



**TD Cowen Healthcare
Conference 2024**

Boston, March 4-5

Søren Tulstrup
President & CEO

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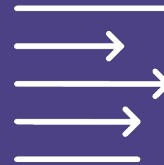
Hansa Biopharma today

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

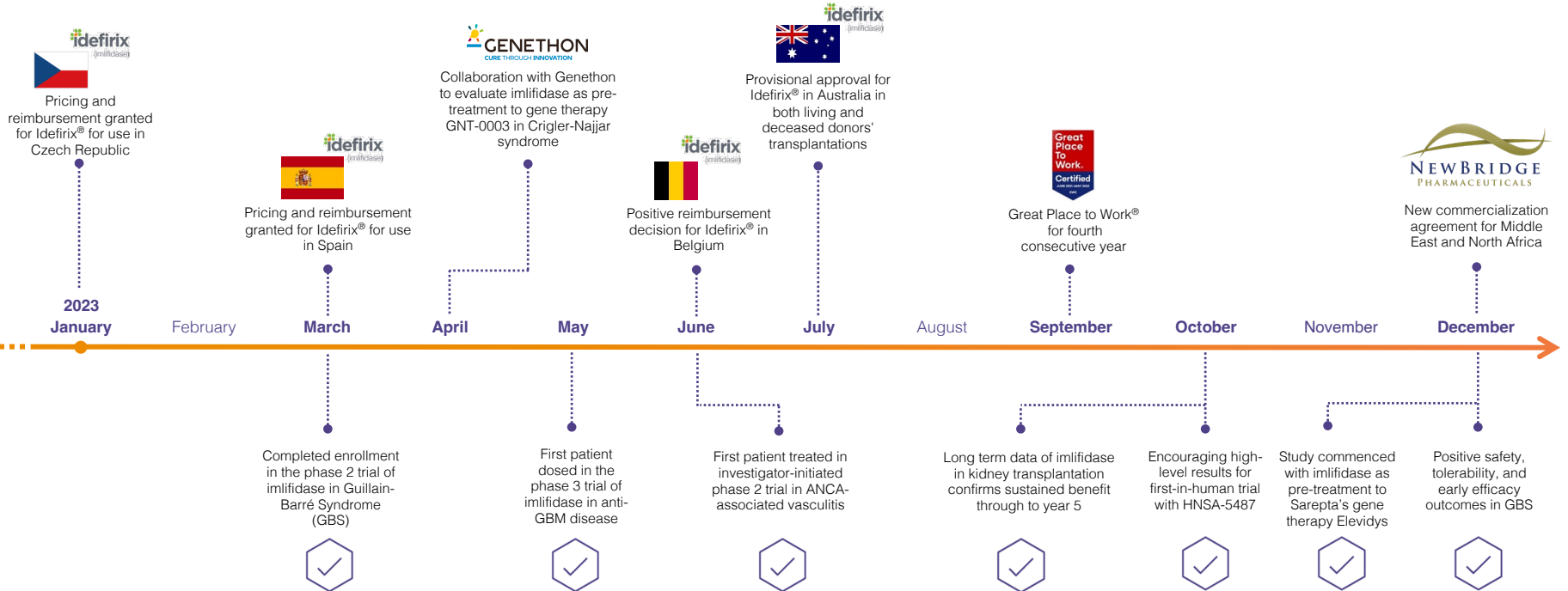
- A high-performance organization with 20 years on average in life science
- Purpose driven culture
- Headquartered in Lund, Sweden (168 employees Dec'23)
- Operations in both EU and the US



Financial position

- Hansa is financed into 2025
- Market cap (USD): ~185m (Feb. 2023)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

Key milestones achieved during the last 12 months



Imlifidase

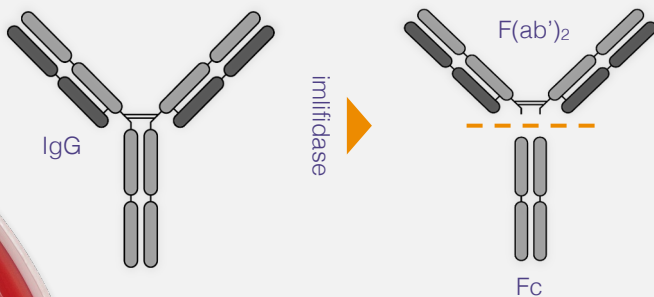
a novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

