



HC Andersen Seminar
Autoimmune Diseases

May 30, 2023

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Hansa Biopharma today

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

160 employees March 2023

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 ~1.3bn in Cash and short term investments (USD ~130m)
End of March 2023

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~300m (May 2023)

Listed on Nasdaq Stockholm
20,000 shareholders
Foreign ownership make up ~47% through leading international life science specialist funds



Patient**

This is a break-through for the patients who need but can't access kidney transplantation today

*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

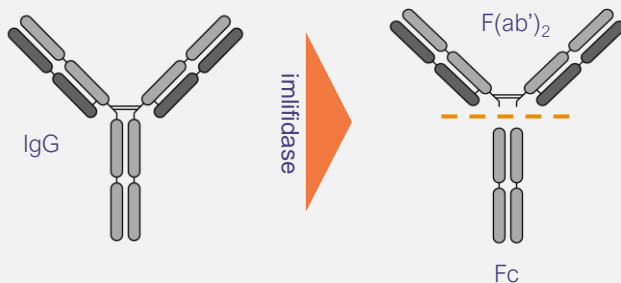
Origins from a bacteria *Streptococcus pyogenes*

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



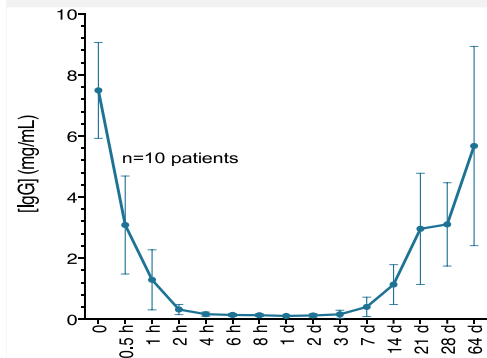
A unique IgG antibody-cleaving enzyme

- 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







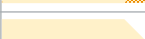
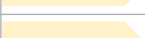
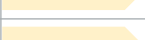




Inactivates IgG in 2-6 hours

- 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	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 H1 2023 / Complete randomization (64 patients) H2 2023
	Anti-GBM antibody disease ³							First patient enrolled (50 patients) H1 2023
	Antibody mediated kidney transplant rejection (AMR)							Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)							Topline data H2 2023 / Comparative efficacy analysis to IGOS data in 2024
	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
	Pre-treatment ahead of gene therapy in Crigler-Najjar disease (Partnered with Genethon)							Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)							Read out of phase 1 in healthy subjects
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

