



HANSA

BIOPHARMA

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February 23, 2023, Stockholm

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Successful track record...
Strong momentum...
Promising future...

A validated technology

VALIDATION ACROSS THREE AREAS

- ✓ Approval in kidney transplantations
- ✓ Proof of concept in autoimmune diseases
- ✓ Partnerships to explore gene therapy

Idefirix® is our first approved drug in Europe*

EUROPE KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Broad pipeline in transplantation and autoimmunity

PROGRAMS IN CLINICAL DEVELOPMENT

US kidney transplants
Anti-GBM
Guillain-Barré syndrome (GBS)
Antibody mediated kidney transplant rejection (AMR)

Established a high-performance organization

NEW COMPETENCIES ADDED

150 employees Dec 31. 2022
(~3x in 3 years)

Highly qualified team with 20 years on average in life science

Purpose driven culture

With current cash position Hansa is financed into 2025

FINANCIALS

SEK ~1.5bn in Cash and short term investments (USD ~143m) Dec 31 2022

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~350m Feb 1, 2023

Listed on Nasdaq Stockholm
19,000 shareholders

Foreign ownership make up ~47% through leading international life science specialist funds



*Idefirix approved in EEA under conditional approval for kidney transplantation

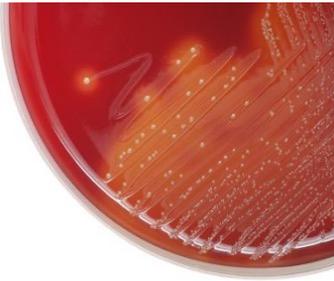
**Actual patient has given consent to provide images

Imlifidase

A novel approach to eliminate pathogenic IgG

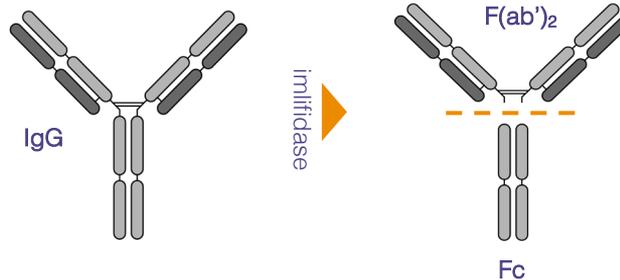
Origins from a bacteria *Streptococcus pyogenes*

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



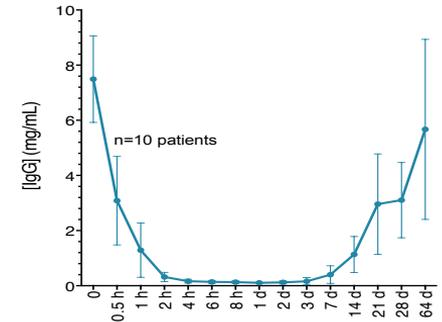
A unique IgG antibody-cleaving enzyme

- 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



Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone	
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}								EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients ^{1,2}								Completion of enrollment (64 patients) H1 2023
	Anti-GBM antibody disease ³								First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)								Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)								Completion of enrollment (30 patients) H1 '23
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)								Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)								Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)								Preclinical research
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology								Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
EnzE	Cancer immunotherapy								Research

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 Mårten Segelmark, Professor at the universities in Linköping and Lund

