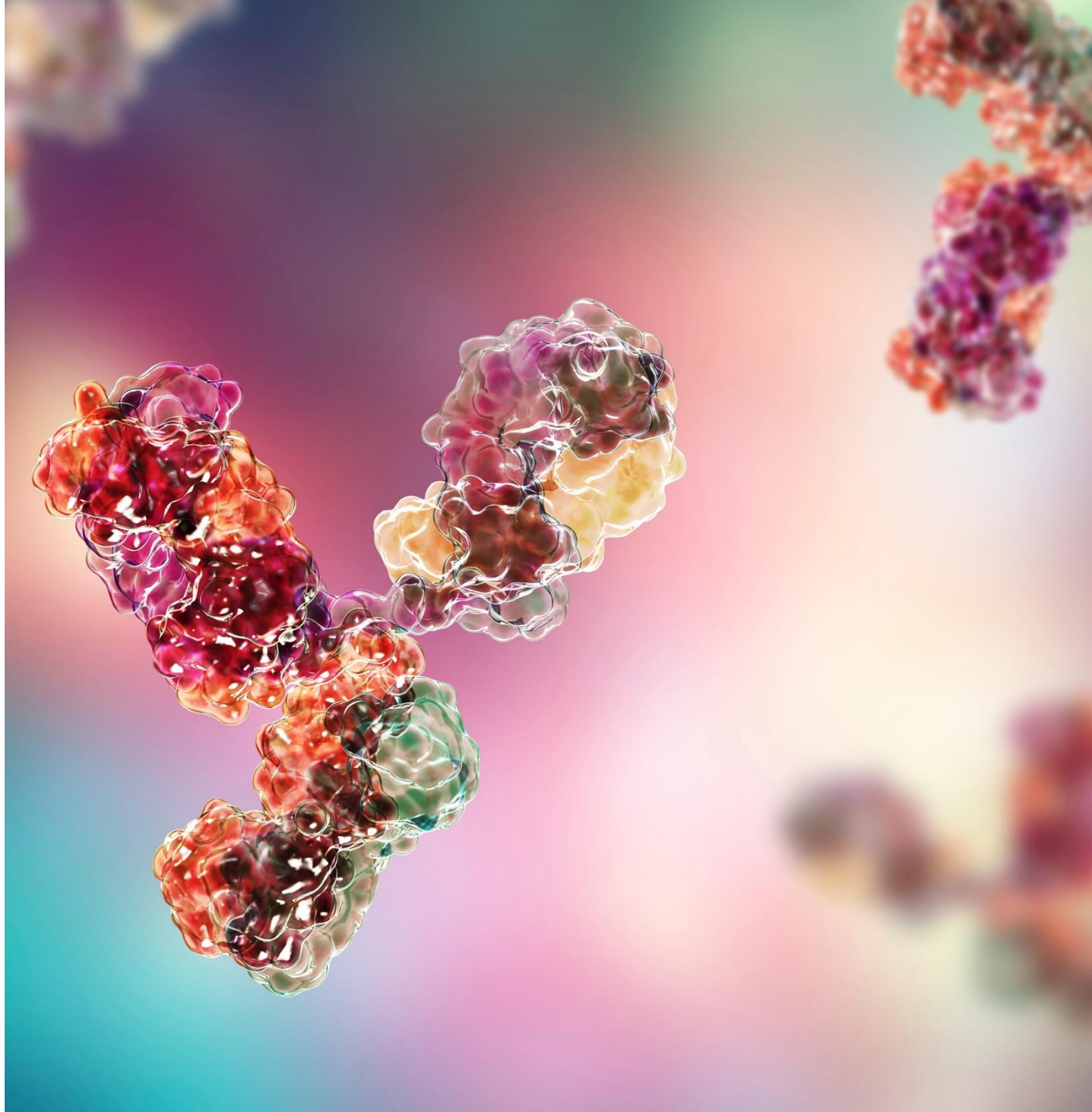
HANSA BIOPHARMA

Søren Tulstrup, President & CEO

TD Cowen
45th Annual Health Care Conference

5 March 2025



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Hansa is a pioneer in the development and commercialization of first in class IgG-cleaving enzymes

Commercial stage, derisked first-in-class asset

- Commercial stage IgG cleaving enzyme
- Long-term data supports value-proposition
- Over 200 patients treated, showcasing both clinical trial and real-world safety, tolerability and efficacy
- Commercial-scale manufacturing to support current and future launches

idefirix® (imlifidase)

Validated pipeline across three therapy areas

1 TRANSPLANTATION

Paradigm shift for highly sensitized kidney transplant patients
Pivotal Phase 3 trial in the U.S.

2 AUTOIMMUNE

Clinical POC for imlifidase in acute monophasic disorders.
Global Phase 3 in anti-GBM fully enrolled and positive Phase 2 in GBS

HNSA-5487 focused in neuro-autoimmune diseases with ability to re-dose

3 GENE THERAPY

Partnerships for pre-treatment to enable AAV gene therapy in patients with anti-AAV antibodies

Funded through key milestones

- Funded into **2026**
- Publicly traded on **NASDAQ Stockholm**
  Significant ownership from global biotech specialist investor
  Considering dual-listing on **NASDAQ**
- **Strong IP portfolio**, with coverage until the 2040s

Near-term milestones

Phase 2 GBS full data

First clinical data in gene therapy (Sarepta)

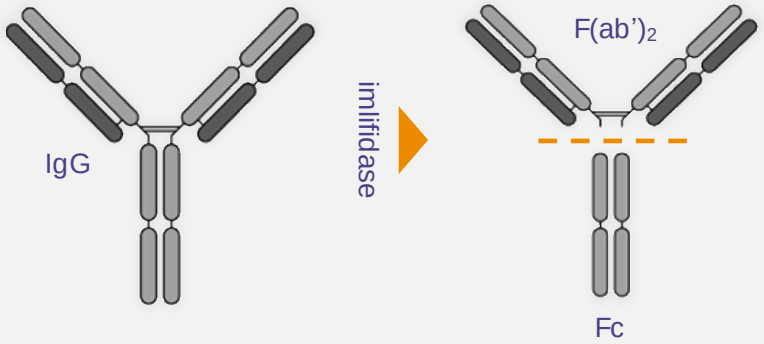
FDA **BLA submission** in kidney transplantation

Two novel molecules with potential for broad application in Autoimmune, Gene Therapy and Transplantation

Two IgG- cleaving compounds

IMLIFIDASE

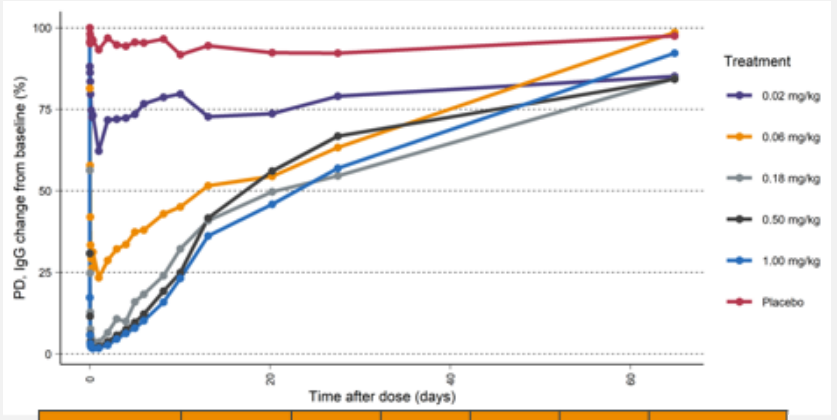
First generation, first-in-class, one-time dosing therapy with proven efficacy and safety



- Reduces IgG in 2-6 hours
- Conditionally approved and commercialized in the EU for desensitization in kidney transplantation
- Eight clinical trials in 7 indications across key therapy areas

HNSA-5487

Next generation molecule with redosing potential



	0.02 mg/kg n=4	0.06 mg/kg n=4	0.18 mg/kg n=6	0.50 mg/kg n=6	1.00 mg/kg n=6	Imlifidase** 0.25 mg/kg n=23
Responders*	0%	25%	83%	100%	100%	88%

*A subject with IgG level <5% of baseline 24 hours post dosing
** Data from 18-1-IMedidase-15 and 21-1-IMedidase-29

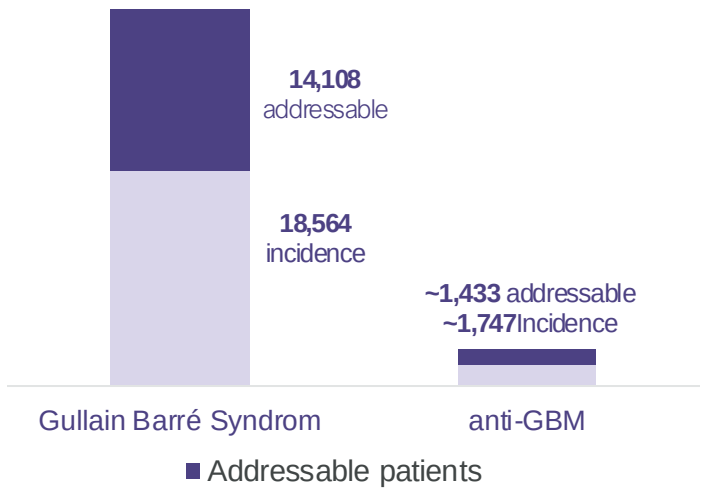
- Rapid and robust reduction in IgG (>95%) with confirmed redosing potential
- Clinical development path focused on acute exacerbations in neuro-autoimmune diseases

Significant addressable patient populations in areas of high unmet medical need

AUTOIMMUNE

IVIg market growth $40B by 2032

Europe and US

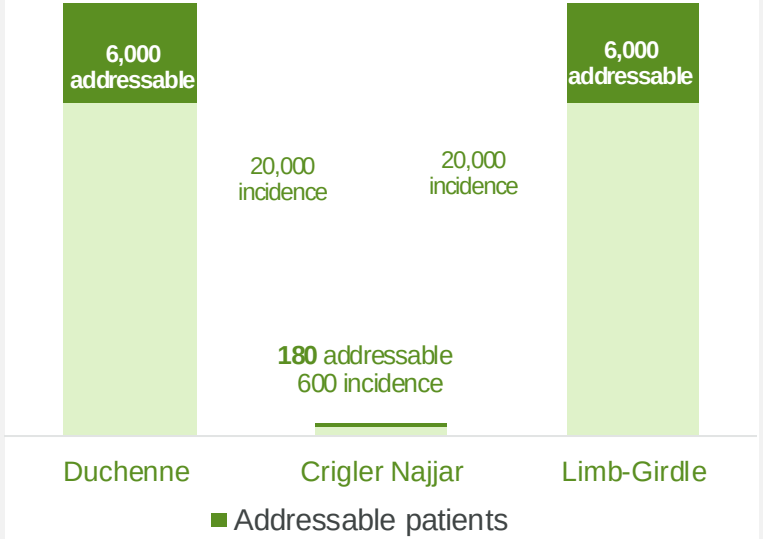


Addressable Populations: GBS: ***14,108*** Anti-GBM: ***1,433***

GENE THERAPY

GT market expected to reach $23.9B by 2028

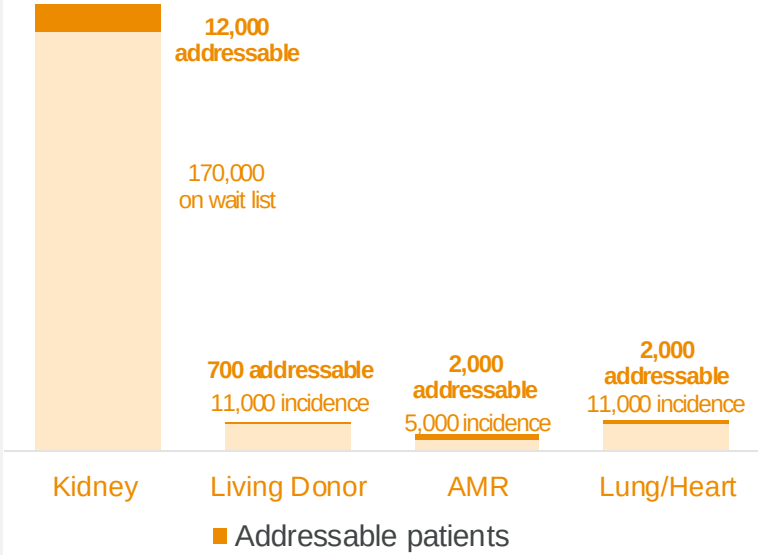
Europe and US



Addressable Populations: DMD: ***6,000*** CNS: ***180*** LGMD: ***6,000***

TRANSPLANTATION

Imlifidase: first and only approved treatment in highly sensitized transplantation



Addressable Populations: Kidney: ***12,000*** Adjacent: ***~5,000***

GBS

McGrogan, A., Madle, G.C., Seaman, H.E., et al. (2009) The Epidemiology of Guillain-Barré Syndrome Worldwide. Neuroepidemiology, 32, 150-163

Anti-GBM

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Lung Transplant

Global Observatory on Donation and Transplantation. https://www.transplant-observatory.org/export-database/. Accessed February 24, 2025.

Appel J, Hartwig M, R. Davis D, Reinsmoen N, Utility of Peri-transplant and Rescue Intravenous Immunoglobulin and Extracorporeal Immunoadsorption in Lung Transplant Recipients Sensitized to HLA Antigens, Human Immunology, Volume 66, Issue 4. 2005, Pages 378-386, ISSN 0198-8859, https://doi.org/10.1016/j.humimm.2005.01.025.

Witt CA, Gaut JP, Yusen RD, Byers DE, Iuppa JA, Bennett Bain K, Alexander Patterson G, Mohanakumar T, Trulock EP, Hachem RR. Acute antibody-mediated rejection after lung transplantation. J Heart Lung Transplant. 2013 Oct;32(10):1034-40. doi: 10.1016/j.healun.2013.07.004. Epub 2013 Aug 13. PMID: 23953920; PMCID: PMC3822761.

Schinstock, C., Stegall, M.D. Acute Antibody–Mediated Rejection in Renal Transplantation: Current Clinical Management. ***Curr Transpl Rep*** **1, 78–85 (2014).** https://doi.org/10.1007/s40472-014-0017-y

Heart

Wu GW, Kobashigawa JA, Fishbein MC, Patel JK, Kittleson MM, Reed EF, Kiyosaki KK, Ardehali A. Asymptomatic antibody-mediated rejection after heart transplantation predicts poor outcomes. J Heart Lung Transplant. 2009 May;28(5):417-22. doi: 10.1016/j.healun.2009.01.015. Epub 2009 Mar 14. PMID: 19416767; PMCID: PMC3829690.

Kobashigawa, J.A. et al.. Post-Transplant Outcome of the Highly Sensitized Patient Awaiting Heart Transplant Treated with Desensitization. The Journal of Heart and Lung Transplantation, Volume 40, Issue 4, S44

Gene Therapy

Muscular Dystrophy Association. Duchenne Muscular Dystrophy Fact Sheet. https://www.mda.org/sites/default/files/2019/03/Duchenne_Muscular_Dystrophy_Fact_Sheet.pdf. Accessed February 2025.

Collaud F, Bortolussi G, Guianvarc'h L, Aronson SJ, Bordet T, Veron P, Charles S, Vidal P, Sola MS, Rundwasser S, Dufour DG, Lacoste F, Luc C, Wittenberghe LV, Marlin S, Le Bec C, Bosma PJ, Muro AF, Ronzitti G, Hebben M, Mingozzi F. Preclinical Development of an AAV8-hUGT1A1 Vector for the Treatment of Crigler-Najjar Syndrome. Mol Ther Methods Clin Dev. 2019 Mar 15;12:157-174.

Ebrahimi A, Rahim F. Crigler-Najjar Syndrome: Current Perspectives and the Application of Clinical Genetics. Endocr Metab Immune Disord Drug Targets. 2018;18(3):201-211.

Mah JK, Korngut L, Fiest KM, Dykeman J, Day LJ, Pringsheim T, Jette N. A Systematic Review and Meta-analysis on the Epidemiology of the Muscular Dystrophies. Can J Neurol Sci. 2016 Jan;43(1):163-77. doi: 10.1017/cjn.2015.311. PMID: 26786644.

IgG-driven diseases and conditions are a significant burden on people, systems and society

Pathogenic IgG is a key element in several diseases and conditions

Excessive or dysregulated immune responses represent a central driving force in many inflammatory and autoimmune diseases

Rapid reduction of IgG levels has the potential to benefit patients

Depletion of IgG antibodies may halt disease progression and prevent organ damage.
Imlifidase and HNSA-5487 effectively and very rapidly cleave IgG.

Safe, targeted treatment options are needed

Many immune-mediated diseases have limited, or no FDA approved treatments. There remain insufficient treatment options for the acute phases.

The global immunoglobulin market is expected to grow exponentially

The immunoglobulin market is expected to reach ~$40B by 2032.
Immune-mediated diseases are the largest field of research behind oncology.

McInnes IB, Gravallese EM. Immune-mediated inflammatory disease therapeutics: past, present and future. Nat Rev Immunol. 2021 Oct;21(10):680-686. doi: 10.1038/s41577-021-00603-1. Epub 2021 Sep 13. PMID: 34518662; PMCID: PMC8436867.
Ortega MA, García-Montero C, Fraile-Martinez O, Alvarez-Mon MA, Gómez-Lahoz AM, Lahera G, Monserrat J, Rodriguez-Jimenez R, Quintero J, Álvarez-Mon M. Immune-Mediated Diseases from the Point of View of Psychoneuroimmunoendocrinology. Biology (Basel). 2022 Jun 28;11(7):973. doi: 10.3390/biology11070973. PMID: 36101354; PMCID: PMC9312038.
Improving Care in Immune-mediated diseases. November 2, 2022. Boston Consulting Group. https://www.bcg.com/publications/2022/improving-research-and-development-in-pharma-industry-for-immune-mediated-diseases. Accessed 2 January 2025.
IgG Mediated Autoimmune Diseases Biologic Drugs Market (2024 Edition): Analysis By Antibody Source (Humanized, Fully Human, Chimeric, Other Sources), By Indication, By Region, By Country: Market Insights and Forecast (2019-2029). https://www.researchandmarkets.com/report/global-igg-mediated-autoimmune-diseases-biologic-drugs-market?utm_source=GNE&utm_medium=PressRelease&utm_code=w2kkv2&utm_campaign=1998450+-+IgG+Mediated+Autoimmune+Diseases+Biologic+Drugs+Research+Report+2024%3a+Humanized%2c+Fully+Human%2c+Chimeric%2c+Other+Sources+Insights+and+Forecasts+20192023+%26+2024-2029&utm_exec=chdomspi. Access 2 January 2025.
Immunoglobulin Market Size, Share & Industry Analysis, By Route of Administration (Intravenous and Subcutaneous), By Indication (Primary Immunodeficiency, Secondary Immunodeficiency, Chronic Inflammatory Demyelinating Polyneuropathy, Guillain-Barré Syndrome, Immune Thrombocytopenic Purpura, Multifocal Motor Neuropathy, and Others), By Form (Liquid and Lyophilized), By End-user (Hospitals, Clinics, and Homecare), and Regional Forecast, 2024-2032. https://www.fortunebusinessinsights.com/industry-reports/immunoglobulins-market-100571. Accessed 2 January 2025.
Cherin P, Marie I, Michallet M, et al. Management of adverse events in the treatment of patients with immunoglobulin therapy: A review of evidence. Autoimmun Rev. 2016 Jan;15(1):71-81. doi: 10.1016/j.autrev.2015.09.002. Epub 2015

Hansa's IgG cleaving enzymes could be a transformative approach to treating IgG driven immune-mediated diseases

Addressing Autoimmune Diseases

80+ autoimmune diseases, including GBS (150K cases/year WW), anti-GBM (1.6 people per million/year), and myasthenia gravis (83K people in the US).

Democratizing Gene Therapy

7,000+ monogenic gene diseases. Gene therapy can be life changing. Up to 1 in 3 people are not eligible due to high anti-AAV antibodies.

Allowing More Transplants

High IgG levels limit organ transplants in 10-15% of the >170k patients waiting for a kidney. Potential for use in other organ transplants.

National Institute of Environmental Health Science. Autoimmune Diseases. https://www.niehs.nih.gov/health/topics/conditions/autoimmune. Accessed 6 January 2025
Boycott K.M, et al. Rare-disease genetics in the era of next-generation sequencing: discovery to translation. Nat Rev Genet. 2013 Oct;14(10):681-91. doi: 10.1038/nrg3555. Epub 2013 Sep 3. PMID: 23999272.
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Calcedo R, Wilson JM. Humoral Immune Response to AAV. Front Immunol. 2013 Oct 18;4:341. doi: 10.3389/fimmu.2013.00341. PMID: 24151496; PMCID: PMC3799231.
Veron P, Leborgne C, Monteilhet V, Boutin S, Martin S, Moullier P, Masurier C. Humoral and cellular capsid-specific immune responses to adeno-associated virus type 1 in randomized healthy donors. J Immunol. 2012 Jun 15;188(12):6418-24. doi: 10.4049/jimmunol.1200620. Epub 2012 May 16. PMID: 22593612.
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Newsletter Transplant 2022. International figures on donation and transplantation. Available at: Newsletter Transplant - latest edition I Freepub (edqm.eu) Accessed: May 2024
Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Accessed: May 2024.

Broad clinical pipeline

	Preclinical	Phase 1	Phase 2	Phase 3	Marketing authorization	Marketed	Partner	Status	Next anticipated milestone
Imlifidase									
EU: Kidney transplantation in highly sensitized patients[1,2]								Commercialization ongoing ● Post approval Clinical Phase 3 ongoing	EU: Additional agreements around reimbursement / Post authorization study to be completed by end of 2025
U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients[1,2]								Clinical Phase 3 ongoing	Data readout in 2H 2025
GOOD-IDES-02: Anti-GBM antibody disease								Clinical Phase 3 ongoing	Data readout in 2025
16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)								Clinical Phase 2 completed	
15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)								Clinical Phase 2 completed	Publication in peer-reviewed journal Preparation of Phase 3 trial
Investigator-initiated trial in ANCA-associated vasculitis[3]								Clinical Phase 2 ongoing	Complete enrolment (10 patients)
SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)							SAREPTA THERAPEUTICS	Clinical Phase 1b ongoing	Complete enrolment
Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)							SAREPTA THERAPEUTICS	Preclinical research ongoing	Preclinical research
Pre-treatment ahead of gene therapy in Pompe disease							AskBio	Preclinical research ongoing	Preclinical research
Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome							GENETHON CURE THROUGH INNOVATION	Clinical Phase 2 ongoing	Complete enrolment
HNSA-5487									
NICE-01: HNSA-5487 – Lead candidate from the NiceR program								Clinical Phase 1 completed	Alignment with regulatory authorities on clinical development pathway in neuro-autoimmune diseases

[1] Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)
[2] Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)
[3] Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

Multiple, value-creating pipeline catalysts in 2025

AUTOIMMUNE DISEASES

IMLIFIDASE

Guillain-Barré Syndrome (GBS)

15-HMedIdeS-09 Ph 2
Data publication. Ph 3 preparation

Anti-GBM

GOOD-IDES-02 Phase 3:
Data read out

HNSA-5487

Myasthenia Gravis (MG)

Clinical development pathway alignment w/ reg agencies

GENE THERAPY

IMLIFIDASE

Gene Therapy

Partnership Strategy

GENETHON CURE THROUGH INNOVATION · AskBio · SAREPTA THERAPEUTICS

Sarepta Phase 1b trial in DMD:
Data read out

Genethon Phase 2 trial in Crigler-Najjar Syndrome:
Complete enrolment

TRANSPLANTATION

IMLIFIDASE

Kidney Transplantation

ConfIdeS US Phase 3:
Data read out

BLA submission to US FDA

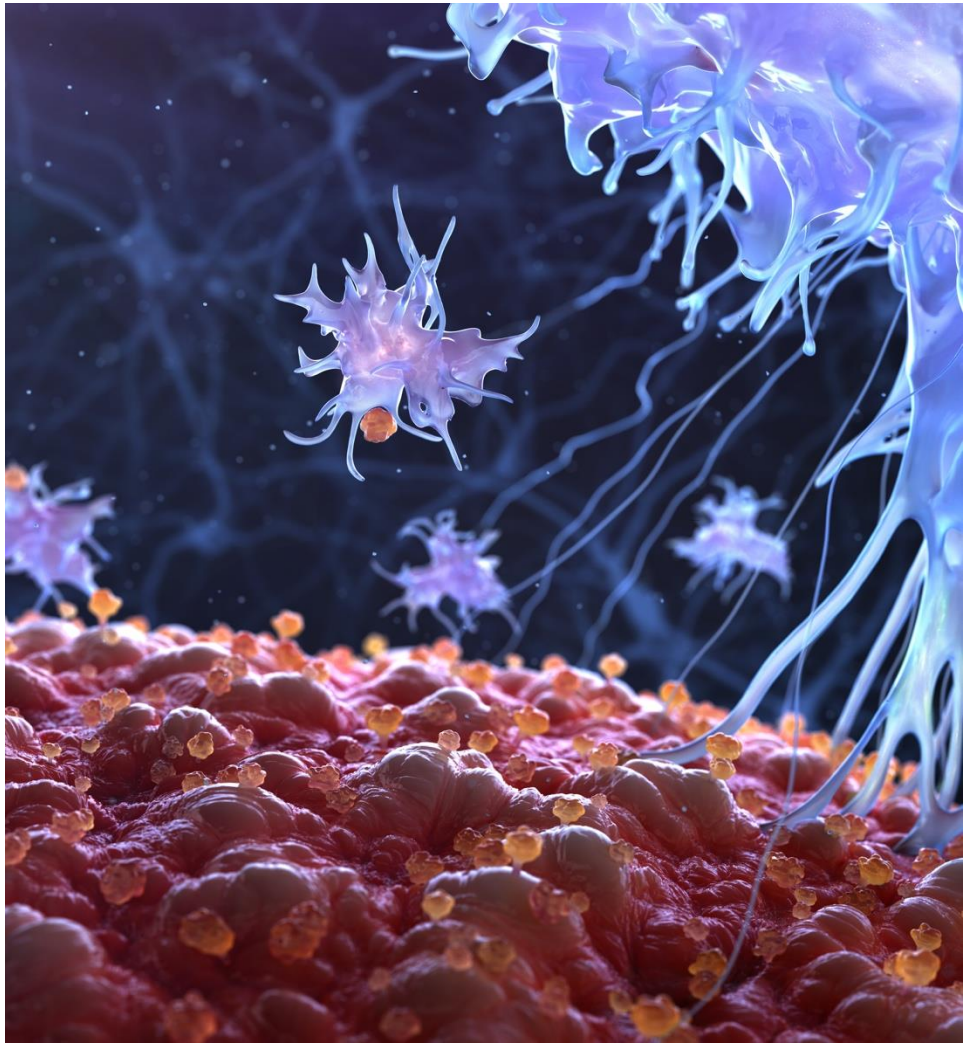
Post Authorization Efficacy Phase 3 Study (PAES):
Enrolment completion

AUTOIMMUNE DISEASES

Autoimmune diseases are conditions caused by the adaptive immune system mistakenly mounting an attack against the body's own cells and tissues

Acute indications can cause life-threatening organ failure and long-term damage.

Chronic indications occur when damage develops over time. Can often include acute attack or exacerbations.



IMLIFIDASE

- Positive Phase 2 results in Guillain-Barré Syndrome (GBS) and indirect treatment comparison to IGOS
- Ongoing Phase 3 trial in anti-GBM

HNSA-5487

- Positive First in Human trial and 12-mth analysis; moving to studies in patients focused on neuro-autoimmunity

Angum F, et al. The Prevalence of Autoimmune Disorders in Women: A Narrative Review. *Cureus*. 2020 May 13;12(5):e8094. doi: 10.7759/cureus.8094.
Wang L, et al. Human autoimmune diseases: a comprehensive update. *J Intern Med*. 2015 Oct;278(4):369-95. doi: 10.1111/joim.12395.
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Promising data in autoimmune for imlifidase and HNSA-5487

15-HMEDIDES-09 PHASE 2 STUDY DEMONSTRATED THE ROLE IMLIFIDASE MAY PLAY IN HALTING THE PROGRESSION OF GBS

Open-label, single arm, multi-center study across the UK, France, and the Netherlands.
Patients with severe GBS were included (GBS DS ≥ 3)
Evaluated safety, tolerability, and efficacy of single dose imlifidase (0.25 mg/kg) in combination with IVIg in 27 adult GBS patients

Rapid overall improvement in functional status including expedited muscle recovery

37% of patients able to walk independently at Week 1
67% of patients able to walk independently at Week 8

63% of patients able to run or had no functional disability (GBS DS<1) at 6 months

Administration of imlifidase was overall safe and well tolerated

GBS disability score (DS) is defined as: 0 = Healthy; 1 = Minor symptoms and capable of running; 2 = Able to walk independently 10 meters or more but unable to run; 3 = Able to walk more than 10 meters across an open space with help; 4 = Bedridden or chair bound; 5 = Needing mechanical ventilation; 6 = Dead

NICE-01 FIRST IN HUMAN TRIAL DATA DEMONSTRATED CLEAR REDOSING POTENTIAL FOR HNSA-5487 WITH ROBUST IGG REDUCTION

Double blind, randomized, placebo-controlled trial in 36 healthy volunteers received a single ascending doses of HNSA-5487 administered as a single intravenous (IV) infusion.
Assessed safety, tolerability, PK and PD, and immunogenicity

Rapid and robust IgG reduction by more than 95% within a few hours

Redosing potential with significantly reduced ADA response*

Efficient IgG reduction in samples at 6 and 12 months post initial dose

As efficacious as imlifidase in reducing total IgG levels

*as compared to imlifidase
ADA: anti-drug antibody

GENE THERAPY

Over 7,000 monogenic diseases and up to 1 in 3 people can't benefit from gene therapy due to anti-AAV antibodies

IMLIFIDASE

- Three partnerships in place with leading gene therapy companies;
- Phase 1 data read out with Sarepta expected in 2025
- Phase 2 trial with Genethon in Crigler Najjar initiated in 2024

Global exclusive agreements with leading gene therapy companies in select indications

SAREPTA THERAPEUTICS

CAPABILITIES & RESOURCES

- World leader in gene therapy in muscular dystrophies
- Pre-clinical and clinical plan
- Regulatory & Promotion
- FDA approval in 2023

INDICATION EXCLUSIVITY

Duchenne Muscular Dystrophy (DMD) - 1/3,500 to 5,000 male births worldwide

Limb-Girdle Muscular Dystrophy - global prevalence of ~1.6 per 100K individual

TERMS

$10M upfront w/ milestones totaling ~$400M

GENETHON

CURE THROUGH INNOVATION

CAPABILITIES & RESOURCES

- A pioneer in the discovery and development of gene therapies
- Conducts pre-clinical and clinical trials (Phase 1/2)

INDICATION EXCLUSIVITY

Crigler-Najjar syndrome - approximate incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S

TERMS

Undisclosed

AskBio

CAPABILITIES & RESOURCES

- Early innovator in gene therapy
- Conducts pre-clinical and clinical trials (Phase 1/2)

INDICATION EXCLUSIVITY

Pompe Disease - ~ 5,000 to 10,000 patients in the US and EU.

In addition, 1 in 40,000 births (200 cases) are diagnosed yearly.

TERMS

$5M upfront option collaboration

TRANSPLANTATION

More than 170K on the kidney transplant wait list; 10-15% highly sensitized and face significantly longer wait times

IMLIFIDASE

- Conditionally approved (2020) and commercialized in EU as desensitization for kidney transplantation
- Positive 5-year survival data shows durable graft and patient survival
- Pivotal Phase 3 US ConfIdeS trial completed enrolment in 2024; data readout in 2H 2025

Solid commercial opportunity in kidney transplantation desensitization

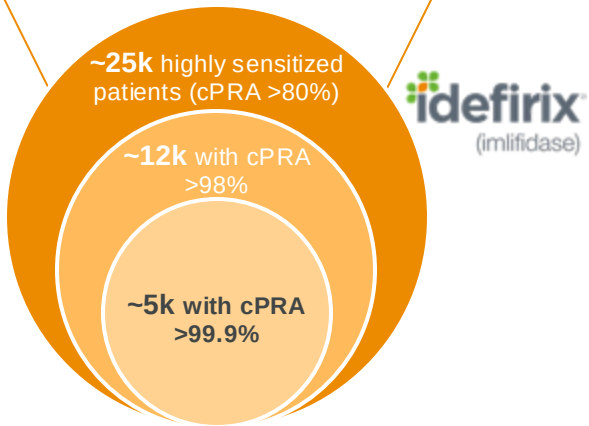
Significant Unmet Medical Need

Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients

~170k patients are waiting for a new kidney in Europe and the U.S.

Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization

10-15% of patients are highly sensitized
(cPRA > 80%)



IDEFIRIX Launch in Europe

European launch has reached inflection point with increasing adoption across major markets

18
Countries with market access

›

~75%
of transplant volume

~110
IDEFIRIX "ready" centers

36
Centers with clinical experience

66%
Clinics in 11 markets have repeat use

83%
Increase in FY sales vs 2023

35%
Increase in IDEFIRIX sales

2
International consensus / guidance on desensitization

7
Markets with clinical guidelines for imlifidase

ConfIdeS Phase 3 Nearing Completion

Pivotal Phase 3 trial

May 2024
fully randomized

2H 2025
Data readout and BLA filing

24
centers involved in trial

>20%
of transplant volume

Broad clinical experience creates foundation for fast commercial uptake

FINANCING AND LEADERSHIP

Leadership team

Søren Tulstrup
President & CEO

Evan Ballantyne
SVP & CFO

Hitto Kaufmann, PhD
SVP and Chief R&D Officer

Anne Säfström
SVP & CHRO

Board of Directors

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Leadership team with significant experience in immune modulating therapies and global healthcare

NASDAQ STOCKHOLM TICKER: HNSA

INSTITUTIONAL HOLDINGS > 45%

CASH (Q4 ‘24) $40 MILLION US

EXPECTED CASH RUNWAY INTO 2026

SHARES OUTSTANDING – 67.8 MILLION

Poised to deliver therapies that will change the immune-mediated treatment landscape

Proprietary IgG-cleaving Platform

3 Therapeutic Areas, Broad Application

Highly Clinically Validated

Well Capitalized into 2026, Experienced Team

Thank you!

IR@hansabiopharma.com