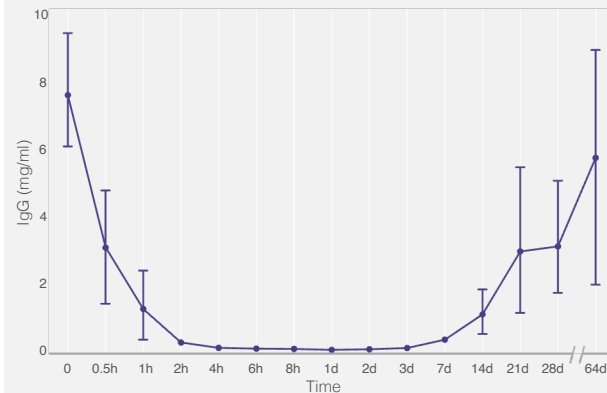
A unique IgG antibody-cleaving enzyme

- 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

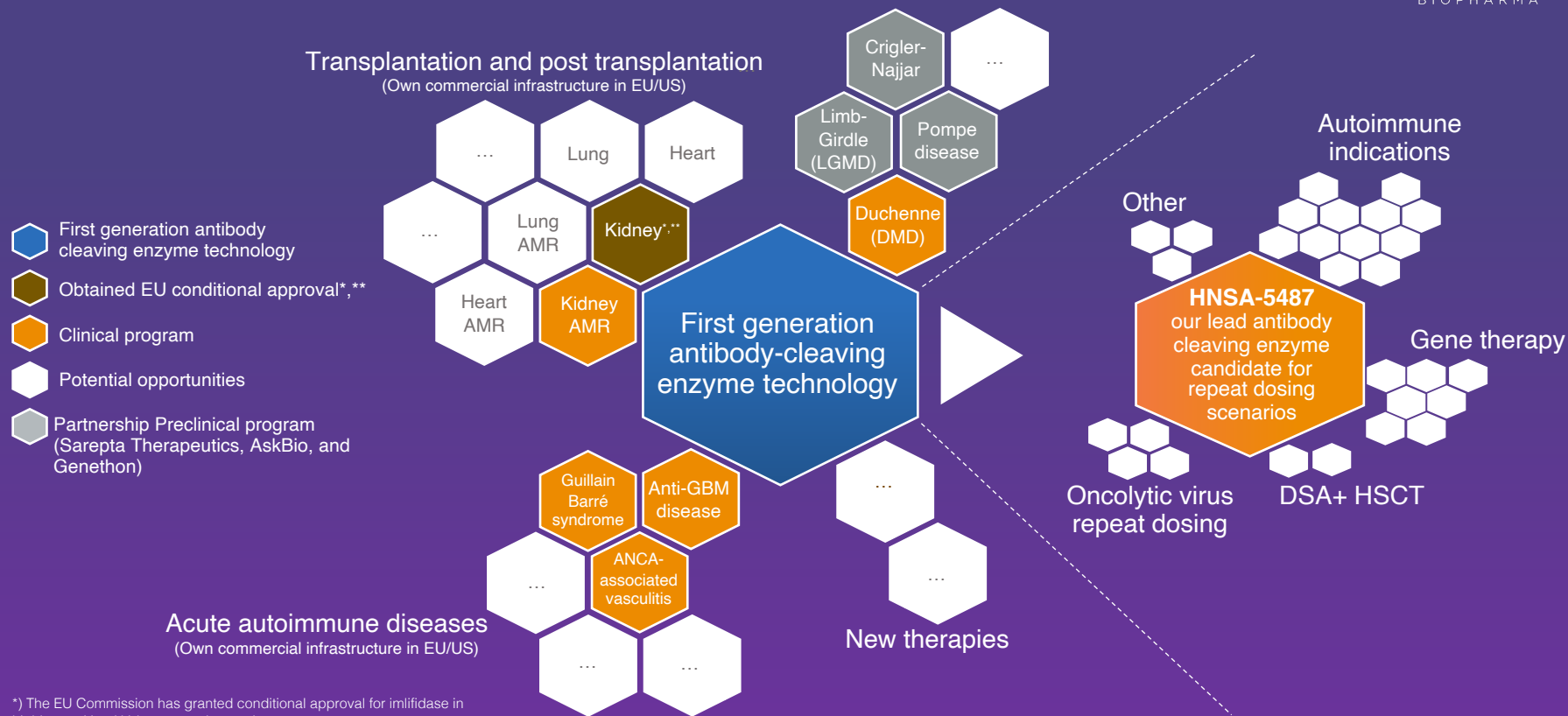


Inactivates IgG in 2-6 hours

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



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
Imilifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}	Completed	Completed	Completed	Planned	Completed	Ongoing		EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	U.S. "ConfIdaS": Kidney transplantation in highly sensitized patients ^{1,2}	Completed	Completed	Completed	Ongoing				Completion of randomization (64 patients) mid 2024
	GOOD-IDES-02: Anti-GBM antibody disease	Completed	Completed	Completed	Ongoing				Complete enrollment (50 patients)
	16-HMedIdes-12: Active Antibody Mediated Rejection (AMR)	Completed	Completed	Completed					Publication in peer-reviewed journal
	15-HMedIdes-09: Guillain-Barré Syndrome (GBS)	Completed	Completed	Ongoing					Comparative efficacy analysis 2024
	Investigator-initiated trial in ANCA-associated vasculitis ³	Completed	Completed	Ongoing					Complete enrollment (10 patients)
	SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)	Completed	Phase 1b					Sarepta Therapeutics	Completion of enrolmen
	Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)	Ongoing						Sarepta Therapeutics	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease	Ongoing						AskBio	Preclinical research
HNSA-5487	Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome	Ongoing						Genethon	Commence clinical study
	NICE-01 phase 1: HNSA-5487 – Lead candidate from the NiceR program	Completed	Ongoing						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 OS+O4 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



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}

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%)

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

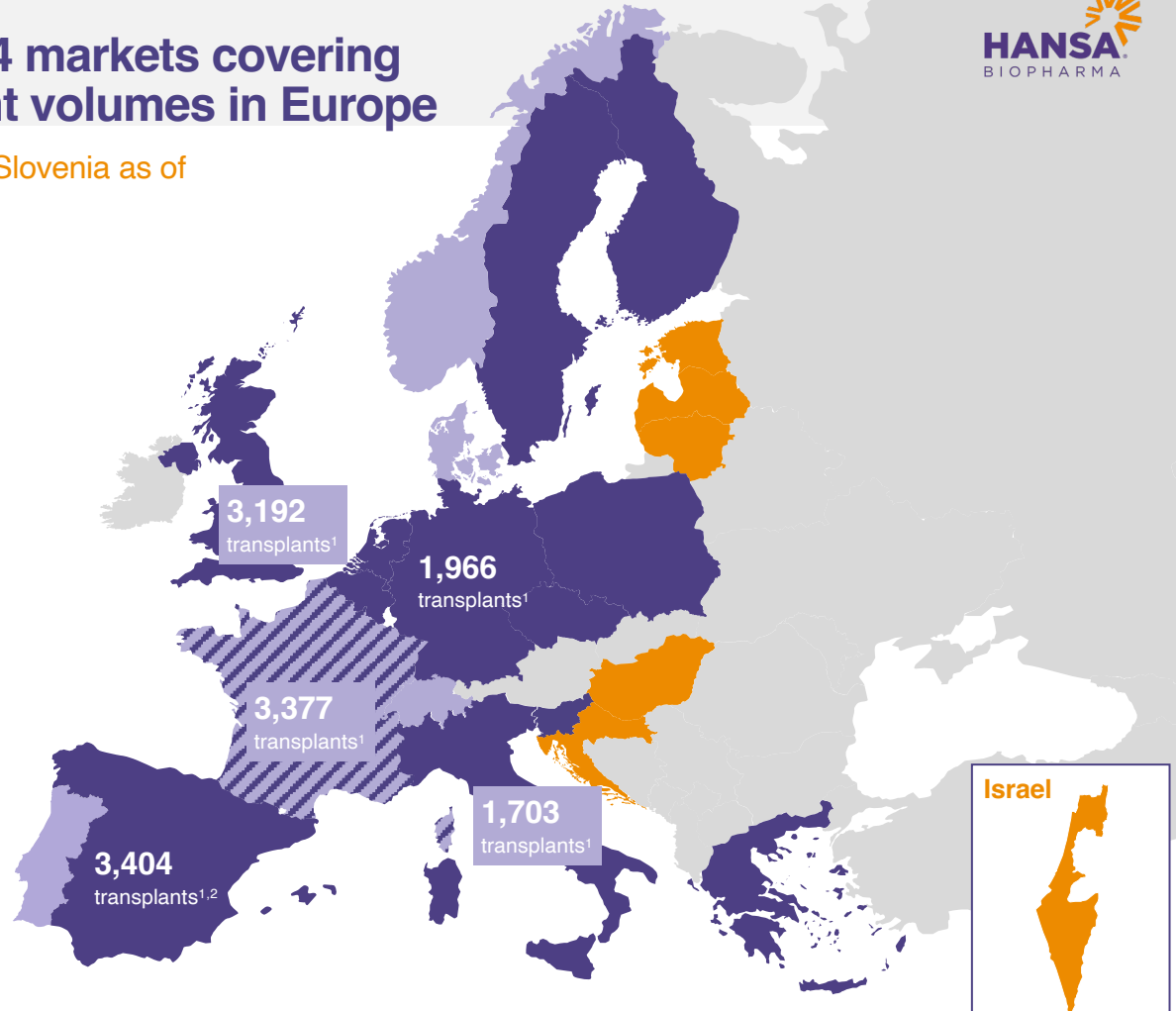


¹ EDQM. (2020). International figures on donation and Transplantation 2019
² SRTR Database and individual assessments of allocation systems

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

-  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

Potential to disrupt transplantation care in the U.S. with imlifidase

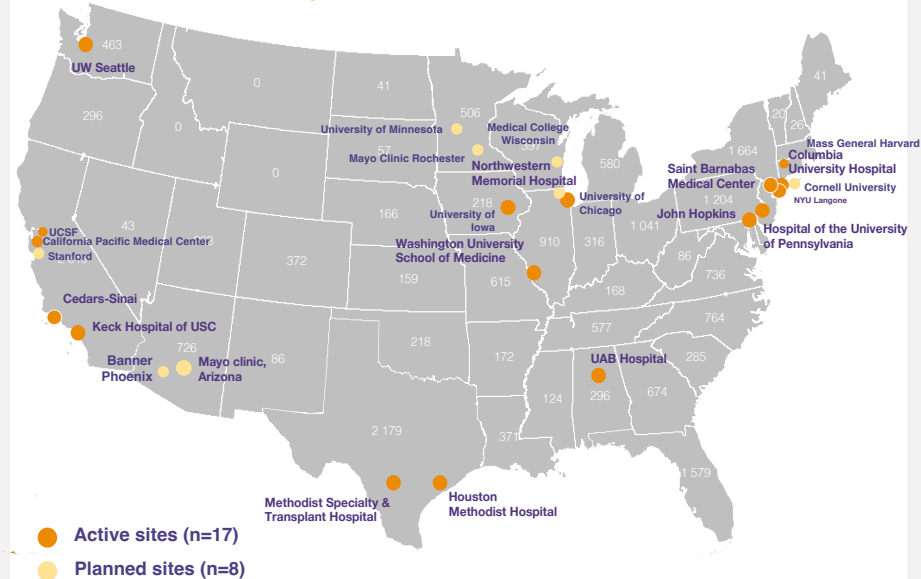
ConfideS phase 3 trial will further advance potential for imlifidase to address unmet need in desensitization

U.S. ConfideS

Phase 3

- Continue enrollment beyond 64 patients
- Currently 104 patients screened and enrolled
- More than 2/3 of targeted patients randomized
- Expansion from 17 to 25 site to accelerate randomization
- Randomization expected to complete mid-2024
- BLA filing in 2025

Involved ConfideS sites cover more than 20% of total transplantation volumes in the U.S¹



Clinical development programs

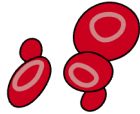


Autoimmune attacks

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



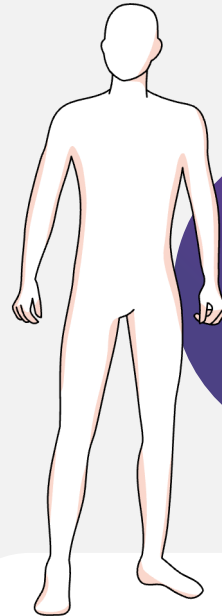
Nerves

Guillain-Barré syndrome,
Myasthenia gravis



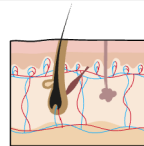
Lung

Wegner's granulomatosis



Skin

Psoriasis, Pemphigus



Over
100 different
types of
Autoimmune
disorders



Brain

Multiple sclerosis,
Neuromyelitis optica



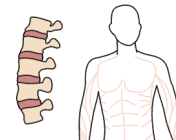
Thyroid

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* patients¹³

AHA

WAHA
~95 000*¹¹

HIT
0.1–5% of patients receiving therapeutic dose of heparin¹⁴

APS
~350 000*¹²

ITP
~75 000*¹⁰

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

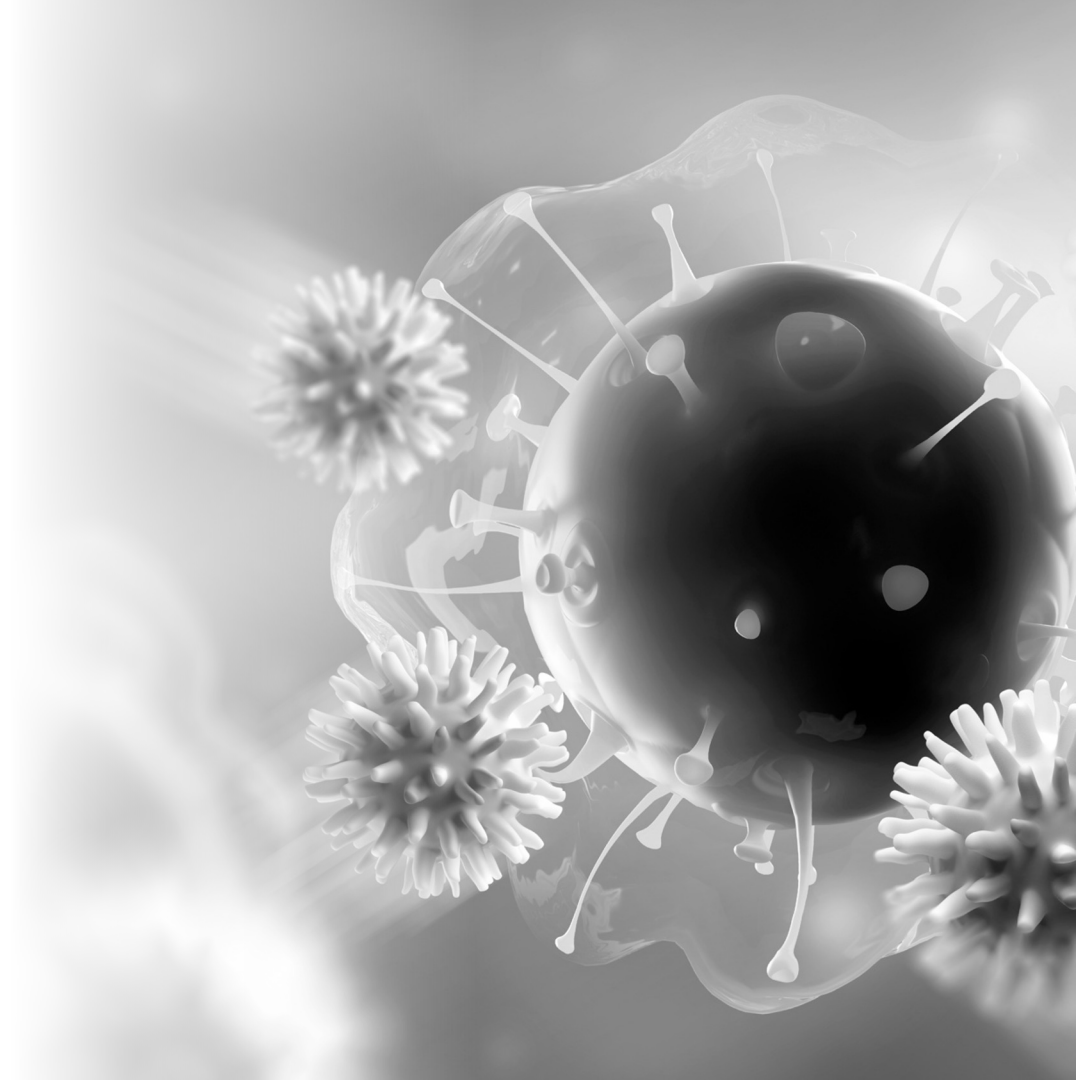
*Total disease populations in EU & US, based on prevalence and population data

