



## **Cowen Health Care Conference 2023**

Boston, March 8 2023

Søren Tulstrup  
*President & CEO*

# 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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# 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\*

### 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

150 employees Dec 31. 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 into 2025

### FINANCIALS

SEK ~1.5bn in Cash and short term investments (USD ~143m)  
Dec 31 2022

## Created shareholder value and diversified our ownership base

### MARKET CAPITALISATION (USD): ~350m Feb 1, 2023

Listed on Nasdaq Stockholm  
19,000 shareholders

Foreign ownership make up ~47% through leading international life science specialist funds



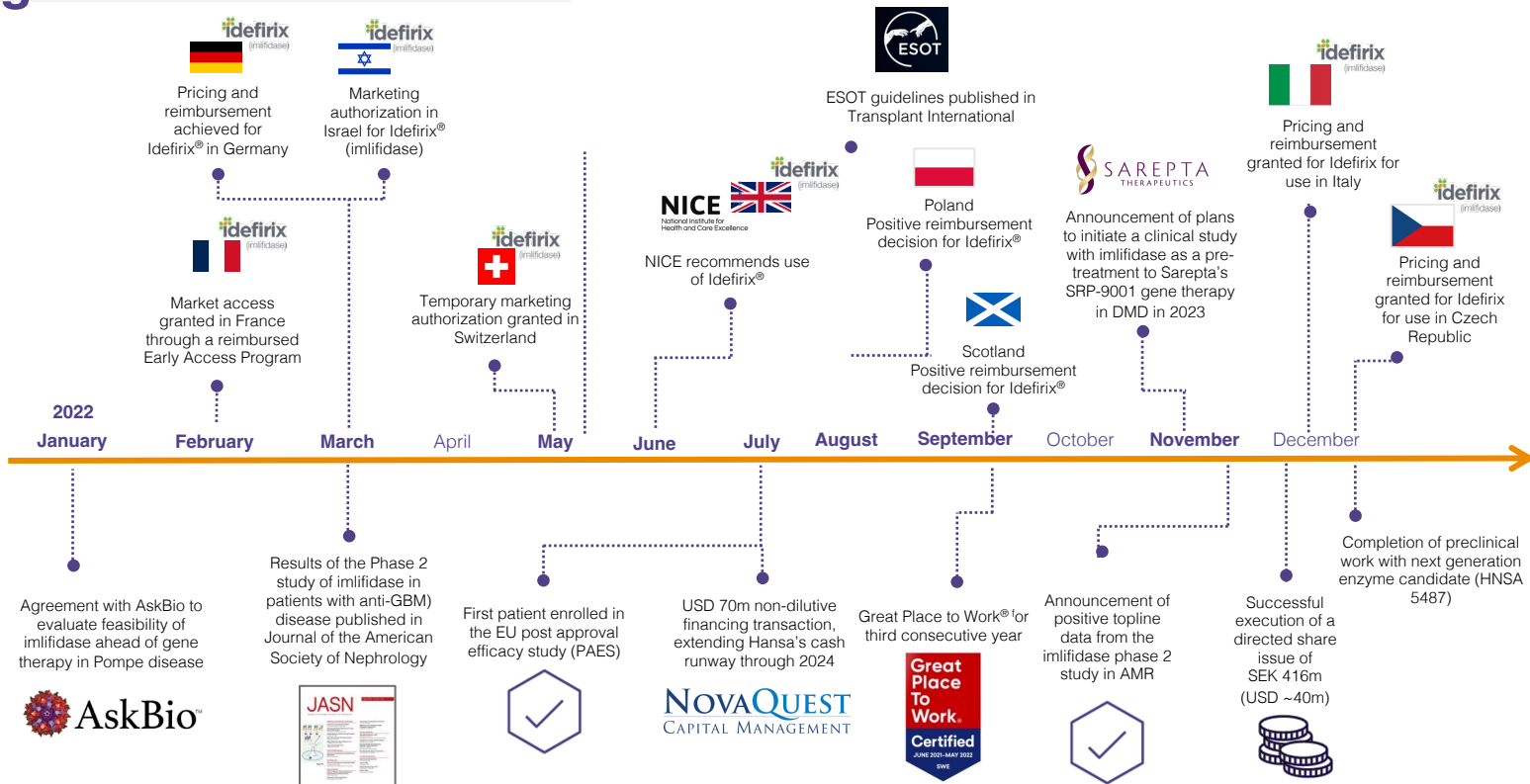
**Patient\***

*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

# Key milestones achieved during 2022





# Imlifidase

A novel approach to eliminate pathogenic IgG

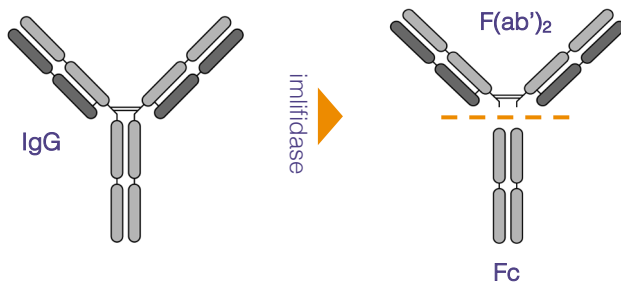
## Origins from a bacteria *Streptococcus pyogenes*

