HANSA BIOPHARMA

Investor Presentation

Redye Growth Day 2023
Stockholm

June 1, 2023

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VP, Head of Investor Relations

Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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HANSA BIOPHARMA

Hansa Biopharma today

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

A validated technology

VALIDATION ACROSS THREE AREAS

- Approval and Market Access in EU 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)
Next gen program “HNSA-5487

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

*Idefirix approved in EEA under conditional approval for kidney transplantation

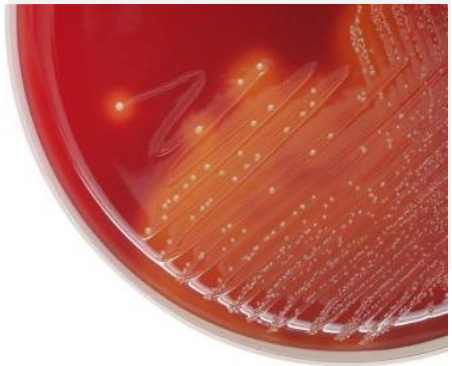
**Actual patient has given consent to provide images

Imlifidase

A novel approach to eliminate pathogenic IgG

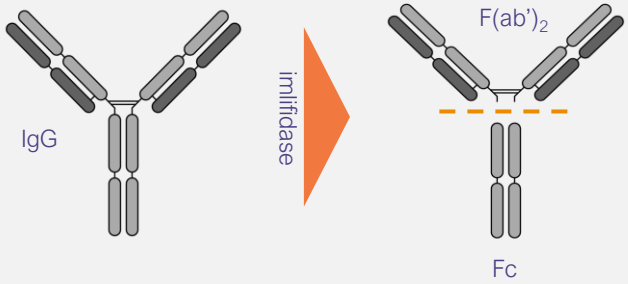
Origins from a bacteria *Streptococcus pyogenes*

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



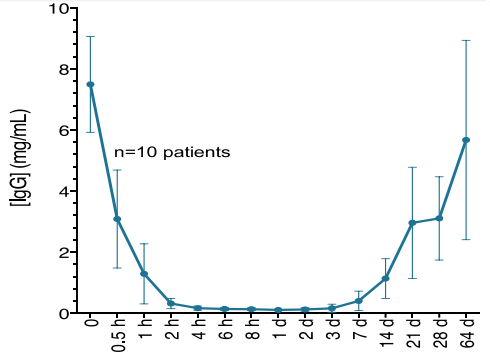
A unique IgG antibody-cleaving enzyme

- 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



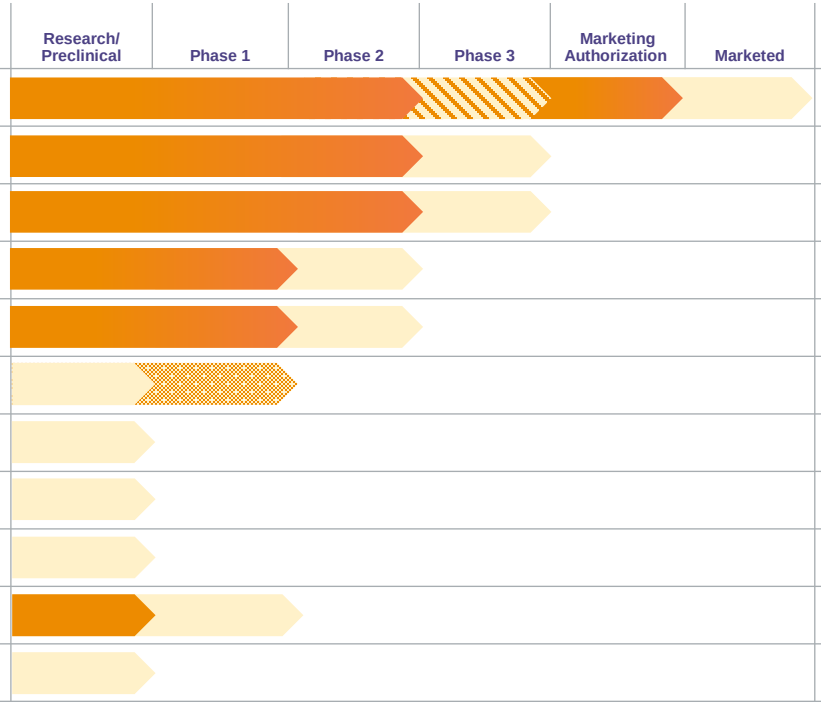
Inactivates IgG in 2-6 hours

- 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	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 el 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
Ongoing
Planned
Post approval study running in parallel with commercial launch