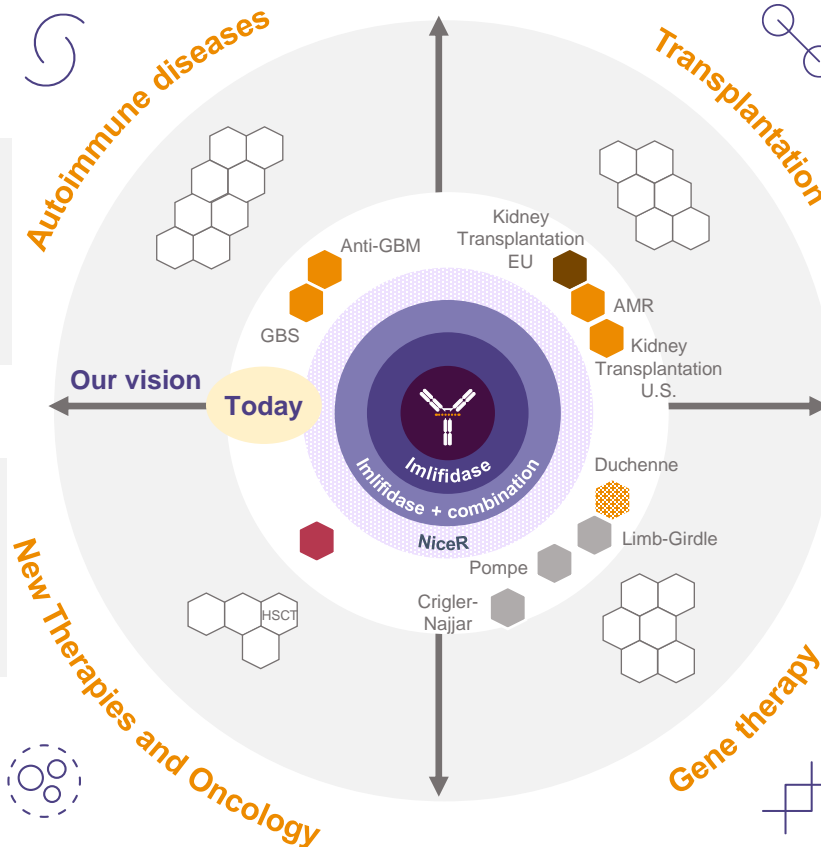
Targeting rare IgG mediated diseases

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, AskBio and Genethon
- Wide indication landscape beyond