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



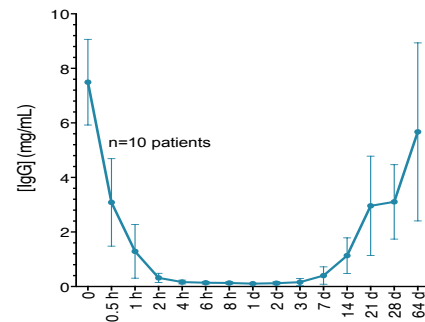
## A unique IgG antibody-cleaving enzyme

- 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



# 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 / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients <sup>1,2</sup>							Completion of enrollment (64 patients) H1 2023
	Anti-GBM antibody disease <sup>3</sup>							First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)							Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)							Completion of enrollment (30 patients) H1 '23
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (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							Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
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

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

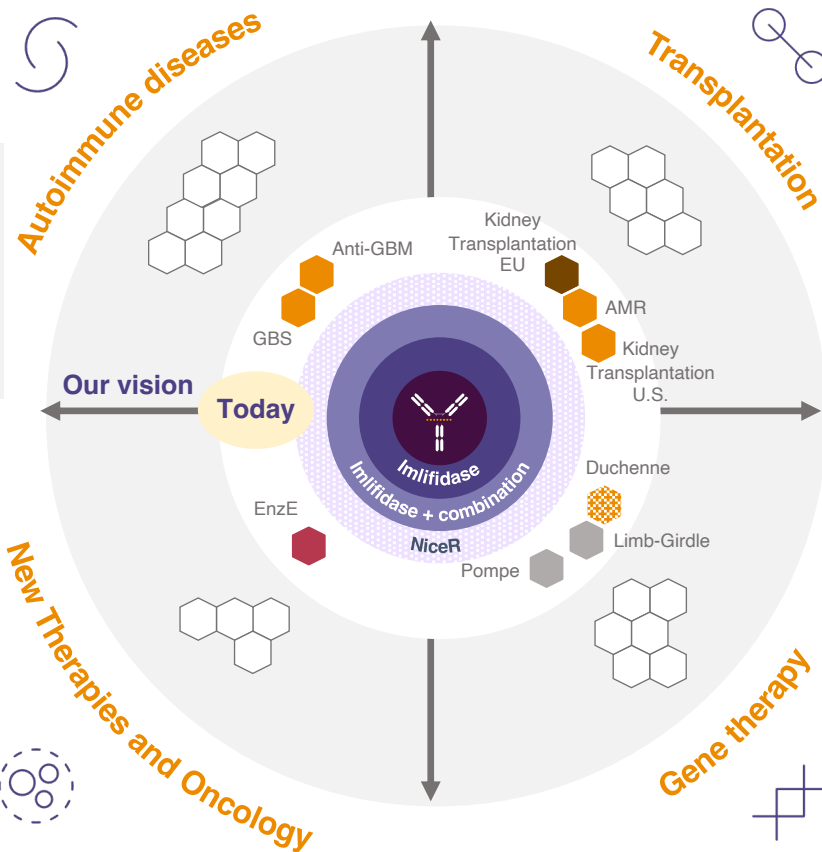
Targeting rare IgG mediated diseases

## 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)



# Imlifidase in kidney transplantation

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# Idefirix® (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

