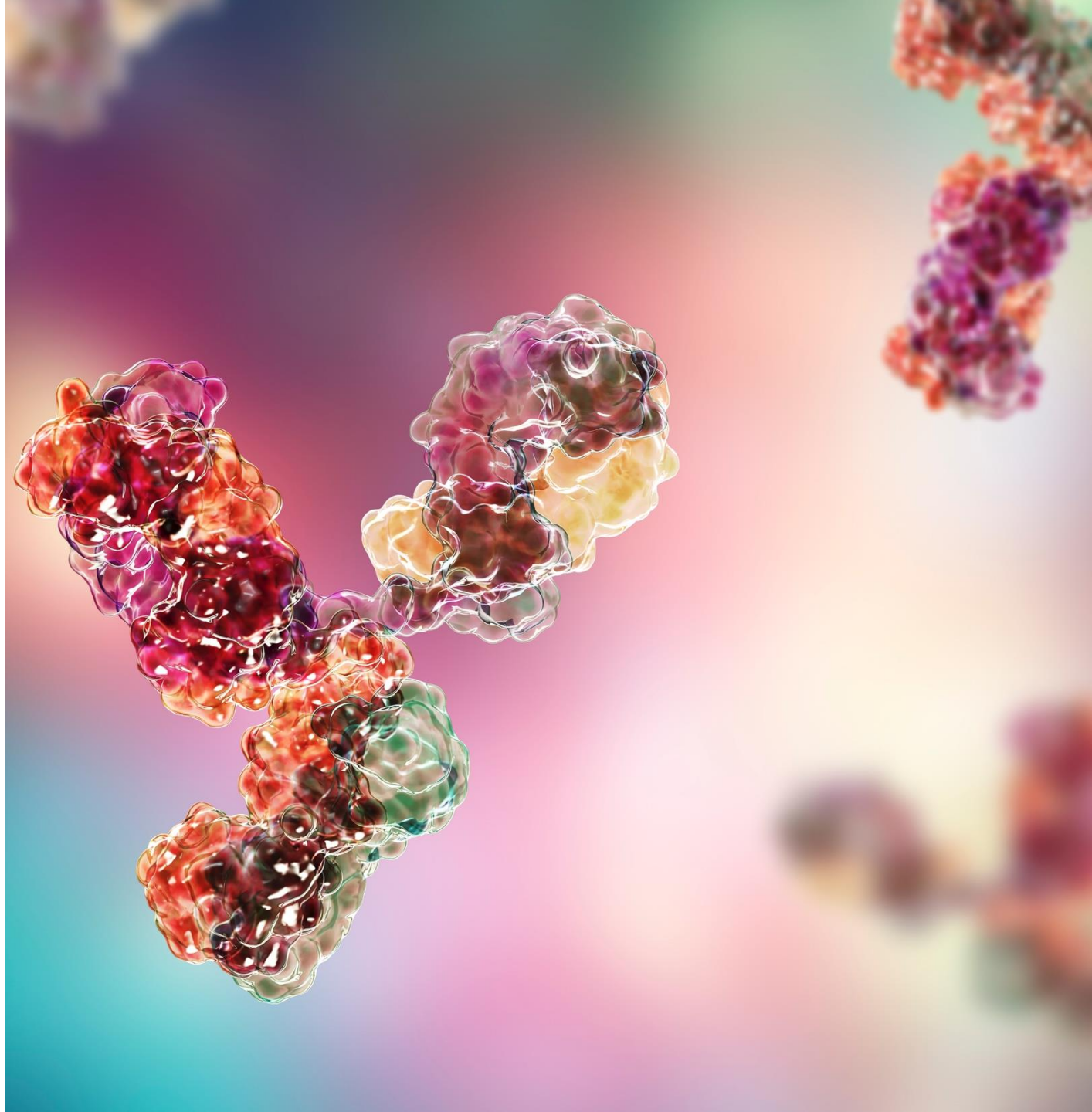
HANSA BIOPHARMA

# Corporate Presentation

February 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)

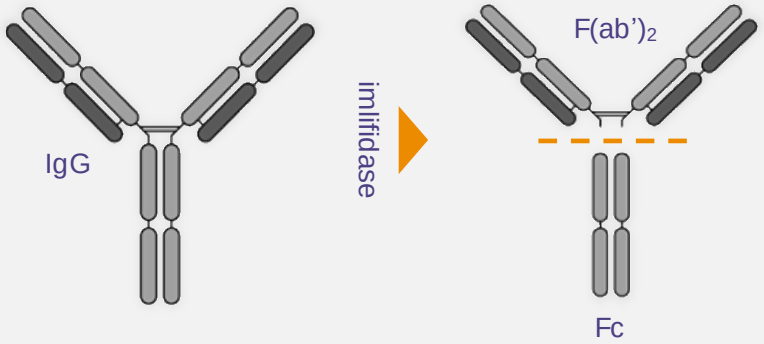
FDA **BLA submission** in kidney transplantation

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

## Two IgG- cleaving compounds

### IMLIFIDASE

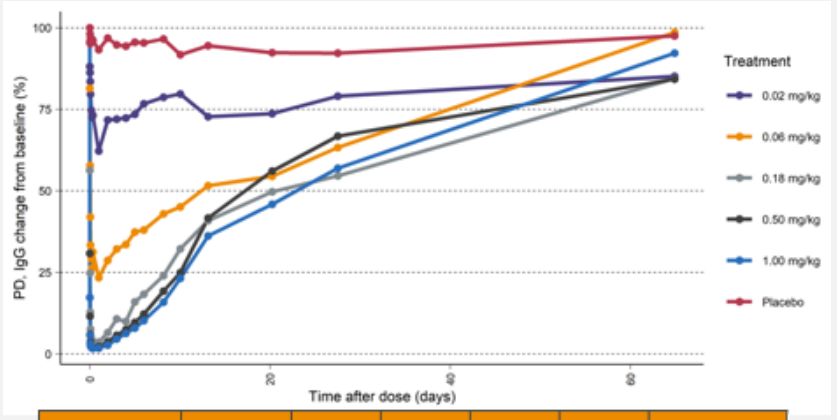
First generation, first-in-class, one-time dosing therapy with proven efficacy and safety




- 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

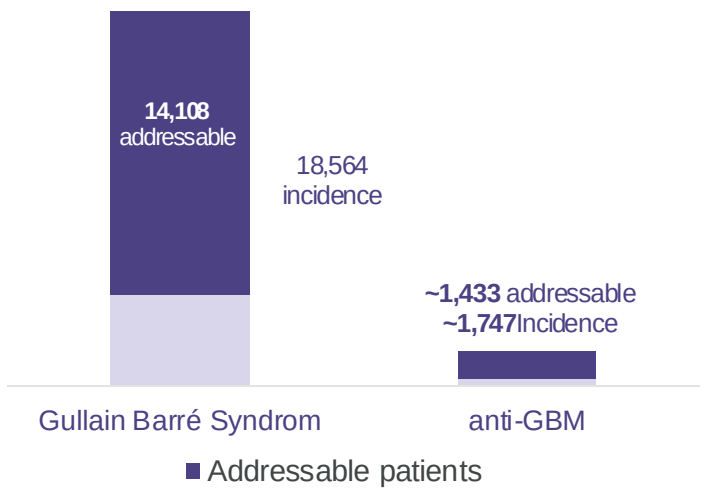
- Rapid and robust reduction in IgG (>95%) with confirmed redosing potential
- Clinical development path focused on acute exacerbations in neuro-autoimmune diseases

# Significant addressable patient populations in areas of high unmet medical need

## AUTOIMMUNE

***IVIg market growth $40B by 2032***

### *Europe and US*

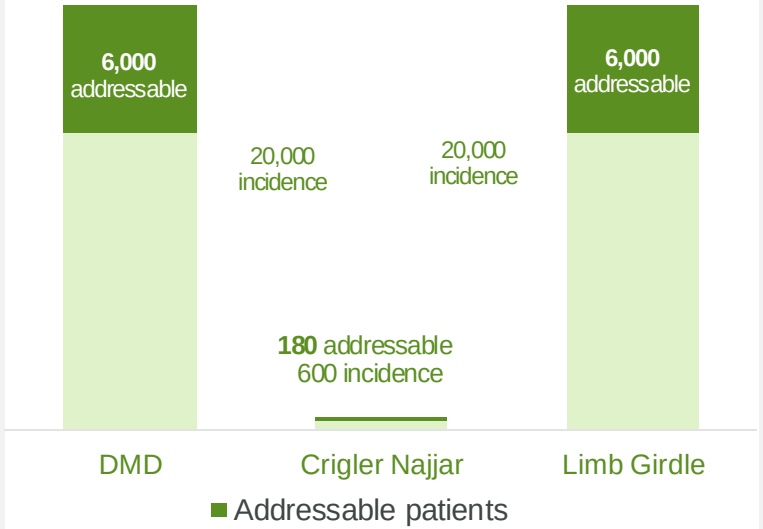



**Addressable Populations:** GBS: ***14,108*** Anti-GBM: ***1,433***

## GENE THERAPY

***GT market expected to reach $23.9B by 2028***

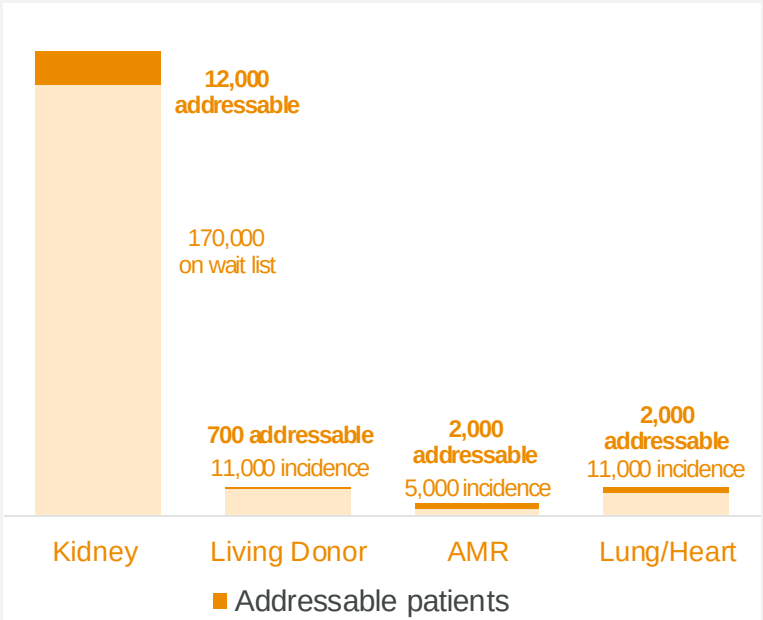
### *Europe and US*




**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*

*Canney et al, Spatial and Temporal Clustering of Anti-Glomerular Basement Membrane Disease. Clin J Am Soc Nephrol. 2016 Aug 8;11(8):1392-1399*

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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.
Boutin S, et al. Prevalence of serum IgG and neutralizing factors against adeno-associated virus (AAV) types 1, 2, 5, 6, 8, and 9 in the healthy population: implications for gene therapy using AAV vectors. Hum Gene Ther. 2010 Jun;21(6):704-12. doi: 10.1089/hum.2009.182. PMID: 20095819.
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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<br>● 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<br>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*

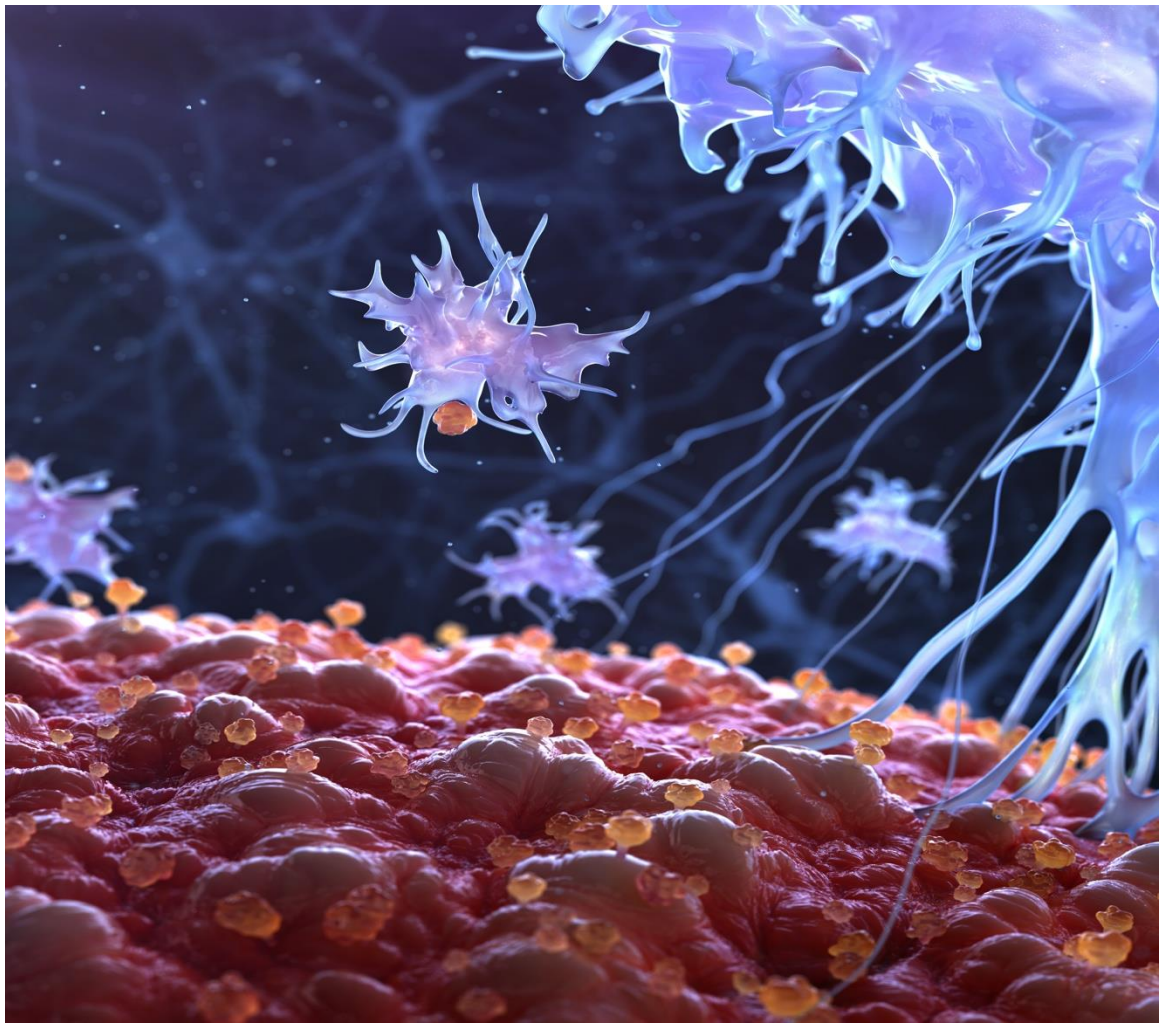
Post Authorization Efficacy Phase 3 Study (PAES):
*Enrolment completion*

# 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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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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Pisetsky, D.S. Pathogenesis of autoimmune disease. *Nat Rev Nephrol* 19, 509–524 (2023). https://doi.org/10.1038/s41581-023-00720-1

# Guillain-Barré Syndrome (GBS) is a rare, acute inflammatory disease driven by IgG

## Guillain-Barré Syndrome

a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system caused by the immune system damaging nerve cells and structures.

### Symptoms

Rapid onset and progression of muscle weakness leading to severe paralysis of the arms and legs. Most GBS patients also have sensory disturbance (tingling or numbness or ataxia) and pain, and some patients have double vision or problems with swallowing.

### Treatment

No FDA approved treatments. IVIg/PLEX are considered standard of care. IVIg is approved in the EU.

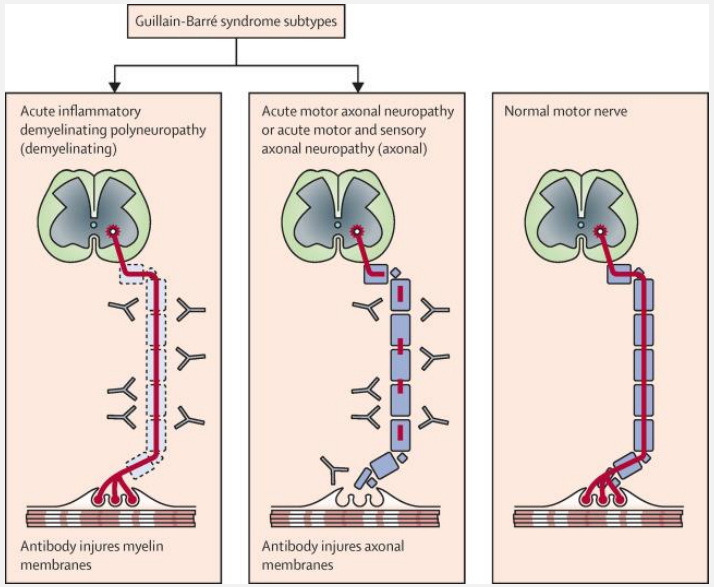
### Prevalence

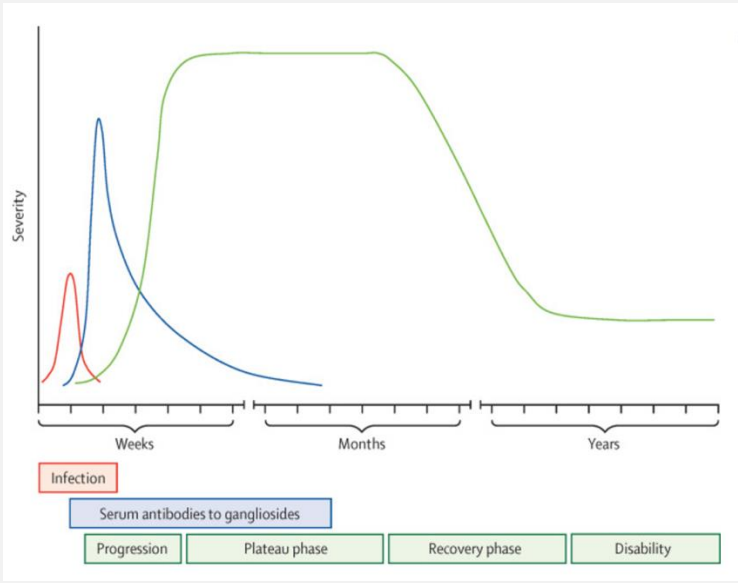
Affects 1-2 in 100,000 people annually. Approximately 3,000 – 6,000 cases annually in the US.

### Unmet Need

~25% of patients require mechanical ventilation for days to months following the acute autoimmune attack, and 20% are unable to walk after six months.

## IgG is a key driver of inflammatory attacks on peripheral nerves and has been clinically linked to the severity and progression of the disease.




Willison et al, Lancet, 2016, Vol 388:10045:717-727

*"In the treatment of GBS and subsequent recovery process, early improvement and the ability to walk independently are important clinical milestones as they indicate a return to basic mobility and independence, and to an improved quality of life for patients. This analysis supports the potential role of imlifidase followed by standard of care IVIg as a potentially new treatment option in GBS. These are important results for patients and clinicians in the GBS community."*

Professor Shahram Attarian,
Head of Department of Neuromuscular Diseases and ALS, Hopitaux Universitaires de Marseille (APHM).



Fletcher DD et al. Long-term outcome in patients with Guillain-Barré syndrome requiring mechanical ventilation. Neurology. 2000 Jun 27;54(12):2311-5. doi: 10.1212/wnl.54.12.2311
Van Doorn PA. Diagnosis, treatment and prognosis of Guillain-Barré syndrome (GBS). Presse Med. 2013 Jun;42(6 Pt 2):e193-201. doi: 10.1016/j.lpm.2013.02.328
McGrogan A, et al. Neuroepidemiology. 2009; 32(2):150-63

# 15-HMedIdeS-09 Phase 2 Study demonstrated the role imlifidase may play in halting the progression of GBS

## Study Overview

- 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

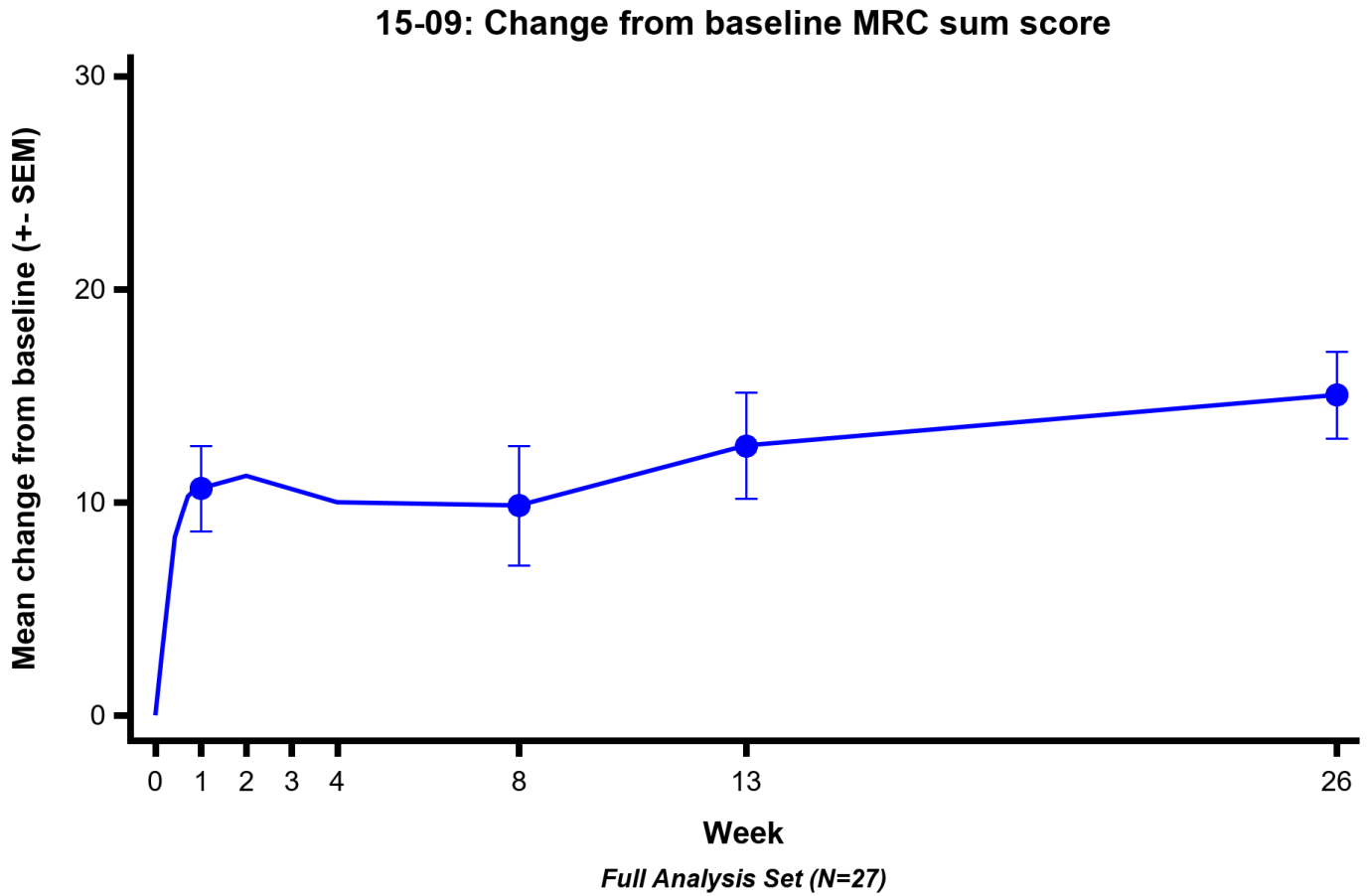
67% of patients able to walk independently at Week 8

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

# Recovery of muscle strength seen as early as week 1 in patients treated with imlifidase in combination with IVIg




## Key Takeaways

- Muscle weakness is a primary symptom of GBS and can lead to paralysis
- Regaining muscle strength is a key factor in recovery and returning to daily activities
- Mean 10.7 improvement in muscle strength at week 1

Ko KJ, Ha GC, Kang SJ. Effects of daily living occupational therapy and resistance exercise on the activities of daily living and muscular fitness in Guillain-Barré syndrome: a case study. J Phys Ther Sci. 2017 May;29(5):950-953. doi: 10.1589/jpts.29.950. Epub 2017 May 16. PMID: 28603379; PMCID: PMC5462706.

