



20-HMedIdeS-19 Topline Results Post Authorization Efficacy Study (PAES)

27th May 2026

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PAES Topline Results: Agenda

27th of May, 2026



Introduction



Renée Aguiar-Lucander

CEO

PAES

Topline Results

Richard Philipson

Chief Medical Officer

Close and Q&A

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

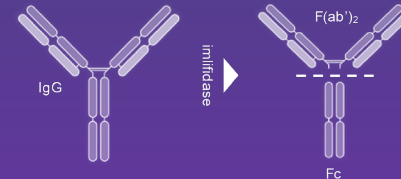
Benefits / Opportunity of IgG Reduction

- 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 11 clinical programs from preclinical to market
- Cleaves all types of IgG both intra and extra vascularily

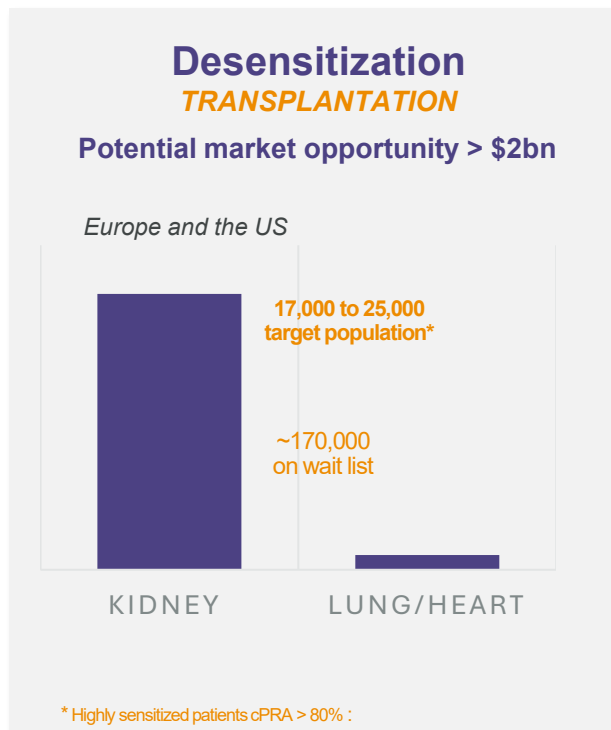


HNSA-5487 – next gen, IgG cleaving enzyme

- Targeting late-stage clinical program in GBS, a serious autoimmune disease with no approved drugs.
- FDA interactions in Q2 2026 to advance clinical development program

Transplantation: High Unmet Need with Significant Market Potential

- Imlifidase represents a pioneering breakthrough for highly sensitized patients
- Commercially available in Europe – conditional approval of Idefixir
- PDUFA date Dec 2026, no approved therapies in the US
- Highly sensitized patients stay on the wait list for a long time and may never find a matching organ
- Organ availability & allocation rules, guidelines, clinical data and physician experience key factors for adoption



- Around 10% of the waitlist is removed annually due to death / too compromised to sustain a transplantation with 25% of those patients being highly sensitized
- Need for a consistent, predictable and efficacious procedure to address this unmet need
- Significant number of new patients being referred to the waitlist on annual basis – list remains stable or grows year over year

Kidney Transplant

EU source Global Observatory on donation and transplant, 2023 report, <https://www.transplant-observatory.org/wp-content/uploads/2025/02/2023-data-global-report-20022025.pdf> US-Organ data on Procurement and Transplantation Network (OPTN) as of March 30 2025

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 Peritransplant 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 0190-9859; <https://doi.org/10.1016/j.humimm.2005.01.025>
Witt CA, Gaud 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.
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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

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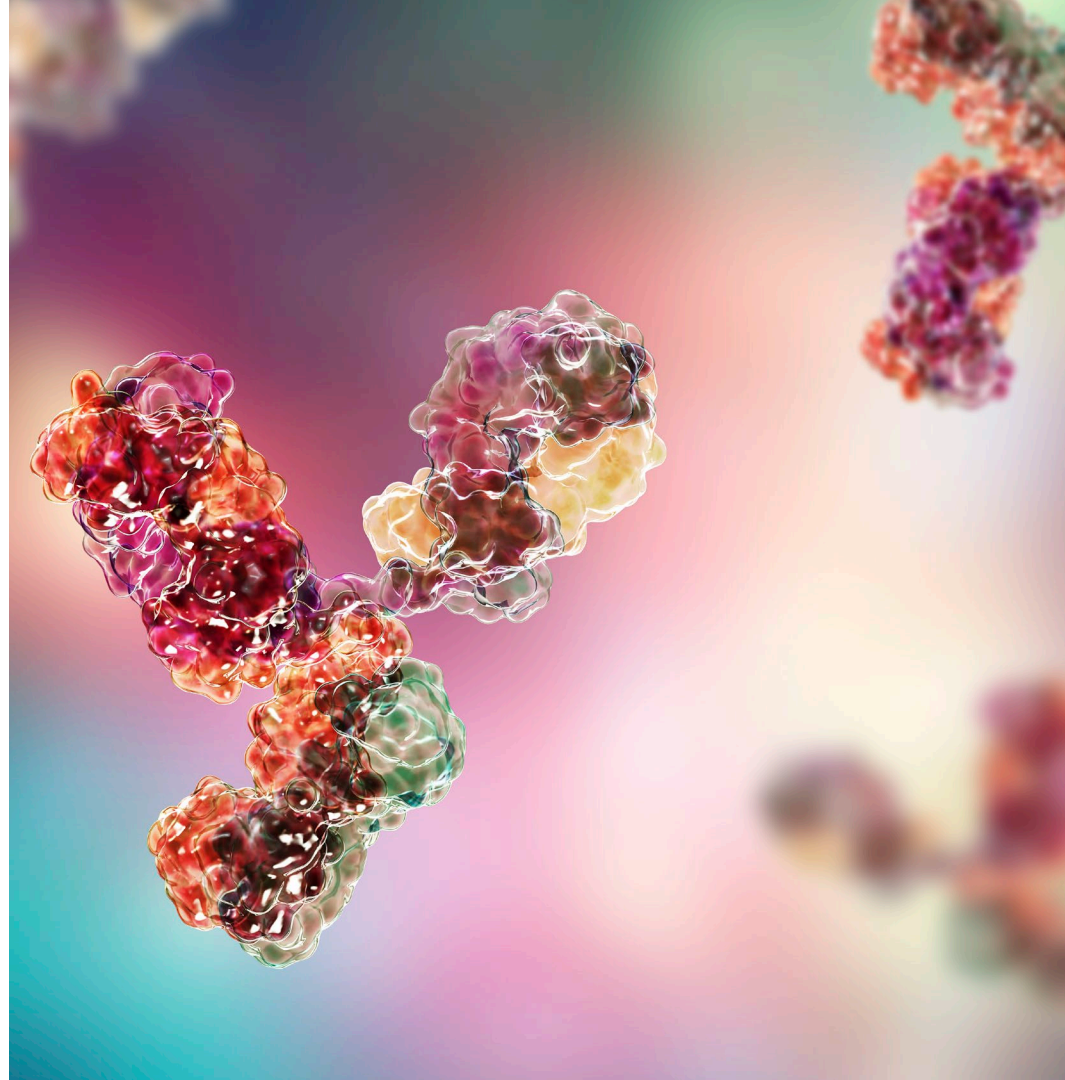
Renée Aguiar-Lucander

CEO



Study 20-HMedIdeS-19 (PAES)

A controlled, open-label post-authorisation efficacy and safety study in imlifidase desensitised kidney transplant patients with positive crossmatch against a deceased donor prior to imlifidase treatment, including non-comparative registry and concurrent reference cohorts



Primary

To determine the 1-year graft failure-free survival in highly sensitised kidney transplant patients, pre-treated with imlifidase to turn a positive crossmatch against a deceased donor into a negative crossmatch

Secondary

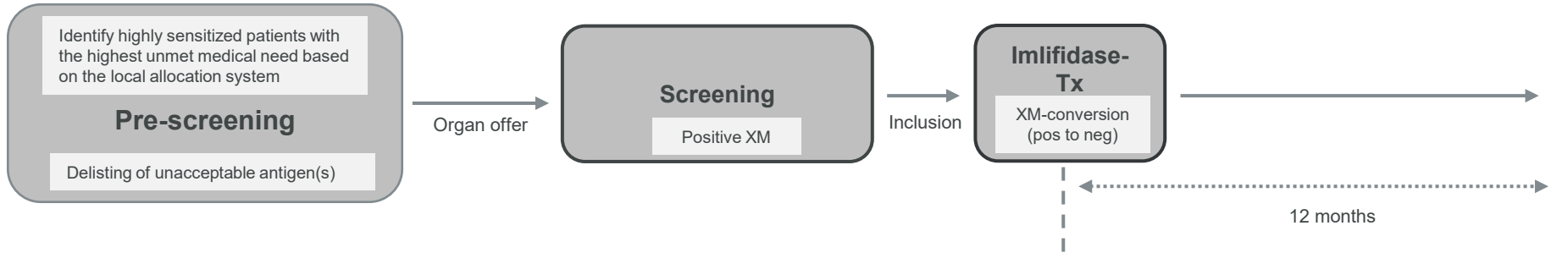
To evaluate, up to 1 year after transplantation:

- Renal function
- Patient survival
- Graft survival

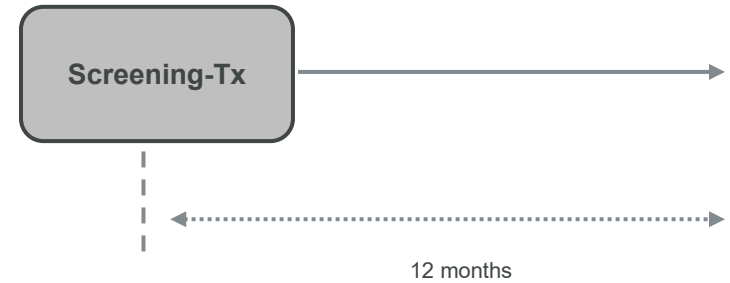
Safety

Study Design

Imlifidase treatment group



Non-comparative concurrent reference group



Non-comparative historical reference group

Eligibility

Imlifidase cohort	Non-comparative concurrent reference cohort	Non-comparative historical reference cohort
Male or female patient aged 18-75 years with ABO-compatible deceased donor aged 10-70 years	Male or female patient aged 18-75 years with ABO-compatible deceased donor aged 10-70 years	Male or female patient aged 18-75 years with ABO-compatible deceased donor aged 10-70 years
Highly sensitised (cPRA or equivalent $\geq 95\%$)	Not sensitised	Sensitised (cPRA or equivalent $\geq 50\%$)
Crossmatch positive to donor organ offer	Crossmatch negative to donor organ offer	Crossmatch negative to donor organ offer
		Transplanted in Europe in the period 2010 to 2017

Disposition, demographics and exposure

Disposition

	Imlifidase	Concurrent reference
Accepted organ offer	51	63
Dosed, n (%)	51	N/A
Transplanted, n (%)	50	63
Analysis sets, n (%)		
Safety	51 (100)	61
Intention to treat (ITT)	48 (94.1)	61
Completed trial, n (%)	48 (94.1)	55 (90.2)

Demographics

	Imlifidase (N=48)	Concurrent reference (N=61)
Age, years (mean)	49.8	55.4
Male, n (%)	29 (60.4)	37 (60.7)
Race, n (%)		
White	37 (77.1)	51 (83.6)
Black	6 (12.5)	5 (8.2)
Asian	1 (2.1)	2 (3.3)
Other	1 (2.1)	1 (1.6)
Not reported	3 (6.3)	2 (3.3)
BMI (mean)	24.5	26.7

Baseline characteristics

	Imlifidase (N=48)	Concurrent reference (N=61)
Currently on dialysis, n (%)	48 (100)	54 (88.5)
Duration of dialysis, years (mean)	8.5	2.3
Dialysis modality, n (%)		
Peritoneal	4 (8.3)	12 (22.2)
Hemodialysis	44 (91.7)	42 (77.8)
Number of previous transplants		
0	6 (12.5)	55 (90.2)
1	25 (52.1)	6 (9.8)
2	13 (27.1)	0 (0.0)
3+	4 (8.3)	0 (0.0)

Exposure

	Imlifidase (N=48)
One dose, n (%)	44 (91.7)
Two doses, n (%)	4 (8.3)

Efficacy and Safety Outcomes

Graft failure-free survival

Imlifidase

	Imlifidase (N=48)
Events, n (%)	5 (10.4)
Kaplan-Meier survival estimate at 1 year (95% CI)	89.6 (76.8, 95.5)

Concurrent reference

	Concurrent reference (N=61)
Events, n (%)	5 (8.2)
Kaplan-Meier survival estimate at 1 year (95% CI)	91.7 (81.3, 96.5)

Imlifidase

	Imlifidase (N=48)
Events, n (%)	1 (2.1)
Kaplan-Meier survival estimate at 1 year (95% CI)	97.9 (86.1, 99.7)

Concurrent reference

	Concurrent reference (N=61)
Events, n (%)	2 (3.3)
Kaplan-Meier survival estimate at 1 year (95% CI)	96.7 (87.4, 99.2)

Imlifidase

	Imlifidase (N=48)
Events, n (%)	4 (8.3)
Kaplan-Meier survival estimate at 1 year (95% CI)	91.6 (79.2, 96.8)

Concurrent reference

	Concurrent reference (N=61)
Events, n (%)	3 (4.9)
Kaplan-Meier survival estimate at 1 year (95% CI)	95.0 (85.3, 98.4)

Imlifidase

	Imlifidase (N=48)
eGFR (mL/min/1.73 m ²) at 1 year, Mean	52.4
95% CI	(45.4, 59.4)

Concurrent reference

	Concurrent reference (N=61)
eGFR (mL/min/1.73 m ²) at 1 year, Mean	56.5
95% CI	(50.4, 62.5)

Safety

Imlifidase was generally well tolerated, with a safety profile consistent with previous clinical trial experience

There were no new safety findings

Conclusions

Conclusions

- >90% of patients completed the trial
- Demographics and baseline characteristics in keeping with a kidney transplant population
- Efficacy outcomes at 12 months in imlifidase-treated patients were excellent:
 - Graft failure-free survival = 89.6%
 - Patient survival = 97.9%
 - Graft survival = 91.6%
 - eGFR = 52.4 mL/min/1.73 m²
- Imlifidase was generally well tolerated, with a safety profile consistent with previous clinical trial experience; there were no new safety findings

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Summary

- Clinically meaningful outcome
- Consistent with previous results
- High unmet need
- Supports filing for conversion to full approval with EMA
- Filing planned for Q4 2026
- An exciting time for highly sensitized patients with limited or no options to receive an organ transplant

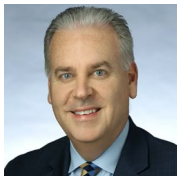
Hansa Biopharma Capital Markets Day

Thursday 25th of June, 2026 from 9:00 AM to 12:00 PM EDT

Location:

The St. Regis Hotel, New York, & Live Webcast

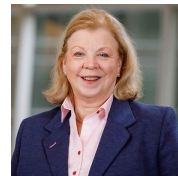
Featuring:



Matthew Cooper, MD



Nassim Kamar, MD, PhD



Roslyn Mannon, MD



Annette Jackson, PhD, F(ACHI)

- Discussions with KOLs on the medical need in the context of existing alternatives today for highly sensitized patients, as well as experiences from the Phase 3 study.
- Review of the results from the pivotal U.S. Phase 3 ConfldeS study presented at ATC on June 22, 2026, and the topline results from the European Post Authorisation Efficacy Study (PAES) with Idefirix in Europe.
- Company presentations on market opportunity, pre-launch and commercialization preparations ahead of a potential U.S. approval.
- Update on development program for the next generation enzyme HNSA-5487 in Guillain-Barré syndrome.

In-Person Sign-up and Webcast Access:

[Hansa Biopharma Capital Markets Day](#)

Q&A



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