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

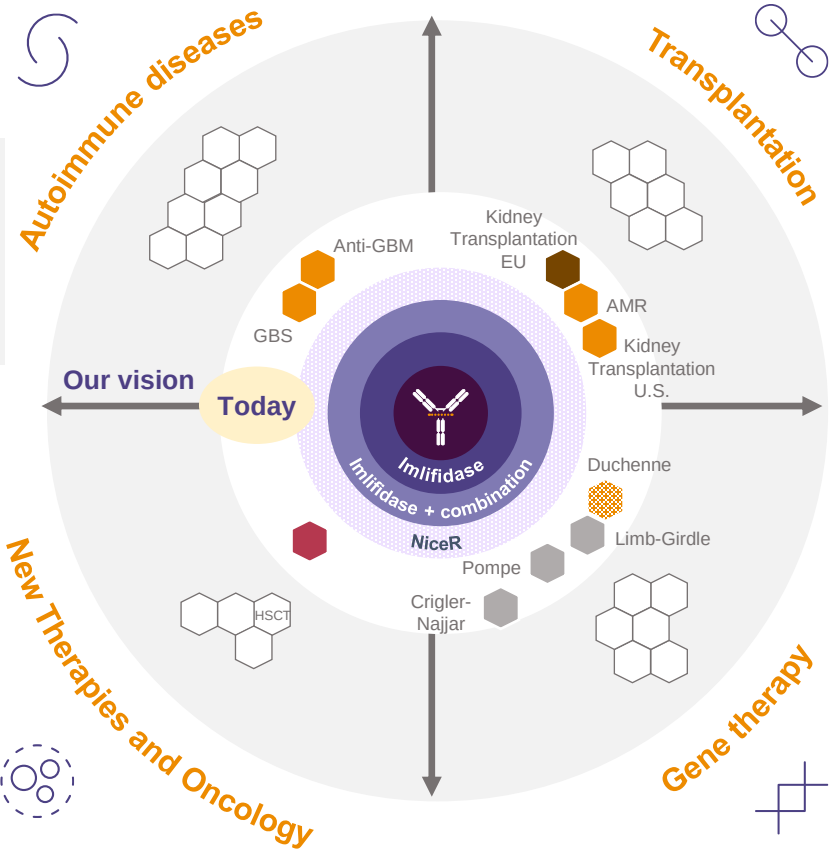
Targeting rare IgG mediated diseases

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

Imlifidase in kidney transplantation

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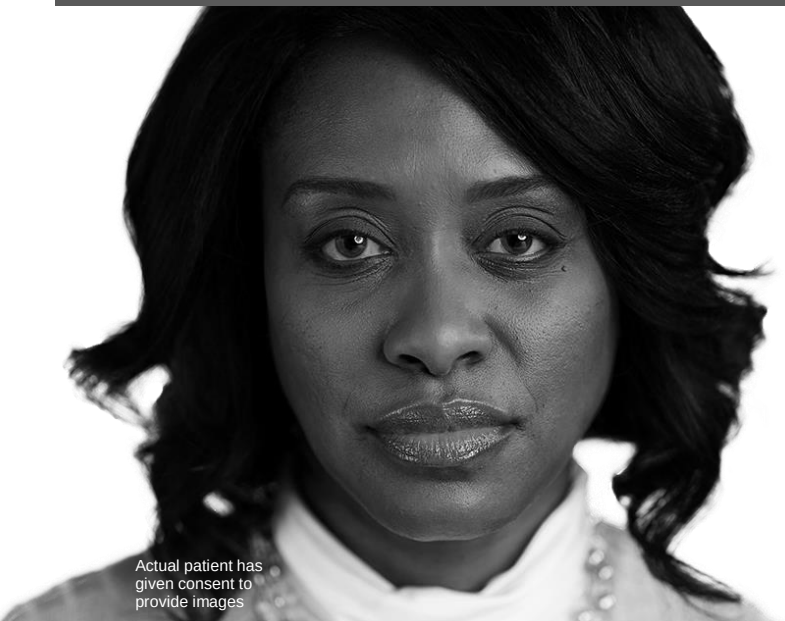
Idefirix® (imlifidase) has received conditional approval in the European Union

Low complexity transplants ⟷ Higher complexity transplants

~70% of patients[1,2]	15-20% of patients[1,2]	10-15% of patients[1,2]
Non or less sensitized (cPRA < 20%)	Moderately sensitized (20% < cPRA < 80%)	Highly sensitized (cPRA > 80%)
		Highly sensitized patients that are likely to be transplanted with a compatible donor
		Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs



Actual patient has given consent to provide images

Idefirix® is indicated for

*desensitization treatment of **highly sensitized** adult kidney transplant patients with positive crossmatch against an available deceased donor.*

The use of Idefirix® should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients

Potential patients

idefirix® imlifidase

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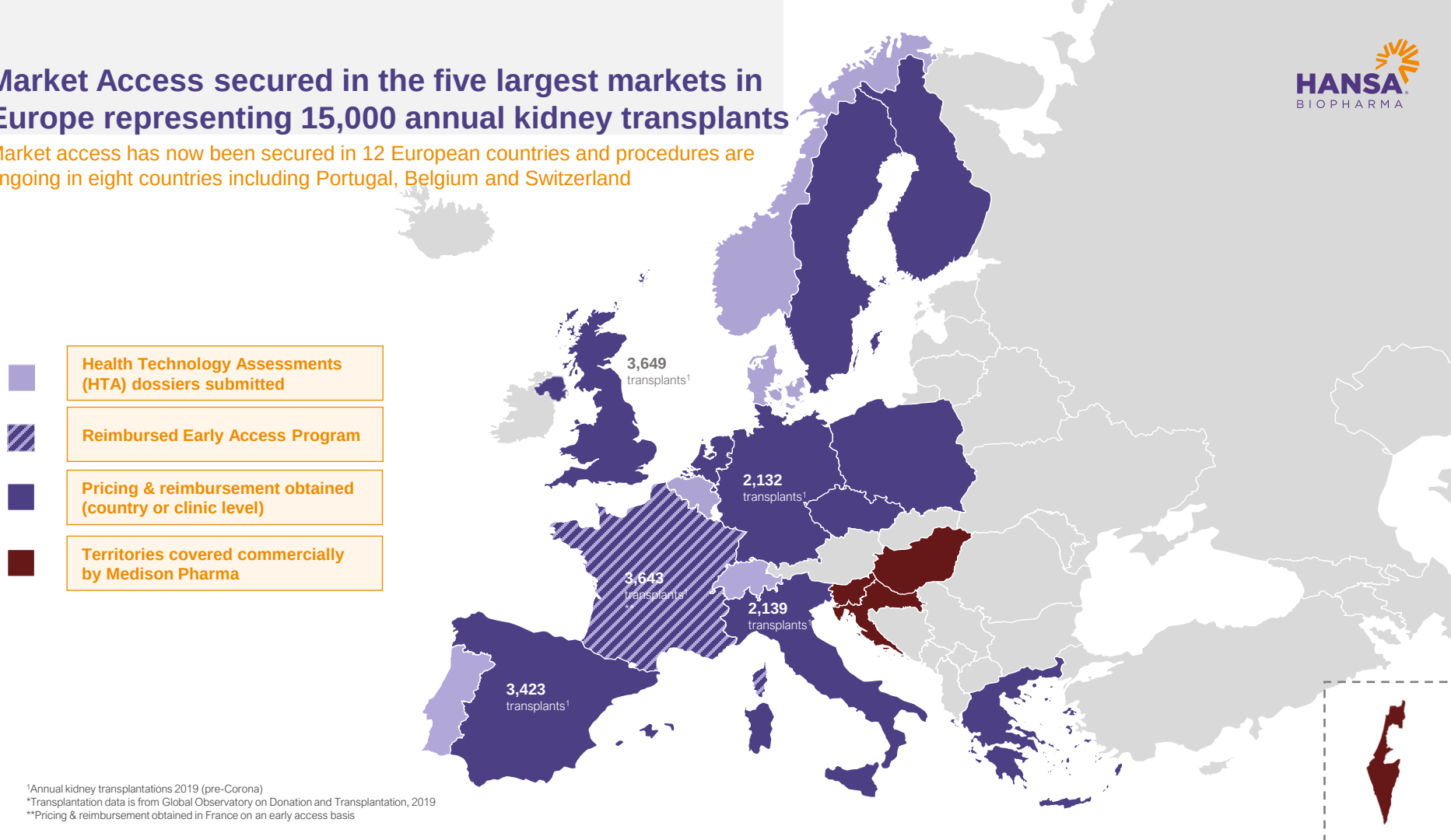
[1] EDQM. (2020). International figures on donation and Transplantation 2019
[2] SRTR Database and individual assessments of allocation systems

Market Access secured in the five largest markets in Europe representing 15,000 annual kidney transplants

Market access has now been secured in 12 European countries and procedures are ongoing in eight countries including Portugal, Belgium and Switzerland



[1]Annual kidney transplantations 2019 (pre-Corona)
*Transplantation data is from Global Observatory on Donation and Transplantation, 2019
**Pricing & reimbursement obtained in France on an early access basis

First patient experiences with Idefirix in highly sensitized kidney patients post approval published

29-year-old woman transplanted with Idefirix at Erasmus Medical Center, Rotterdam

The woman has had kidney disease since childhood and has been dialysis dependent since 2016, after previously having had two transplantations where the organs were rejected.

Due to high levels of antibodies, it was virtually impossible for her to find a match through Euro transplant but in March 2022, the 29-year-old was transplanted using Idefirix and is since doing well.

"She gained new perspective on a good life through transplantation" says nephrologist Annelies de Weerd

Link article in Amazing Erasmus from July 7, 2022

54-year-old man successfully transplanted at Vall d'Hebron, Barcelona after being on dialysis since 1984

The first patient transplanted in the post-approval study was a 54-year-old man who had been on dialysis since 1984. After two failed transplantation attempts in the 90s, the patient's immune system became sensitized, with very high antibody levels.

In May 2022, the patient received imlifidase treatment followed by a kidney transplant. After three months, he continues to be followed up on and does not require dialysis.

"This drug may open the door to transplantation for a group of highly sensitized individuals with virtually no option for a compatible transplant." says Dr. Francesco Moreso

Link article from Vall d'Hebron news forum August 25, 2022

Clinical development programs

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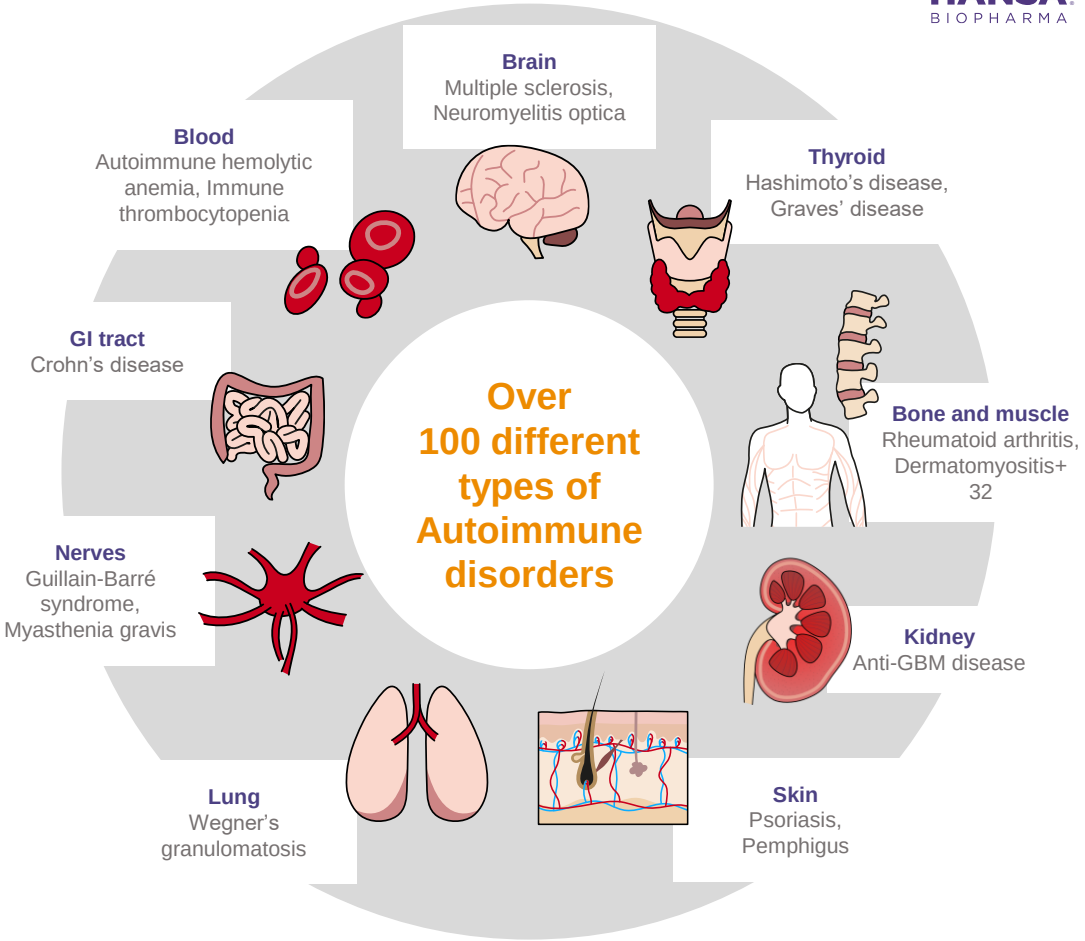
Autoimmune attacks

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

- **Anti-GBM** ~1 000 patients*[1]
- Lupus nephritis ~35 000*[2]
- ANCA-associated vasculitis ~325 000*[3]

Neurological disorders

- Myasthenia gravis ~210 000*[4]
- **GBS** ~10 000 patients*[5]
- CIDP ~55 000*[6]
- NMO ~20 000*[7]

Skin disorders

- EBA <1 000 patients*[8]
- Pemphigus vulgaris ~40 000*[9]

Blood disorders

- WAHA ~95 000*[11]
- ITP ~75 000*[10]
- HIT 0.1–5% of patients receiving therapeutic dose of heparin[14]
- AHA ~1 000* patients[13]
- APS ~350 000*[12]

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

[1]DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021. https://www.ncbi.nlm.nih.gov/books/NBK459291/ [accessed 2021-03-29]
[2]Patel, M et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK.* Arthritis & Rheumatism, 2006.
[3]Berti 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.
[4]*Myasthenia Gravis*. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/myasthenia-gravis/ [accessed 2021-03-29]
[5]*Guillain-Barré syndrome*. Orpha.net, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=2103 [accessed 2021-03-29]
[6]*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]
[7]Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica.* International Journal of MS Care, 2013 Fall: 113-118
[8]Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05
[9]Werteteil, S. et al. Prevalence *Estimates for Pemphigus in the United States.* JAMA Dermatol, May 2019: 627-629.
[10]*Immune Thrombocytopenia*. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/immune-thrombocytopenia// [accessed 2021-03-29]
[11]*Warm Autoimmune Hemolytic Anemia*. National Organization for Rare Disorders, https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/ [accessed 2021-03-29]
[12]Litvinova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria.* Frontiers in Immunology, 2018-12-14.
[13]NORD, Acquired Hemophilia [accessed 2022-10-17], available at https://rarediseases.org/rare-diseases/acquired-hemophilia/
[14]Hogan 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]

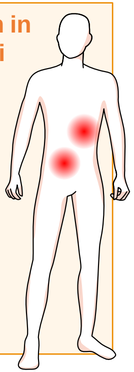
Today's Standard of Care

- 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

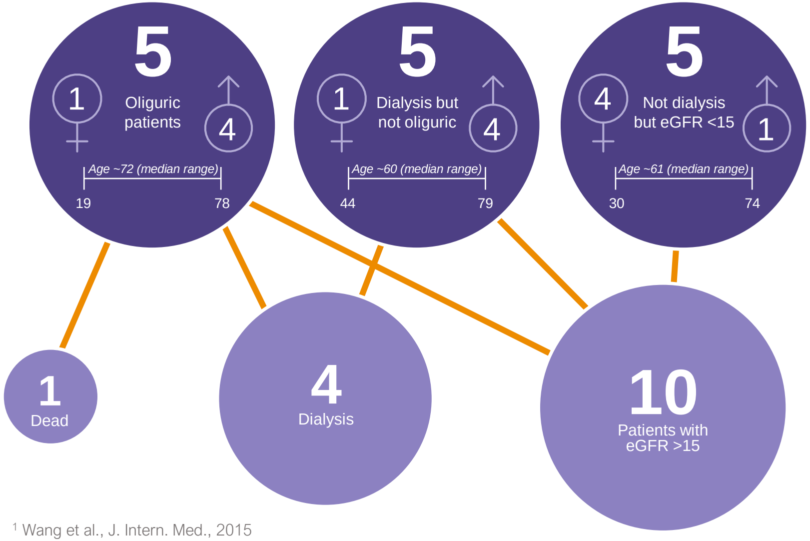
CLINICAL RESEARCH www.jasn.org

Endopeptidase Cleavage of Anti-Glomerular Basement Membrane Antibodies in vivo in Severe Kidney Disease: An Open-Label Phase 2a Study

ABSTRACT

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 cohort[4], 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

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

Today's Standard of Care

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

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 heterogenicity

High unmet need

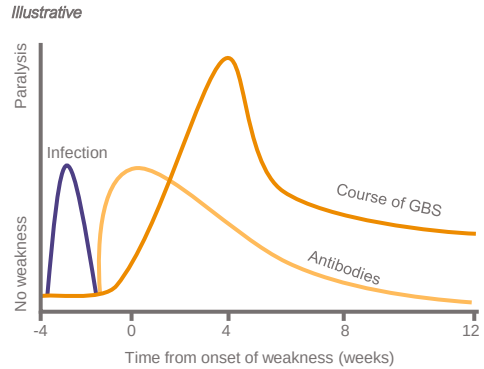
1/3 of hospitalized GBS patients require mechanical ventilation

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

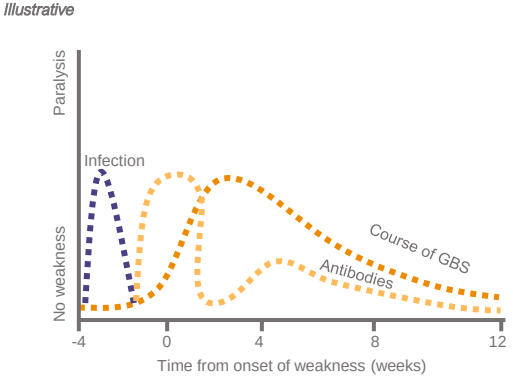
Mortality 3-7%

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

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 (H1'23) announced March 31, 2023
- Topline data H2'23
- Comparative efficacy analysis to IGOS data in 2024

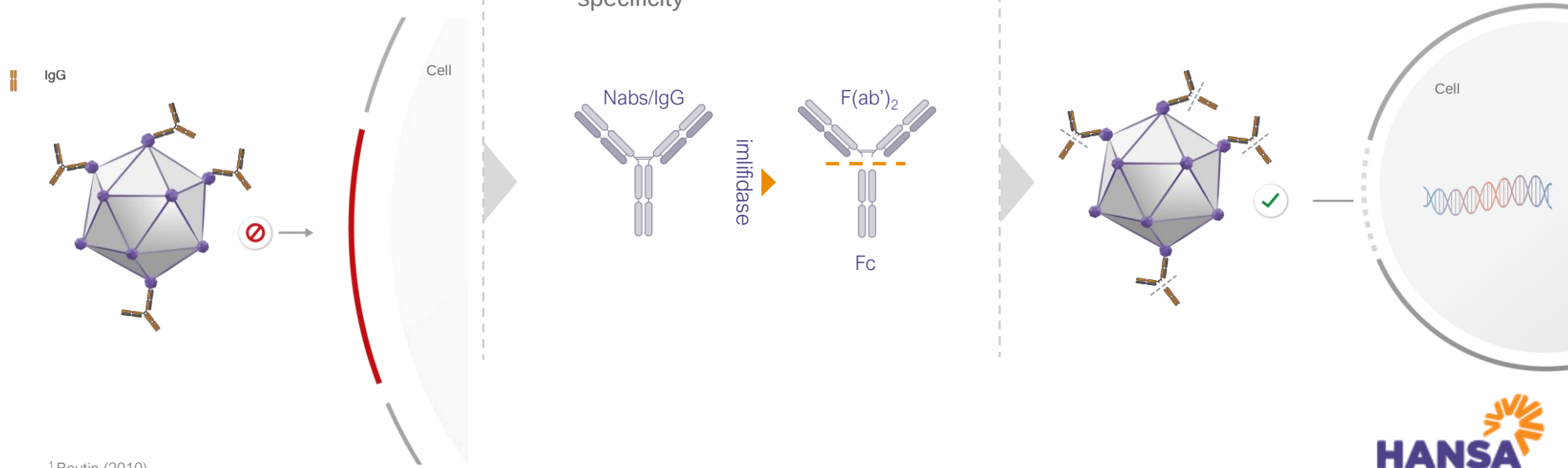
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

Between approximately 5% and 70%[1,2] of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern

2 Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity

3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



[1] Boutin (2010)
[2] Kruzik (2019)

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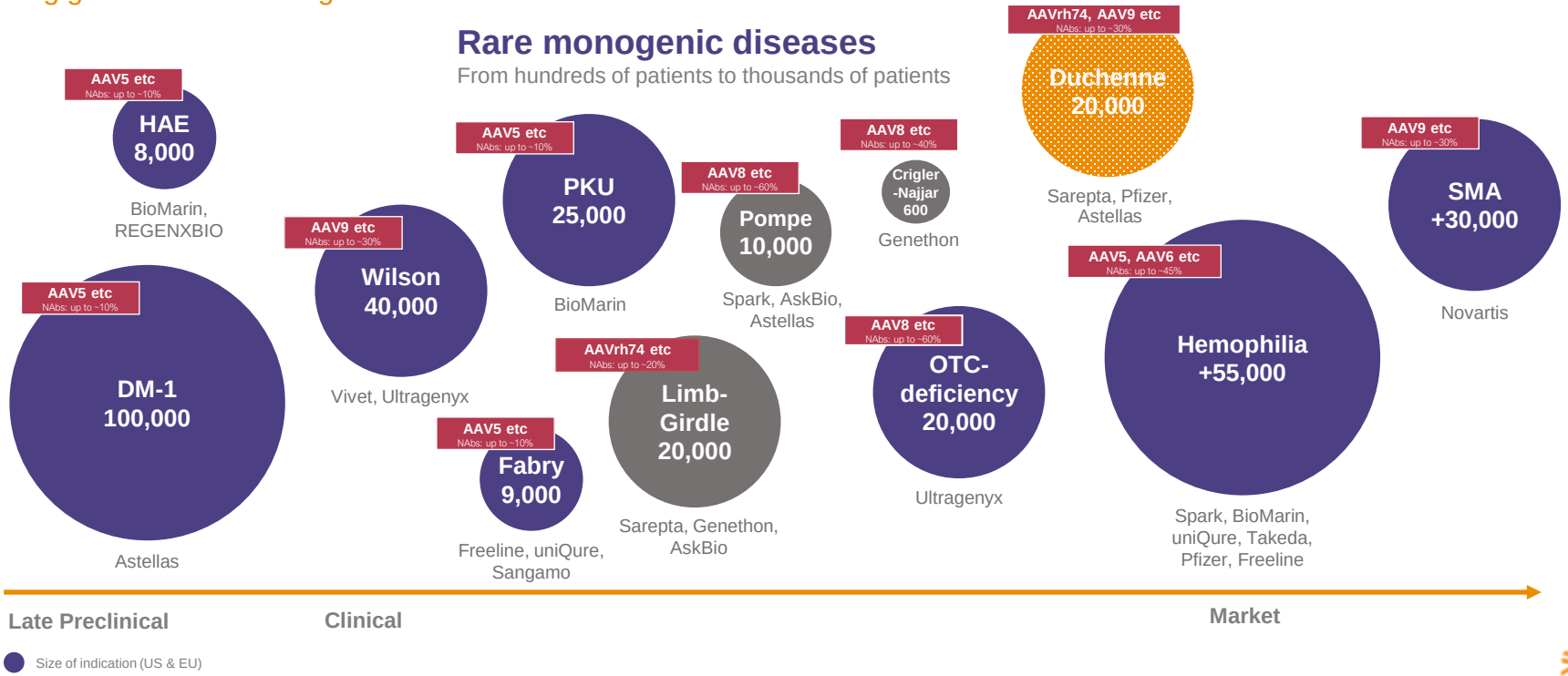
Systemic gene therapy is an emerging opportunity

with a focus on the potential to correct issues causing genes in rare monogenic diseases

- Preclinical programs with Sarepta, AskBio and Genethon
- Planned clinical studies with Sarepta
- Potential gene therapy indications (currently not pursued)

Rare monogenic diseases

From hundreds of patients to thousands of patients



At Hansa Biopharma we are committed to driving our business forward in a sustainable way

Healthy people

Address unmet need and ensure equitable access to care

Healthy business

Make a difference by operating an ethical, transparent and responsible business and cultivate an engaged culture of collaboration, inspiration and innovation

Healthy planet

Embrace sustainable decision making and environment stewardship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