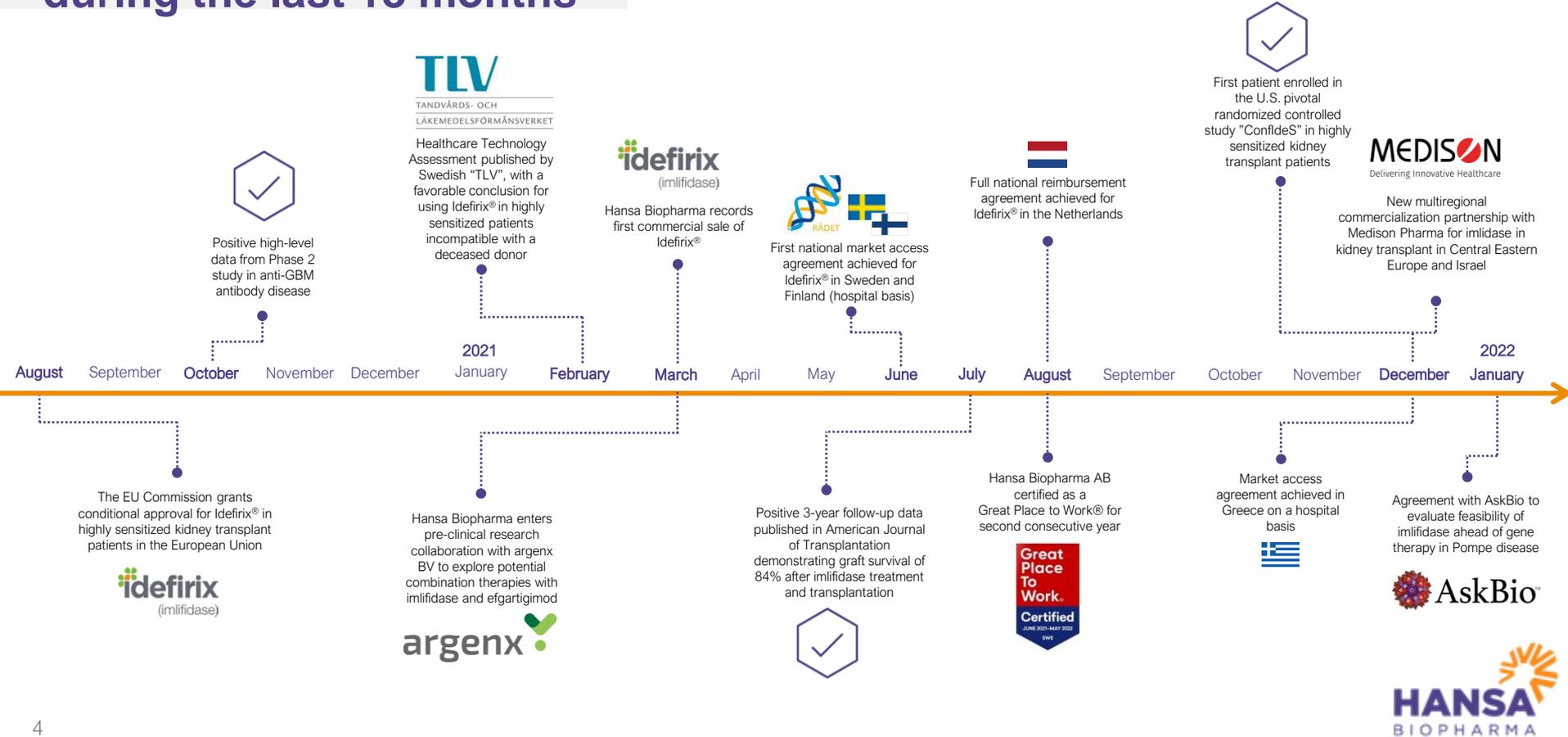
Foreign ownership make up ~50% through leading international life science specialist funds



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

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

# Many milestones achieved during the last 18 months



# Imlifidase

A novel approach to eliminate pathogenic IgG

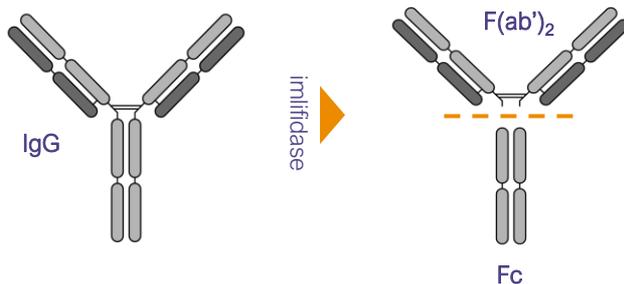
## Origins from a bacteria *Streptococcus pyogenes*

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



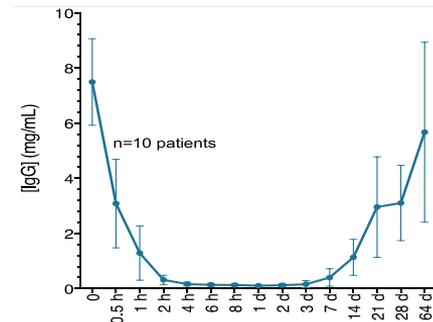
## A unique IgG antibody-cleaving enzyme

- 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

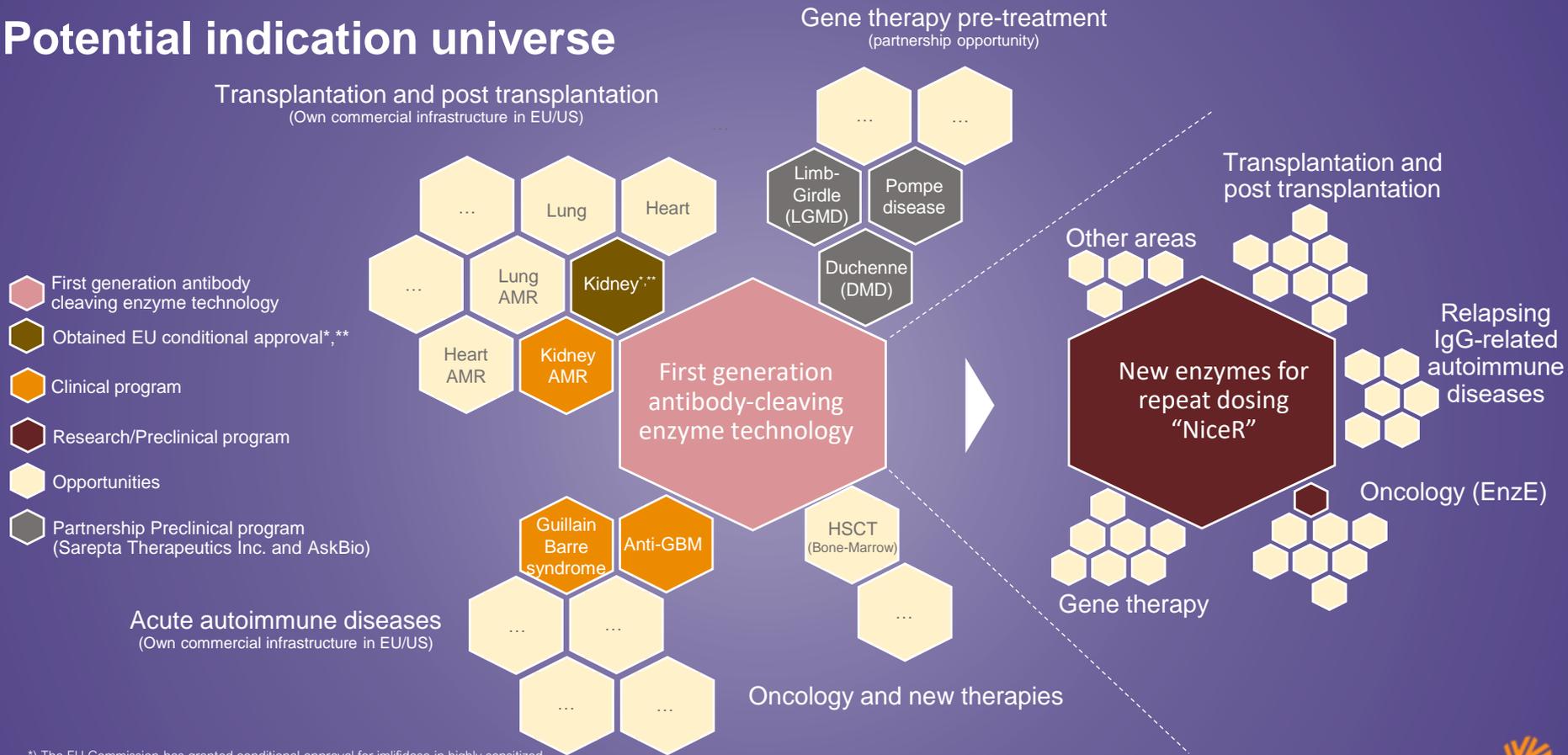


## Inactivates IgG in 2-6 hours

- 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

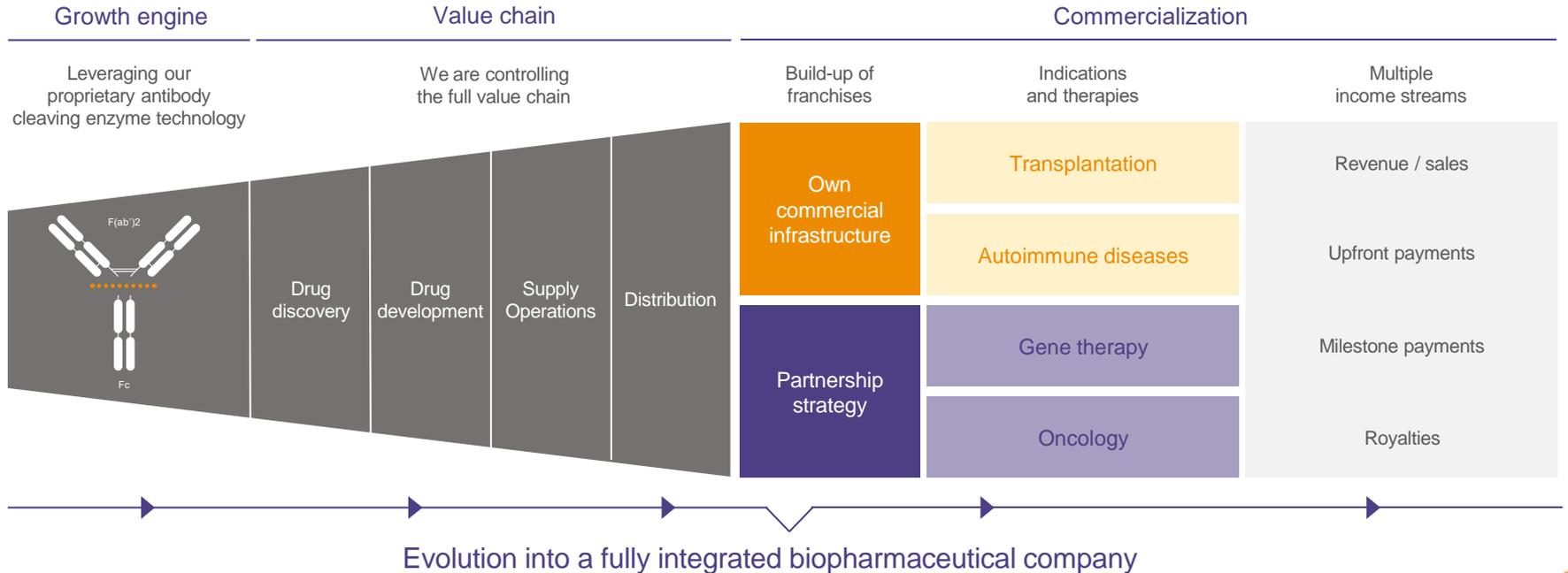


\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.

\*\*) 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



# Idefirix® (imlifidase) has received conditional approval in the European Union

Low complexity transplants

Higher complexity transplants

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

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

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

Non or less sensitized  
(cPRA < 20%)

Moderately sensitized  
(20% < cPRA < 80%)

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

## Idefirix® is indicated for

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

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

Potential patients

**idefirix®**  
imlifidase

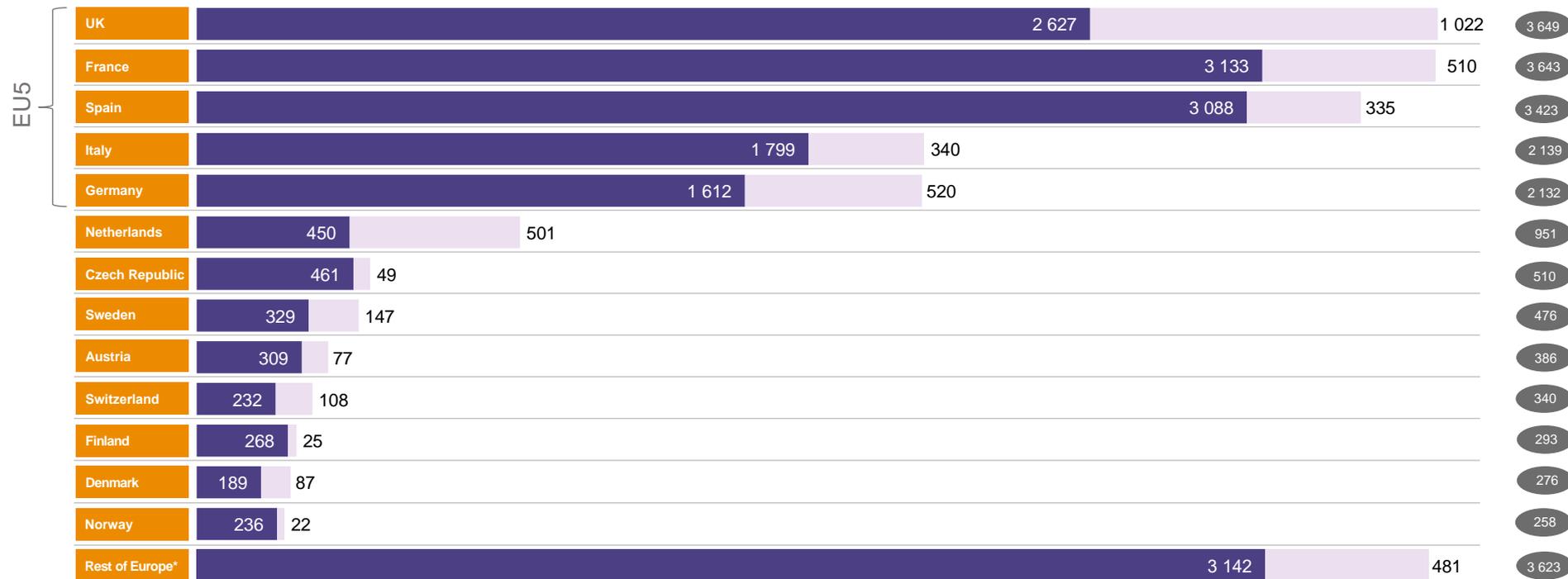
Actual patient has given consent to provide images

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

# European kidney transplantation landscape

Approximately 28,000 kidney transplants are carried out in Europe annually; ~72% of transplants are from deceased donors<sup>1</sup>

- Deceased donor transplants
- Living donor transplants
- Total kidney transplantations



<sup>1</sup>Transplant data from 2019.

\*Belgium, Croatia, Cyprus, Greece, Hungary, Iceland, Ireland, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia  
Source: Global Observatory on Donation & Transplantation, 2019

# Progress with commercial metrics; Market access procedures are ongoing in thirteen countries

Pricing and Reimbursement processes on track;  
Completion of HTA filings in EU4+UK expected during Q1 2022

Growing number of patient candidates as select priority  
centers get clinically ready and awareness increased

## Pricing and Reimbursement

- 4
- ✓ Agreements on funding obtained:
    - Sweden
    - Netherlands
    - Finland (on hospital basis)
    - Greece (on hospital basis)
  - ✓ Additional milestones
    - Preparing for market access in additional international markets beyond Europe and the US (e.g. Israel)
    - Pursuing early access opportunities where possible

## Market access procedures

- 13
- ✓ Market access procedures are ongoing in thirteen countries
    - Sweden
    - Netherlands
    - Finland
    - Norway
    - Denmark\*
    - France
    - Belgium
    - UK
    - Germany
    - Italy
    - Scotland
    - Israel
    - Greece
  - ✓ Health Technology Assessment (HTA) dossier for Spain is expected to be submitted during Q1 2022 which will complete HTA filings in all the five largest markets in Europe.

\* In Denmark, the HTA has been pre-submitted

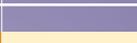
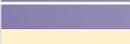
## Clinical readiness

- 10
- ✓ Ten priority centers clinical ready to take on patients include among others:
    - Akademiska, Uppsala
    - Erasmus, Rotterdam
    - University Hospital, Helsinki
  - 10
  - ✓ Hansa to continue to work closely with another ten priority centers on clinical readiness
  - ✓ Growing number of highly sensitized patient candidates identified and prioritized for incompatible kidney transplantations in the coming months

## Awareness

- ✓ Over 30 experts are engaged and committed to operationalizing HLA-incompatible kidney transplants for some of their highly sensitized patients.
- ✓ European Society for Organ Transplantation (ESOT) workstream, formed with leading experts, continued its work on advancing clinical guidelines in the complex field of desensitization; 2<sup>nd</sup> part of the workstream expected to begin in 2022.

# Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Program	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
	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)
Imlifidase	Antibody mediated kidney transplant rejection (AMR)							Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)							Completion of enrollment (30 patients) H1 2022
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy							Research phase

<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

\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

 Completed

 Ongoing

 Planned

 Conditional approval based on Phase 2 data

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

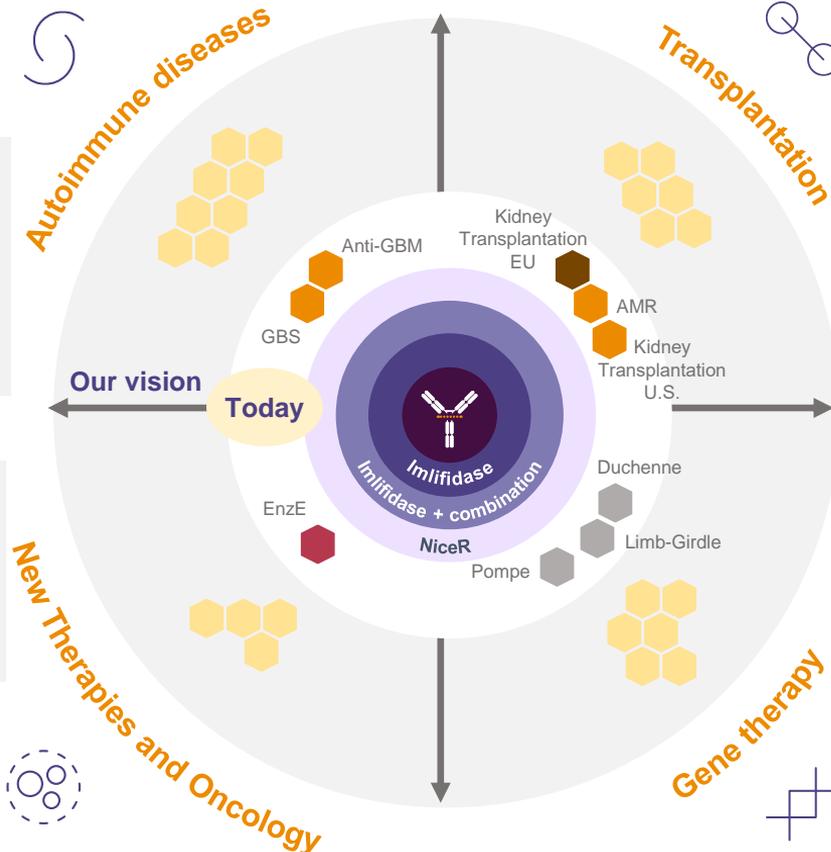
## Targeting rare IgG mediated diseases

### 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

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

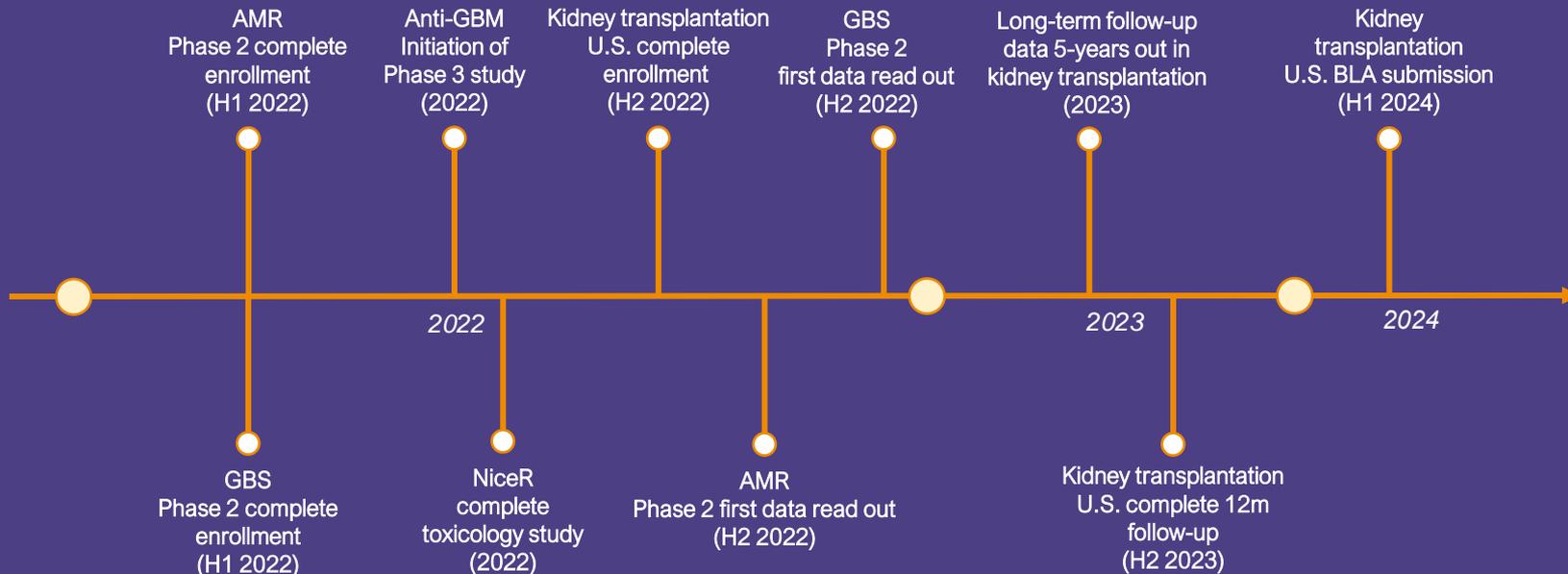
- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

### Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Partnership with Sarepta
- Wide indication landscape beyond

# Upcoming milestones

Milestones subject to potential COVID-19 impact





**HANSA**

BIOPHARMA

# Corporate Contacts

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[www.hansabiopharma.com](http://www.hansabiopharma.com)



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## Calendar and events

Feb 3, 2022

Year-End report for Jan - Dec 2021

Mar 10, 2022

Erik Penser Bolagsdag, Stockholm

Mar 10, 2022

Redeye Investor Forum, Gothenburg

Mar 15, 2022

Carnegie Healthcare Seminar 2022, Stockholm

Mar 31, 2022

Redeye Investor Forum, Malmö

April 7, 2022

Annual Report 2021

April 21, 2022

Interim Report for January-March 2022

April 21, 2022

Kempen Life Sciences Conference 2022, Amsterdam

April 27, 2022

Redeye Orphan Drugs 2022, Stockholm

May, 2022

RBC Global Healthcare Conference 2022, New York City

June 16, 2022

Annual General Meeting 2022

July 21, 2022

Half year 2022 report

Oct 20, 2022

Interim Report for January-September 2022