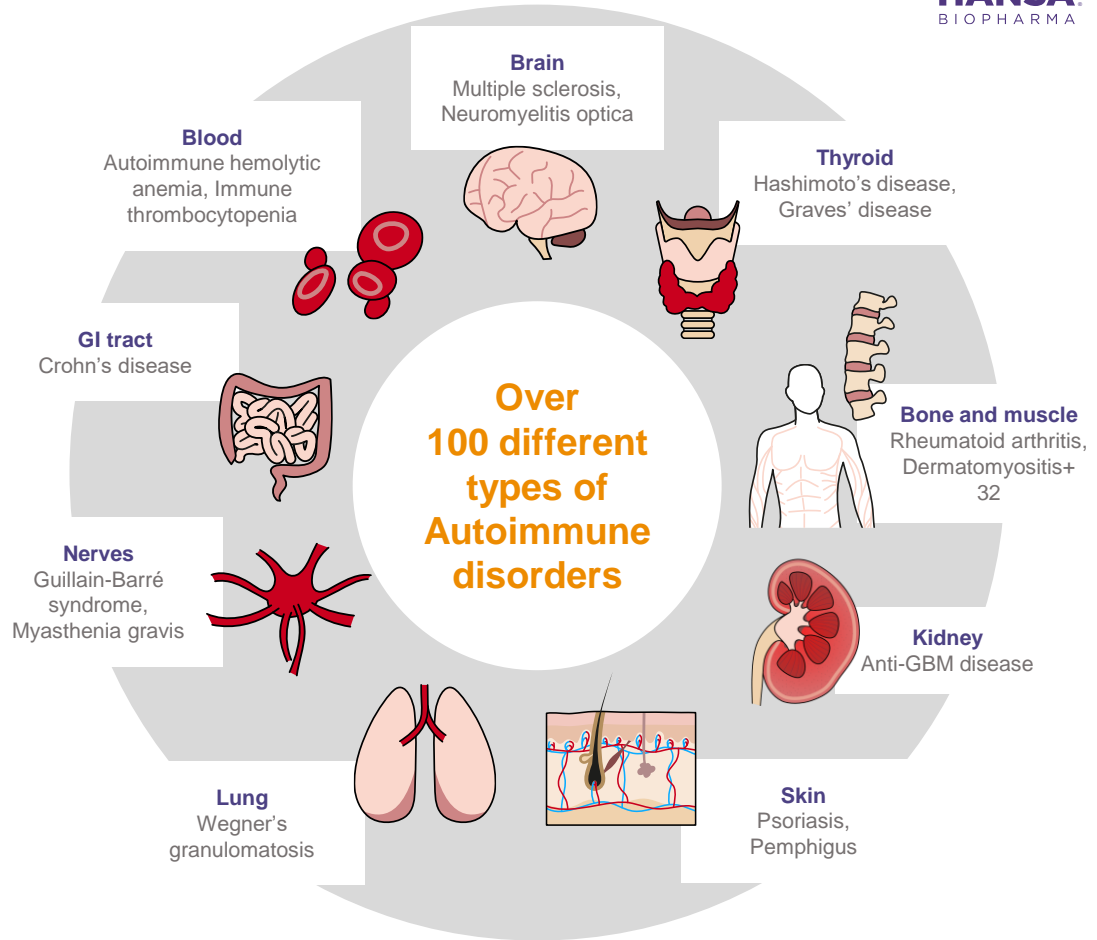
Autoimmune attacks

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

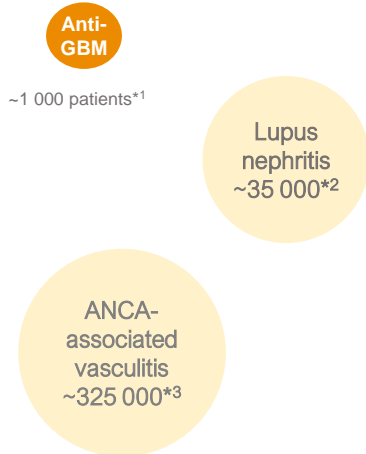
may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

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



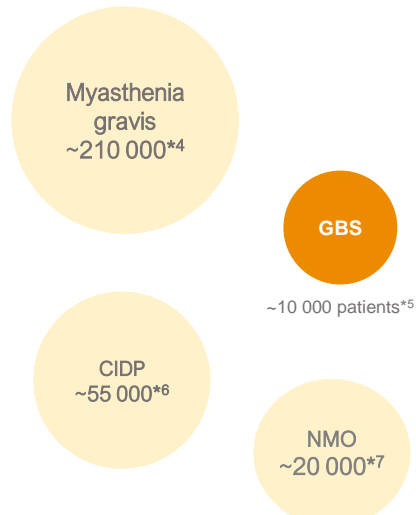
*Total disease populations in EU & US, based on prevalence and population data

Rapidly progressive glomerulonephritis



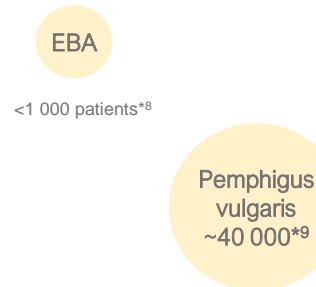
CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita
ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome
AHA: acquired hemophilia A
HIT: Heparin-induced thrombocytopenia

Neurological disorders



¹DeVrieze, B.W. and Hurley, J.A. Goodpasture Syndrome. StatPearls Publishing, Jan 2021. <https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]
²Patel, M et al. The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK. Arthritis & Rheumatism, 2006.
³Berti 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.
⁴Myasthenia Gravis. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]
⁵Guillain-Barré syndrome. Orpha.net, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=GB&Expert=2103 [accessed 2021-03-29]
⁶Chronic 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]
⁷Marrie, R.A. The Incidence and Prevalence of Neuromyelitis Optica. International Journal of MS Care, 2013 Fall: 113-118

Skin disorders



⁸Mehren, C.R. and Gniadecki, R. Epidermolysis bullosa acquisita: current diagnosis and therapy. Dermatol Reports, 2011-10-05
⁹Wertenteil, S. et al. Prevalence Estimates for Pemphigus in the United States. JAMA Dermatol, May 2019: 627-629.
¹⁰Immune Thrombocytopenia. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]
¹¹Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders, <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]
¹²Litvinova, E. et al. Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria. Frontiers in Immunology, 2018-12-14.
¹³NORD. Acquired Hemophilia [accessed 2022-10-17], available at <https://rarediseases.org/rare-diseases/acquired-hemophilia/>
¹⁴Hogan M, Berger JS. Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

Blood disorders



Anti-GBM, a rare acute autoimmune disease

Incidences

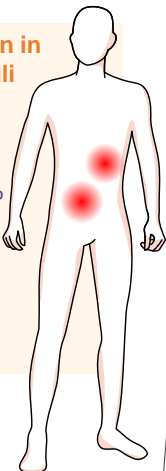
1.6

in a million affected annually^{1,2}

Inflammation in the glomeruli

Early symptoms are unspecific...

...but can lead to rapid destruction of the kidney and/or the lung.



Today's Standard of Care

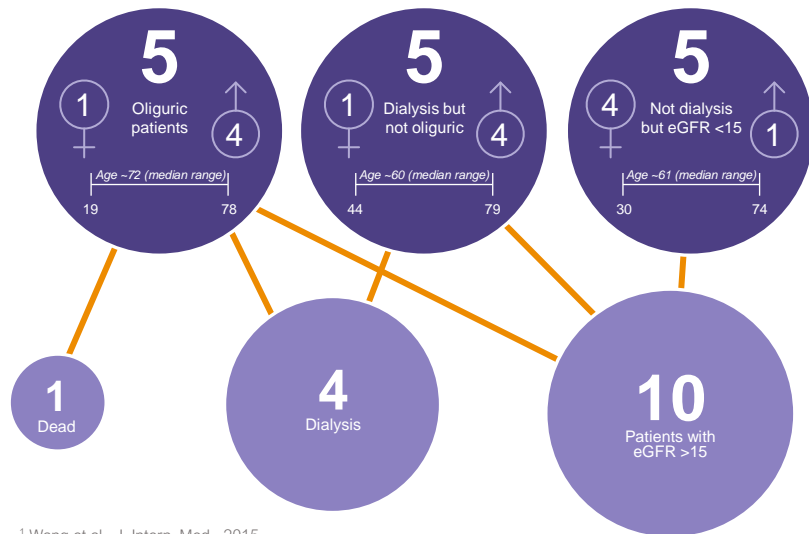
- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids

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

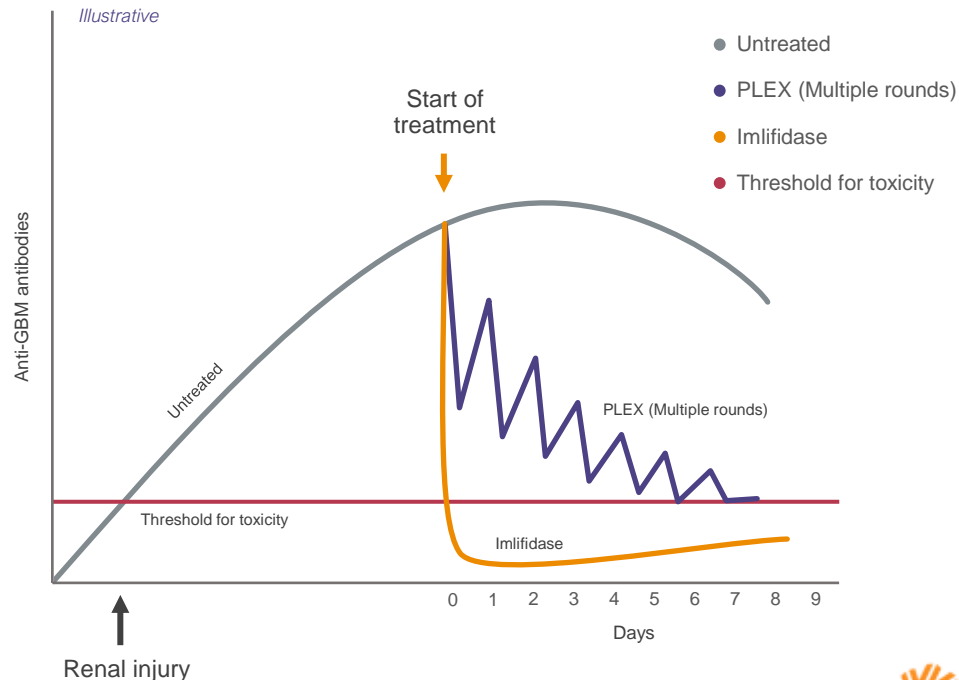
- Dosage 0.25mg/kg with 180 days follow up

MAIN OBJECTIVES

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

STATUS

- First sites 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

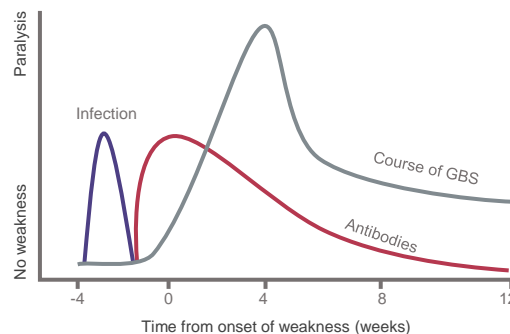
1/3 of hospitalized GBS patients
require mechanical ventilation

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

Mortality 3-7%

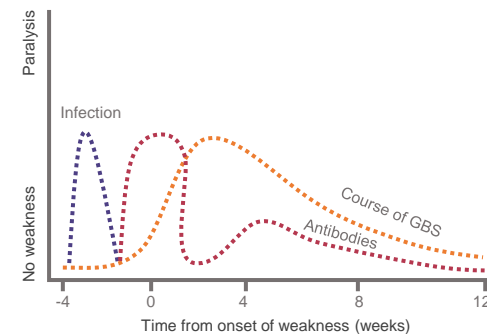
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



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)

Status

- Enrollment completed
- High level data readout H2 2023 and IGOS comparison during 2024, as previously guided



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

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

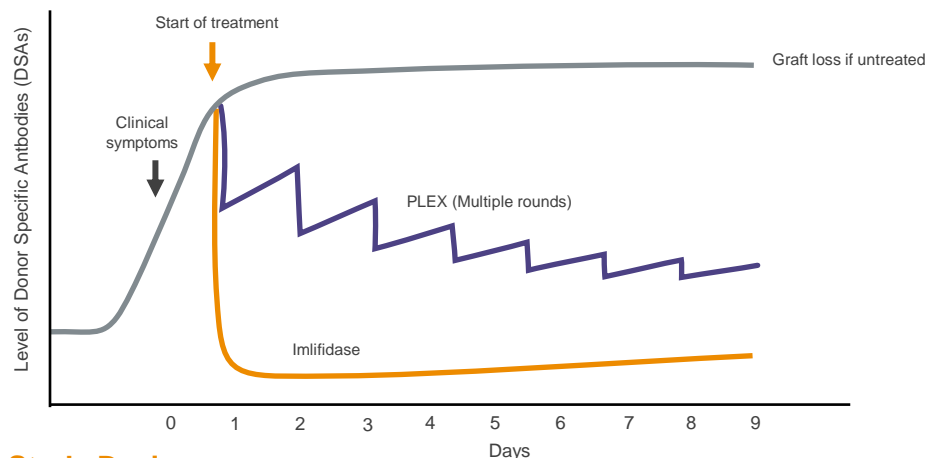
High unmet need

AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist

There is **no approved treatment for AMR**

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

Status

- 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

Full data expected to be published in H2 2023



Contact our Investor Relations and Corporate Affairs team

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Calendar and events

May 30, 2023	H.C. Andersen Capital: Autoimmune diseases (virtual)
May 31, 2023	ABG Life Science Summit, Stockholm
June 1, 2023	Redeye Growth Day, Stockholm
June 29, 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
Sept 14, 2023	Erik Penser Company Day, Malmö
Sept 14, 2023	Pareto Annual Healthcare Conference, Stockholm
Oct 19, 2023	Interim Report for January-September 2023
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen