HANSA BIOPHARMA

Investor Presentation

Ökonomisk Ugrebrev Life Science konference

February 28, 2024

Klaus Sindahl
VP, Head of Investor Relations

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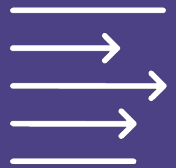
Hansa Biopharma today

A successful track record and a promising future…

A validated technology

- Commercial stage biotech company
- Approval in kidney transplantation (EU)
- Market Access in 14 European markets
- PoC in autoimmune diseases
- Three partnerships in gene therapy

Broad clinical pipeline



- Imlifidase being investigated in seven ongoing clinical programs in transplantation and autoimmune disease
- Ongoing 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 (168 employees Dec'23)
- Operations in both EU and the US

Financial position

- Hansa is financed into 2025
- Market cap (SEK): ~1.8bn (Feb 2024)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

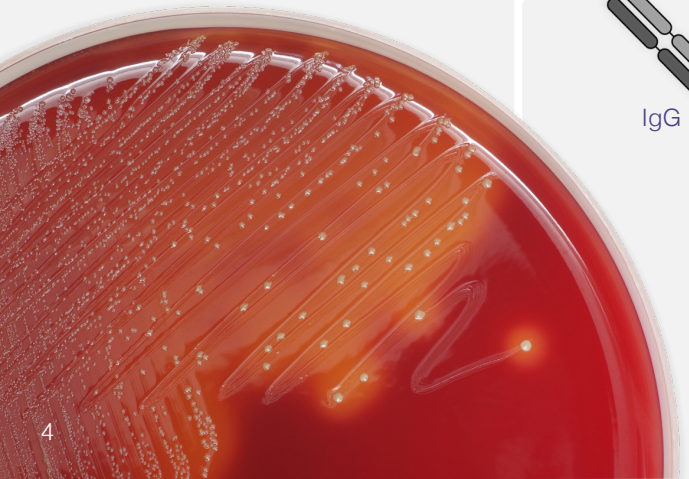
3

Imlifidase

a novel approach to eliminate pathogenic IgG

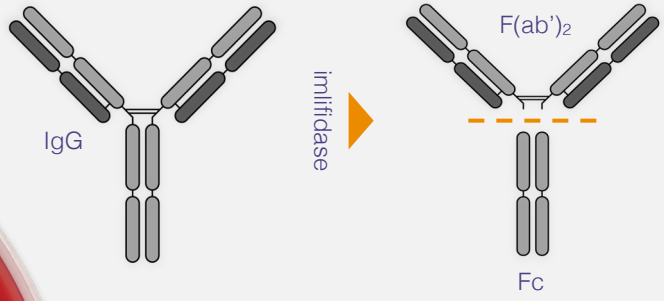
Origins from a bacteria *Streptococcus pyogenes*

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



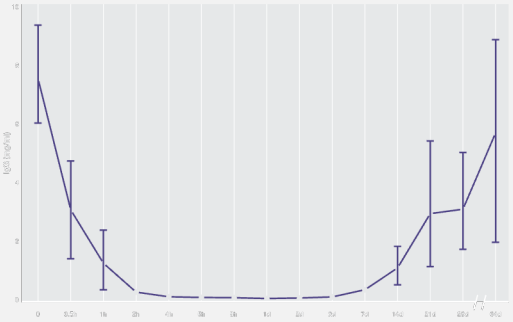
A unique IgG antibody-cleaving enzyme

- 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

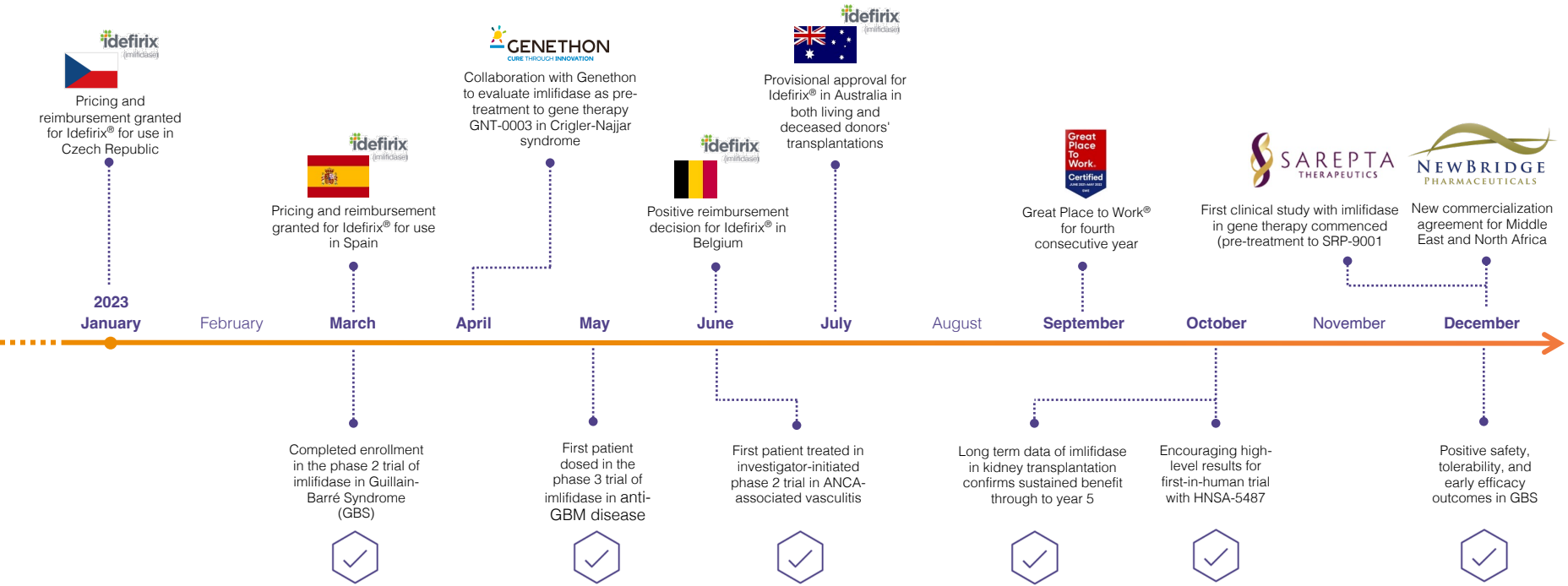


Inactivates IgG in 2-6 hours

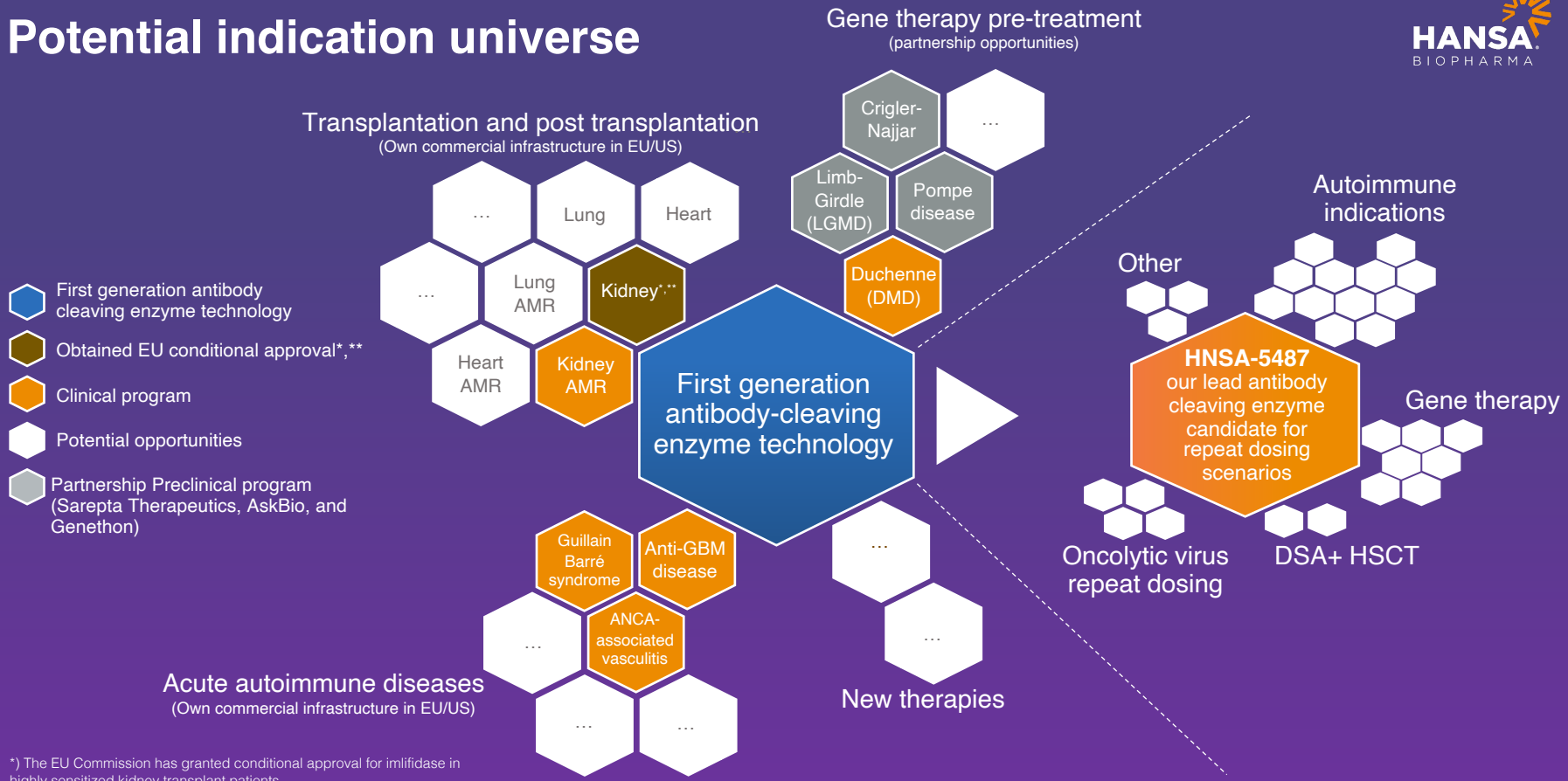
- Rapid onset of action that inactivates IgG below detectable level in 2-6 hours
- IgG antibody-free window for approximately one week



Key milestones achieved during the last 12 months



Potential indication universe



*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.
**) In the US a new study has commenced targeting a BLA filing in 2025

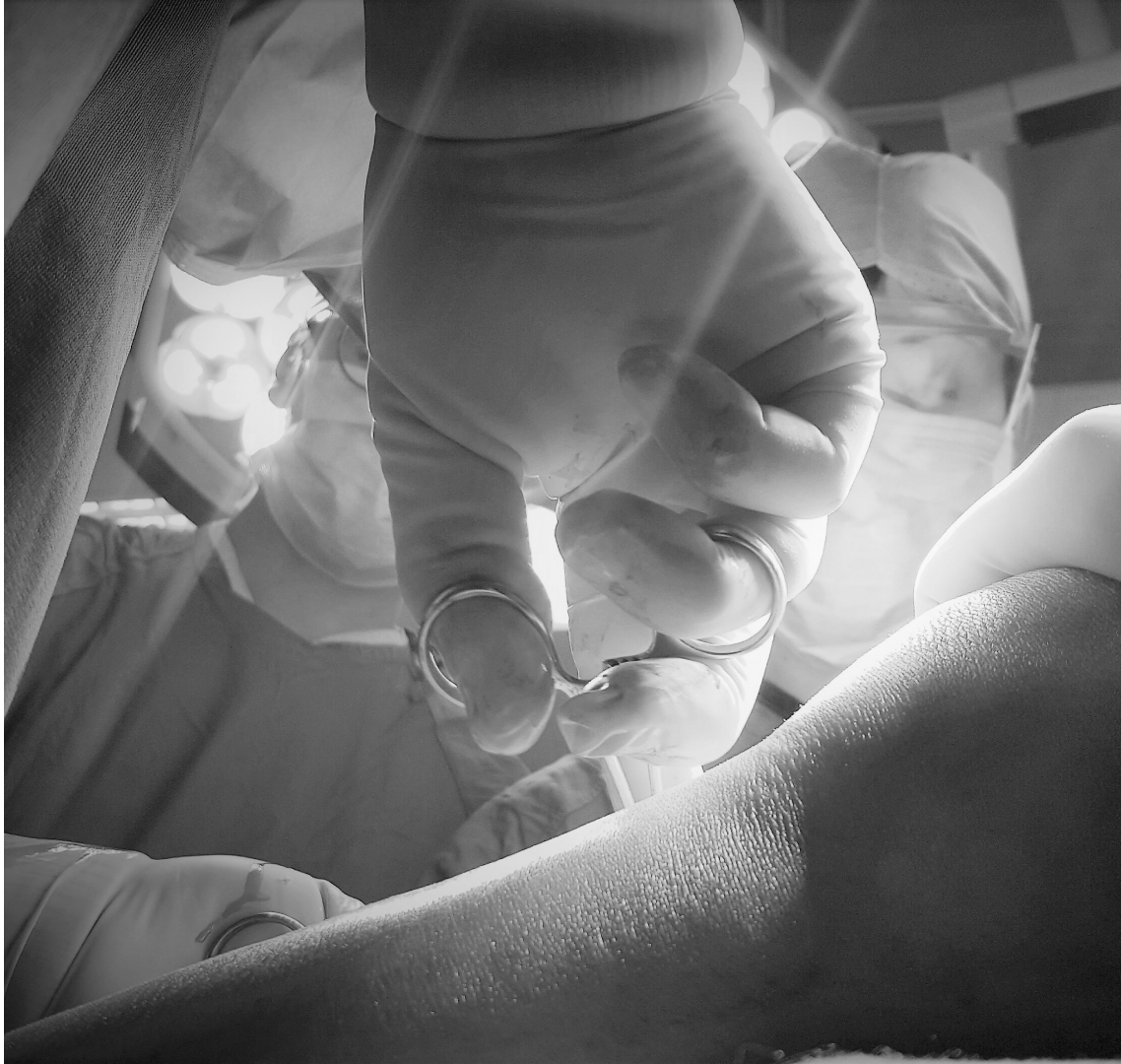
Broad clinical pipeline in transplantation, autoimmune diseases, and gene therapy

Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	Partner	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
	U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients[1,2]								Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease								Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)								Publication in peer-reviewed journal
	15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)								Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis[3]								Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)		Phase 1b					**Sarepta Therapeutics**	Completion of enrolment
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)							**Sarepta Therapeutics**	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease							**AskBio**	Preclinical research
	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome							**Genethon**	Commence clinical study
HNSA-5487	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program								Further analysis around endpoints from Phase 1 to be completed in 2024 incl. selection of lead indication

Completed | Ongoing | Planned | Post approval study running in parallel with commercial launch

[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 Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

Imlifidase in kidney transplantation



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

Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients.
Between 80,000 and 100,000 kidney transplant patients are waiting for a new kidney in both Europe and the U.S.

Low complexity transplants ← Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization → High 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%)

Causes of sensitization include

Pregnancy

Blood transfusion

Previous transplantations

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] SRTR Database and individual assessments of allocation systems

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

First living donor transplantation in Australia enabled by imlifidase was carried out in a 64-year-old highly sensitized male patient (cPRA 99.8)

The patient had been waitlisted for more than 4 years and received two incompatible kidney offers previously

Link article in The Age from November 5, 2023

54-year-old man successfully transplanted at Vall d'Hebron, Barcelona after two failed transplantation attempts in the 90s and being on dialysis since 1984

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

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

This transplantation was the first imlifidase-enabled kidney transplantation in Italy

Link article Veneto.it from December 14, 2022

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

Key activity matrix

1 Build the foundation for Idefirix®

- ✓ 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

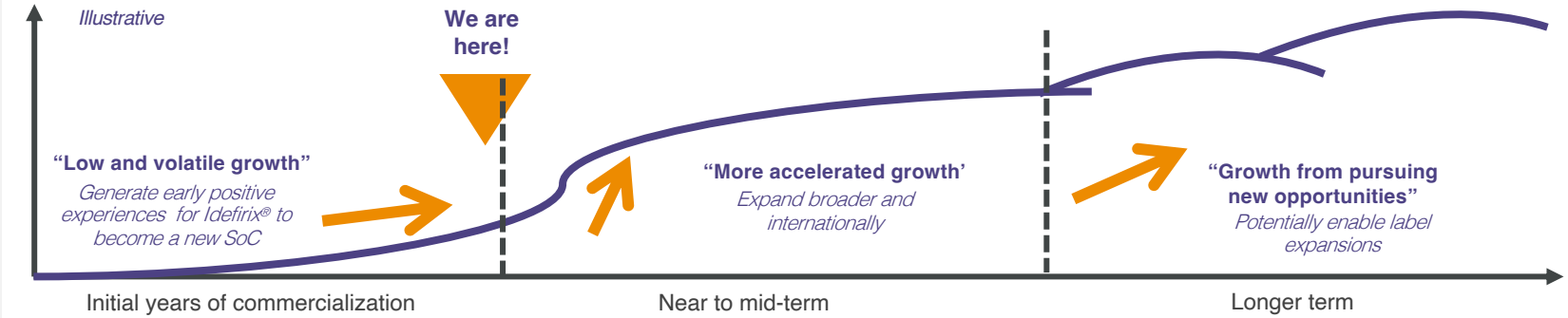
2 Expanding internationally

- Leverage experience to scale Idefirix 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

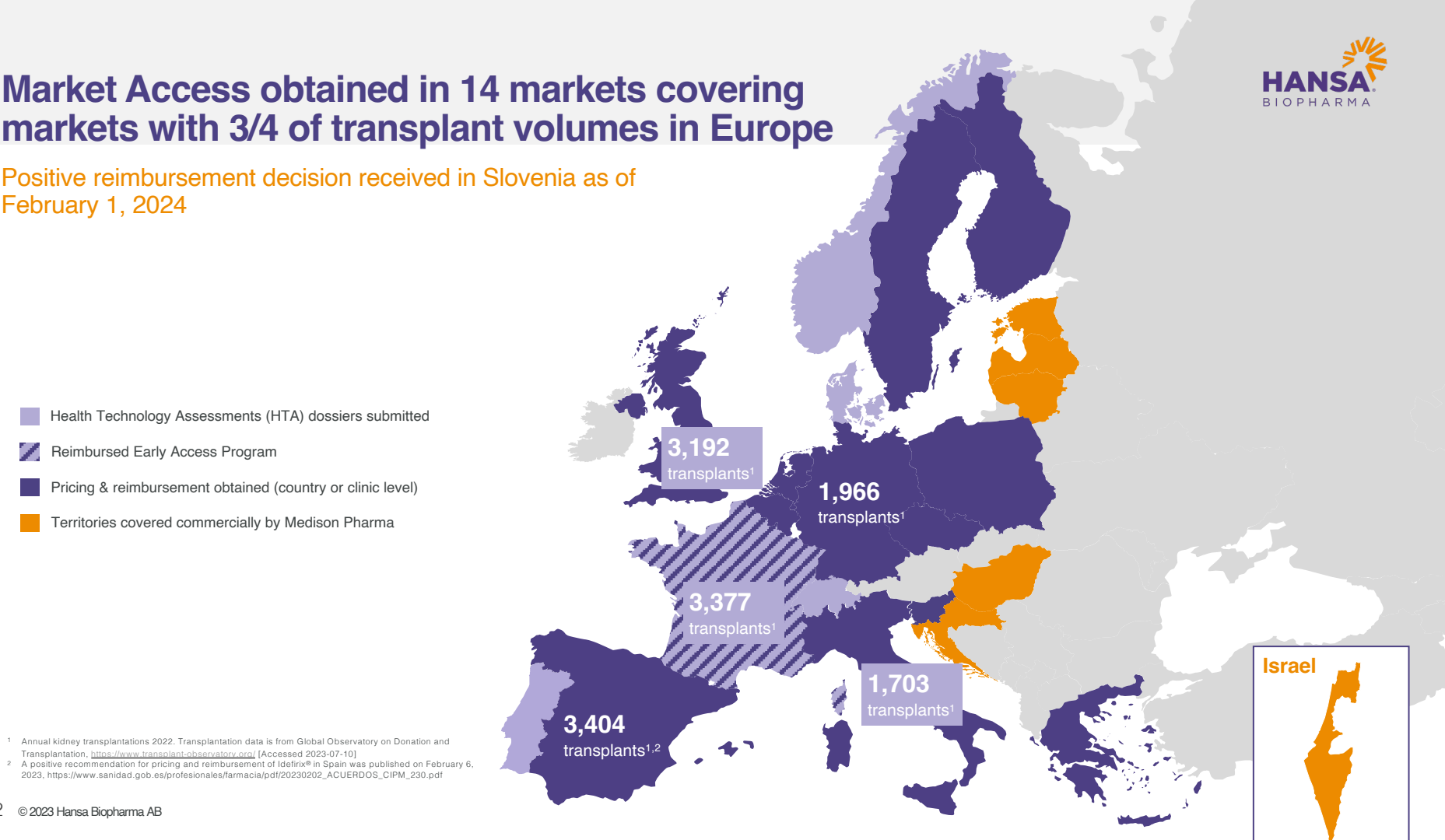
- Potentially expand into living donor transplantation
- Potentially expand into other solid organs

Commercial sales uptake



Market Access obtained in 14 markets covering markets with 3/4 of transplant volumes in Europe

Positive reimbursement decision received in Slovenia as of February 1, 2024



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

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

Continued progress against our key launch metrics led by in-market growth

Market Development

7 / -

Medical guidelines implemented on a national level in 7 countries

Market Access

14 / 9

Market access secured in 14 European markets, more recently in Slovenia

Patient Identification

28 / 6

Post Approval Study ~56% into completion

Transplant Center Readiness & Use

~50 / 25

~50 clinics are Idefirix "ready" to treat patients

10 / 8

Ongoing HTA processes in 10 countries incl. Portugal and Switzerland

✓

Eurotransplant:
First patient treated in the ET desensitization program; 1st and 2nd wave patient assessment initiated in Q4'23

23 / 10

23 centers have treated patients overall; 14 centers have repeat usage

Major markets to support growth going forward France, U.K., Germany, Spain and Italy

Q4 2023 Q4 2022

Clinical development programs

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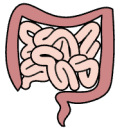
Autoimmune attacks

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

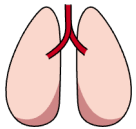
Blood
Autoimmune hemolytic anemia,
Immune thrombocytopenia

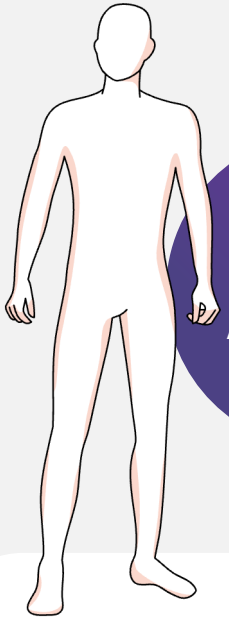
GI tract
Crohn's disease



Nerves
Guillain-Barré syndrome,
Myasthenia gravis

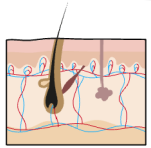
Lung
Wegner's granulomatosis





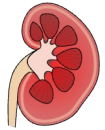
Over 100 different types of Autoimmune disorders

Skin
Psoriasis, Pemphigus

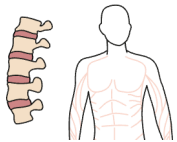


Brain
Multiple sclerosis,
Neuromyelitis optica

Thyroid
Hashimoto's disease,
Graves' disease



Kidney
Anti-GBM disease



Bone and muscle
Rheumatoid arthritis,
Dermatomyositis+ 32

Hansa's antibody cleaving enzyme technology

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

Rapidly progressive glomerulonephritis

~1 000 patients*[1]

- Anti-GBM
- Lupus nephritis ~35 000*[2]
- ANCA-associated vasculitis ~20 000*[3]

Neurological disorders

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

~10 000 patients*[5]

Skin disorders

<1 000 patients*[8]

- EBA
- Pemphigus vulgaris ~40 000*[9]

Blood disorders

~1 000* patients[13]

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

■ Clinical programs

□ Potential autoimmune indications (currently not pursued)

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

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]Wertenteil, 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

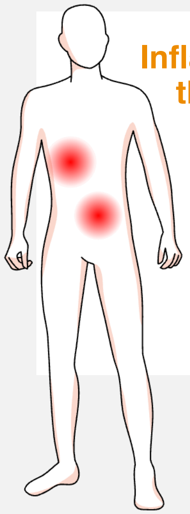
Incidence

1.6

in a million affected annually[1,2]

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

Fredrik Uhlin,[1,2] Wladimir Szpirt,[3] Andreas Kronbichler,[4] Annette Bruchfeld,[1,5] Inga Soveri,[6] Lionel Rostaing,[7] Eric Daugas,[8] Arnaud Lionet,[9] Nassim Kamar,[10] Cédric Rafat,[11] Marek Mysliveček,[12] Vladimír Tesař,[12] Anders Fernström,[1] Christian Kjellman,[13] Charlotte Elfving,[13] Stephen McAdoo,[14] Johan Mölne,[15] Ingeborg Bajema,[16] Elisabeth Sonesson,[13] and Mårten Segelmark[1,17]

Due to the number of contributing authors, the affiliations are listed at the end of this article.

ABSTRACT

Background The prognosis for kidney survival is poor in patients presenting with circulating anti–glomerular basement membrane (GBM) antibodies and severe kidney injury. It is unknown if treat- ment with an endopeptidase that cleaves circulating and kidney bound IgG can alter the prognosis.

Methods An investigator-driven phase 2a one-arm study (EudraCT 2016–004082–39) was performed in 17 hospitals in five European countries. A single dose of 0.25 mg/kg of imlifidase was given to 15 adults with circulating anti-GBM antibodies and an eGFR <15 ml/min per 1.73m². All patients received standard treatment with cyclophosphamide and corticosteroids, but plasma exchange only if autoantibodies rebounded. The primary outcomes were safety and dialysis independency at 6 months.

Results At inclusion, ten patients were dialysis dependent and the other five had eGFR levels between 7 and 14 ml/min per 1.73m². The median age was 61 years (range 19–77), six were women, and six were also positive for anti–neutrophil cytoplasmic antibodies. Then 6 hours after imlifidase infusion, all patients had anti-GBM antibodies levels below the reference range of a prespecified assay. At 6 months 67% (ten out of 15) were dialysis independent. This is significantly higher compared with 18% (nine out of 50) in a histori- cal control cohort (*P*<0.001, Fisher's exact test). Eight serious adverse events (including one death) were reported, none assessed as probably or possibly related to the study drug.

Conclusions In this pilot study, the use of imlifidase was associated with a better outcome compared with earlier publications, without major safety issues, but the findings need to be confirmed in a randomized controlled trial.

Clinical Trial registration number: EUDRACT 2016–004082–39 https://www.clinicaltrialsregister.eu/ctr- search/trial/2007-001377-28/results

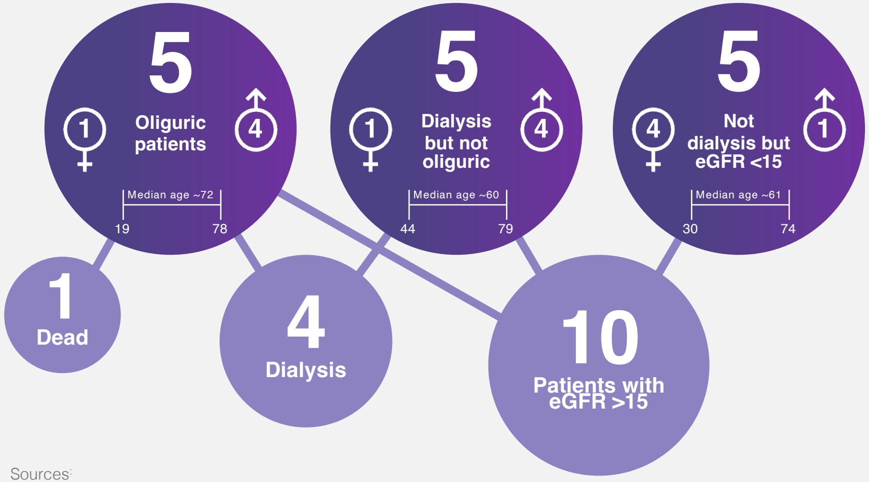
JASN 33: •••–•••, 2022. doi: https://doi.org/10.1681/ASN.2021111460

Kidney survival is poor in patients presenting with circulating anti–glomerular basement mem- brane (anti-GBM) antibodies and advanced kid- ney failure.[1,2]

Received November 12, 2021. Accepted February 1, 2022.

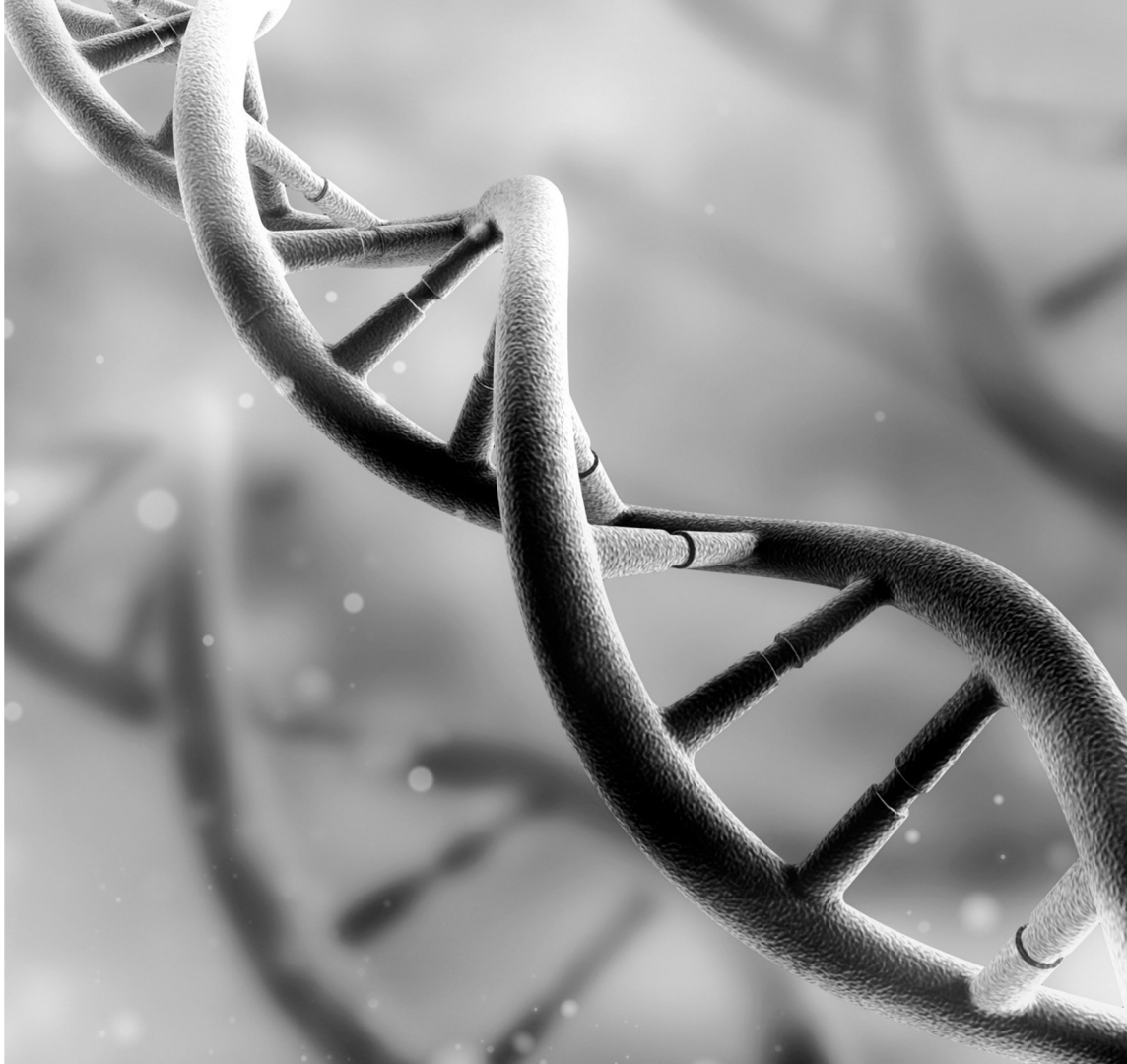
Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)[3]

10 out of 15 patients were dialysis independent after six months vs. the historical cohort[4], where only 18% had functioning kidney



Sources:
[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

Gene Therapy



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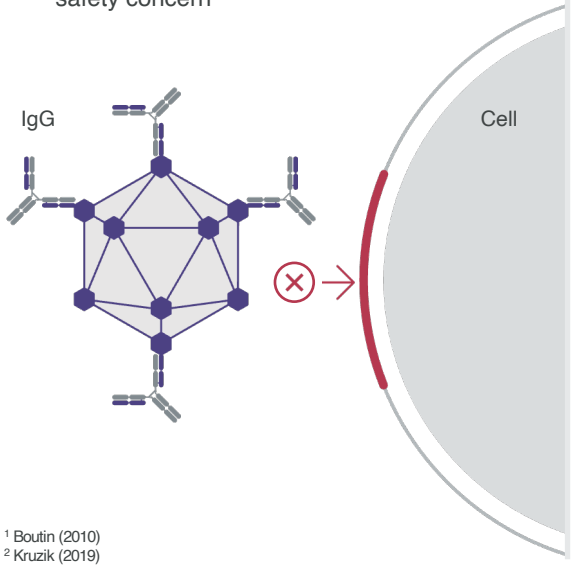
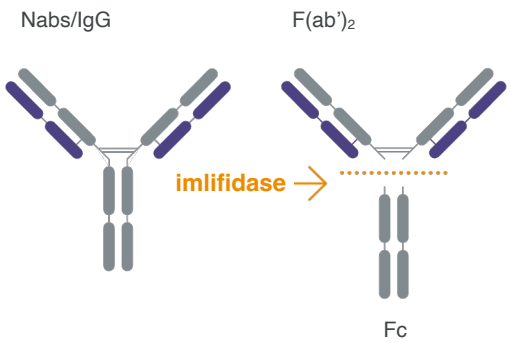
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

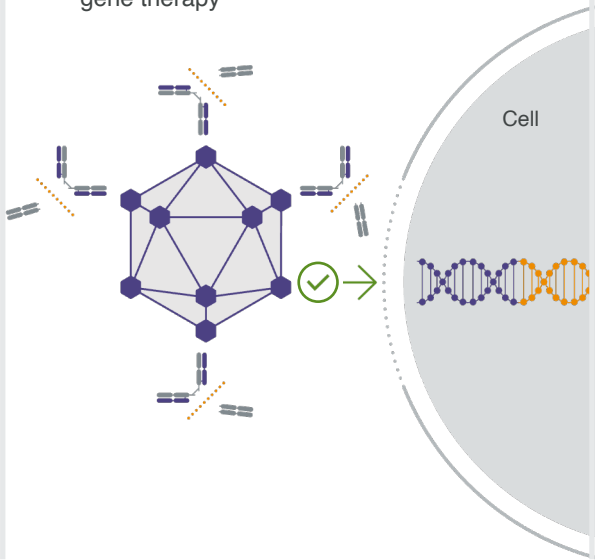
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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)

Global exclusive agreements with three partners in gene therapy

To develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

Partner	Access to key resources	Indication exclusivity	Collaborative research, development and commercialization
SAREPTA THERAPEUTICS	▪ World leader within gene therapy targeted at muscular dystrophies ▪ Pre-clinical and clinical plan ▪ Regulatory ▪ Promotion ▪ FDA approval in 4–5-year-old kids suffering with DMD	**Duchenne Muscular Dystrophy (DMD)** 1/3,500 to 5,000 male births worldwide	Antibody cleaving enzyme technology ✓ → Preclinical Development ✓ → Initiated Clinical Development → Regulatory Approvals → Commercialization
		Limb-Girdle Muscular Dystrophy Global prevalence of ~1.6 per 100k individuals	Antibody cleaving enzyme technology ✓ → Preclinical Development → Clinical Development → Regulatory Approvals → Commercialization
AskBio	▪ Early innovator in gene therapy ▪ Conducts pre-clinical and clinical trials (Phase 1/2)	**Pompe disease** Approximate incidence is 1 per 40,000 births, or ~200 per year in the US + EU	Antibody cleaving enzyme technology ✓ → Preclinical Development → Clinical Development Phase 1/2 study (feasibility)
GENETHON CURE THROUGH INNOVATION	▪ A pioneer in the discovery and development of gene therapies ▪ Conducts pre-clinical and clinical trials (Phase 1/2)	**Crigler-Najjar syndrome** Approximately incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S	Antibody cleaving enzyme technology ✓ → Preclinical Development → Clinical Development Phase 1/2 study (feasibility)

Exclusive option for AskBio to negotiate a potential full development and commercialization agreement

The initial agreement is focused on research and development

The companies will consider a subsequent agreement for commercialization at a later stage

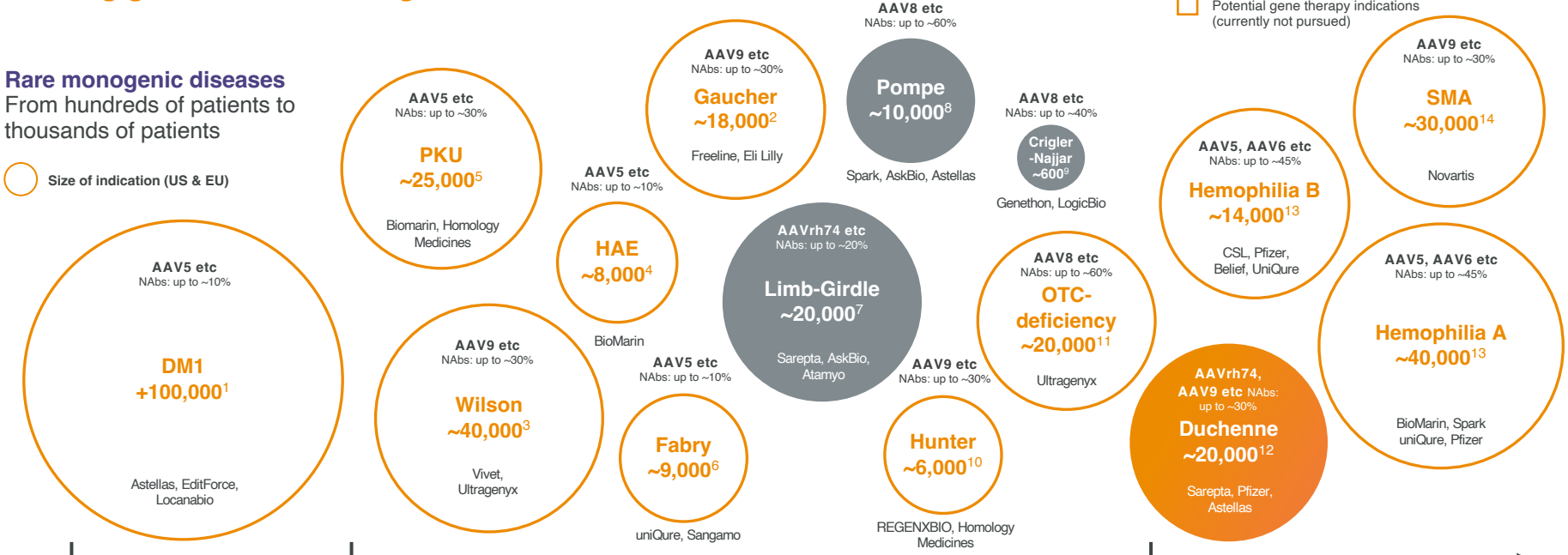
Systemic gene therapy is an emerging opportunity

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

Rare monogenic diseases
From hundreds of patients to thousands of patients

Size of indication (US & EU)

Preclinical programs with Sarepta, AskBio and Genethon
Ongoing clinical study with Sarepta
Potential gene therapy indications (currently not pursued)



Numbers are estimated based on population and prevalence

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

Targeting rare IgG mediated diseases

Auto-immune diseases

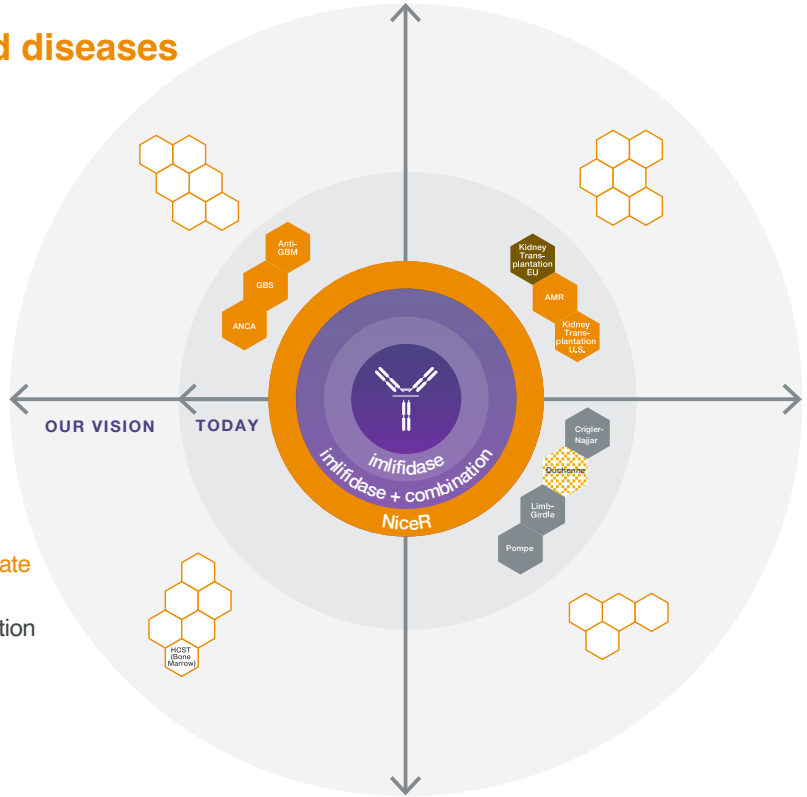
Anti-GBM disease paves the way for development in other autoimmune diseases

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

New therapies and oncology

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic 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

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


HANSA
BIOPHARMA

2023 achievements and upcoming milestones

2023

Q4 2023

- **HNSA-5487 (Lead NiceR candidate):** High-level data readout from Phase 1
- **Long-term follow-up (Kidney tx):** 5-year data readout
- **GBS Phase 2:** First data readout
- **AMR Phase 2:** Full data readout
- **Sarepta DMD pre-treatment Phase 1b:** Commence clinical study

2024

- **GBS Phase 2:** Outcome of the comparative efficacy analysis to IGOS data
- **Genethon Crigler-Najjar Phase 1/2:** Initiate clinical study with imlifidase prior to GNT-0003
- **HNSA-5487 (Lead NiceR candidate):** Further analysis around endpoints to be completed in 2024 incl. lead indication
- **U.S. ConfIdeS (Kidney tx) Phase 3:** Complete randomization
- **Sarepta imlifidase in phase 1b in DMD:** First high level data read-out from phase 1b

2025

- **U.S. ConfIdeS (Kidney tx) Phase 3:** BLA submission
- **Anti-GBM disease Phase 3:** Complete enrolment

Contact our Investor Relations and Corporate Affairs team

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Calendar and events

Feb 6, 2024 Aktiespararna, Falkenberg

Feb 8, 2024 Frankfurt MidCap Seminar, Frankfurt

Feb 14, 2024 Redeye Cell Therapy & Growth Day, Stockholm

Feb 28, 2024 Ökonomisk Ugebrev Life Science Event, Copenhagen

March 4-5, 2024 TD Cowen Healthcare Conference, Boston

March 6, 2024 Life Sciencedagen, Sahlgrenska Universitetssjukhuset Gothenburg

Mar 20, 2024 Annual Report 2023

April 8-11, 2024 Needham Healthcare Conference (virtual)

April 16-17, 2024 Van Lanschot Kempen Life Science Conference, Amsterdam

Apr 18, 2024 Interim Report for January-March 2024

June 27, 2024 2024 Annual General Meeting

July 18, 2024 Half-year Report January-June 2024

Oct 24, 2024 Interim Report for January-September 2024