



Carlsquare Life Science Investor Day

Virtual, December 6, 2023

Matt Shaulis

CCO and US President

Forward-looking statements

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The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

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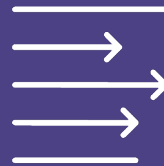
Hansa Biopharma today

A successful track record and a promising future...



A validated technology

- ✓ Commercial stage biotech company
- ✓ Approval in kidney transplantation (EU)
- ✓ Market Access in 13 European markets
- ✓ PoC in autoimmune diseases
- ✓ Three partnerships in gene therapy



Broad clinical pipeline

- Imlifidase is being investigated in seven ongoing clinical programs in transplantation and autoimmune disease
- Planned clinical study in gene therapy
- HNSA-5487: Encouraging data from phase I first-in-human trial



Skilled and experienced team

- A high-performance organization with 20 years on average in life science
- Purpose driven culture
- Headquartered in Lund, Sweden with 168 employees (September 2023)
- Operations in both EU and the US



Financial position

- Hansa is financed into 2025
- Market cap (USD): ~124m (Oct. 2023)
- Listed on Nasdaq Stockholm
- 21,000 shareholders
- Foreign ownership make up ~43%

Imlifidase

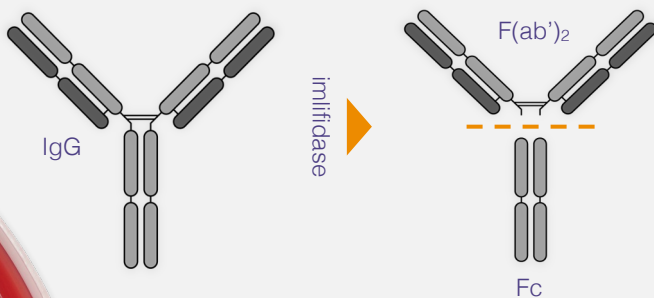
a novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

- Species of Gram-positive, spherical bacteria in the genus *Streptococcus*
- Usually known from causing a strep throat infection

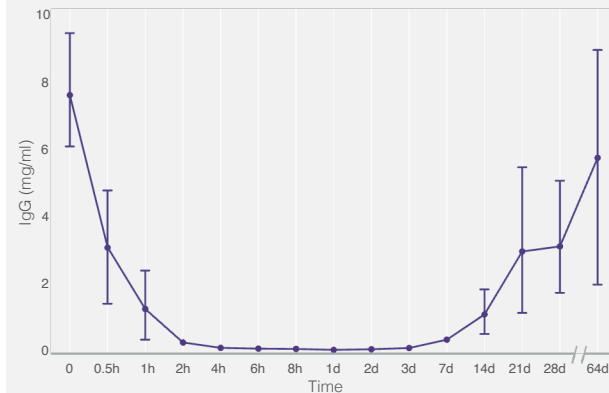
A unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one F(ab')₂ fragment and one homo-dimeric Fc-fragment



Inactivates IgG in 2-6 hours

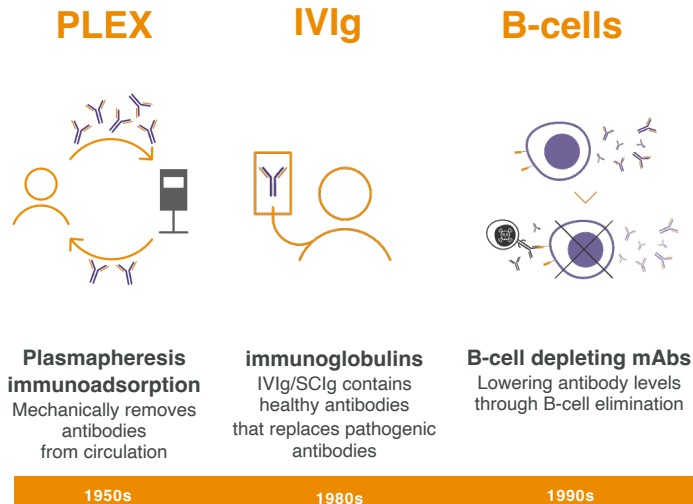
- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours
- IgG antibody-free window for approximately one week



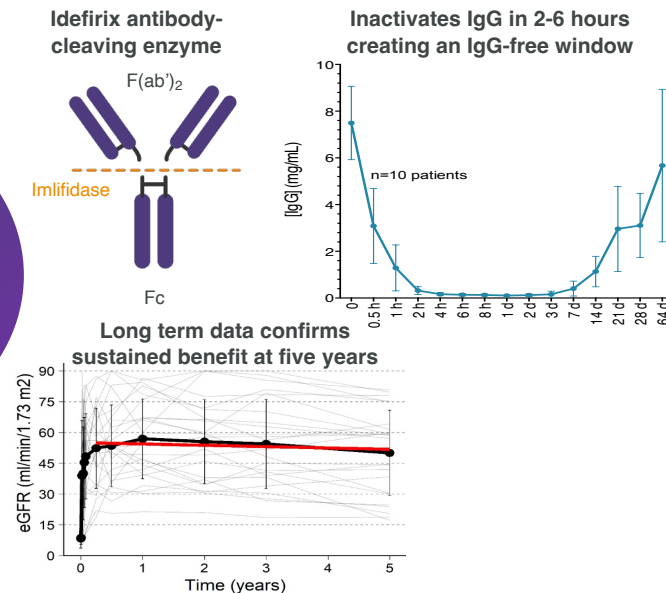
The long-term market uptake of Idefirix is highly dependent on successful early experiences in patients

For decades, medical practice (SoC) in transplantation has been predicated on compatibility as modalities came with certain limitations

Idefirix addresses the limitations of these other modalities and is the first and only approved drug to enable incompatible kidney transplants



..with Idefirix we are changing the entire ecosystem in transplantation



Idefirix® is the first and only approved drug in Europe for desensitization of highly sensitized kidney transplant patients

Between 80,000 and 100,000 kidney transplant patients are waiting for a new kidney in both Europe and the U.S. Availability of organs remain a big challenge since only 1 in 4 patients are offered access to a lifesaving transplantation, while many highly sensitized patients are unlikely to be transplanted even under current prioritization programs

Low complexity transplants

High complexity transplants

~70% of patients^{1,2}

Non or less sensitized
(cPRA < 20%)

15-20% of patients^{1,2}

Moderately sensitized
(20% < cPRA < 80%)

10-15% of patients^{1,2}

Highly sensitized
(cPRA > 80%)

Encouraging patient outcome in new markets following imlifidase-enabled kidney transplantations



MEDIZINISCHE
UNIVERSITÄT WIEN

51-year-old highly sensitized male patient, who had been on dialysis for four years was transplanted at the University Hospital Vienna following a graft loss 20 years after receiving a kidney from his father

[Link article in Medical University of Vienna News from August 8, 2023](#)



43-year-old highly sensitized female kidney transplant patient was transplanted at University Hospital of Padua after being on dialysis for almost 14 years and experiencing one graft loss

[Link article Veneto.it from December 14, 2022](#)

Addressable market (annually)

4,000-6,000

split across Europe and the US

Patients that are likely to be transplanted with a compatible donor

Patients unlikely to be transplanted under current prioritization programs

idefirix
imlifidase

¹ EDQM. (2020). International figures on donation and Transplantation 2019

² SRTM Database and individual assessments of allocation systems

The unique market position of Idefirix® requires consideration of both the sales- and the transplant cycle