 Completed

 Planned

 Ongoing

 Post approval study running in parallel with commercial launch

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

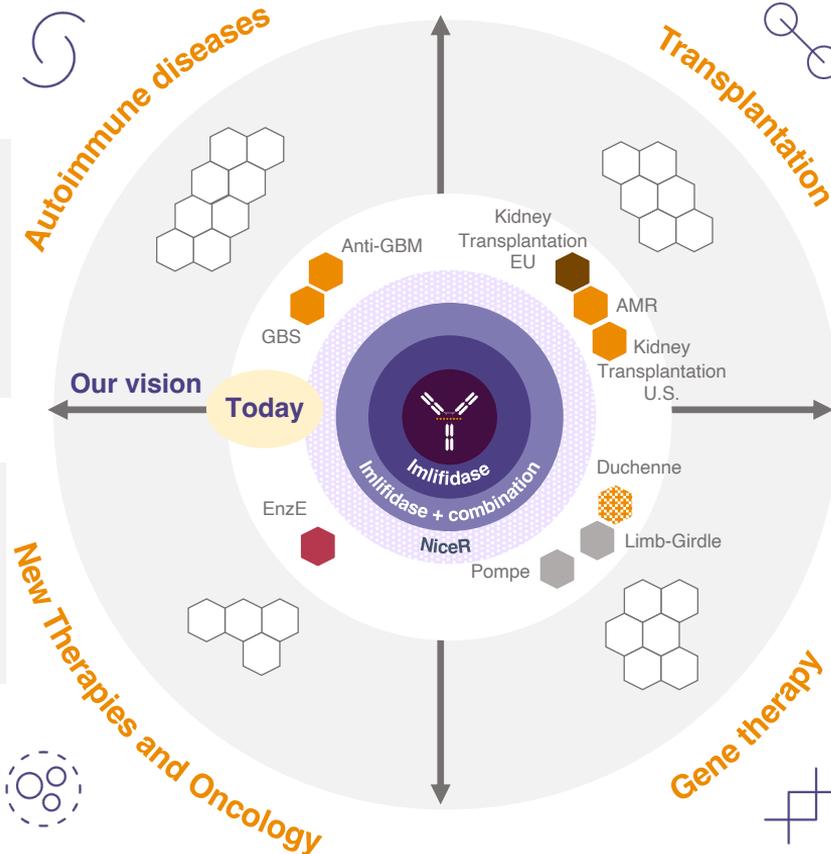
Targeting rare IgG mediated diseases

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

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

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic stem cell (bone marrow) transplantation (HSCT)
- Enzyme-based antibody Enhancement (EnzE)



Expanding our commercial franchises

- Regulatory approval (conditional)
- Clinical development
- Planned clinical trial
- Partnership (preclinical development)
- Preclinical development
- Potential indications (currently not pursued)