# Indirect treatment comparison demonstrates the robust, consistent benefit of imlifidase in combination with IVIg in GBS

## 15-HMedIdeS-09 data compared to IGOS

- Indirect comparison of 15-HMedIdeS-09 Phase 2 single arm trial data (n=27) to IGOS real-world IVIg comparator group with severe GBS patients (n=754)
- Unanchored matched-adjusted indirect comparison method

## Weighted Prognostic Variables

Time from weakness onset to treatment initiation and baseline values for:

Age ● GBS DS ● Cranial Nerve Involvement ● MRC sum score ● Preceding Diarrhea

## Clinically Meaningful Endpoints

Identified four clinically meaningful endpoints related to disease recovery including GBS DS and MRC sum score

Median time to return to independently walking **6 weeks sooner** than IVIg comparator group (*p=0.03*)

Median time to improvement by at least one grade on GBS DS **3 weeks sooner** (*p=0.002*)

Phillippo DM, et al. NICE DSU Technical Support Document 18. 2016.

# Imlifidase in combination with IVIg delivered clinically meaningful benefit to patients with severe GBS

## Substantial early improvement in functional status in Phase 2 study

*well tolerated/consistent safety profile*

**Patients treated with imlifidase plus IVIg in Phase 2 study had rapid overall improvement in functional status**

| | |
|---|---|
| **Rapid overall improvement in functional status** | **37%** returned to walking independently at 1 week |
| | Median time to independently walking (**16 days**) |
| | Median time to improve **by at least one** grade on GBS DS (6 days) |
| | MRC sum score of **10.7 points** at 1 week |
| **4 WEEKS** | **33%** regained the ability to run |
| **8 WEEKS** | **67%** able to walk independently |
| | **41%** regained the ability to run |
| | **37%** improved by at least 3 points in GBS DS |
| **6 MONTHS** | **63%** able to run or had no functional disability |

## Significantly faster improvement in clinically meaningful measures vs standard of care IVIg

**In comparison to IGOS-IVIg group (n=754), patients experienced significantly faster improvement across clinically relevant measures**

Median time to return to independently walking **6 weeks sooner** than IVIg comparator group (p=0.03)

Median time to improvement by at least one grade on GBS DS **3 weeks sooner** (p=0.002)

**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
**IGOS** – International GBS Outcome Study
**OR** - odds ratio

# Anti-GBM is a rare, acute inflammatory disease driven by IgG

## Anti-Glomerular Basement Membrane Disease

an acute, rare, and very severe inflammatory disease in which IgG autoantibodies attack the glomerular basement membrane in the kidneys and, in some patients, the lungs.

### Symptoms

Early signs are often unspecific which can vary from malaise, weight loss, fatigue and fever. Kidney symptoms usually include blood and protein in the urine. Lung symptoms include coughing up blood, chest pain, cough, and shortness of breath.

### Prevalence

Affects around 1.6 people per million annually. Only one in three will have a preserved renal function after six months with current standard of care.[5]

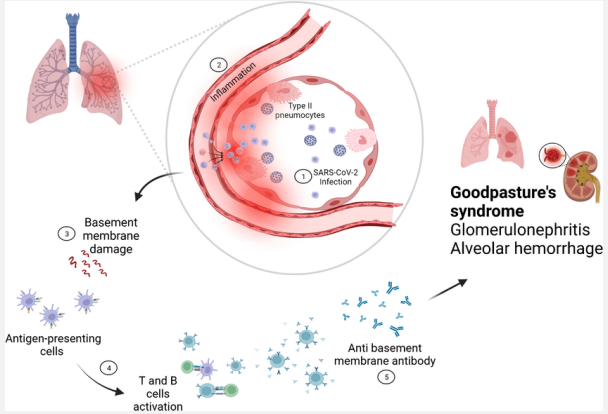
### Treatment

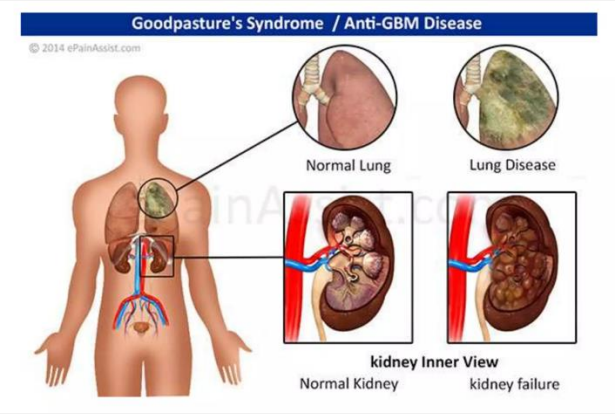
There are no approved drugs for anti-GBM. Standard of care consists of a combination of immunosuppressives, glucocorticoids, and plasma exchange.

### Unmet Need

Severe anti-GBM can be life-threatening resulting in kidney failure and bleeding in the lungs. The acute autoimmune attacks can become fatal in up to one in eight patients in the first year, while most patients lose their kidney function and end up on dialysis.

## IgG plays a central role in anti-GBM binding to the GBM and causing damage to the kidneys




*"Given the severity of anti-GBM's acute phase, the autoimmune reaction needs to be counteracted and stopped as quickly as possible if we want to limit the damage to the organs. Only if treatment is instituted early, there is a chance of salvaging the organ's function."*

Mårten Segelmark,
Professor of Nephrology at Lund University.


UNC Kidney Center: Anti-GBM Disease. Available at: https://unckidneycenter.org/kidneyhealthlibrary/glomerular-disease/anti-gbm-disease/.
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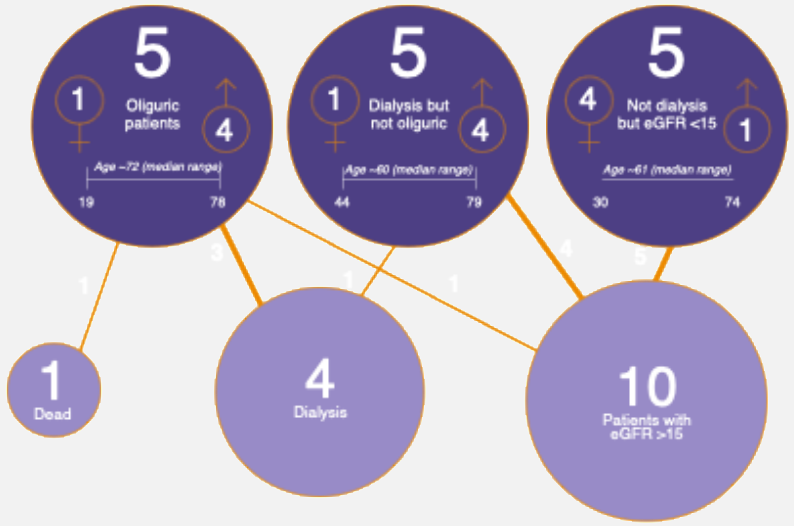
Uhlin et al JASN (2022)
McAdoo et al: Kidney Int 92: 693–702, 2017

# Topline data from GOOD-IDES-02 Phase 3 anti-GBM trial expected in 2H 2025

## Results from Phase 2 Study Results Published in JASN (2022)

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




**Imlifidase granted orphan drug designation by US FDA and EMA**

## GOOD-IDES-03 Open Label Phase 3 Trial

- Fully enrolled 50 patients from 30+ centers in US, UK and EU
- Primary Endpoints: eGFR at 6 months and need for dialysis
- Secondary Endpoints: anti-GBM antibody levels, pulmonary symptoms, safety, PK/PD and health related quality of life
- 25 patients were randomized to receive imlifidase in combination with SOC and 25 patients received only SOC

SOC: Standard of Care consisting of a combination of immunosuppressives, glucocorticoids, and plasma exchange,


Segelmark et al. JASN (2022)
Journal of the American Society of Nephrology https://pubmed.ncbi.nlm.nih.gov/35260419/
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

# HNSA-5487 could address unmet need in neuro-autoimmune conditions including Myasthenia Gravis (MG)

## Myasthenia Gravis (MG)

A rare, chronic autoimmune neuromuscular disorder that is characterized by fluctuating weakness of the voluntary muscle groups.

### Symptoms

Weakness in eye muscles including double or blurred vision and drooping eyelid. Can develop widespread weakness in face, arms, or legs.

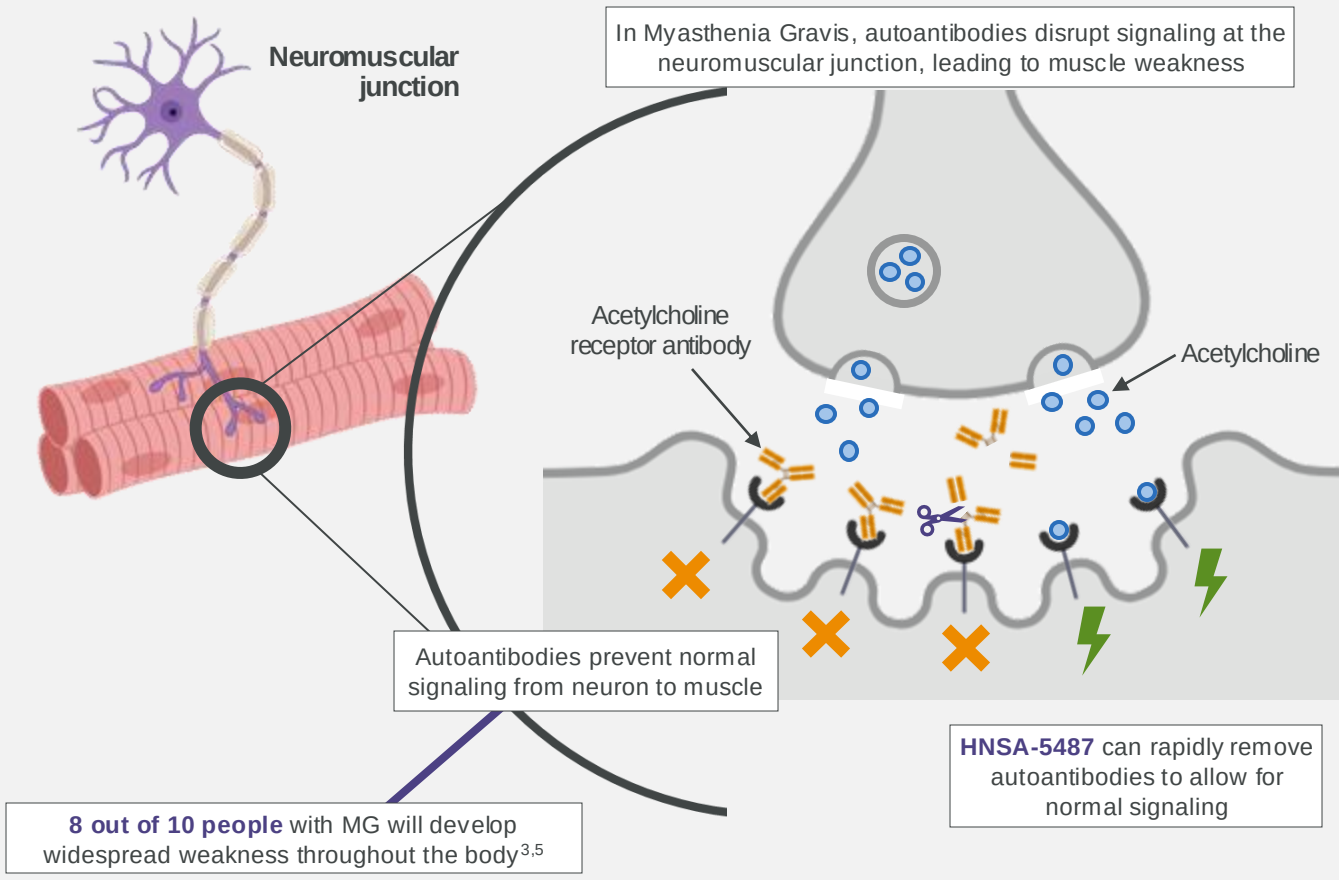
### Prevalence

Globally, approximately 150 to 200 out of every million people have MG. In the US 37 out of every 100,000 people have MG.

### Treatment

Current immunomodulatory treatments do not achieve sufficient improvement or resolution of symptoms and more targeted therapies are needed. **No approved treatments for severe exacerbations and myasthenic crisis.**

## Most people with MG have IgG antibodies against the acetylcholine receptor




Created with BioRender.com


Dresser L, Wlodarski R, Rezania K, et al. Myasthenia gravis: epidemiology, pathophysiology and clinical manifestations. *J Clin Med* 2021; 10: 2235.
Schneider-Gold, Christiane, and Nils Erik Gilhus. "Advances and challenges in the treatment of myasthenia gravis." Therapeutic advances in neurological disorders vol. 14 17562864211065406. 21 Dec. 2021, doi:10.1177/17562864211065406
Punga A, Maddison P, Heckmann J, et al. Epidemiology, diagnostics, and biomarkers of autoimmune neuromuscular junction disorders. Lancet Neurol 2022; 21: 176–188.

# NICE-01 first in human trial data demonstrated clear redosing potential for HNSA-5487 with robust IgG reduction

## Study Overview

- 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*

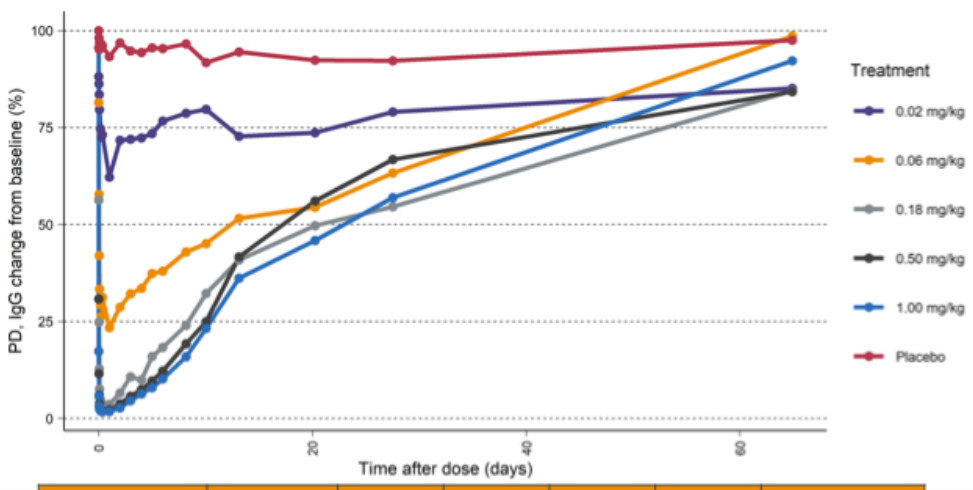
Efficient IgG reduction in samples at 6 and 12 months post initial dose

As efficacious as imlifidase in reducing total IgG levels

*as compared to imlifidase
ADA: anti-drug antibody

# HNSA-5487 demonstrated rapid, robust reduction of IgG by 95% after a single dose

## As efficacious as imlifidase in IgG reduction

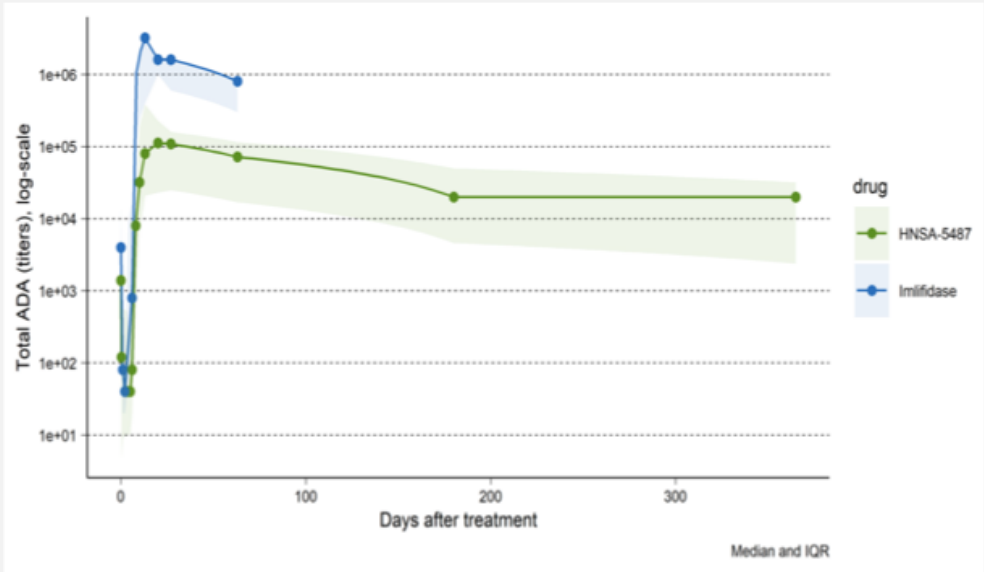



| | 0.02 mg/kg n=4 | 0.06 mg/kg n=4 | 0.18 mg/kg n=6 | 0.50 mg/kg n=6 | 1.00 mg/kg n=6 | Imlifidase** 0.25 mg/kg n=23 |
|---|---|---|---|---|---|---|
| Responders* | 0% | 25% | 83% | 100% | 100% | 88% |

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

## Effective redosing at 6 and 12-months

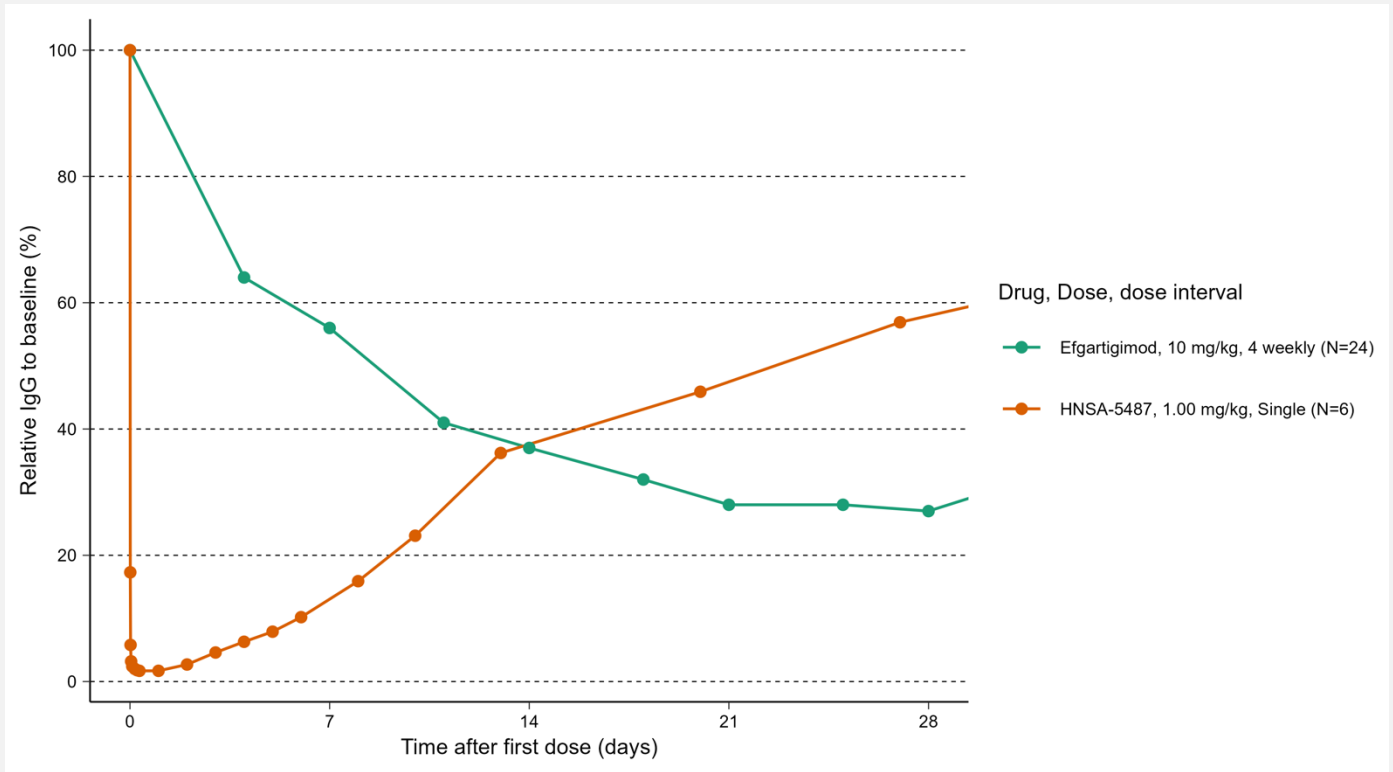
Data plotted using two separate Phase 1 trials in healthy human subjects
No head-to-head trial has been conducted between HNSA-5487 and imlifidase




HNSA-5487 data from NICE 01, healthy subjects (n=26)
Imlifidase data from 18-HMedIdeS-15, healthy subjects (n=11)

# HNSA-5487 is uniquely positioned to treat acute and chronic conditions due to its rapid IgG reduction

## HNSA-5487 provides unmatched speed in reducing IgG




## IgG cleaving enzymes cleave antibodies across all domains

| IgG lowering modalities | Intravascular IgG | Extravascular IgG | Cell bound IgG |
|---|---|---|---|
| Imlifidase | ✓ | ✓ | ✓ |
| HNSA-5487 | ✓ | ✓ | ✓ |
| FcRn inhibitor | ✓ | - | ✗ |
| PLEX | ✓ | ✗ | ✗ |

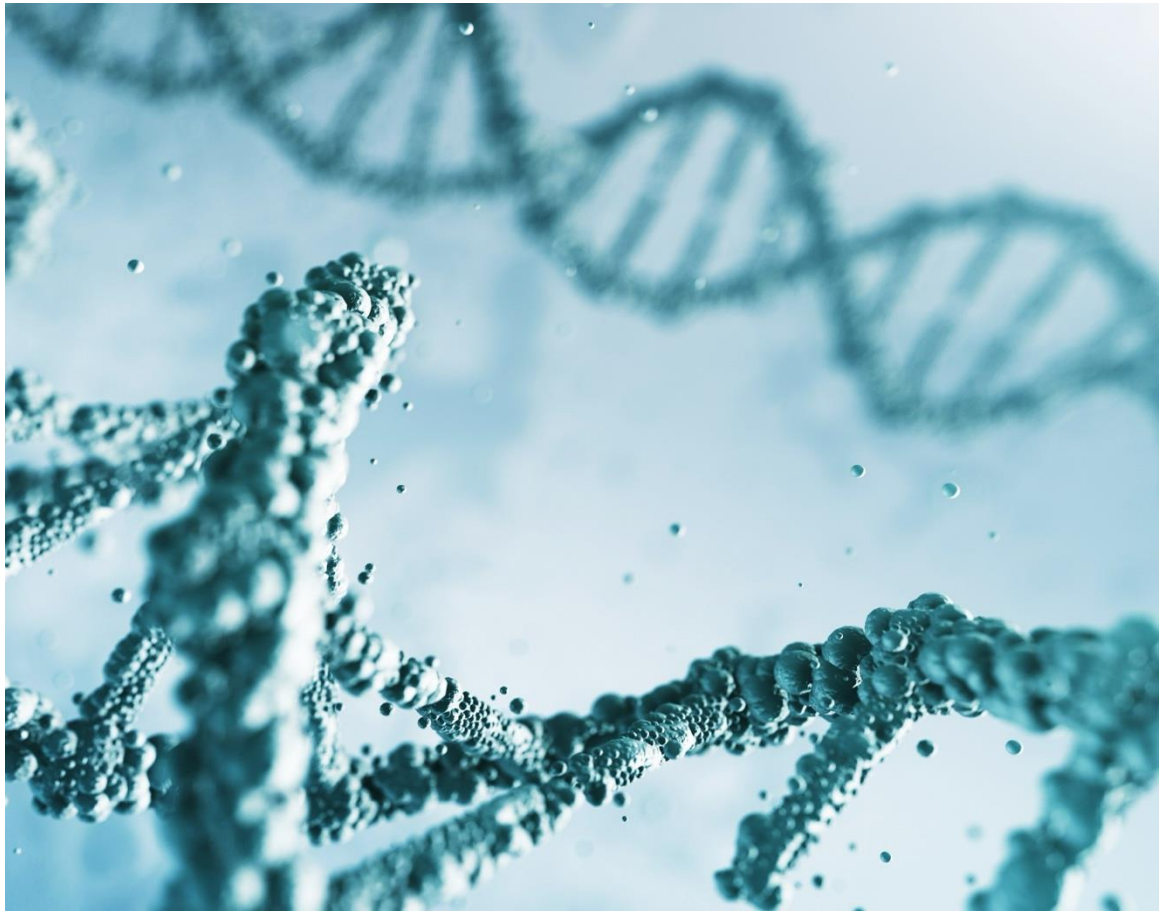

Idefirix Summary of Product Characteristics. https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf. Accessed June 2024.
Gil I. Wolfe, E. Sally Ward, Hans de Haard, Peter Ulrichts, Tahseen Mozaffar, Mamatha Pasnoor, Gestur Vidarsson,. gG regulation through FcRn blocking: A novel mechanism for the treatment of myasthenia gravis, Journal of the Neurological Sciences,Volume 430, 2021,118074, ISSN 0022-510X,https://doi.org/10.1016/j.jns.2021.118074.(https://www.sciencedirect.com/science/article/pii/S0022510X2100770X).

# 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




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.
Boutin S, et al. Prevalence of serum IgG and neutralizing factors against adeno-associated virus (AAV) types 1, 2, 5, 6, 8, and 9 in the healthy population: implications for gene therapy using AAV vectors. Hum Gene Ther. 2010 Jun;21(6):704-12. doi: 10.1089/hum.2009.182. PMID: 20095819.
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# 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


Emery AE. Population frequencies of inherited neuromuscular diseases--a world survey. Neuromuscul Disord. 1991;1(1):19-29. doi: 10.1016/0960-8966(91)90039-u. PMID: 1822774.
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https://www.genethon.com/our-pipeline/crigler-najjar-syndrome/. Last accessed: 29 November 2024
Taglia A, Picillo E, D'Ambrosio P, Cecio MR, Viggiano E, Politano L. Genetic counseling in Pompe disease. Acta Myol. 2011 Dec;30(3):179-81. PMID: 22616199; PMCID: PMC3298105.
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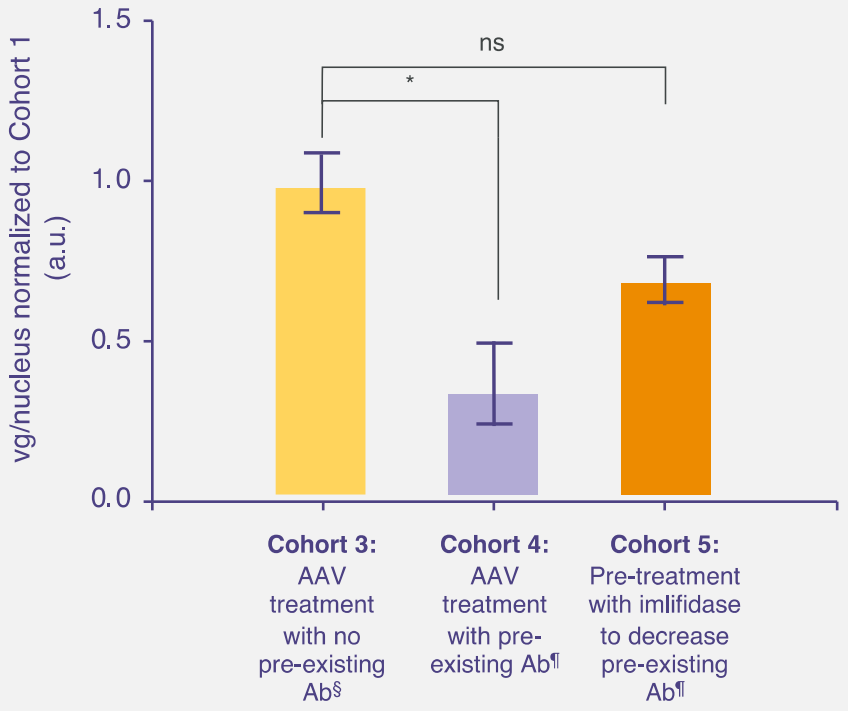
2.Narayanaswami, P. *et al.* Evidence-based guideline summary?: Diagnosis and treatment of limb-girdle and distal dystrophies. *Neurology* (2014).
3.Wicklund, M. P. Limb-Girdle Muscular Dystrophies. in *Encyclopedia of the Neurological Sciences* (2014). doi:10.1016/B978-0-12-385157-4.00623-0

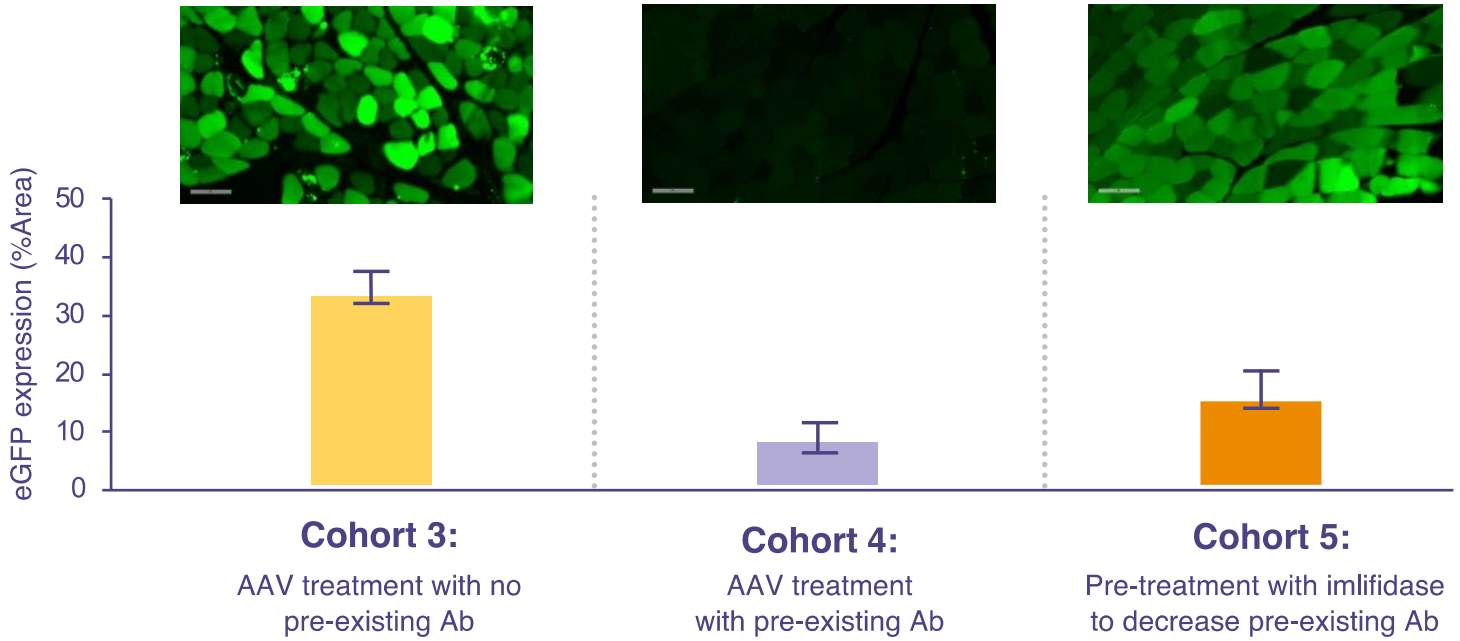
# Imlifidase pre-treatment decreases pre-existing antibodies and enhances transduction and transgene expression in animal models

## TRANSDUCTION




## EXPRESSION IN SKELETAL MUSCLE+

### Expression in Skeletal Muscle‡




*Data from animal models*

*P<0.05. †Data are represented as mean ± SEM and analyzed by one-way ANOVA followed by post-hoc analysis with Dunnett's multiple comparison test . ‡Data are represented as the mean ± SEM for the percent area for all of the muscle tissues analyzed at terminal necropsy. §AAVrh74 titer ≤1:400. ¶AAVrh74 titer 1:800–1:1600.

AAV, adeno-associated virus; AAVrh74, adeno-associated virus rhesus isolate serotype 74; Ab, antibody; a.u., arbitrary units; eGFP, enhanced green fluorescent protein; NHP, non-human primate; ns, not significant; vg, viral genome.

# 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

Burns T, Fernandez R, Stephens M. The experiences of adults who are on dialysis and waiting for a renal transplant from a deceased donor: a systematic review. JBI Database System Rev Implement Rep. 2015 Mar 12;13(2):169-211. doi: 10.11124/jbisrir-2015-1973. PMID: 26447040.
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 February 2025,

# Kidney transplantation is viewed as optimal treatment for end stage renal disease (ESRD)

## End Stage Renal Disease (ESRD)

A serious condition that requires renal replacement therapy – either dialysis or kidney transplantation. Transplantation is viewed as optimal treatment for ESRD.

### Current Situation

Highly sensitized kidney transplant patients face extended transplant waiting list time. Dialysis patients may need up to 4 hours of treatment several times a week.

### Prevalence

ESRD impacts 2.5M people worldwide. 170K ppl are waiting for a transplant.10-15% are highly sensitized and unlikely to be transplanted.

### Desensitization Strategies

Desensitization strategies have been predicated on compatibility and current approaches have limitations (e.g., plasmapheresis, immunoglobulins). Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients.

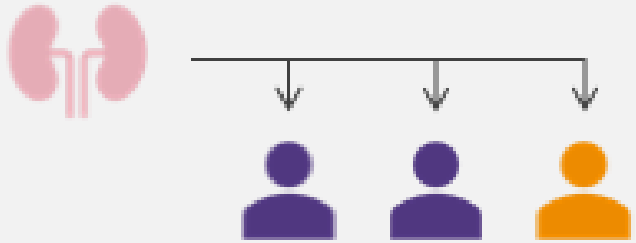
## Causes of Sensitization

Pregnancy

Blood transfusion

Previous transplantations

## Transplantation of highly sensitized patients has increased since the introduction of the US Kidney Allocation System however, thousands of patients are still unlikely to find a match



**Highly sensitized patients are less likely to find a matching organ from a deceased donor through KAS**

| Degree of sensitization | | cPRA% | Est. no. of organs to find match[2] | Estimated number of patients on waitlist (U.S)[3] |
|---|---|---|---|---|
| | Less or moderate | 0-20 | 1-2 | ~66,000 |
| | | 20-80 | 2-14 | ~16,000 |
| | Highly sensitized | 80-98 | 14-300 | ~5,000 |
| | | 98-99.9 | 300-3,000 | ~3,500 |
| | | >99.9 | 3,000-300,000 | ~2,500 |

[1] OPTN, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf
[2] p=95%, Clinical Journal of the American Society of Nephrology, 2016
[3] Company estimates, OPTN and Global Observatory on Donation and Transplantation


Jager KJ, et al. A single number for advocacy and communication—worldwide more than 850 million individuals have kidney diseases. Nephrol Dial Transplant. 2019;34(11):1803-1805
Bikbov B, et al. Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2020;395(10225):709-733.
Burns T, Fernandez R, Stephens M. The experiences of adults who are on dialysis and waiting for a renal transplant from a deceased donor: a systematic review. JBI Database System Rev Implement Rep. 2015 Mar 12;13(2):169-211. doi: 10.11124/jbisrir-2015-1973. PMID: 26447040.
51. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of 5. Health and Human Services, Health Resources and Services Administration; 2024. Accessed June 4, 2024.
Abecassis M, Bartlett ST, Collins AJ, Davis CL, Delmonico FL, Friedewald JJ, Hays R, Howard A, Jones E, Leichtman AB, Merion RM, Metzger RA, Pradel F, Schweitzer EJ, Velez RL, Gaston RS. Kidney transplantation as primary therapy for end-stage renal disease: a National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQI™) conference. Clin J Am Soc Nephrol. 2008 Mar;3(2):471-80. doi: 10.2215/CJN.05021107. Epub 2008 Feb 6. PMID: 18256371; PMCID: PMC2390948.

# Solid commercial opportunity in kidney transplantation desensitization

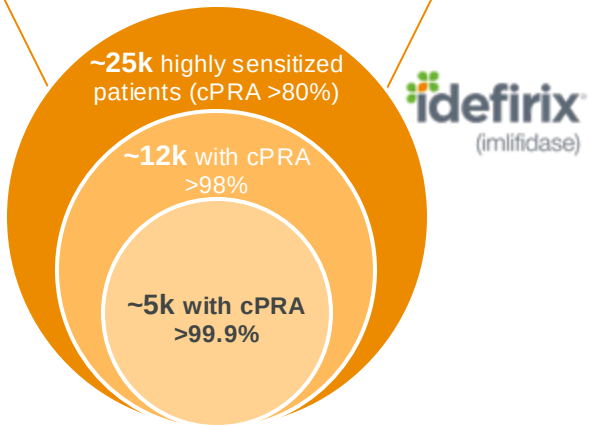
## Significant Unmet Medical Need

**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**

# US Phase 3 pivotal ConfIdeS trial data expected in 2H 2025

## STUDY OVERVIEW

Open-label, controlled, randomized trial evaluating 12-month kidney function in highly sensitized kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care.

## PRESCREENING

- Organ offer received via virtual crossmatch
- Key inclusion criteria: positive crossmatch against deceased donor

## 12-MONTH POST TRANSPLANT FOLLOW UP

All patients will receive:

- Induction therapy
- Maintenance immunosuppression

At 12-months:

- All patients will undergo a kidney biopsy

## PRIMARY ENDPOINT

- Estimated glomerular filtration rate (eGFR)

## SECONDARY ENDPOINT

- Graft and patient survival parameters
- Antibody mediated rejection parameters
- Anti-drug antibody measures
- Imlifidase PK

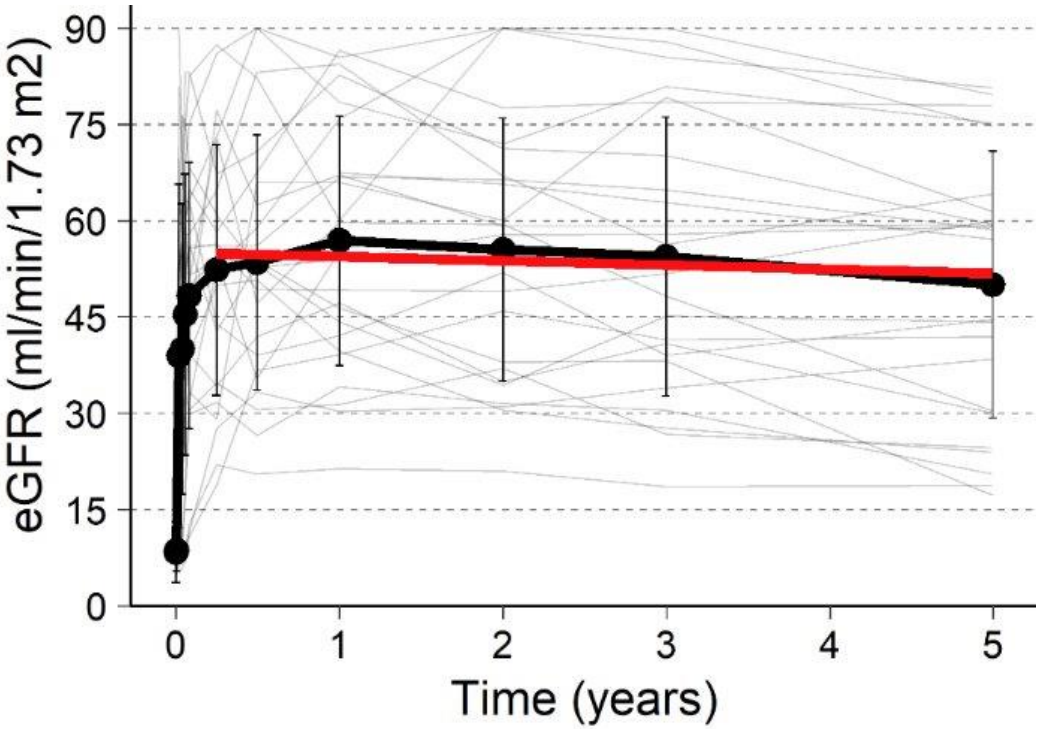
## CURRENT STATUS

- Randomization completed (May 2024)
- Topline data expected 2H 2025

# Long-term follow-up study showed durable graft and patient survival

## Study Overview

Extended pooled analysis from the 17-HMedIdeS-14 study
A long-term follow-up study of patients who have received a kidney transplant following desensitization with imlifidase.




### KEY TAKEAWAYS

- 82% five-year graft survival
- 90% patient survival
- 50 ml/min/$m^2$ eGFR
- Presented at AST (June 2024)
- ESOT: recommended imlifidase as a desensitization strategy for kidney transplant
- Kidney International Reports/AST: Real World Evidence Study (June 2024)

EGFR estimated glomerular filtration rate is a measure of how well kidneys are functioning

# 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**

# FINANCING AND LEADERSHIP

## Leadership team

**Søren Tulstrup**
President & CEO

VIFOR PHARMA · Shire · santaris pharma

**Evan Ballantyne**
SVP & CFO

GAIN THERAPEUTICS · OncXerna THERAPEUTICS · Orchestra

**Hitto Kaufmann, PhD**
SVP and Chief R&D Officer

pieris · Boehringer Ingelheim · sanofi

**Anne Säfström**
SVP & CHRO

ESS EUROPEAN SPALLATION SOURCE · CELLAVISION

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| Florian Reinaud | Director |

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


**Thank you**

IR@hansabiopharma.com