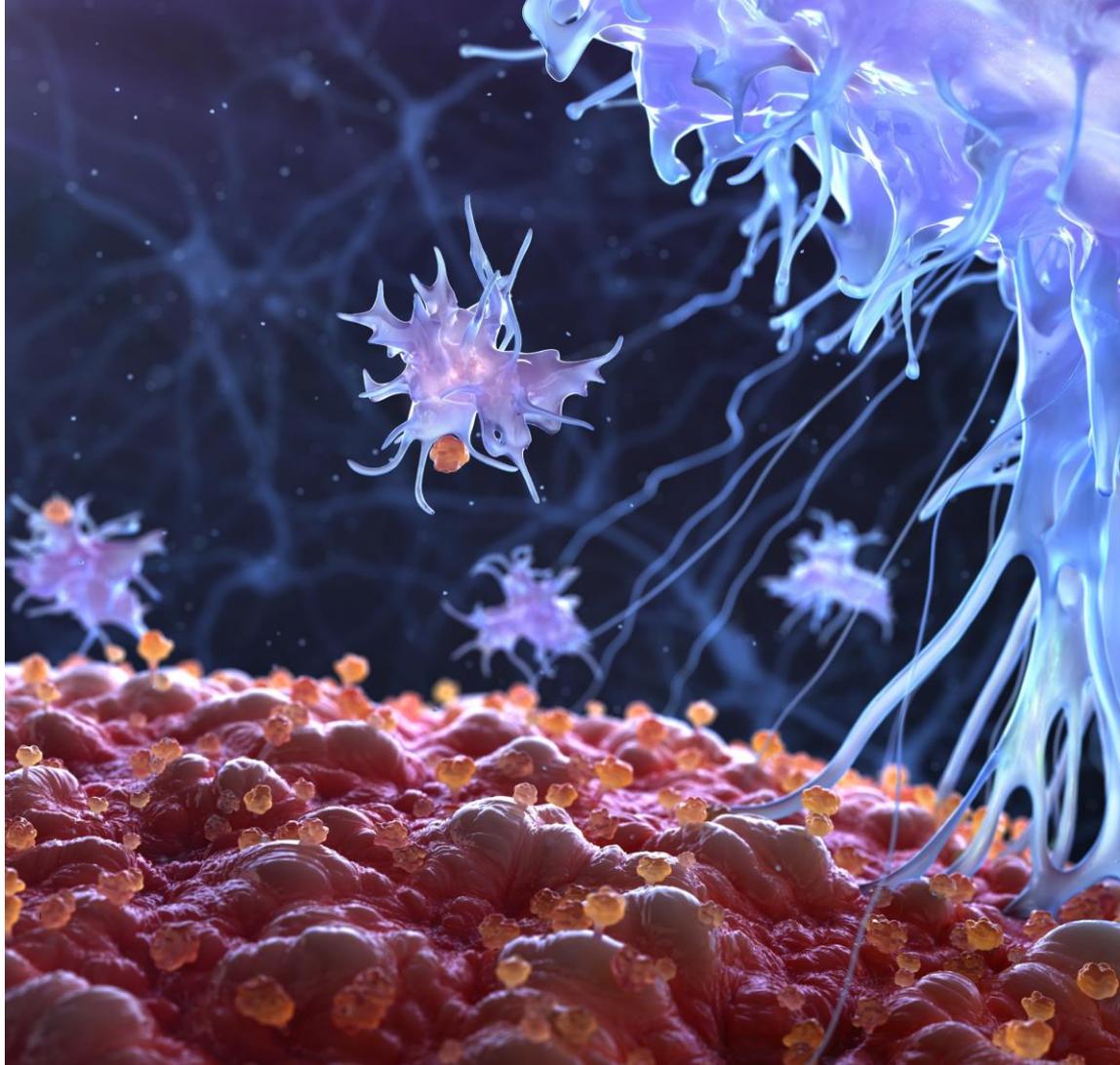




**Søren Tulstrup,**  
President & CEO

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Chief R&D Officer

27 May 2024



# Broad clinical pipeline in transplantation, autoimmune diseases, and gene therapy



| Project    | Indication   | Research/<br>Preclinical | Phase 1   | Phase 2   | Phase 3 | Marketing<br>Authorization | Marketed | Partner              | Next Anticipated Milestone  |
|------------|--|--------------------------|-----------|-----------|---------|----------------------------|----------|----------------------|---|
|            | EU: Kidney transplantation in highly sensitized patients <sup>1,2</sup>                | Completed                | Completed | Completed | Planned | Completed                  | Ongoing  |                      | EU: Additional agreements around reimbursement / Post approval study to be completed by 2025              |
|            | U.S. "ConfIdes": Kidney transplantation in highly sensitized patients <sup>1,2</sup>   | Completed                | Completed | Completed | Ongoing |                            |          |                      | Completion of randomization (64 patients) mid 2024  |
|            | GOOD-IDES-02: Anti-GBM antibody disease  | Completed                | Completed | Completed | Ongoing |                            |          |                      | Complete enrollment (50 patients)   |
|            | 16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)                               | Completed                | Completed | Completed |         |                            |          |                      | Publication in peer-reviewed journal  |
| Imlifidase | 15-HMedIdes-09: Guillain-Barré Syndrome (GBS)  | Completed                | Completed | Ongoing   |         |                            |          |                      | Comparative efficacy analysis 2024  |
|            | Investigator-initiated trial in ANCA-associated vasculitis <sup>3</sup>                | Completed                | Completed | Ongoing   |         |                            |          |                      | Complete enrollment (10 patients)   |
|            | SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD) | Completed                | Phase 1b  |           |         |                            |          | Sarepta Therapeutics | Completion of enrollment  |
|            | Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)           | Ongoing                  |           |           |         |                            |          | Sarepta Therapeutics | Preclinical research  |
|            | Pre-treatment ahead of gene therapy in Pompe disease                                   | Ongoing                  |           |           |         |                            |          | AskBio               | Preclinical research  |
|            | Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome                         | Ongoing                  |           |           |         |                            |          | Genethon             | Commence clinical study   |
| HNSA-5487  | NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program                     | Completed                | Ongoing   |           |         |                            |          |                      | Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication |

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

<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 Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

# Hansa Biopharma – a biotech to believe in

Commercial stage, science driven biotechnology company in Sweden with financing into 2026

## At a glance

**2007** founded in Lund, Sweden

**160** employees globally

**\$250M** market cap

**\$34.6M** recent financing round

## Purpose driven culture

**33** different nationalities

**4<sup>th</sup> year** Great Place to Work<sup>®</sup> certified

**18%** reduction in energy consumption\*

## Proprietary technology platform



**Autoimmune**



**Gene Therapy**



**Transplantation**

## Portfolio

**IMLIFIDASE**  
1st in class IgG cleaving molecule

**HNSA-5487**  
Next-gen IgG cleaving molecule

## Pipeline

### Two Phase 1

✓ 5487 FIH, DMD gene therapy

### Three Phase 2

✓ AMR, GBS, ANCA (IIT)

### Three Phase 3

✓ US kidney, EU post approval, anti-GBM

# Imlifidase is an innovative, first in class molecule with a novel approach to eliminate pathogenic IgG



## Originates from a bacteria

Streptococcus pyogenes known from causing a strep throat infection



## IgG antibody-cleaving enzyme

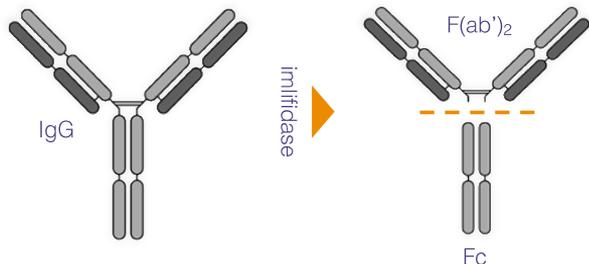
Interacts with Fc-part of IgG with extremely high specificity



## Inactivates IgG in 2-6 hours

Rapid onset of action that inactivates IgG below detectable level in 2-6 hours

## Unique MOA cleaves IgG creating an IgG free window for approximately one week



\*The 5-year data is a continuation of the analysis at 3-years of crossmatch positive patients published in the American Journal of Transplantation

## 7 clinical trials in key disease areas



**Autoimmune**



**Gene Therapy**



**Transplantation**

## First & only treatment approved for desensitization

**EU Approval\*\***  
in kidney TX as IDEFIRIX®

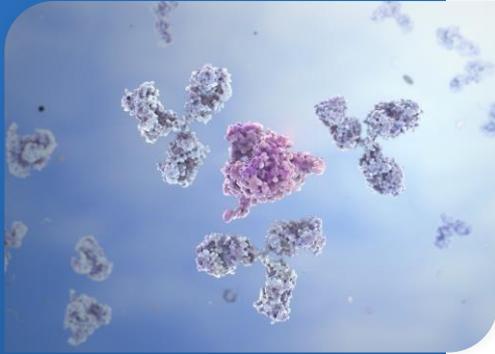
**75%**  
access in the EU transplant market

**2025**  
planned US BLA filing; US trial ongoing

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



# Transplantation



Imlifidase may enable incompatible kidney transplantation in highly sensitized patients

**80-100k**

patients waiting for a kidney transplant

**DSAs**

Donor specific antibodies that reject organ transplantation

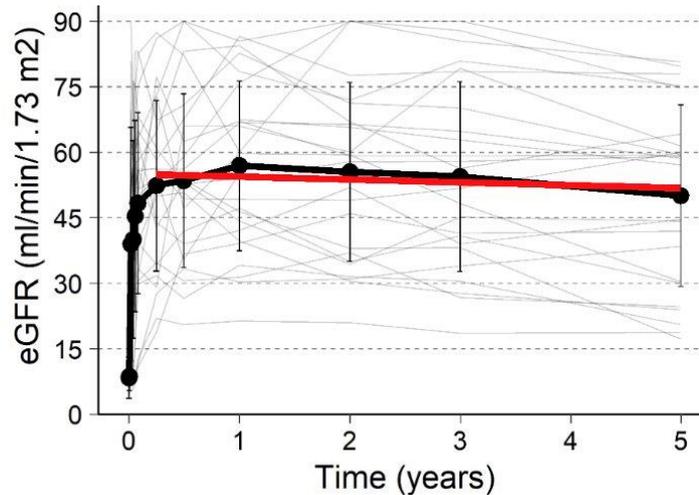
**SOC**

based on organ compatibility

**10-15%**

patients with donor specific antibodies (DSAs) or highly sensitized - unlikely to be transplanted due to incompatibility

## Long term data in kidney transplantation confirms sustained benefit of imlifidase



- 82% five-year graft survival
- 90% patient survival rate
- 50 ml/min/m<sup>2</sup> eGFR

## EU Approval\* as desensitization treatment as IDEFIRIX®



Addresses the limitations of other modalities



The **first and only** approved drug to enable incompatible kidney transplants



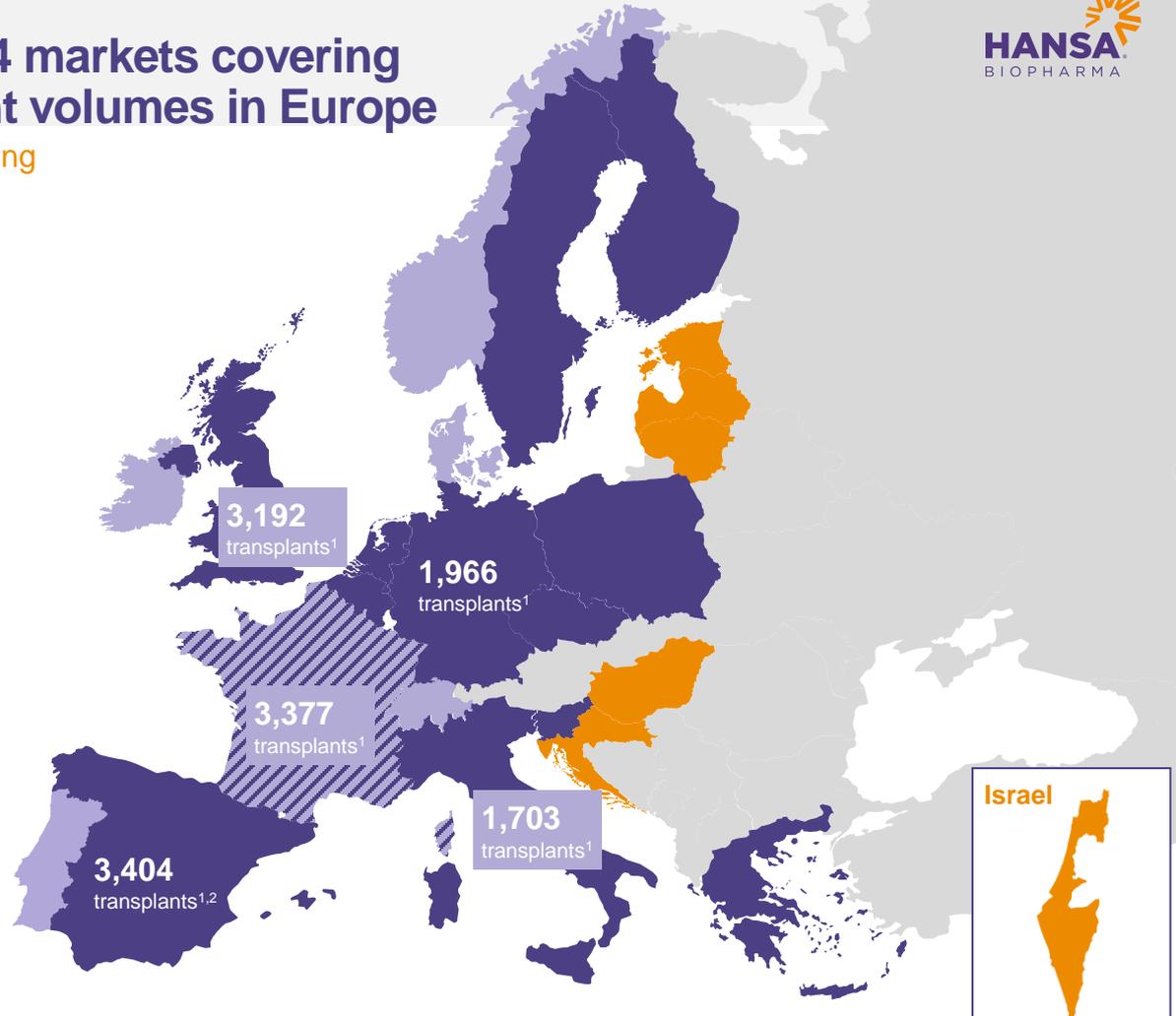
**Market access in 75%** of the EU transplant market

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

# Market Access obtained in 14 markets covering markets with 3/4 of transplant volumes in Europe

HTA processes running in 11 countries including Portugal, Switzerland

-  Health Technology Assessments (HTA) dossiers submitted
-  Reimbursed Early Access Program
-  Pricing & reimbursement obtained (country or clinic level)
-  Territories covered commercially by Medison Pharma



<sup>1</sup> Annual kidney transplantations 2022. Transplantation data is from Global Observatory on Donation and Transplantation. <https://www.transplantobservatory.org/> [Accessed 2023-07-10]

<sup>2</sup> A positive recommendation for pricing and reimbursement of Idefirix® in Spain was published on February 6, 2023. [https://www.sanidad.gob.es/profesionales/farmacial/pdf/20230202\\_ACUERDOS\\_CIPM\\_230.pdf](https://www.sanidad.gob.es/profesionales/farmacial/pdf/20230202_ACUERDOS_CIPM_230.pdf)



# Autoimmunity

**+100** autoimmune diseases



Rapidly progressive glomerulonephritis



Neurological disorders



Skin disorders

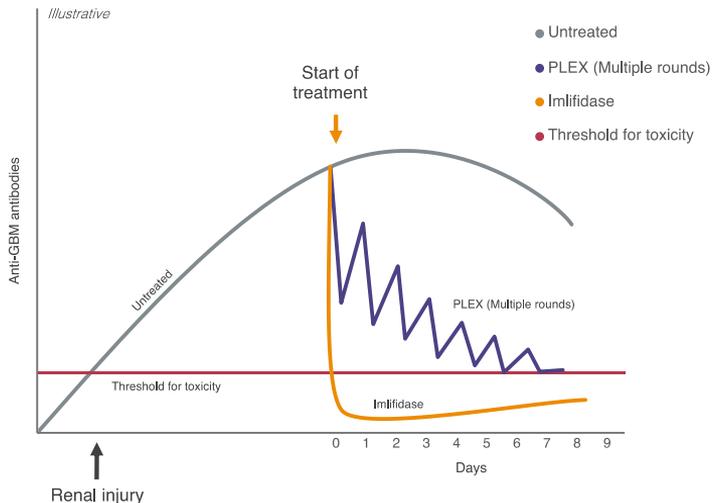


Blood disorders



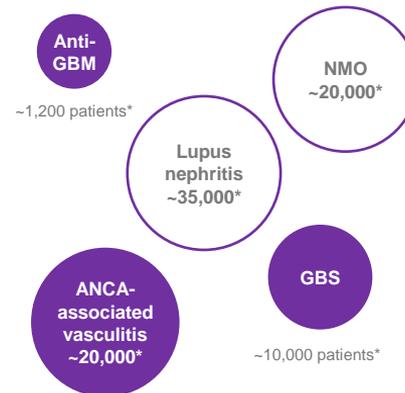
Imlifidase may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

## Pivotal Phase 3 trial in anti-GBM disease to evaluate kidney function after 6 months



- 1,200 people affected in US and EU annually
- Standard of care deemed insufficient
- Phase 3 trial 50% enrolled

## Catalyst to more IgG mediated conditions



*Combination and stand-alone*

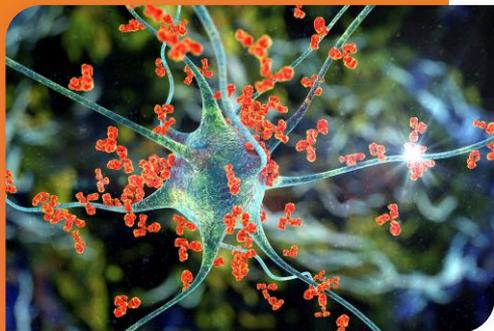
- Potential autoimmune indications (currently not pursued)
- Clinical programs

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





# Gene Therapy



Imlifidase may enable gene therapy treatment in rare disease patients with pre-existing antibodies

## AAVs

the delivery system of most gene therapies

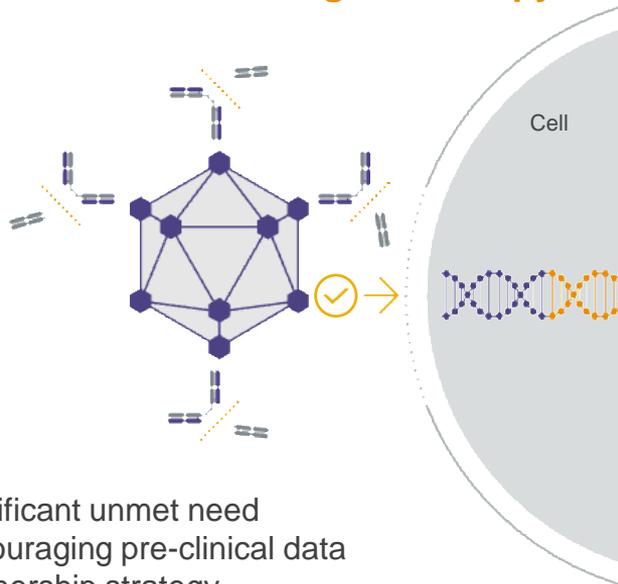
## 5-70%

patients considered for gene therapy have anti-AAV antibodies

## Pre-existing antibodies

excludes patients from trials & treatment

## Eliminate antibodies as a pre-treatment to enable gene therapy



- Significant unmet need
- Encouraging pre-clinical data
- Partnership strategy

## Global partnerships with gene therapy companies



- World leader within gene therapy targeted at muscular dystrophies
- High level read out in DMD expected 2024



- Early innovator in gene therapy
- Encouraging Ph 1 data presented at ASGCT 2024



- A not-for-profit pioneer in gene therapies
- Preclinical work underway in Crigler-Najjar syndrome

# HNSA-5487 is a next gen enzyme with long and short interval redosing potential



## Lower immunogenicity

could apply to diseases where prolonged or intermittent IgG free window is needed



## Short interval redosing

create a longer IgG-low period



## Long interval redosing

keeps IgG at a low level, potentially leading to greater efficacy vs monotherapy

## Encouraging high level Phase 1 study results

single ascending dose in 36 healthy volunteers



Administration was safe and well tolerated



Fast and complete cleavage of IgG; PK in line with expectations



Further analysis and lead indication selection completed in 2024

## Potential indication landscape

through two different redosing regimens

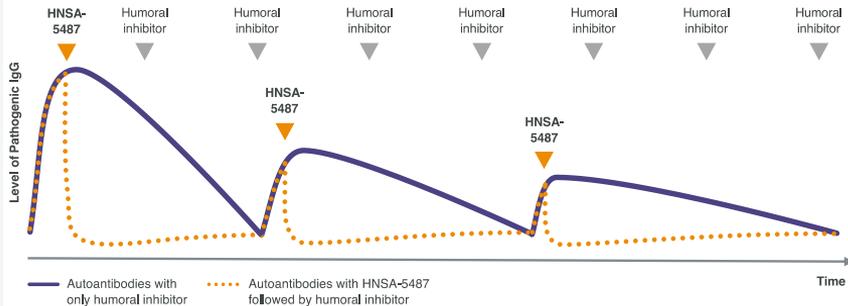
 Short interval  
5487 redosing

 Long interval  
5487 redosing  
in combination with humoral inhibitor



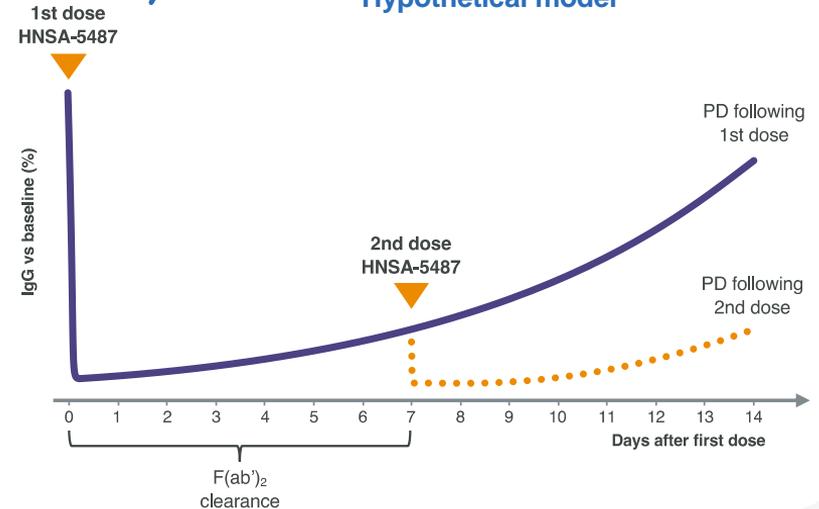
# Long and short interval redosing could broaden indication universe

## Long interval 5487 repeat dosing Hypothetical model



- Could be used when humoral inhibitors/modulators are too slow
- chronic humoral inhibition can keep the IgG at a low level, potentially leading to greater efficacy vs monotherapy

## Short interval 5487 redosing Hypothetical model



- Short-term treatment in autoimmune diseases
- AAV gene therapy redosing
- HSCT in DSA+ patients
- Repeat dosing of systemic oncolytic virus therapy



**HANSA**

BIOPHARMA

# Continued progress against our key launch metrics led by in-market growth

## Market Building



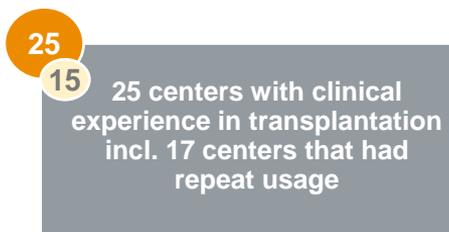
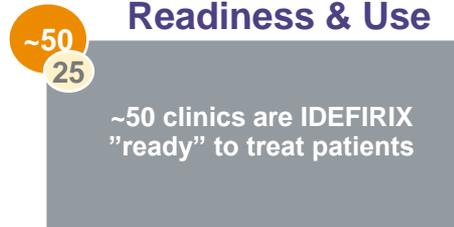
## Market Access



## Patient Identification



## Transplant Center Readiness & Use



Major markets to support growth going forward: France, U.K., Germany, Spain and Italy

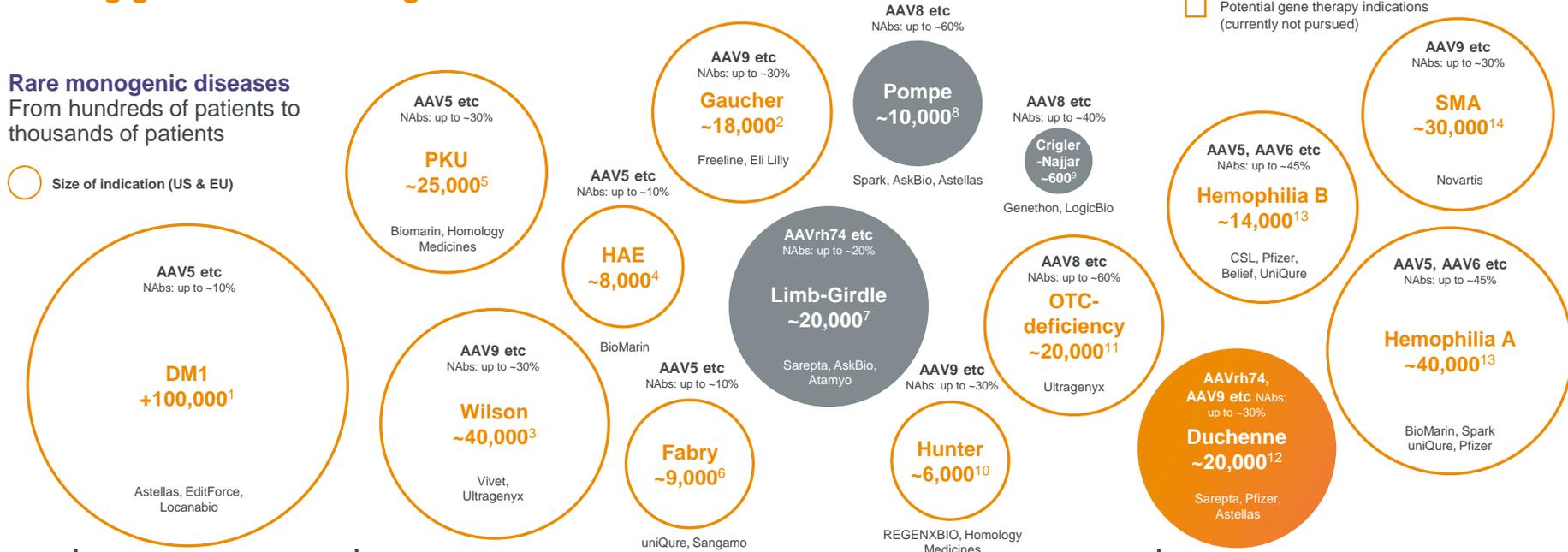


# Systemic gene therapy is an emerging opportunity

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

**Rare monogenic diseases**  
From hundreds of patients to thousands of patients

○ Size of indication (US & EU)



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

Late Preclinical

Clinical

Market

Numbers are estimated based on population and prevalence

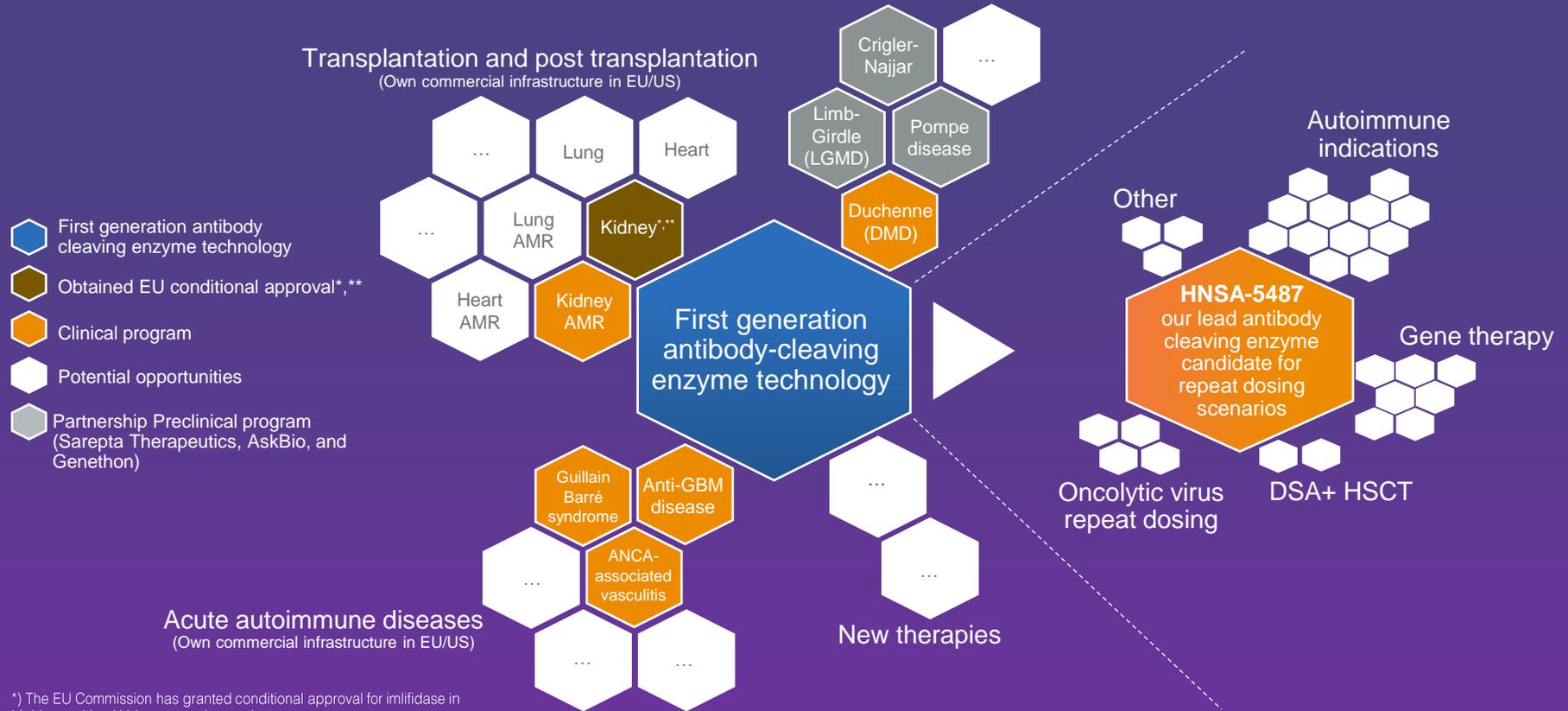
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# Global exclusive agreements with three partners in gene therapy

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

| Partner  | Access to key resources   | Indication exclusivity  | Collaborative research, development and commercialization   |
|--|---|---|---|
|  | <ul style="list-style-type: none"> <li>World leader within gene therapy targeted at muscular dystrophies</li> <li>Pre-clinical and clinical plan</li> <li>Regulatory</li> <li>Promotion</li> <li>FDA approval for treatment of 4–5-year-old DMD patients</li> </ul> | <p><b>Duchenne Muscular Dystrophy (DMD)</b><br/>1/3,500 to 5,000 male births worldwide</p>  |    |
|  |   | <p><b>Limb-Girdle Muscular Dystrophy</b><br/>Global prevalence of ~1.6 per 100k individuals</p>   |    |
|  | <ul style="list-style-type: none"> <li>Early innovator in gene therapy</li> <li>Conducts pre-clinical and clinical trials (Phase 1/2)</li> </ul>  | <p><b>Pompe disease</b><br/>Affecting ~ 5,000 – 10,000 patients in the US and EU. In addition, 1 in 40,000 births (200 cases) are diagnosed yearly.</p> |  <p><b>Exclusive option for AskBio to negotiate a potential full development and commercialization agreement</b></p>   |
|  | <ul style="list-style-type: none"> <li>A pioneer in the discovery and development of gene therapies</li> <li>Conducts pre-clinical and clinical trials (Phase 1/2)</li> </ul>   | <p><b>Crigler-Najjar syndrome</b><br/>Approximately incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S</p>            |  <p><b>The initial agreement is focused on research and development</b><br/><b>The companies will consider a subsequent agreement for commercialization at a later stage</b></p> |

# 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 2025