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

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

Exploring opportunities in gene therapy

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

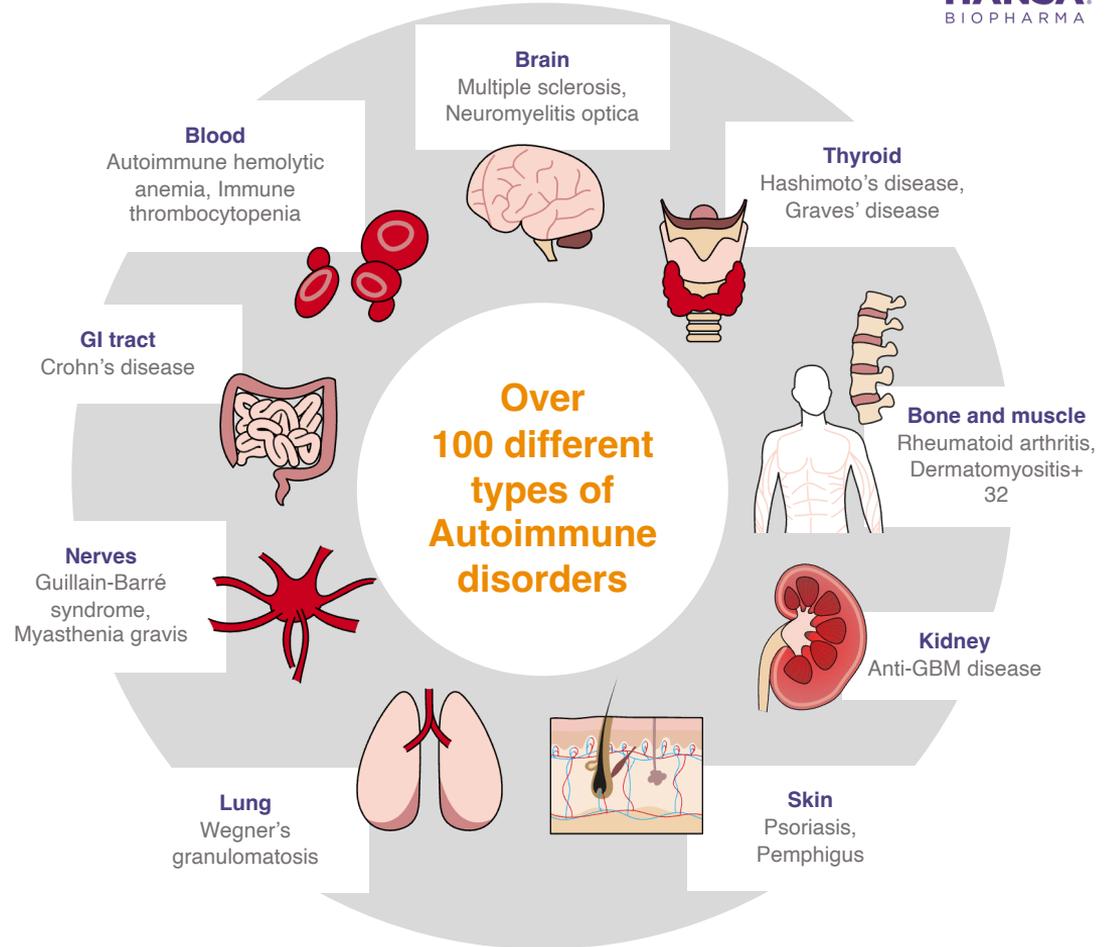
Autoimmune attacks

A result of when the body's immune system by mistake damages its own tissue

Autoimmune disease remains a big challenge and requires immediate treatment

What is an autoimmune disease?

- Immune-mediated destruction of autologous cells and/or tissues
- Interplay between predisposing genes and triggering environmental factors (e.g. bacteria or virus), leading to loss of self-tolerance
- 3-5%¹ of populations affected; more common in women (75%)²



¹ Wang et al., J. Intern. Med., 2015

² Desai et al., Front. Endocrinol., 2019

Hansa's antibody cleaving enzyme technology

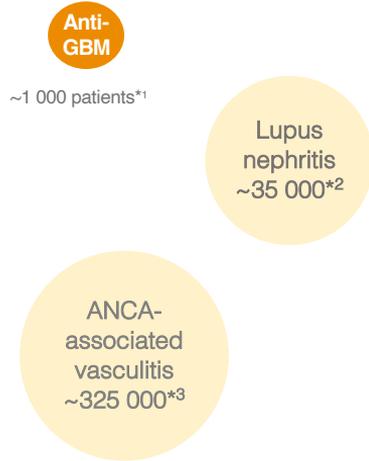
may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

- Clinical programs
- Potential autoimmune indications (currently not pursued)

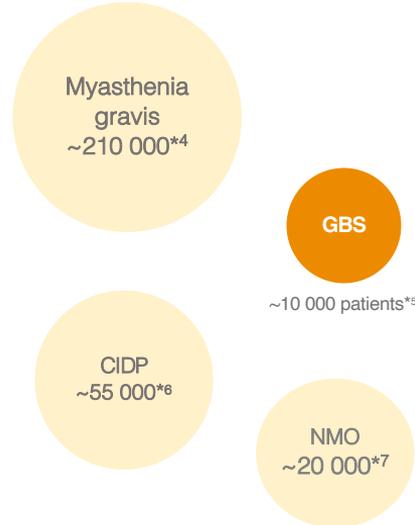


*Total disease populations in EU & US, based on prevalence and population data

Rapidly progressive glomerulonephritis



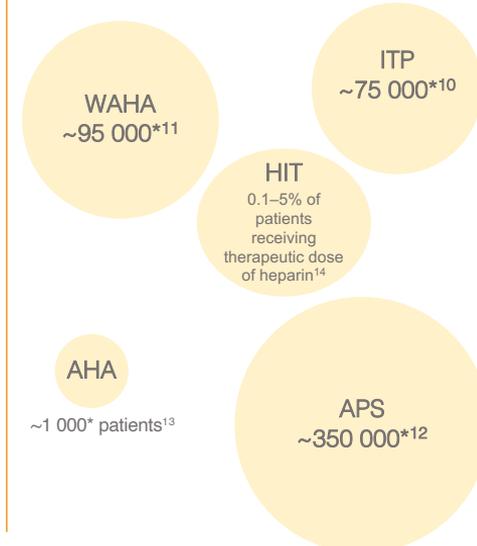
Neurological disorders



Skin disorders



Blood disorders



CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita
ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome
AHA: acquired hemophilia A
HIT: Heparin-induced thrombocytopenia

¹DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021.

²<https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]

³Patel, M et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK*. Arthritis & Rheumatism, 2006.

⁴Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. *The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study*. Arthritis Rheumatol. 2017;69.

⁵*Myasthenia Gravis*. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]

⁶*Guillain-Barré syndrome*. Orpha.net. https://www.orpha.net/consor/cgi-bin/OC_Exp.php?id=GB&Expert=2103 [accessed 2021-03-29]

⁷*Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health*. The American Journal of Managed Care. <https://www.ajmc.com/view/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health> [accessed 2021-03-29]

⁸Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica*. International Journal of MS Care. 2013 Fall: 113-118

⁹Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05

¹⁰Wentzell, S. et al. *Prevalence Estimates for Pemphigus in the United States*. JAMA Dermatol, May 2019: 627-629.

¹¹*Immune Thrombocytopenia*. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]

¹²*Warm Autoimmune Hemolytic Anemia*. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]

¹³Itvinova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.

¹⁴NORD. *Acquired Hemophilia* [accessed 2022-10-17], available at <https://rarediseases.org/rare-diseases/acquired-hemophilia/>

¹⁵Hogan M, Berger JS. *Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management*. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

Anti-GBM, a rare acute autoimmune disease

Incidences

1.6
in a million
affected annually^{1,2}

Today's Standard of Care

- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids

Inflammation in the glomeruli

Early symptoms are unspecific...
...But can lead to rapid destruction of the kidney and/or the lung

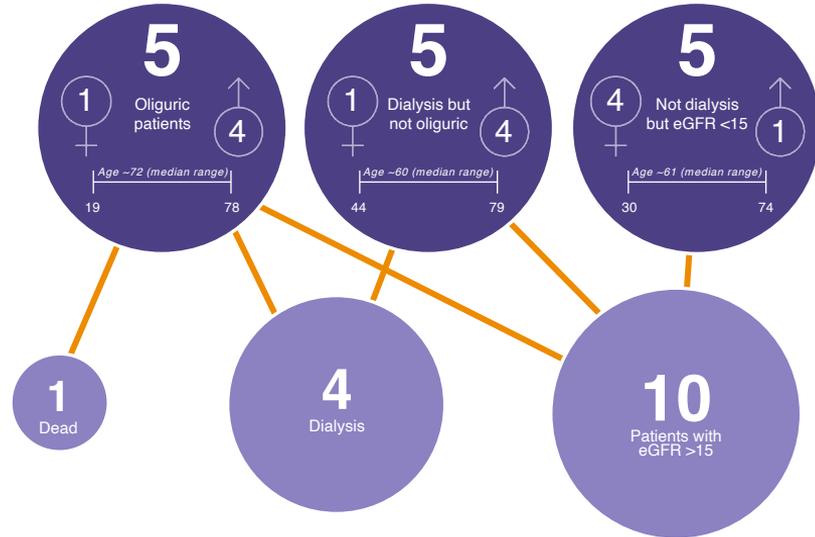


Data published in JASN



Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)³

- 10 out of 15 patients were dialysis independent after six months vs. the historical cohort⁴, where only 18% had functioning kidney



¹ Wang et al., J. Intern. Med., 2015

² Desai et al., Front. Endocrinol., 2019

³ Uhlin et al. JASN (2022)

⁴ 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

New pivotal phase 3 trial with imlifidase in 50 anti-GBM patients to evaluate kidney function after six months

STUDY DESIGN

- Open-label, controlled, randomised, multi-centre Phase 3 trial evaluating renal function in patients with severe anti-GBM disease imlifidase + SoC vs SoC

SUBJECTS

- 50 anti-GBM patients to be enrolled
- Patients will be followed for six months
- Recruitment at 30-40 clinics across US/UK/EU

DOSES/FOLLOW UP TIME

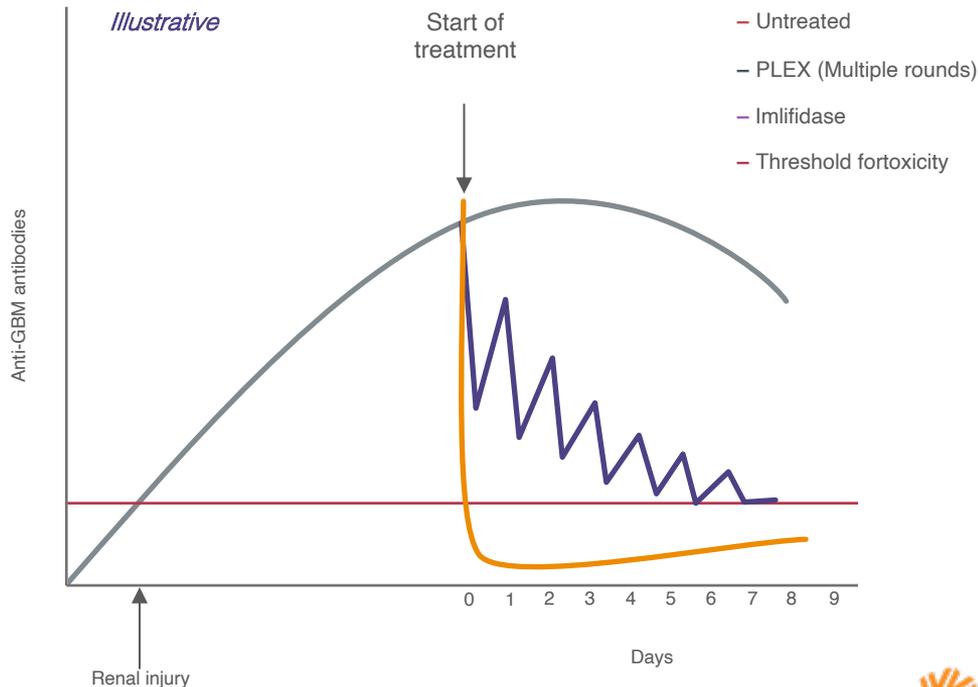
- Dosage 0.25mg/kg with 180 days follow up

MAIN OBJECTIVES

- Renal function is evaluated by estimated glomerular filtration rate (eGFR) at 6 months
- Dialysis need at 6 months

STATUS

- First clinics were activated December 2022
- First patient enrolled expected H1 2023



Guillain-Barré Syndrome (GBS) is an aggressive acute autoimmune attack on the peripheral nervous system

Phase 2 study to evaluate safety and effectiveness of imlifidase in patients diagnosed with GBS

Incidences

1-2

in 100,000 annually
or ~10,000 in 7MM

Indication

Rapidly and progressively
weakens extremities
(e.g. paralyzing arms, legs)

Triggered frequently by viral
infections (such as Influenza,
Zika virus, EBV, CMV and
COVID-19)

Diagnosis and management
complicated due to
heterogeneity

Today's Standard of Care

- Intravenous immune globulin (IVIg) or
- Plasma Exchange (PLEX)

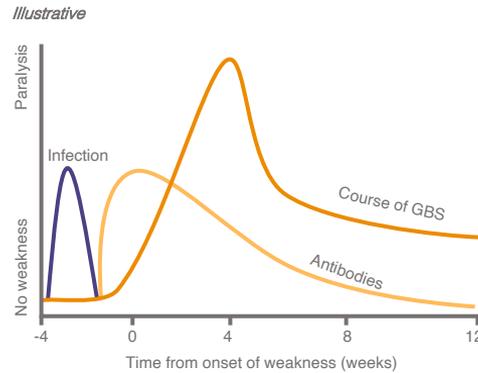
High unmet need

1/3 of hospitalized GBS
patients require mechanical
ventilation

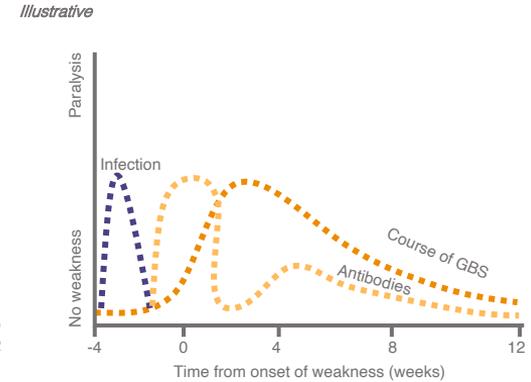
Remaining long lasting
symptoms in ca 40% of
patients incl. fatigue, pain,
psychological distress and
muscle weakness

Mortality 3-7%

Today's Standard of Care IVIg or PLEX



Potential with imlifidase



STUDY DESIGN

- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS
- Data will be compared with a control group from the International Guillain-Barré Syndrome Outcome Study (IGOS)

