Insights on clinical practice and ConfIdeS Phase 3 Results

Call with distinguished transplant surgeons

November 12 2025

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12 November 2025

Introduction		**Renée Aguiar-Lucander** **CEO**
ConfIdeS Topline data		Dr. Richard Philipson Chief Medical Officer
Insights on clinical practice		Prof. Robert Montgomery Prof. Matthew Cooper Dr. Richard Philipson
Q&A		Prof. Robert Montgomery Prof. Matthew Cooper
Close		Renée Aguiar-Lucander CEO

Novel, first-in-class IgG-cleaving enzyme from proprietary technology platform

What is IgG

- Immunoglobulin G (IgG): a protective antibody
- Transplantation / Gene Therapy: High antibody (IgG) levels prevents delivery of therapy or procedure
- Autoimmune Disease: IgG becomes harmful and attacks the body's cells and tissues

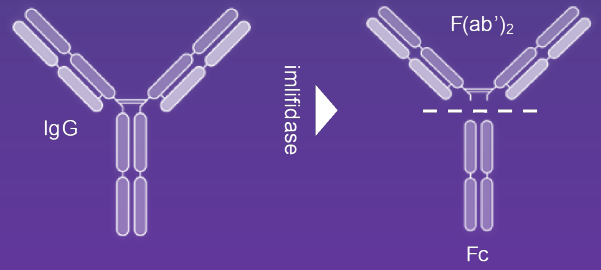
Benefits / Opportunity of IgG Reduction

- Rapid IgG reduction key to enable life saving treatments
- Targeted treatments to rapidly cleave antibodies and enable dosing of gene therapy for appropriate patients
- Potential for addressing acute / severe autoimmune diseases
- Orphan indications / no approved agents

Hansa's IgG-cleaving Platform

Imlifidase – proprietary, first in class IgG cleaving enzyme

- Rapid and targeted reduction of all IgG to > 95% in 2-6 hours
- Have run 8 clinical programs from preclinical to market
- US Phase 3 trial (Sep 25) with clinically relevant 12-month eGFR endpoint ($p < 0.0001$)

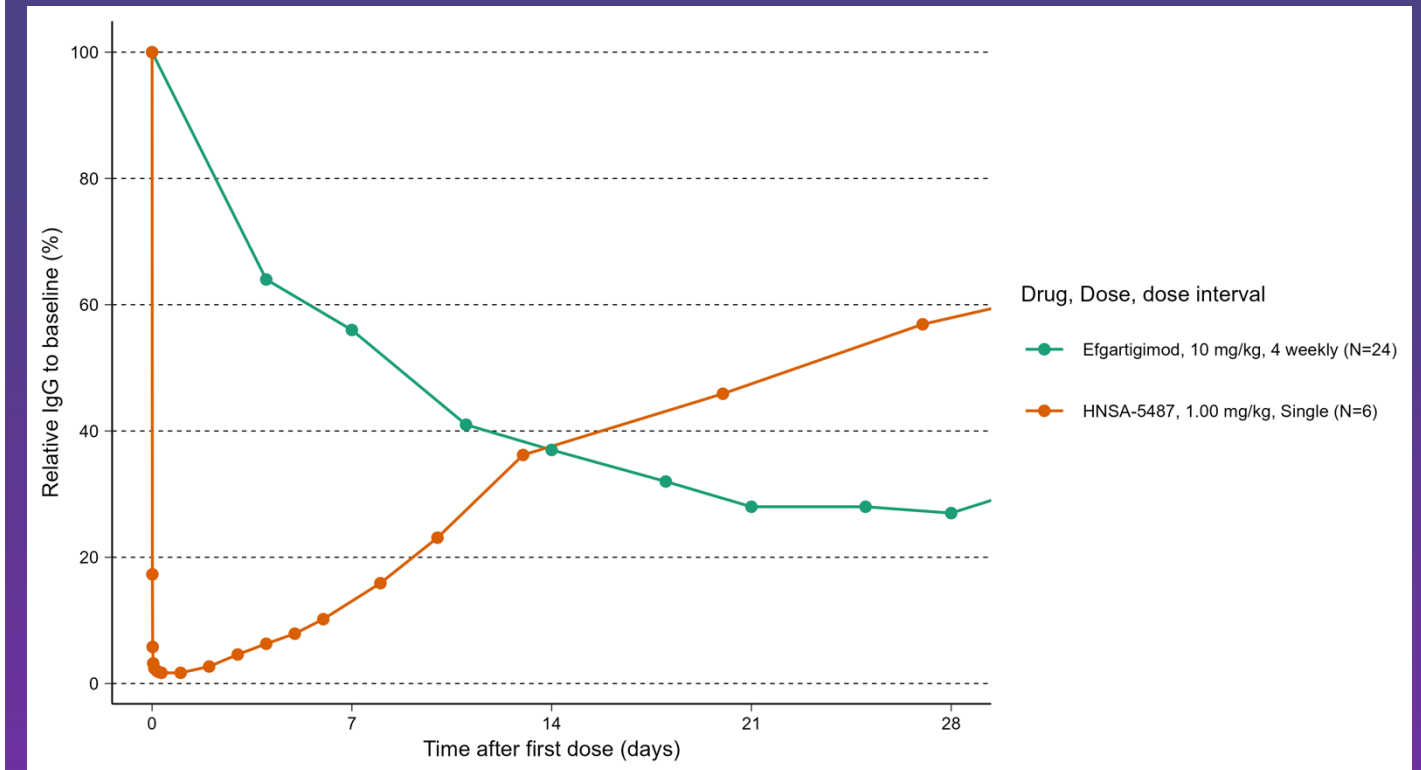


HNSA-5487 – next gen, IgG cleaving enzyme

- Targeting late-stage clinical program in GBS, a serious autoimmune disease with no approved drugs. Exploring redosing of gene therapies.
- FDA meeting in 1H 2026 to advance clinical development program

Platform is uniquely positioned to treat serious immune mediated diseases or challenges due to its rapid IgG reduction

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).

Addressing Serious Immune Mediated Conditions

THERAPEUTIC FOCUS

Desensitization

Enabling Transplantation
Paradigm shift for highly sensitized kidney transplant patients

Enabling Gene Therapy
Partnerships for pre-treatment to enable AAV gene therapy treatments

Rare autoimmune disease

Anti-GBM
Phase 3 readout in Q4 2025

GBS
Following successful POC Phase 2 trial; plan FDA interaction in 1H26 for clinical development program

21+
Countries with reimbursement

11
Clinical & preclinical programs

+30
Nationalities represented in our workforce

idefirix® (imlifidase)

IDEFIRIX® conditionally approved in the EU
For desensitization prior to kidney transplantation

Revenue generating
IDEFIRIX® YTD 9m 2025 sales of ~SEK 144m

Positive US Phase 3 trial (p<0.0001)
Supporting a planned BLA submission end of Q4 2025

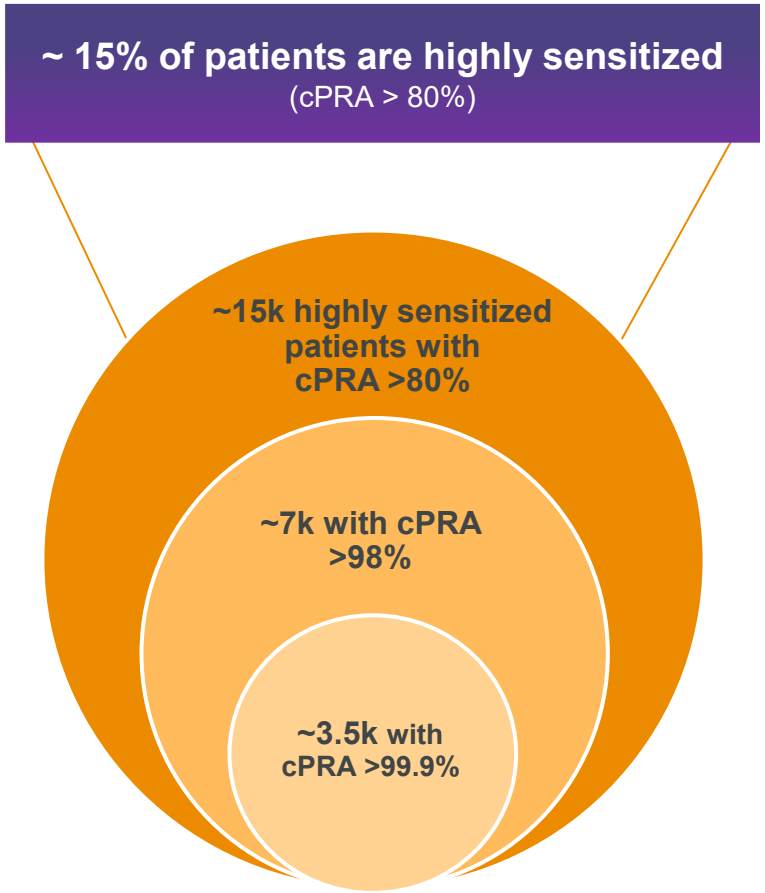
Diversified market segments
Desensitization for kidney transplants, enable AAV gene therapy and to treat IgG-mediated monophasic autoimmune diseases

Listed on Nasdaq OMX Stockholm (HNSA)
US$71m capital raised on October 1, 2025

Thousands of highly sensitized U.S. patients face indefinite dialysis

Significant Unmet Medical Need

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



US Transplant Waitlist

The US represents a significant market opportunity

~100,000
on the wait list

~45,000
new additions to the wait list each year with highly sensitized representing 20%

~10,000
die or become too sick to transplant, with highly sensitized representing 25%

up to 7 years
median time on waitlist for highly sensitized patients

~27,000
transplants each year with diseased donor representing 80%

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

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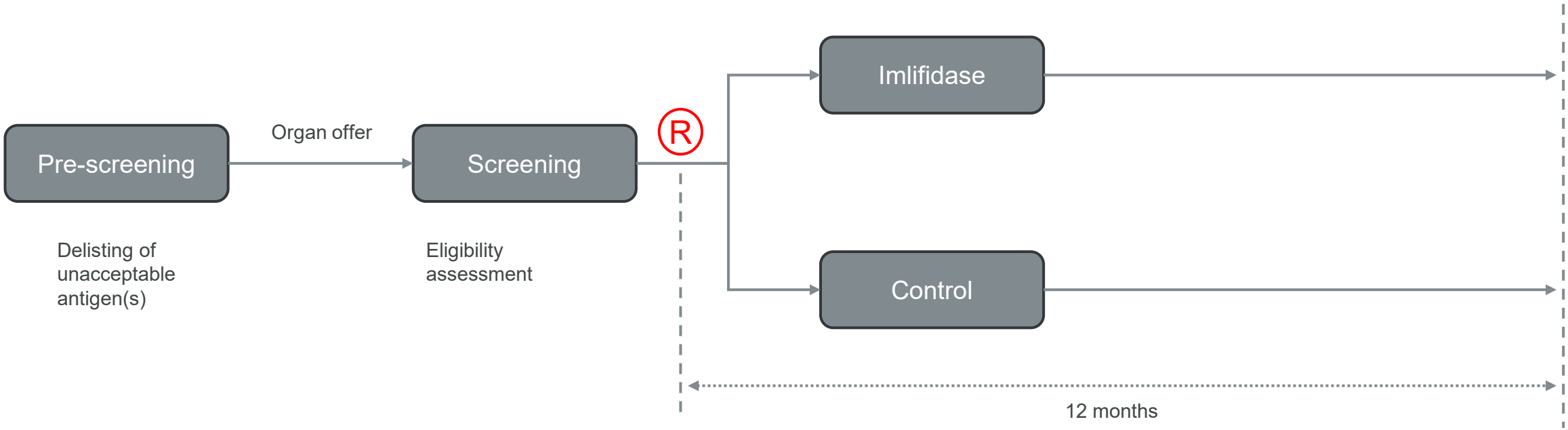
ConfIdeS

An open-label, controlled, randomized Phase 3 trial evaluating 12-month kidney function in highly sensitized (cPRA>99.9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care

Renal function in highly sensitized patients 12 months after desensitization with imlifidase and transplantation of kidneys from deceased donors

Study Design



Imlifidase arm: accept organ offer; if treatment results in xm-conversion from positive to negative, then proceed to transplant

Control arm: EITHER accept organ offer, use non-approved desensitisation* and proceed to transplant, OR reject organ offer and wait for more compatible organ offer(s) later in the 12-month follow-up period

* institution-specific desensitisation protocol may include any combination of PLEX, rituximab and other anti-CD20 antibodies, IVIg and eculizumab

Disposition and Demographics

Disposition n (%)	Imlifidase (N=32)	Control (N=32)	Total (N=64)
Randomized	**32 (100)**	**32 (100)**	**64 (100)**
Treated with imlifidase	**30 (93.8)**	**0 (0)**	**30 (46.9)**
Completed study	**30 (93.8)**	**28 (87.5)**	**58 (90.6)**
Sex, n (%)			
Female	18 (56.3)	15 (46.9)	33 (51.6)
Male	14 (43.8)	17 (53.1)	31 (48.4)
Age, (years)			
Mean (SD)	45.8 (12.3)	44.7 (12.5)	45.3 (12.3)

Efficacy Outcomes

	Imlifidase n	Control n	Imlifidase eGFR (mean)	Control eGFR (mean)	p-value
Primary endpoint eGFR at 12 months in FAS	32	32	51.5	19.3	<0.0001
Rank-based non-parametric analysis of eGFR at 12 months	32	32	50.0*	0*	0.0001
eGFR at 12 months in patients transplanted based on organ offer at randomization	27	3	59.3	23.1	0.0138

*Median

- At 12 months, mean eGFR was 51.5 mL/min/1.73m^2 in the imlifidase arm vs 19.3 mL/min/1.73m^2 in the control arm with a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m^2 **(p<0.0001)**
- A key secondary endpoint of dialysis dependency at 12 months was statistically significant **(p=0.0007)** in favor of imlifidase

Safety Outcomes in Imlifidase-Treated Patients

- **Tolerability of imlifidase was good**
  - There was a low incidence of infusion reactions, and no infusions were interrupted due to an infusion reaction
- **Infections observed in imlifidase-treated patients were typically not related to treatment**
- **The AE and SAE profile of imlifidase reflected a population of patients undergoing kidney transplantation**
  - Most SAEs were considered unrelated to imlifidase treatment

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