Sales and transplant cycle adds complexity and time to patient treatment

Excellence revolves around four strategic themes



Market Access



Clinical readiness

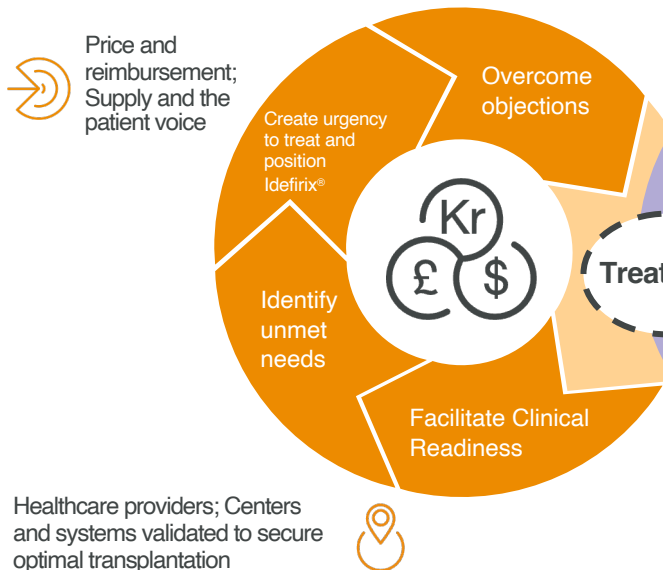


Patient selection and treatment

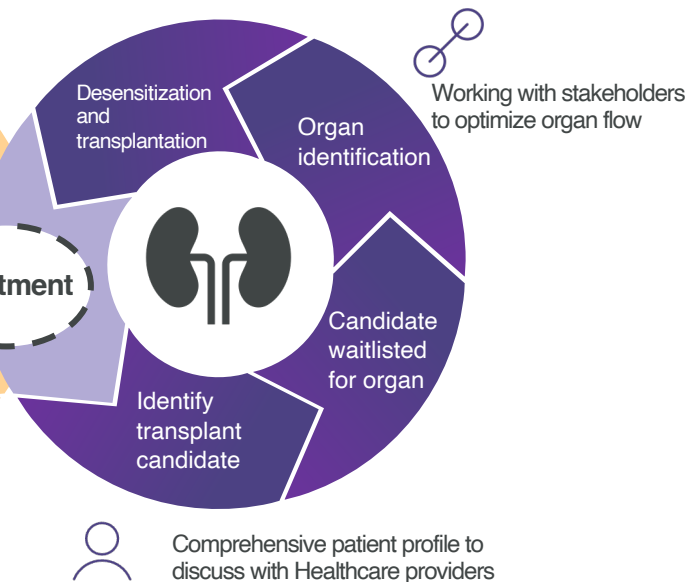


Organ allocation

Sales Cycle



Transplant Cycle



Scaling Idefix[®] globally as we transform the desensitization treatment landscape and advance a new way of transplanting patients

1 Build the foundation for Idefix[®]

Key activity matrix

- ✓ Commercialize in early-launch countries
- ✓ Secure Market Access in key markets
- ✓ Ensure clinical readiness/KOL engagement
- ✓ Implement medical guidelines (ESOT and country specific guidelines)
- ✓ Increase awareness on unmet need
- ✓ Initiate post approval study in Europe
- ✓ Support patient and organ access

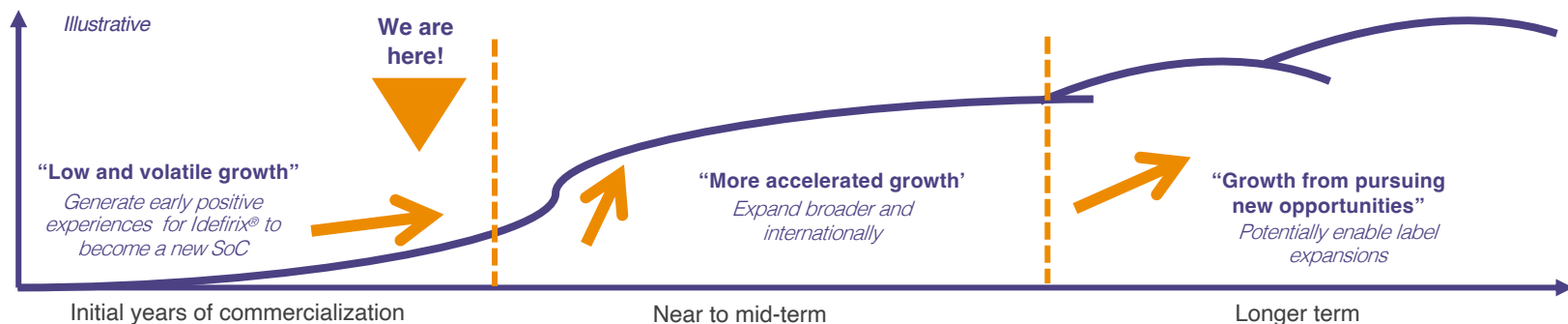
2 Expanding internationally

- Leverage experience to scale Idefix in Europe
- Secure FDA approval and launch in the U.S.
- Geographical expansion beyond core markets
- Full marketing authorization in Europe

3 Potential label expansion

- Potentially expand into living donor transplantation
- Potentially expand into other solid organs

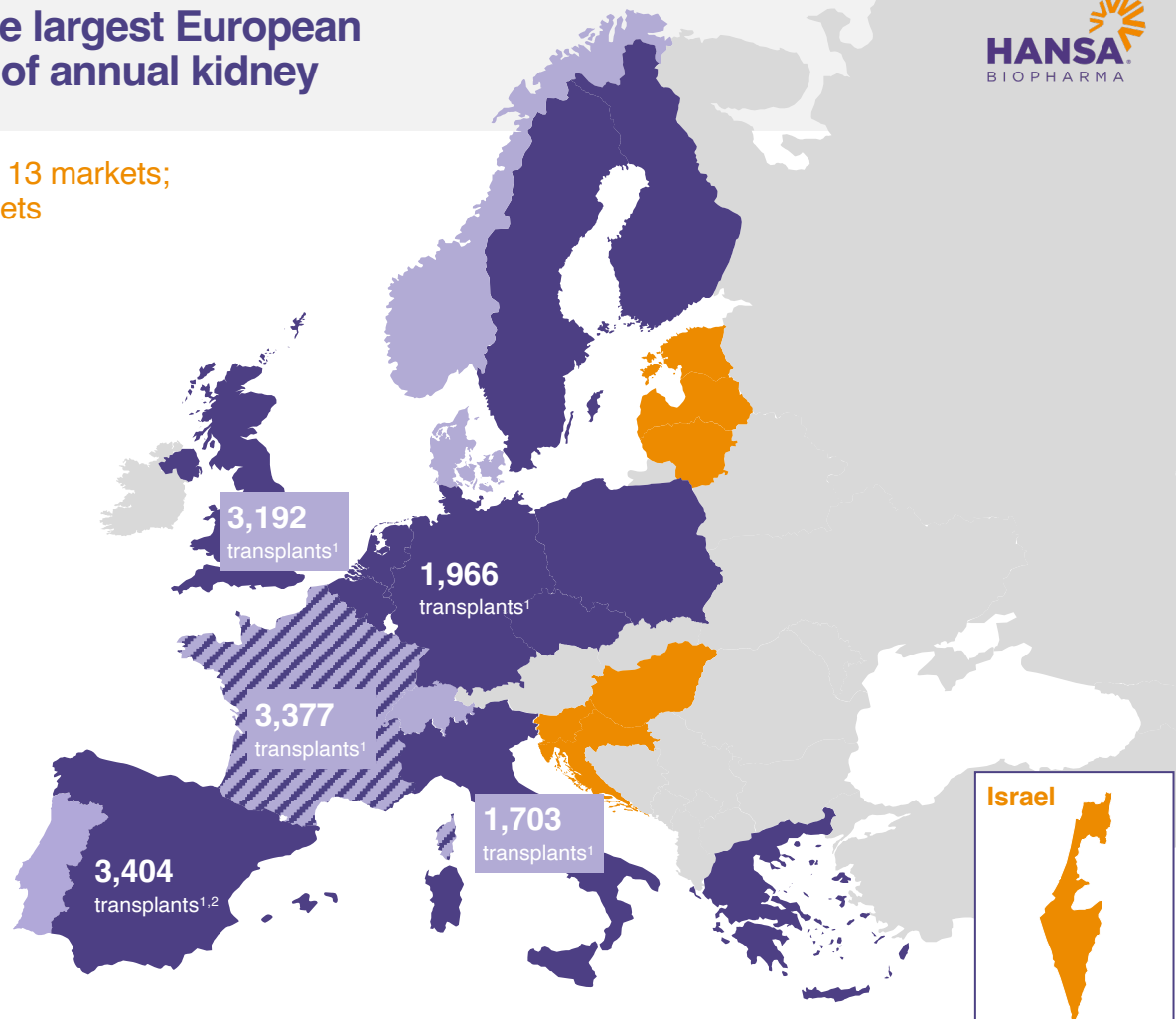
Commercial sales uptake



Market Access secured in the five largest European markets representing two thirds of annual kidney transplants

Positive reimbursement decisions received in 13 markets;
HTA processes ongoing in additional 10 markets

- Health Technology Assessments (HTA) dossiers submitted
- Reimbursed Early Access Program
- Pricing & reimbursement obtained (country or clinic level)
- Territories covered commercially by Medison Pharma



¹ Annual kidney transplantations 2022. Transplantation data is from Global Observatory on Donation and Transplantation, <https://www.transplantobservatory.org/> [Accessed 2023-07-10]

² A positive recommendation for pricing and reimbursement of Idefix® in Spain was published on February 6, 2023, https://www.sanidad.gob.es/profesionales/farmacologia/pdf/20230202_ACUERDOS_CIPM_230.pdf

Continued progress against key launch metrics; Major markets to support growth going forward

Market Development

5

-

Medical guidelines issued by ESOT

National level



Market Access

13

9

Market access secured in 13 key European markets incl. EU4+UK

Patient Identification

16

2

Post Approval Study
~1/3 into completion

Transplant Center Readiness & Use

~50

25

~50 clinics are Idefirix "ready" to treat patients

600+

ESOT Congress:
Hansa-sponsored symposium with participation from >600

10

8

Ongoing HTA processes in ten countries incl. Portugal and Switzerland

✓

Eurotransplant:
First patients selected for new desensitization program

20+

10

20+ centers have treated patients overall

Major markets to support growth going forward
France (repeat usage); Market expansion into new markets incl. U.K., Germany, Spain and Italy



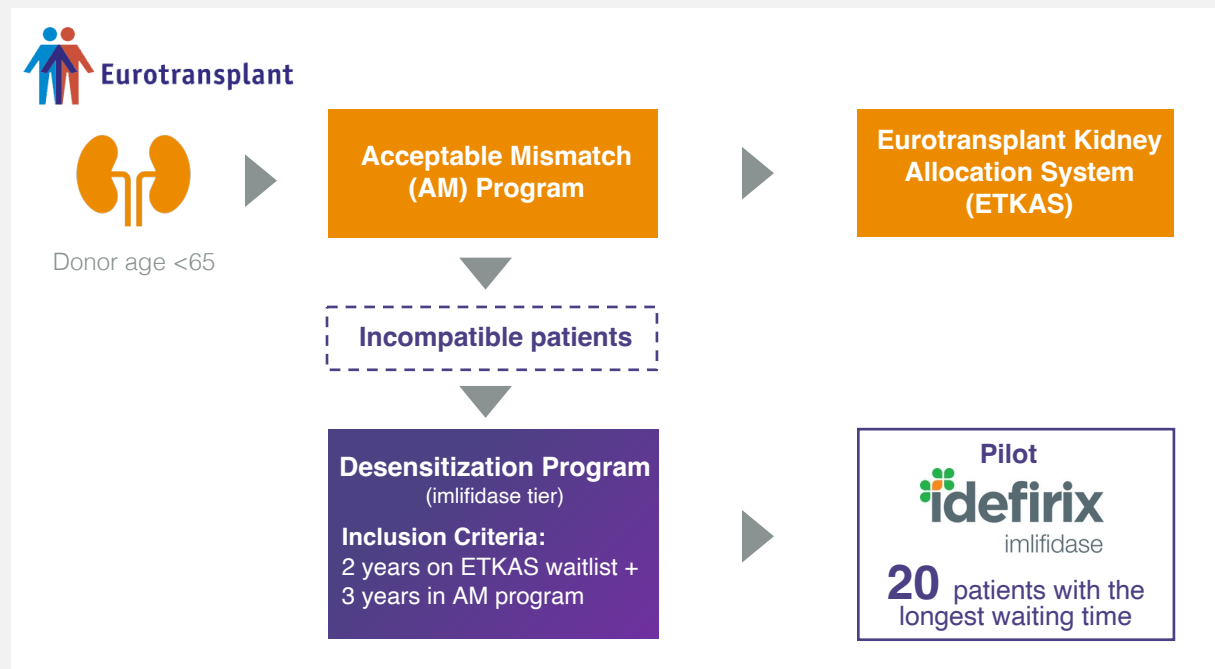
Oct 2023



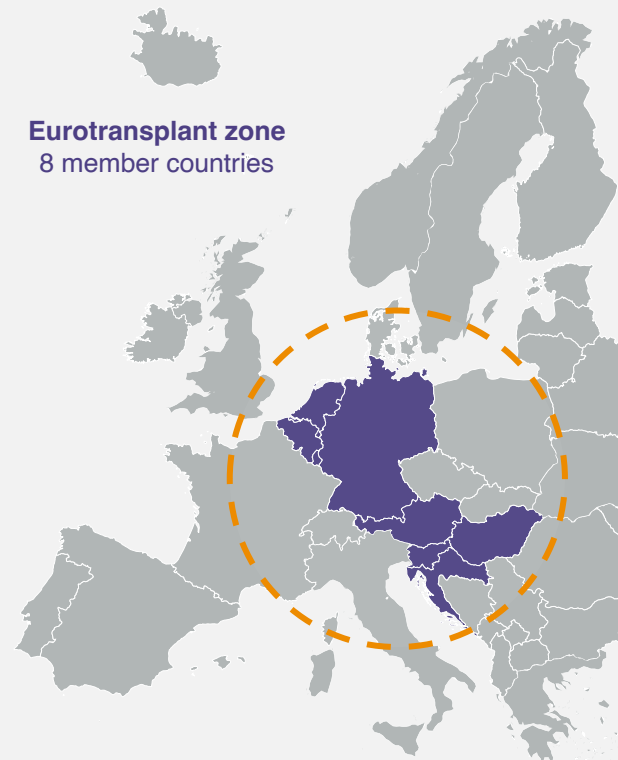
Oct 2022

Eurotransplant Desensitization Program set to transform desensitization across eight European membership countries

First patients selected for treatment through the Desensitization Program



Eurotransplant zone
8 member countries



Imlifidase may complement the US Kidney Allocation System, as thousands of patients are still unlikely to find a match

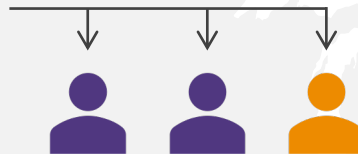
Factors impacting the KAS score¹

- Waiting time
- Age
- Transplantation history
- Sensitization (cPRA score)
- Distance and recipient
- Quality of donor kidney (KDPI)

KAS gives patients points with regards to levels of sensitization, increasing the likelihood of finding a match for sensitized patients

Transplantation of highly sensitized patients has increased since the introduction of KAS.

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
	Highly sensitized	20-80	2-14	~16,000
		80-98	14-300	~5,000
		98-99.9	300-3,000	~3,500
		>99.9	3,000-300,000	~2,500

KAS was revised in the U.S. in 2014 to increase equity of transplantation. However, thousands of highly sensitized patients are still not treated

idefix
(imlifidase)

If approved, Idefix® may address highly sensitized kidney transplant patients, who are incompatible to a deceased donor in the US Kidney Allocation System

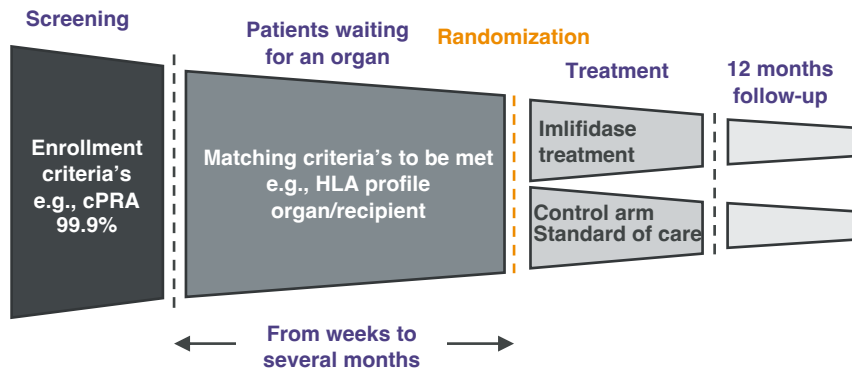
¹ OPTN, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

² p=95%, Clinical Journal of the American Society of Nephrology, 2016

³ Company estimates, OPTN and Global Observatory on Donation and Transplantation

~2,500 highly sensitized patients that have not been transplanted despite prioritization points on the waitlist

Increasing patient enrollment and number of active sites to complete randomization by mid-2024



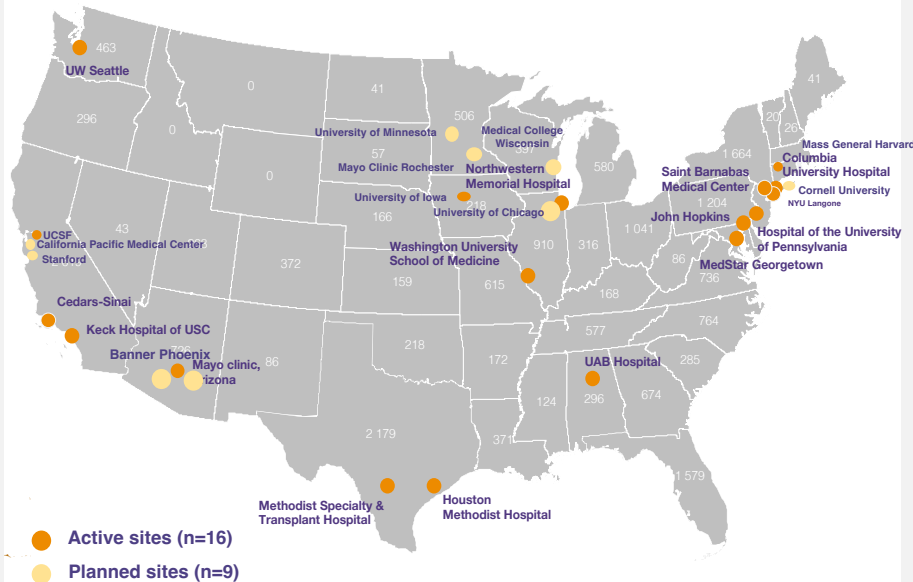
U.S. ConfideS

Phase 3

- Continue enrollment beyond 64 patients; Currently 87 patients screened and enrolled, and more than half of the targeted patients randomized
- Expansion of no sites from currently 16 to 25 to accelerate randomization
- Randomization expected to be completed Mid-2024 with BLA filing under the accelerated approval path in 2025

ConfideS phase 3 trial will further advance potential for imlifidase to address unmet need in desensitization

Involved ConfideS sites cover more than 20% of total transplantation volumes in the U.S.¹



Our unique antibody cleaving enzyme technology may have relevance across a range of indications

Targeting rare IgG mediated diseases



Auto-immune diseases

Anti-GBM disease paves the way for development in other autoimmune diseases

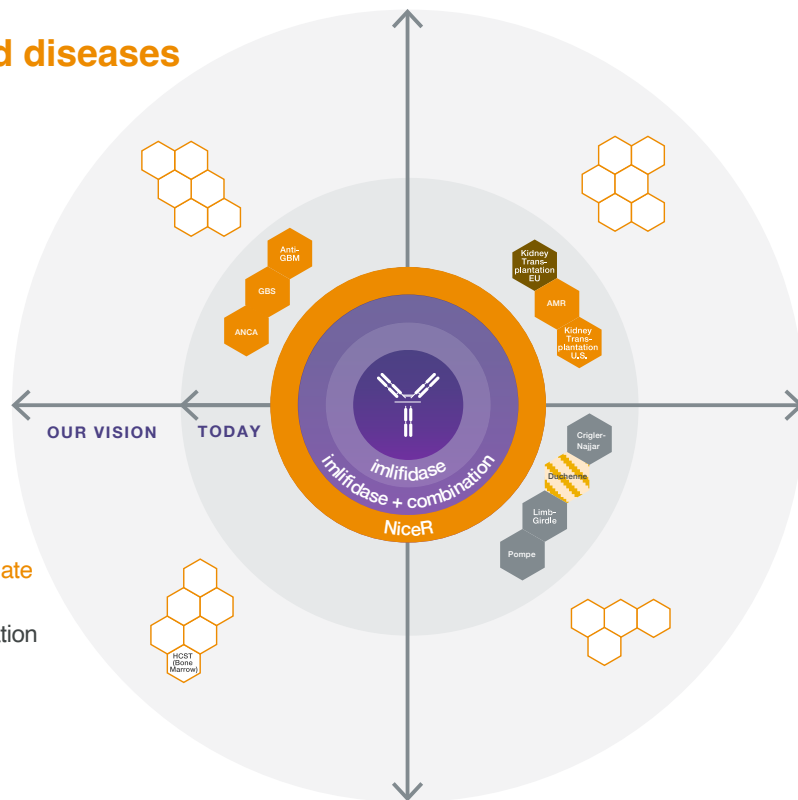
- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders



New therapies

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogeneic stem cell (bone marrow) transplantation (HSCT)



Transplantation

Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types



Gene therapy

Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta, AskBio, and Genethon
- Wide indication landscape beyond



Contact our Investor Relations and Corporate Affairs team

Contact



Klaus Sindahl

VP, Head of Investor Relations

Mobile: +46 (0) 709-298 269

Email: klaus.sindahl@hansabiopharma.com



Stephanie Kenney

VP, Global Corporate Affairs

Mobile: +1 (484) 319 2802

E-mail: stephanie.kenney@hansabiopharma.com

Calendar and events

Dec 6, 2023

Dec 11, 2023

Dec 14-16, 2023

Jan 8, 2024

Jan 8, 2024

Feb 6, 2024

Feb 2, 2024

Feb 28, 2024

March 4-6, 2024

March 10-12, 2024

Mar 20, 2024

April 8-11, 2024

April 16-17, 2024

Apr 17, 2024

July 17, 2024

Oct 23, 2024

Carlssquare Life Science Day, Stockholm/virtual

Redeye Investor lunch, Stockholm

H.C. Wainwright virtual road show

JPM week, San Francisco

H.C. Wainwright & Co. during JPM week 2024, San Francisco

Aktiespararna, Falkenberg

Full-year Report for January-December 2023

Ökonomisk Ugebrev Life Science Event, Copenhagen

TD Cowen Healthcare Conference, Boston

Carnegie Healthcare Seminar, Stockholm

Annual Report 2023

Needham Healthcare Conference (virtual)

Van Lanschot Kempen Life Science Conference, Amsterdam

Interim Report for January-March 2024

Half-year Report January-June 2024

Interim Report for January-September 2024