SUBJECTS

- 30 patients targeted at ten clinics 
- Completion of enrollment (H1 2023)

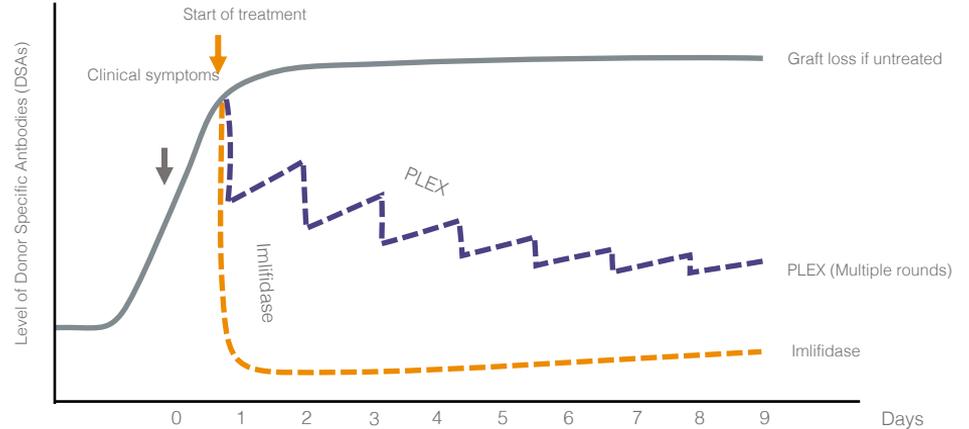
FDA granted Orphan Drug Designation to
imlifidase for the treatment of GBS

Graft survival continues to be a significant challenge for patients affected by AMR episodes post-transplantation

The topline data from the phase 2 trials associated with the primary endpoint demonstrated that imlifidase has significantly superior efficacy compared to plasma exchange in reducing DSAs during the five days following the start of treatment

Potential of using imlifidase vs. PLEX in AMR

Illustrative



STUDY DESIGN

- Randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

SUBJECTS

- 30 patients targeted (20 patients will be treated with imlifidase and 10 with Plasma exchange). Recruitment from 11 sites in the U.S., EU and Australia

Incidences

5-7%

of kidney transplants experience AMR

Today's Standard of Care

- Plasma Exchange (PLEX)
- Steroids
- Intravenous immune globulin (IVIG)

Indication

Antibody Mediated Rejection (AMR) is one of the most challenging adverse events after kidney transplantation and is a significant challenge to long term graft survival

High unmet need

AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist
There is no approved treatment for AMR

Full data expected to be published in H2 2023



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Contact

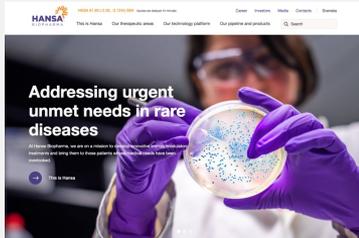


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Calendar and events

Feb 23, 2023	Erik Penser Healthcare seminar, Stockholm
Mar 7, 2023	Redeye Healthcare seminar: Commercialization, Stockholm
Mar 7, 2023	Intron Health non-deal road show, London
Mar 8, 2023	Cowen Healthcare Conference, Boston
Mar 9-10, 2023	H.C. Wainwright non-deal road show, Connecticut/NYC
Mar 30, 2023	2022 Annual Report
April 4, 2023	Guggenheim Healthcare Talks Rare Disease Days, virtual
April 18, 2023	Needham Healthcare Conference, virtual
April 20, 2023	Interim Report for January-March 2023
April 20, 2023	Redeye Investor Forum, Gothenburg
April 21, 2023	Redeye Lunch presentation, Stockholm
April 25, 2023	Kempen Life Sciences Conference 2023, Amsterdam
May 11, 2023	Erik Penser Company Day, Malmö
May 11, 2023	Redeye Investor forum, Malmö
May 25, 2023	Erik Penser Company Day, Stockholm
June 14, 2023	Annual General Meeting
July 20, 2023	Half-year Report for January-June 2023
Aug 24, 2023	Erik Penser Company Day, Stockholm
Sept 7, 2023	CITI Annual BioPharma Conference, Boston
Sept 11, 2023	MorganStanley Global Healthcare Conference, NYC
Oct 19, 2023	Interim Report for January-September 2023
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen