



B I O P H A R M A

## Investor Presentation

Redeye Orphan Drug Seminar 2022  
Stockholm April 27, 2022

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*Head of Investor Relations*



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# Hansa Biopharma today

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\*

### KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Solid sales growth reported in Q1  
Sales expected to remain volatile during the initial launch years

## 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

140 employees March 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 754m in Cash (USD ~80m)  
end of March 2022

## Created shareholder value and diversified our ownership base

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

Listed on Nasdaq Stockholm  
18,000 shareholders

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



**Patient\***

*This is a break-through for the patients who need but can't access kidney transplantation today*

\*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

TLV

TANDVÅRDS- OCH  
LÄKEMEDELSFORMÄNSVERKET

Healthcare Technology Assessment published by Swedish "TLV", with a favorable conclusion for using Idefix® in highly sensitized patients incompatible with a deceased donor

idefix®  
(imlifidase)

Hansa Biopharma records first commercial sale of Idefix®



First national market access agreement achieved for Idefix® in Sweden and Finland (hospital basis)



Full national reimbursement agreement achieved for Idefix® in the Netherlands



First patient enrolled in the U.S. pivotal randomized controlled study "ConfideS" in highly sensitized kidney transplant patients

MEDISON  
Delivering Innovative Healthcare

New multiregional commercialization partnership with Medison Pharma for imlifidase in kidney transplant in Central Eastern Europe and Israel



Pricing and reimbursement achieved for Idefix® in Germany



Marketing authorization in Israel for Idefix® (imlifidase)



Pricing and reimbursement for Idefix® obtained in France on an early access basis

2021

January

February

March

April

May

June

July

August

September

October

November

December

2022

January

February

March

Hansa Biopharma enters pre-clinical research collaboration with argenx BV to explore potential combination therapies with imlifidase and efgartigimod

argenx

Positive 3-year follow-up data published in American Journal of Transplantation demonstrating graft survival of 84% after imlifidase treatment and transplantation



Hansa Biopharma AB certified as a Great Place to Work® for second consecutive year



Market access agreement achieved in Greece on a hospital basis



Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease



Results of the Phase 2 study of imlifidase in patients with anti-GBM disease published in Journal of the American Society of Nephrology



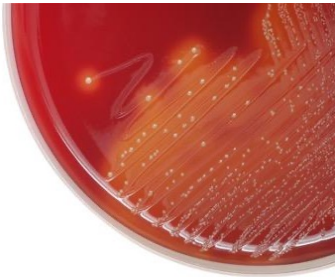
HANSA  
BIOPHARMA

# Imlifidase

A novel approach to eliminate pathogenic IgG

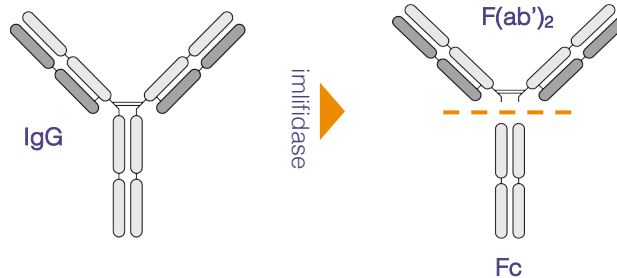
## Origins from a bacteria *Streptococcus pyogenes*

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



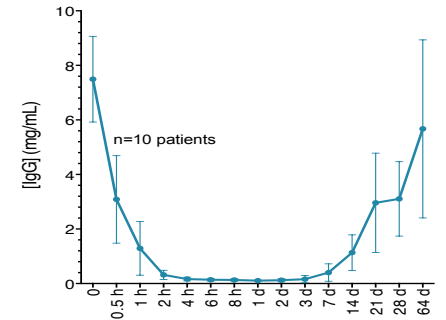
## A unique IgG antibody-cleaving enzyme

- 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

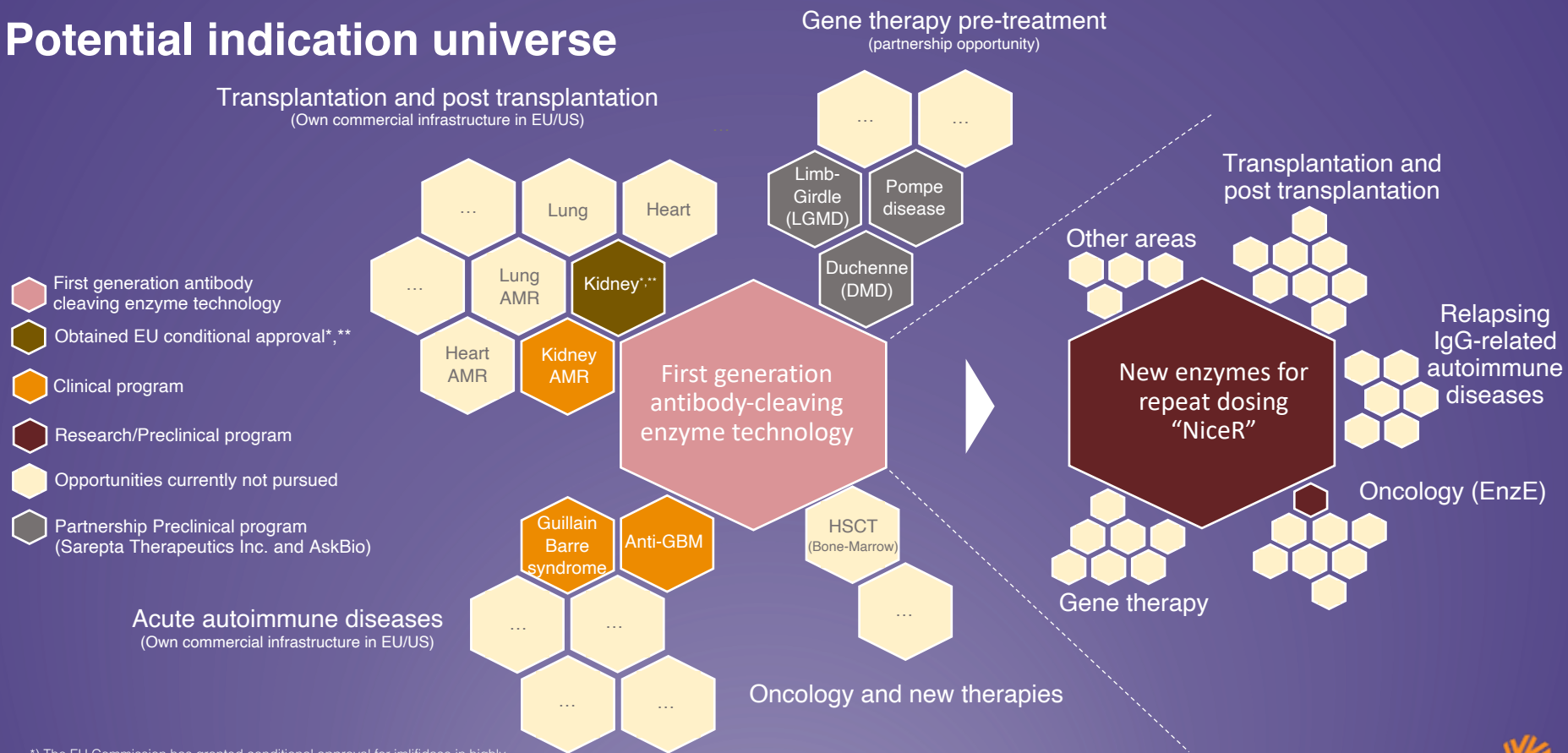


## Inactivates IgG in 2-6 hours

- 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

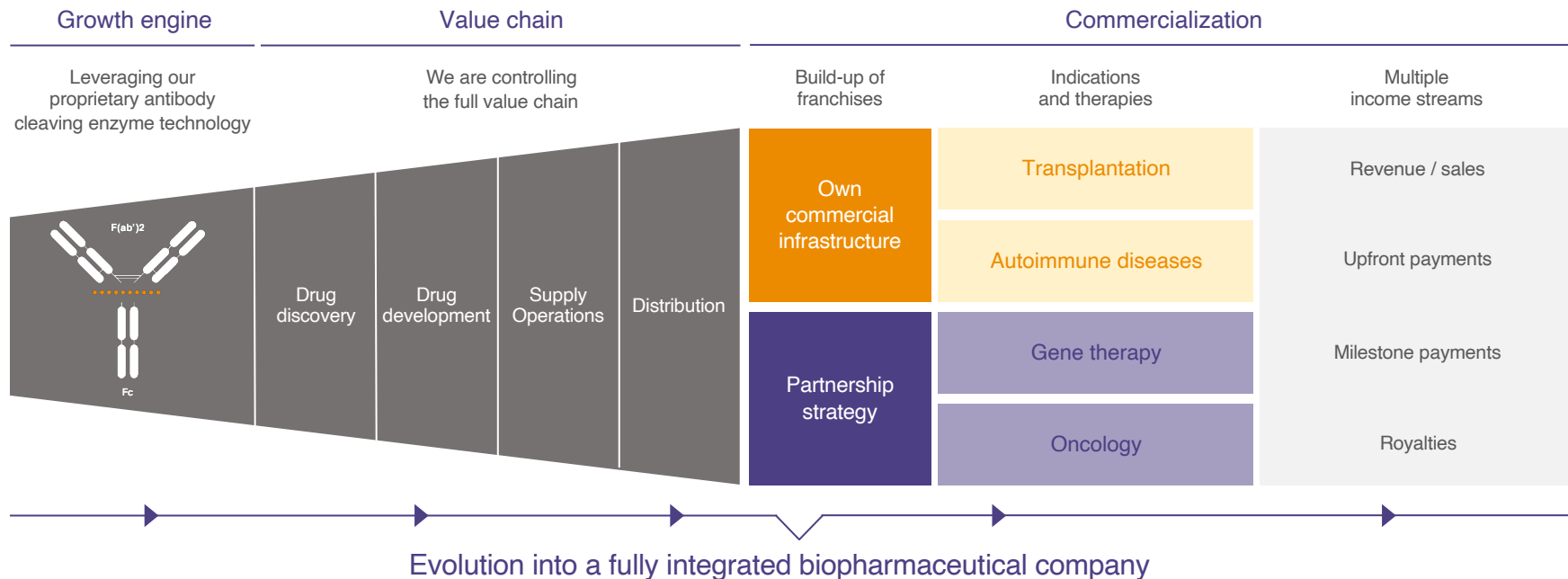


\*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.

\*\*) 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

**HANSA**  
BIOPHARMA

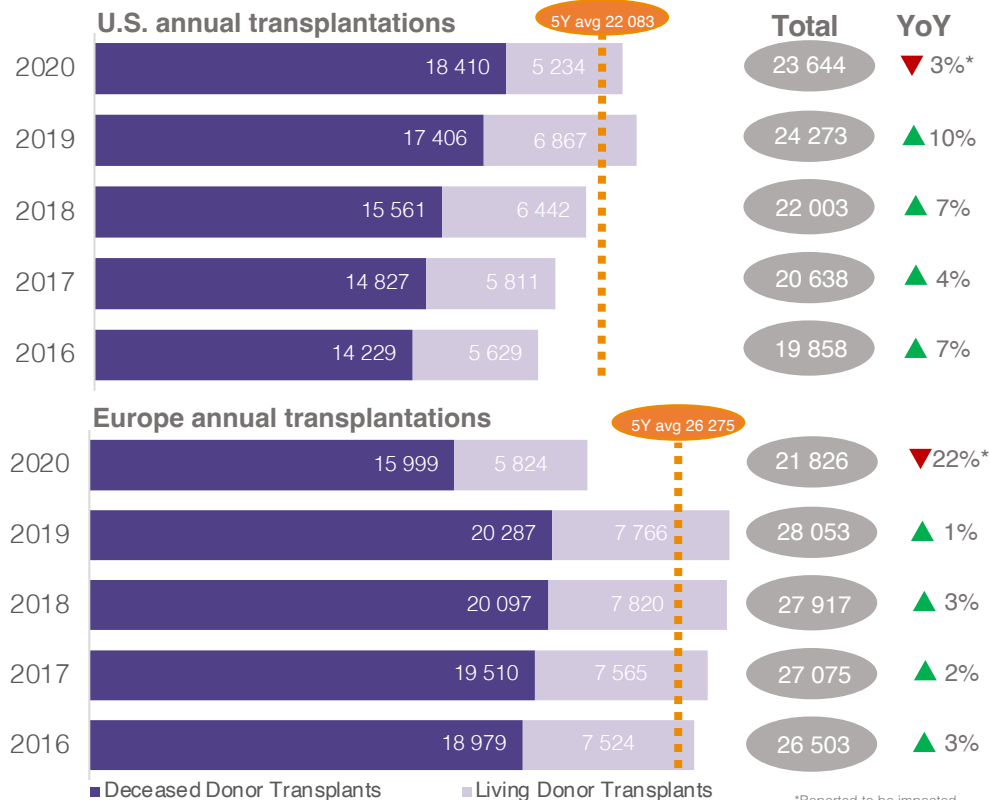
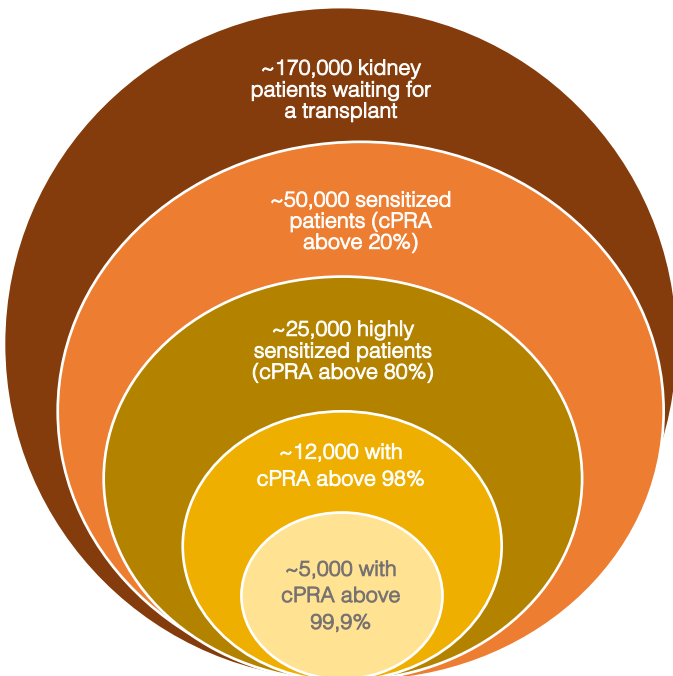


# The kidney transplantation landscape in Europe and the U.S.

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

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

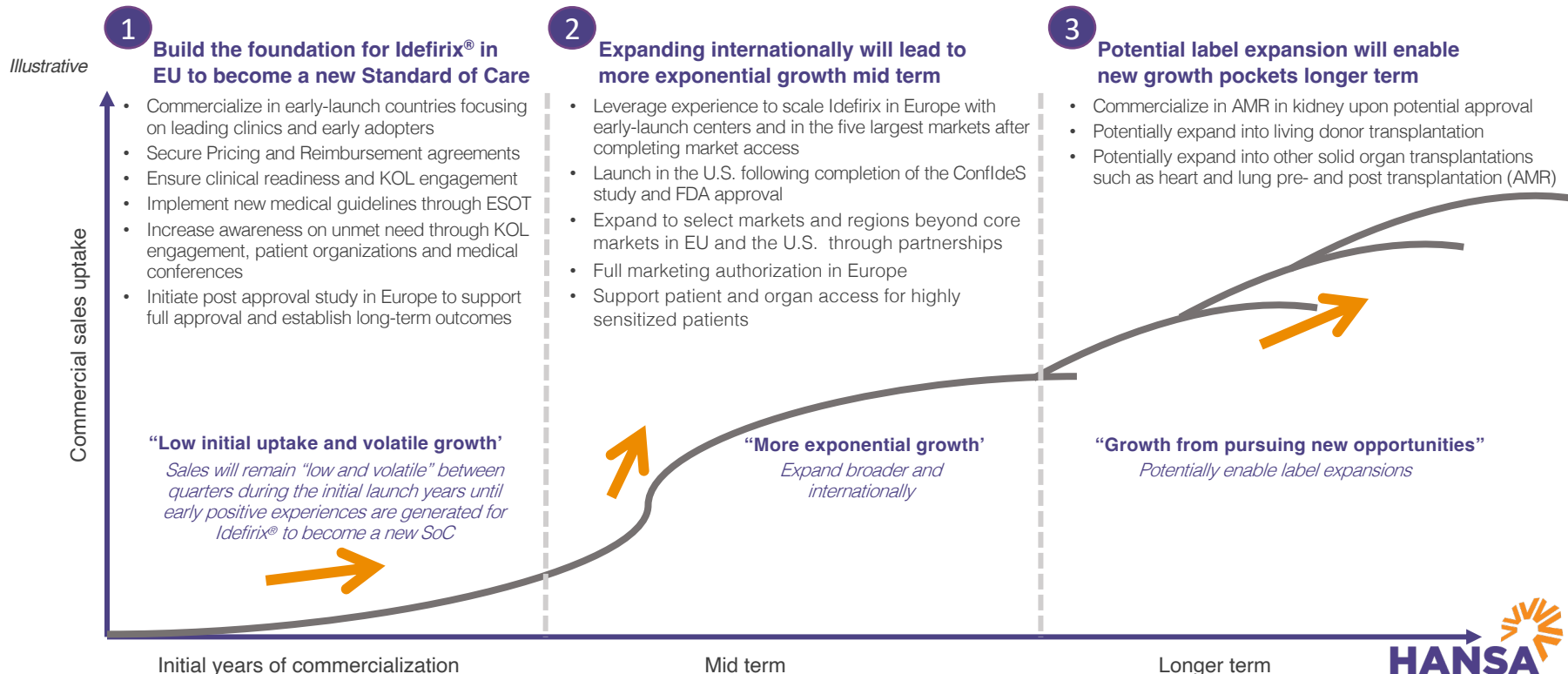
**Breakdown of the kidney transplant waitlist in U.S. and EU**



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

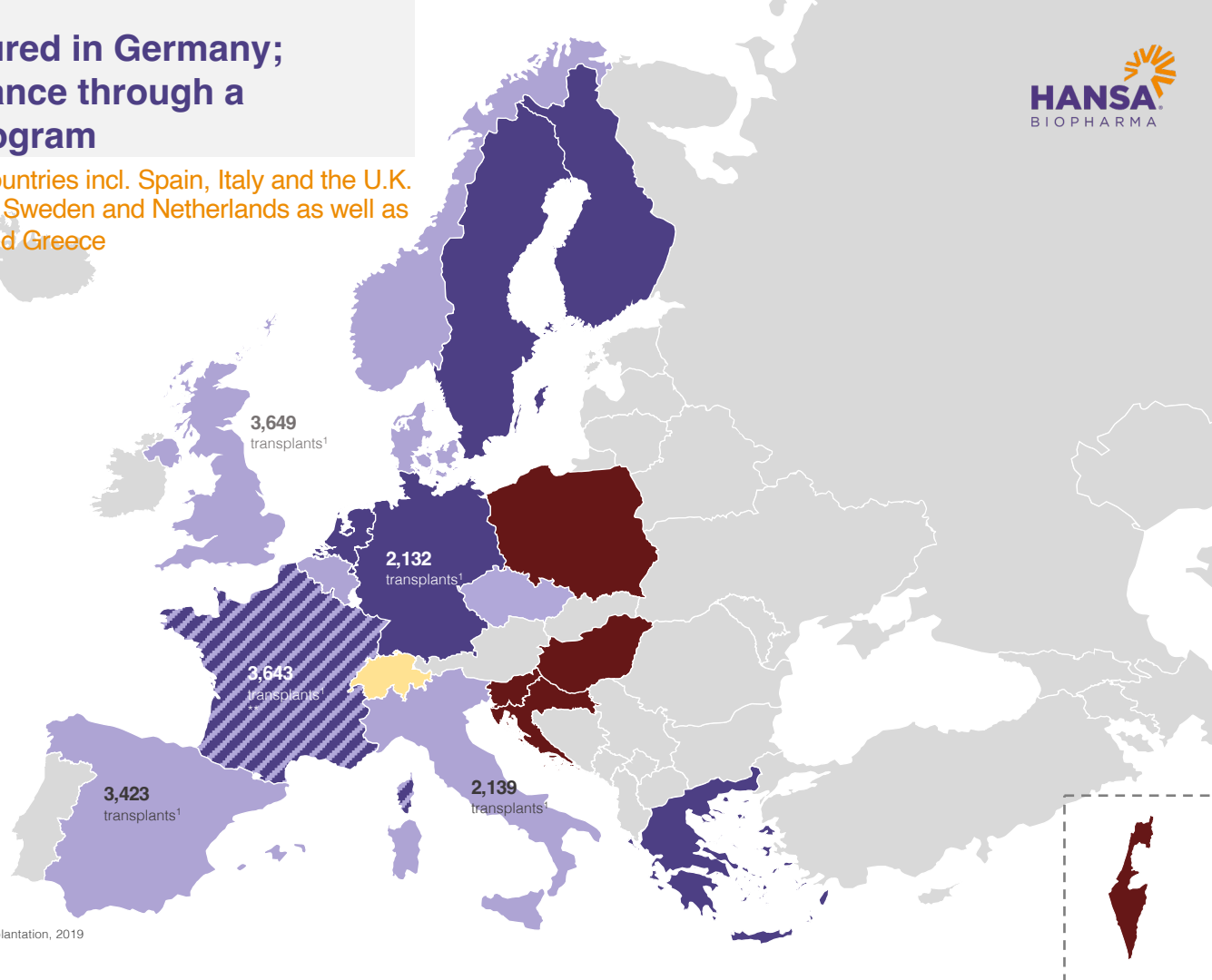
# Our center focused and sequenced launch process will help build the foundation for Idefirix® to become a new Standard of Care in transplantation

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



# Full commercial access secured in Germany; Market access granted in France through a reimbursed Early Access Program

Market access procedures ongoing in 11 countries incl. Spain, Italy and the U.K.  
During 2021 market access was secured in Sweden and Netherlands as well as  
on an individual hospital basis in Finland and Greece



<sup>1</sup>Annual kidney transplantations 2019 (pre-Corona)

<sup>\*</sup>Transplantation data is from Global Observatory on Donation and Transplantation, 2019

<sup>\*\*</sup>Pricing & reimbursement obtained in France on an early access basis

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

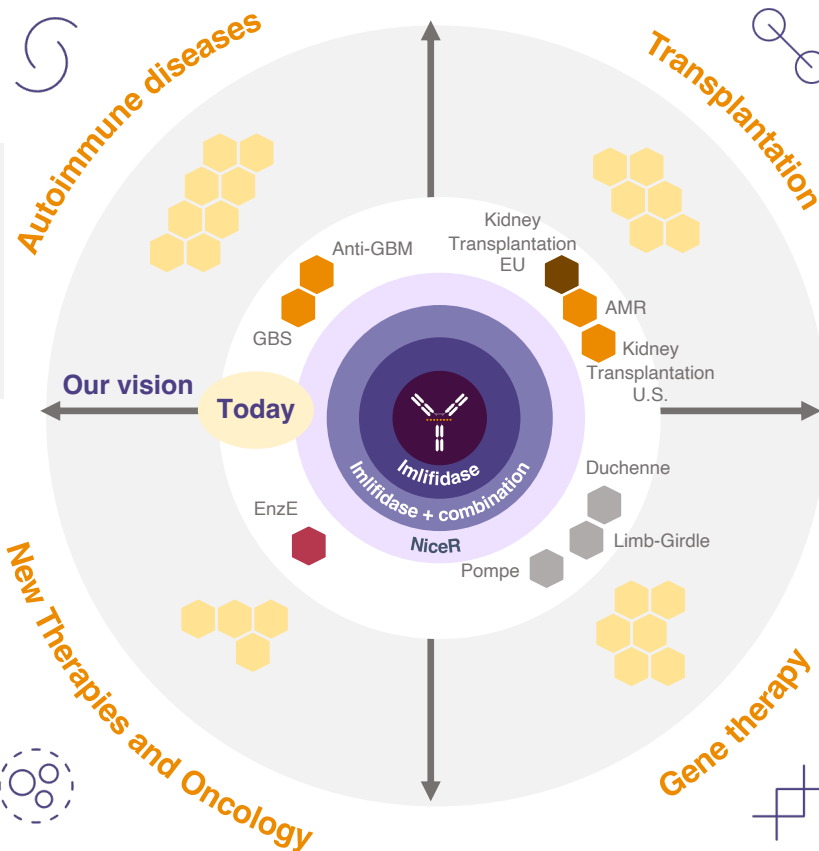
Targeting rare IgG mediated diseases

## 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

- Allogeneic 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

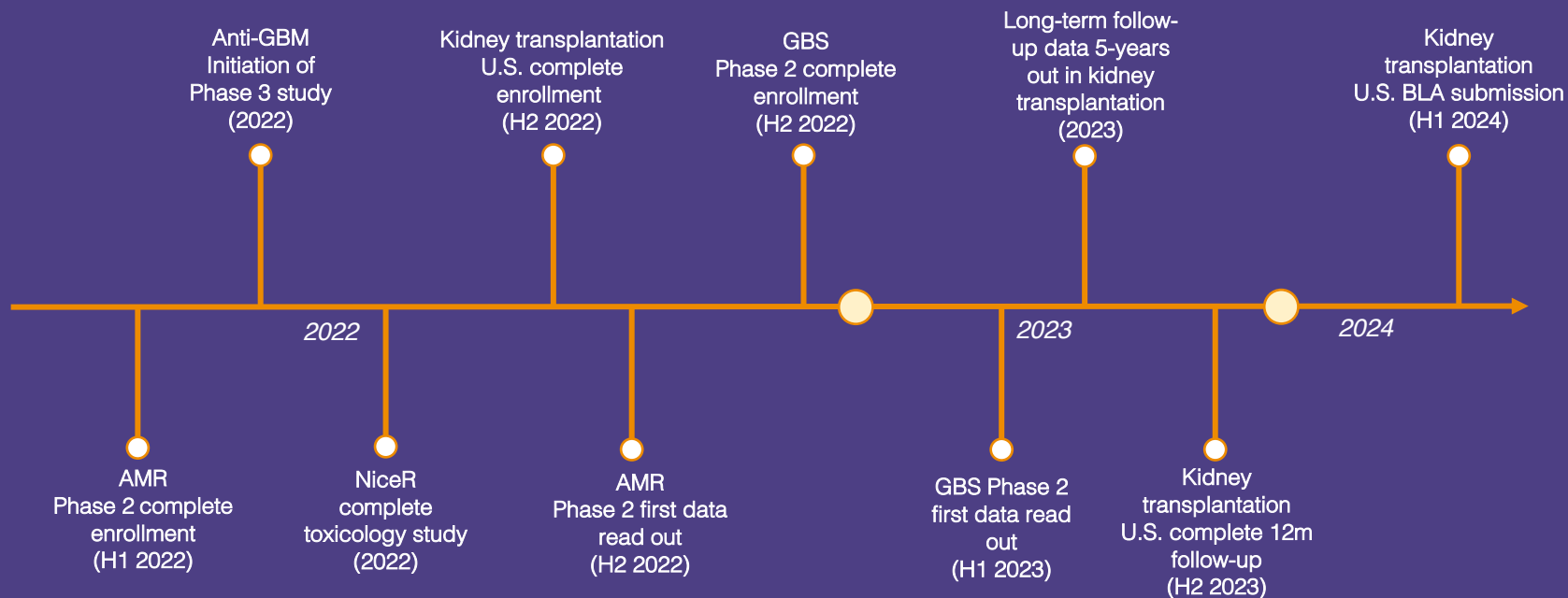
- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

## Exploring opportunities in gene therapy

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

# Upcoming milestones

Milestones subject to potential COVID-19 impact



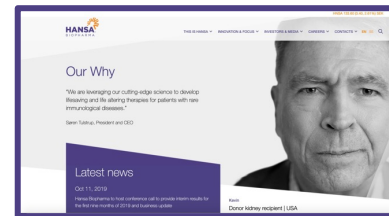
*Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.*



# Corporate Contacts

Investor Relations and  
Corporate Communications

Visit our web site  
[www.hansabiopharma.com](http://www.hansabiopharma.com)



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## Calendar and events

April 27 2022

Redeye Orphan Drugs 2022, Stockholm

May 15 2022

ABG ABGSC Life Science Summit 2022, Stockholm

May 16, 2022

European Midcap Event, Copenhagen

June 16 2022

**Annual General Meeting 2022**

July 12, 2022

William Blair's Biotech Focus Conference 2022, New York

July 21 2022

**Half year 2022 report**

Aug 9, 2022

BTIG Biotechnology Conference 2022, New York

Aug 10, 2022

Canaccord Annual Growth Conference, Boston

Sept 7, 2022

Pareto annual Healthcare Conference 2022, Stockholm

Sept 7-8, 2022

Citi's 17th Annual BioPharma Conference, Boston

Oct 20, 2022

**Interim Report for January-September 2022**

Nov 23, 2022

Økonomisk Ugebrev Life Science conference, Copenhagen