## 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

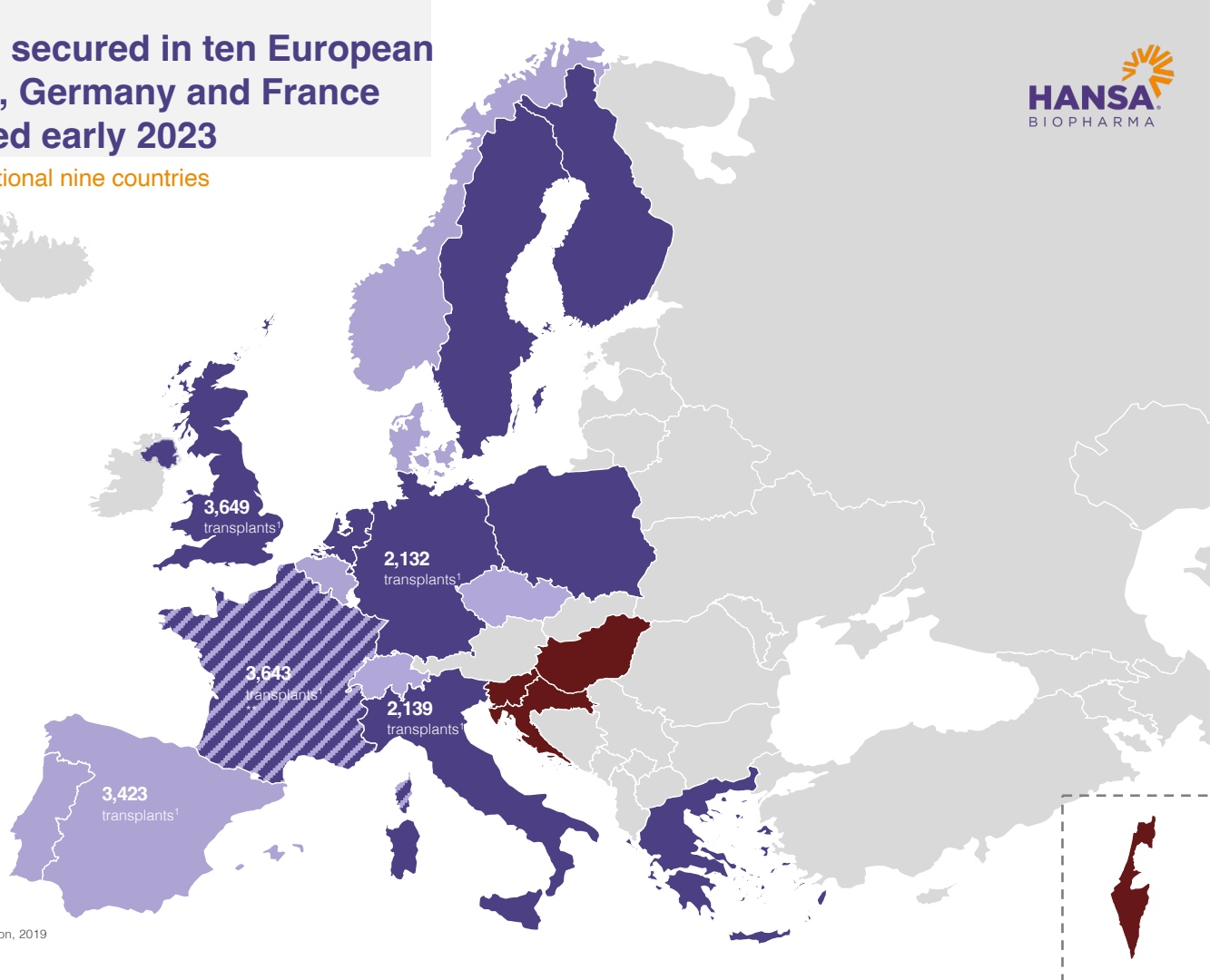
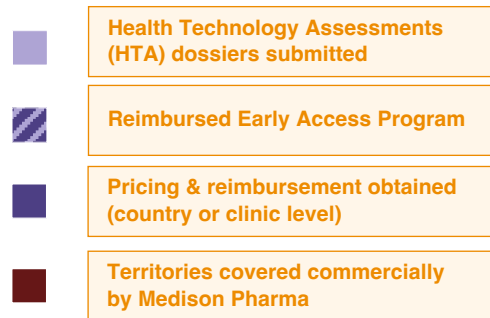
**idefirix®**  
imlifidase

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

# Market access has now been secured in ten European countries including Italy, U.K, Germany and France (early access); Spain expected early 2023

Market access procedures are ongoing in additional nine countries including Spain and Italy



<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



# 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 Euro transplant 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. Francesco Moreso

[Link article from Vall d’Hebron news forum August 25, 2022](#)

# Clinical development programs

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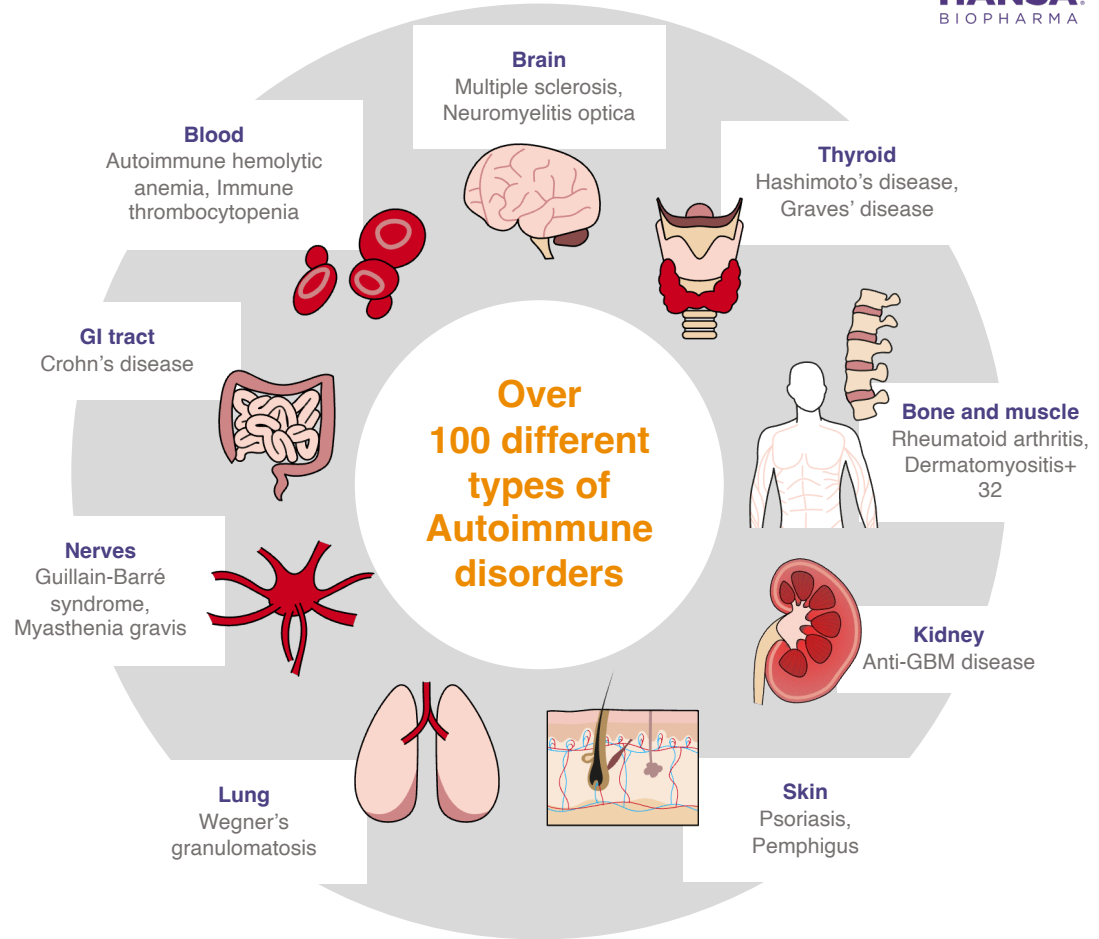
# Autoimmune attacks

A result of when the body's immune system by mistake damages its own tissue

Autoimmune disease remains a big challenge and requires immediate treatment

## What is an autoimmune disease?

- Immune-mediated destruction of autologous cells and/or tissues
- Interplay between predisposing genes and triggering environmental factors (e.g. bacteria or virus), leading to loss of self-tolerance
- 3-5%<sup>1</sup> of populations affected; more common in women (75%)<sup>2</sup>



<sup>1</sup> Wang et al., J. Intern. Med., 2015

<sup>2</sup> Desai et al., Front. Endocrinol., 2019

# Hansa's antibody cleaving enzyme technology

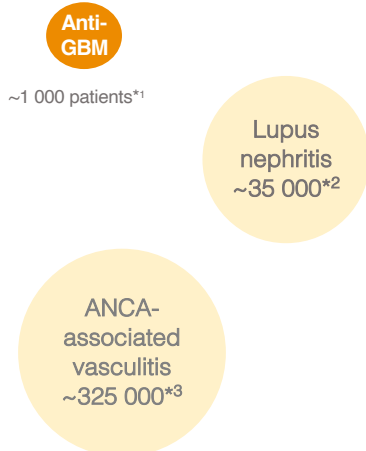
may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

- Clinical programs
- Potential autoimmune indications (currently not pursued)



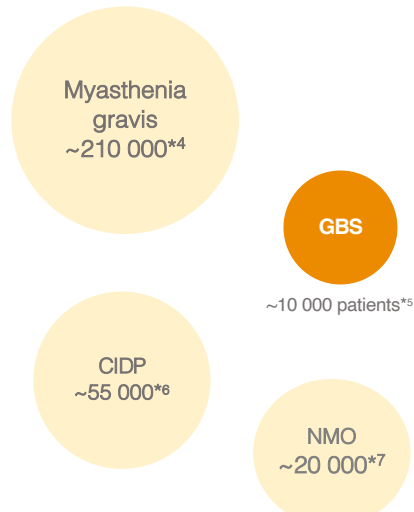
\*Total disease populations in EU & US, based on prevalence and population data

## Rapidly progressive glomerulonephritis



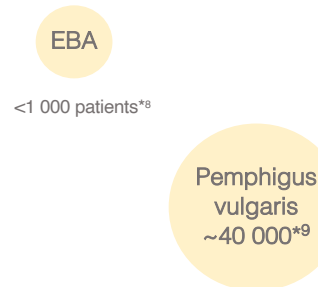
**CIDP:** Chronic inflammatory demyelinating polyradiculoneuropathy  
**NMO:** Neuromyelitis optica  
**EBA:** Epidermolysis bullosa acquisita  
**ITP:** Immune thrombocytopenia  
**WAHA:** Warm antibody hemolytic anemia  
**APS:** Antiphospholipid syndrome  
**AHA:** acquired hemophilia A  
**HIT:** Heparin-induced thrombocytopenia

## Neurological disorders



<sup>\*1</sup>DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021. <https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]  
<sup>\*2</sup>Patel, M. et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK*. Arthritis & Rheumatism, 2006.  
<sup>\*3</sup>Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. *The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study*. Arthritis Rheumatol. 2017;69.  
<sup>\*4</sup>Myasthenia Gravis. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]  
<sup>\*5</sup>Guillain-Barré syndrome. Orpha.net. [https://www.orpha.net/consor/cgi-bin/OC\\_Eyn.php?lng=GB&Expert=2103](https://www.orpha.net/consor/cgi-bin/OC_Eyn.php?lng=GB&Expert=2103) [accessed 2021-03-29]  
<sup>\*6</sup>Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health. The American Journal of Managed Care. <https://www.ajmc.com/view/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health> [accessed 2021-03-29]  
<sup>\*7</sup>Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica*. International Journal of MS Care, 2013 Fall: 113-118

## Skin disorders



<sup>\*8</sup>Mehren, C.R. and Gnidecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05  
<sup>\*9</sup>Vertenteil, S. et al. *Prevalence Estimates for Pemphigus in the United States*. JAMA Dermatol, May 2019: 627-629.  
<sup>\*10</sup>Immune Thrombocytopenia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]  
<sup>\*11</sup>Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]  
<sup>\*12</sup>Itivnova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.  
<sup>\*13</sup>NORD. *Acquired Hemophilia* [accessed 2022-10-17], available at <https://rarediseases.org/rare-diseases/acquired-hemophilia/>  
<sup>\*14</sup>Hogan M, Berger JS. *Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management*. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

## Blood disorders



# Anti-GBM, a rare acute autoimmune disease

## Incidences

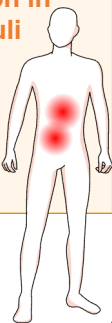
**1.6**  
in a million  
affected annually<sup>1,2</sup>

## Today's Standard of Care

- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids

## Inflammation in the glomeruli

Early symptoms are unspecific...  
...But can lead to rapid destruction of the kidney and/or the lung

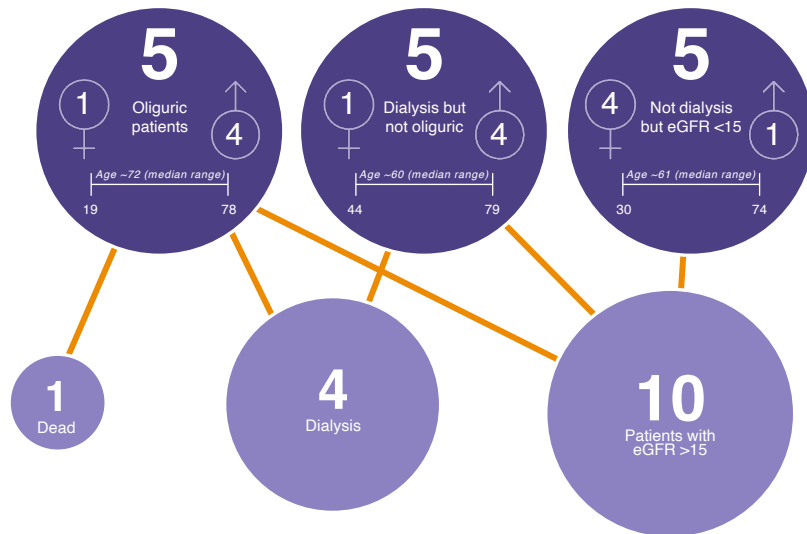


## Data published in JASN



## Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)<sup>3</sup>

- 10 out of 15 patients were dialysis independent after six months vs. the historical cohort<sup>4</sup>, where only 18% had functioning kidney



<sup>1</sup> Wang et al., J. Intern. Med., 2015

<sup>2</sup> Desai et al., Front. Endocrinol., 2019

<sup>3</sup> Uhlin et al. JASN (2022)

<sup>4</sup> McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. Kidney Int 92: 693–702, 2017

# Guillain-Barré Syndrome (GBS) is an aggressive acute autoimmune attack on the peripheral nervous system

Phase 2 study to evaluate safety and effectiveness of imlifidase in patients diagnosed with GBS

## Incidences

1-2

in 100,000 annually  
or ~10,000 in 7MM

## Indication

Rapidly and progressively  
weakens extremities  
(e.g. paralyzing arms, legs)

Triggered frequently by viral  
infections (such as Influenza,  
Zika virus, EBV, CMV and  
COVID-19)

Diagnosis and management  
complicated due to  
heterogeneity

## Today's Standard of Care

- Intravenous immune globulin (IVIg) or
- Plasma Exchange (PLEX)

## High unmet need

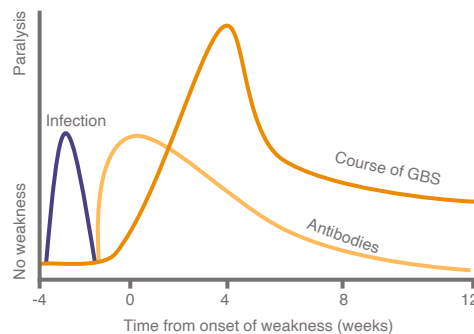
1/3 of hospitalized GBS  
patients require mechanical  
ventilation

Remaining long lasting  
symptoms in ca 40% of  
patients incl. fatigue, pain,  
psychological distress and  
muscle weakness

Mortality 3-7%

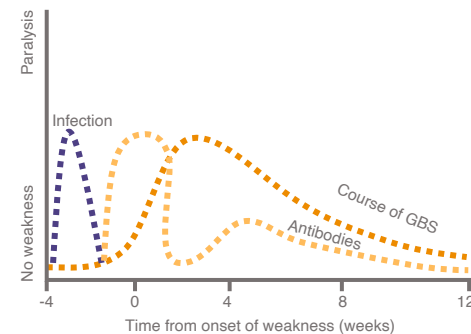
## Today's Standard of Care IVIg or PLEX

*Illustrative*



## Potential with imlifidase


*Illustrative*



## STUDY DESIGN

- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS
- Data will be compared with a control group from the International Guillain-Barré Syndrome Outcome Study (IGOS)

## SUBJECTS

- 30 patients targeted at ten clinics 
- Completion of enrollment (H1 2023)

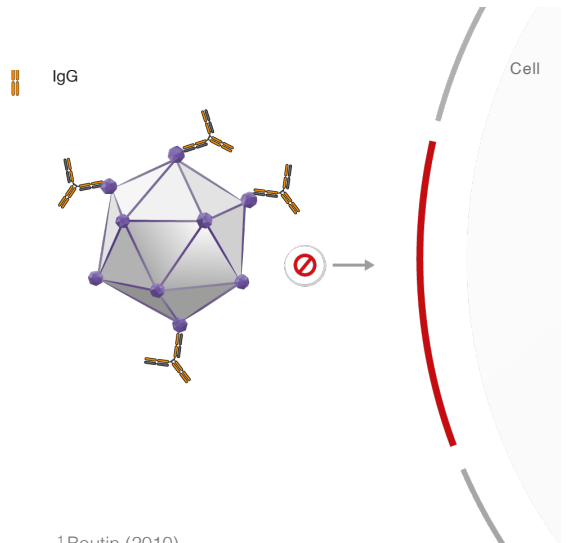
FDA granted Orphan Drug Designation to  
imlifidase for the treatment of GBS



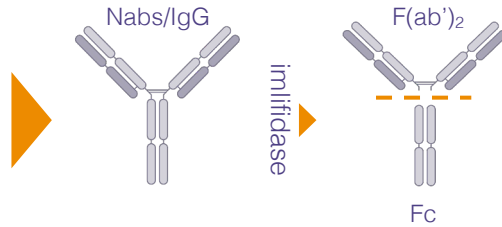
# Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

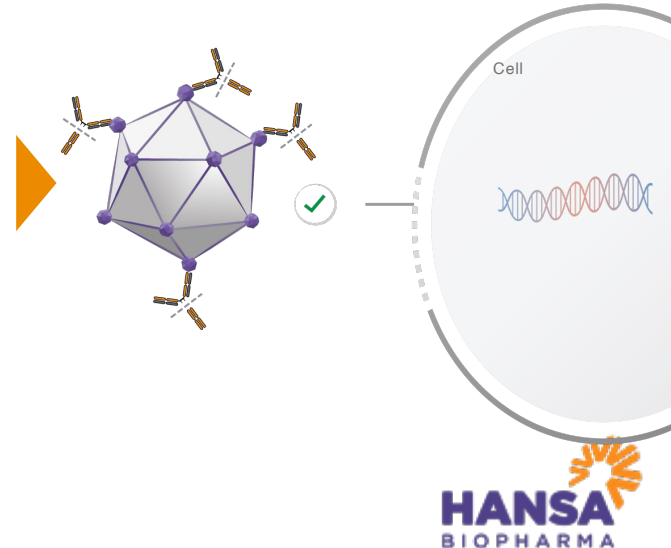
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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



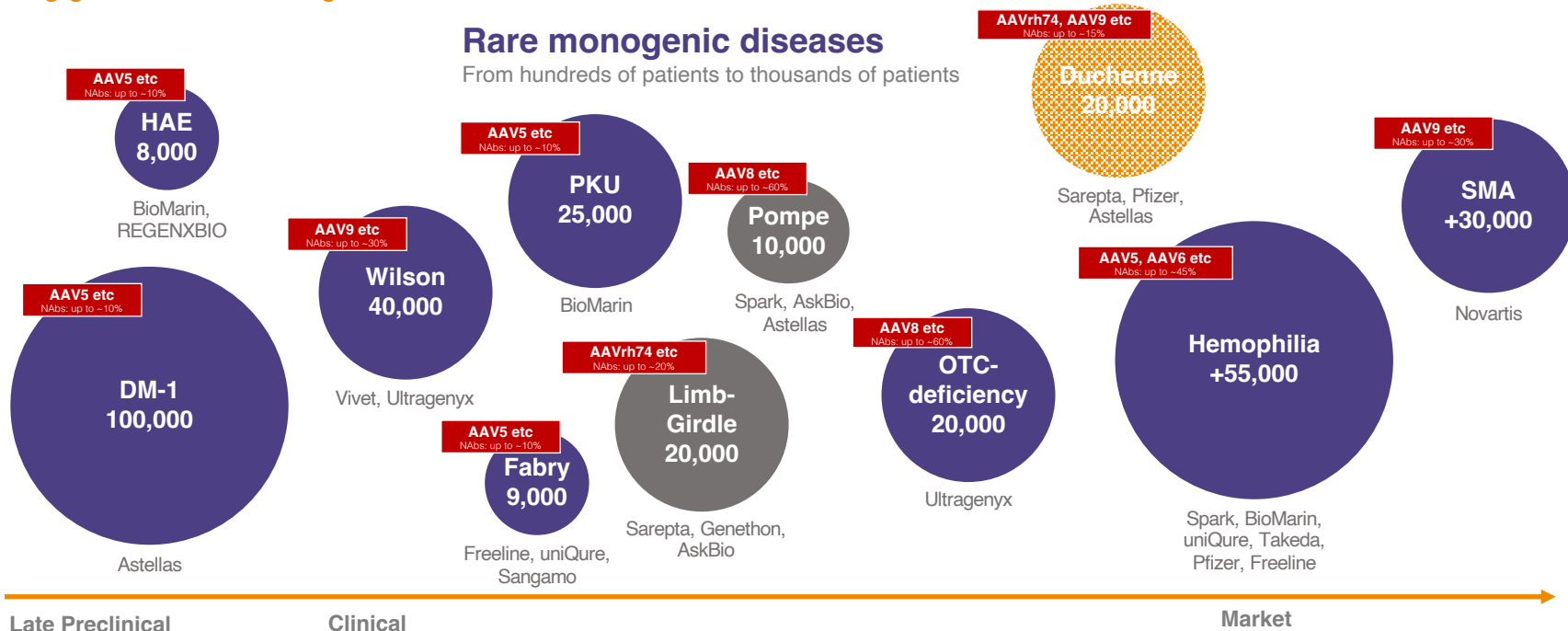
# Systemic gene therapy is an emerging opportunity

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

- Preclinical programs with Sarepta and AskBio
- Planned clinical study with Sarepta
- Potential gene therapy indications (currently not pursued)

## Rare monogenic diseases

From hundreds of patients to thousands of patients



Late Preclinical

Clinical

Market

● Size of indication (US & EU)

# 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



# Our strategic priorities

Our mission is to become a global leader in rare diseases

1

**Commercialize Idefirix® in first indications and markets**

- **Successfully launch Idefirix® in Europe**
- **Secure FDA approval and launch Idefirix® in the US**
- **Geographical expansion**

2

**Advance ongoing imlifidase clinical programs in transplantation and autoimmune diseases**

- **Achieve approval/ usage of imlifidase in follow-on indications**
- **Broaden our Idefirix® label beyond kidney transplantation**

3

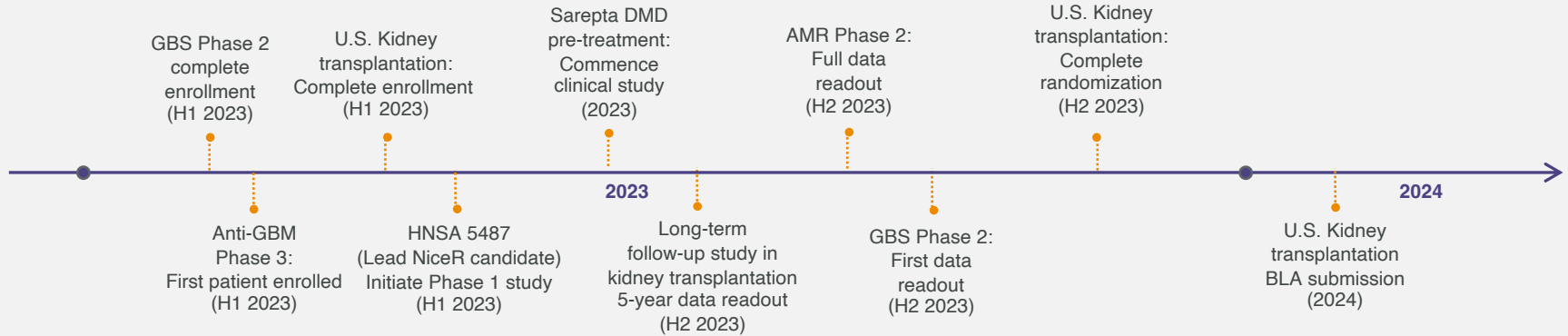
**Expand IgG-cleaving enzyme technology platform into new disease areas and indications**

- **Explore gene therapy opportunity**
- **Explore opportunities in Oncology and stem cell transplantation (HSCT)**
- **Develop our next generation IgG-cleaving enzymes to allow for recurring treatment**

**Build focused, integrated, agile and empowered international organization and seek partnerships to accelerate growth and reduce risk**

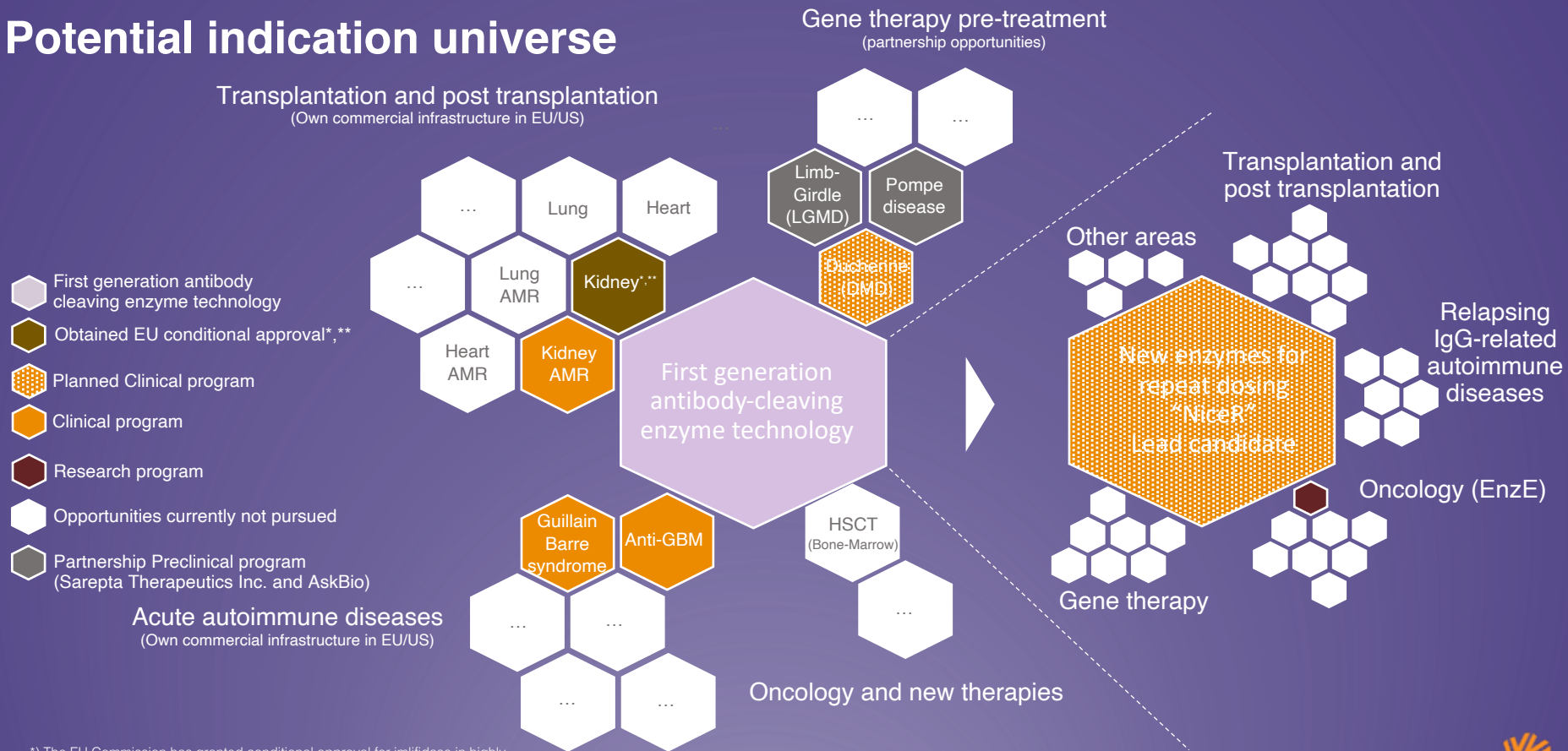


## Near term milestones





# 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 in 2024

# Investor Relations

## Contact

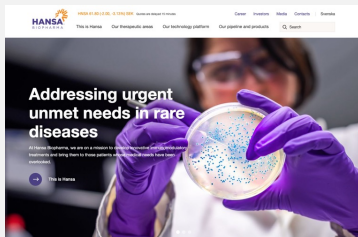


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## Calendar and events

Mar 8, 2023	Cowen Healthcare Conference, Boston
Mar 30, 2023	2022 Annual Report
April 4, 2023	Guggenheim Healthcare Talks Rare Disease Days, virtual
April 18, 2023	Needham Healthcare Conference, virtual
April 20, 2023	Interim Report for January-March 2023
April 20, 2023	Redeye Investor Forum, Gothenburg
April 21, 2023	Redeye Lunch presentation, Stockholm
April 25, 2023	Kempen Life Sciences Conference 2023, Amsterdam
May 11, 2023	Erik Penser Company Day, Malmö
May 11, 2023	Redeye Investor forum, Malmö
May 25, 2023	Erik Penser Company Day, Stockholm
June 14, 2023	Annual General Meeting
July 20, 2023	Half-year Report for January-June 2023
Aug 24, 2023	Erik Penser Company Day, Stockholm
Sept 7, 2023	CITI Annual BioPharma Conference, Boston
Sept 11, 2023	MorganStanley Global Healthcare Conference, NYC
Oct 19, 2023	Interim Report for January-September 2023
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen