



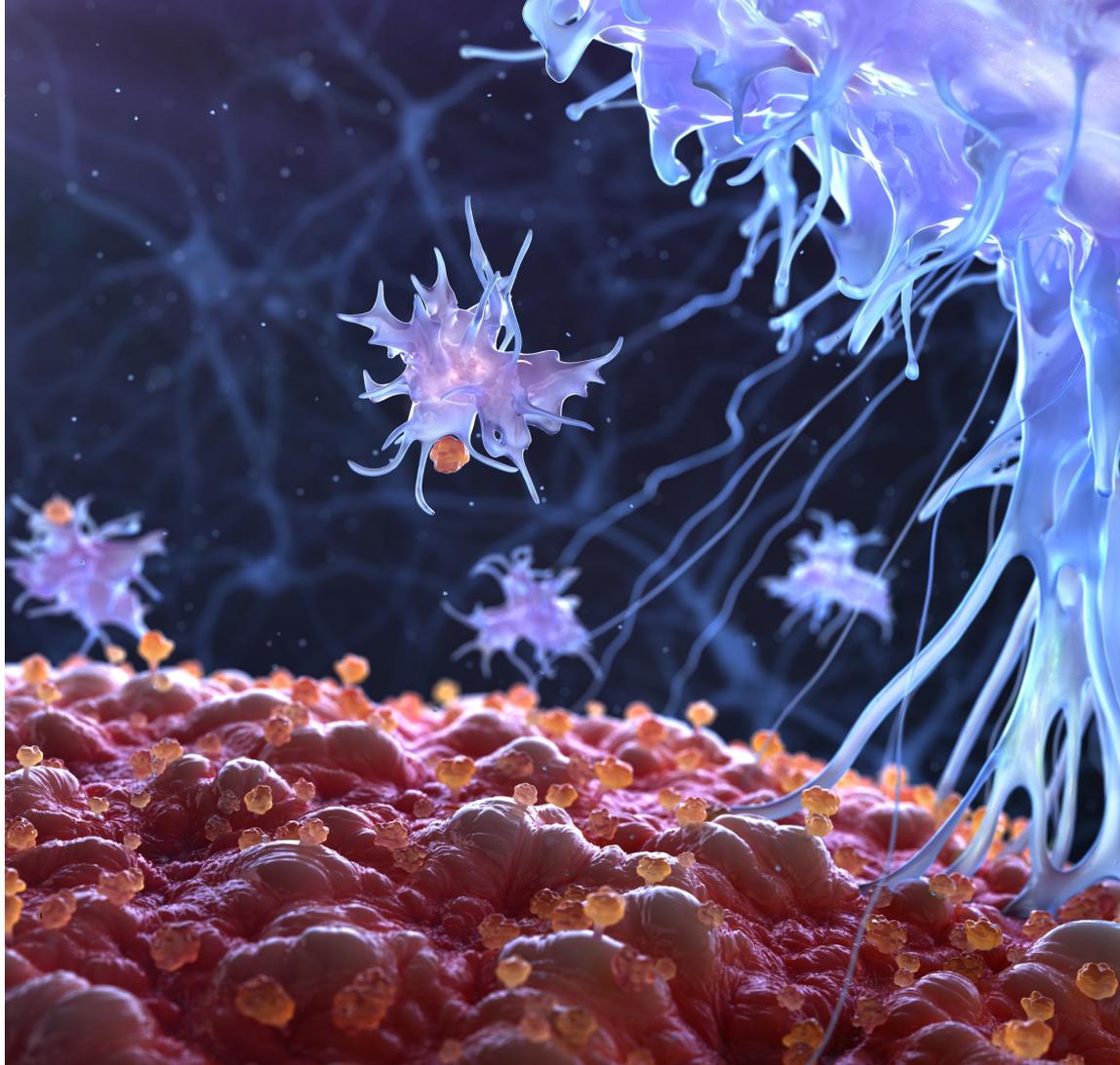
# HANSA

BIOPHARMA

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*Hitto Kaufmann, Chief R&D Officer*

*June 2024*



# Hansa Biopharma – a biotech to believe in

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

## At a Glance

**2007**  
founded in Lund

**160**  
employees globally

**\$170M**  
market cap

**\$34.6M**  
recent financing round

## Purpose driven Culture

**33**  
different nationalities

**4th year**  
Great Place to Work® 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: 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

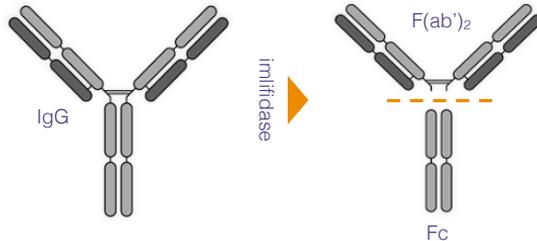
Interacts with Fc-part of IgG with extremely high specificity



## Inactivates IgG in 2-6 hours

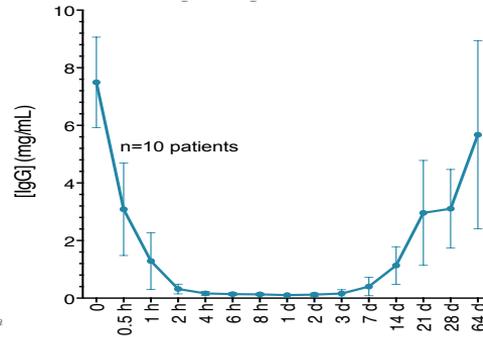
Rapid onset of action that inactivates IgG below detectable level in 2-6 hours

## 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*

## Inactivates IgG in 2-6 hours creating an IgG free window



## 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

7 clinical trials in key disease areas



Autoimmune



Gene Therapy



Transplantation

# HNSA-5487: 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 Ph 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



# Broad clinical pipeline in autoimmune, gene therapy and transplantation



Project	Indication	Research/Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	Next Anticipated Milestone
Imifidase	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
	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
HNSA-5487	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
	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

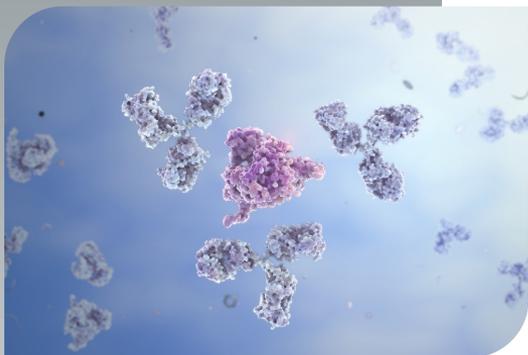
<sup>1</sup> Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

<sup>2</sup> Lorant et al., American Journal of Transplantation and OS+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



# TRANSPLANTATION



Imlifidase may enable incompatible kidney Tx in highly sensitized patients

**100k\***

patients waiting for a kidney transplant

\*\*In the US

**DSAs**

Donor specific antibodies that reject organ transplantation

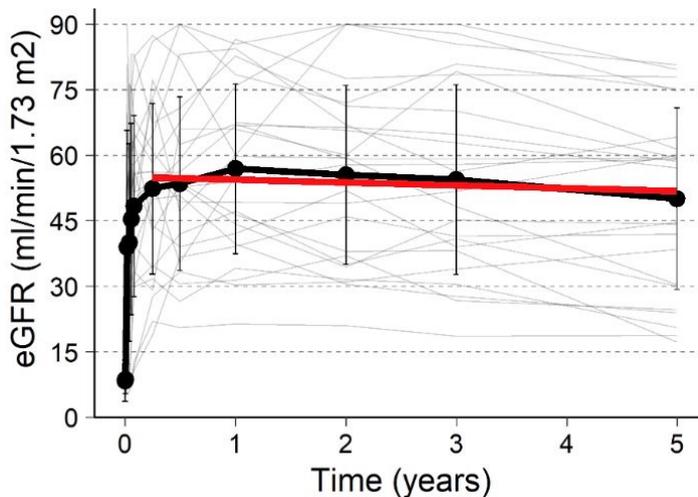
**SOC**

based on organ compatibility

**10-15%**

patients with 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/m2 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



# AUTOIMMUNE



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

**+100** autoimmune diseases



Rapidly progressive glomerulonephritis



Neurological disorders



Skin disorders



Blood disorders

**Imlifidase** rapidly cleaves autoantibodies to stop disease progression in monophasic conditions

**Proof of concept in two indications**

### Anti-GBM disease

**1.6** in a million affected annually

### Imlifidase Ph. 2 results

**67%** of patients were dialysis independent after six months vs. the historical cohort, where **only 18%** had functioning kidney

### Guillain-Barré Syndrome

**1.7-4.3** per 100,000 annually

### Imlifidase Ph. 2 results

**Rapid improvement** across several efficacy outcome measures, as compared with previously published data

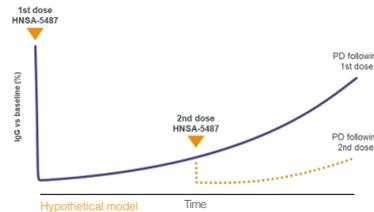


**Phase 3 ongoing**  
50% enrolled



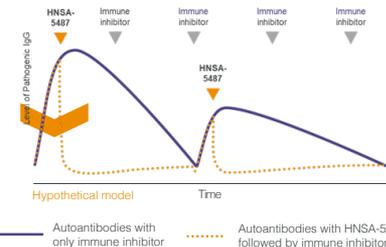
**Phase 3 plans under review**

**Next-gen enzyme** could provide novel treatment options of acute flairs in chronic conditions through redosing



**Short interval redosing**

Potential to **rapidly reverse autoimmune attack** through longer IgG-low window



**Longer intervals redosing**

**HNSA-5487 quickly removes IgG** – chronic immune inhibition adds to duration of effect



# GENE THERAPY



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

## AAVs

the delivery system of gene therapy

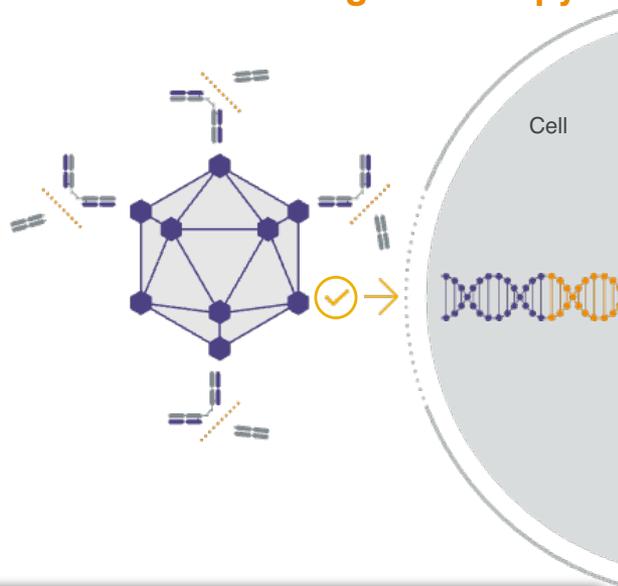
## 5-70%

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

# Key milestones over the next 18-24 months

## 2024

### AUTOIMMUNE

**GBS Phase 2:** Outcome of comparative efficacy analysis

### GENE THERAPY

**DMD Phase 1B:** High level data read-out (Sarepta)

**Crigler-Najjar Phase 1:** Trial initiation (Genethon)

### TRANSPLANTATION

**Kidney TX US Phase 3:** Randomization completed May 2024

**AMR:** publication in peer-reviewed journal

### EARLY DEVELOPMENT

**HNSA-5487:** Further analysis and lead indication identified

## 2025

### AUTOIMMUNE

**Anti-GBM Phase 3:** Complete enrolment

**ANCA:** Complete enrolment

### TRANSPLANTATION

**Kidney TX US:** BLA submission

**Kidney TX EU:** Post approval study complete



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