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

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]
⁵Gullain-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

⁸Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011;10-05
⁹Wentzell, 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:10.1177/1358863X19988253

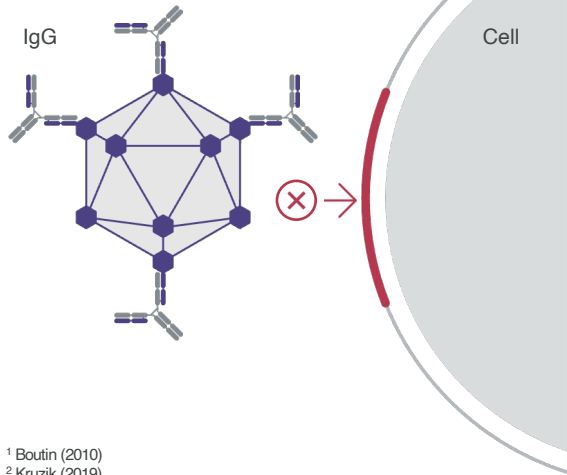
Gene Therapy



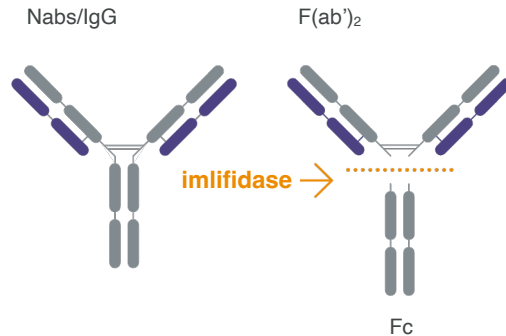
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

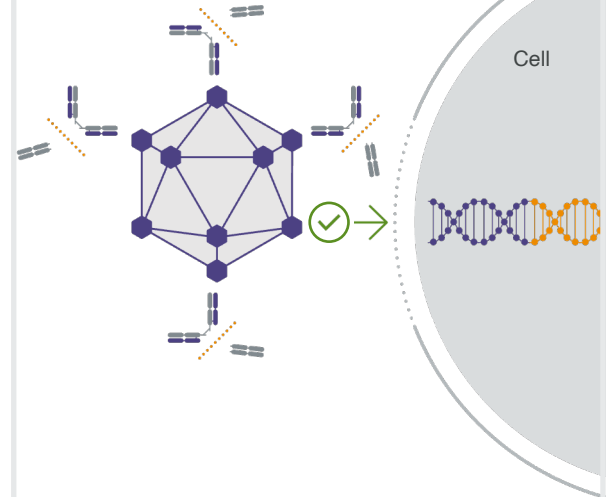
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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)

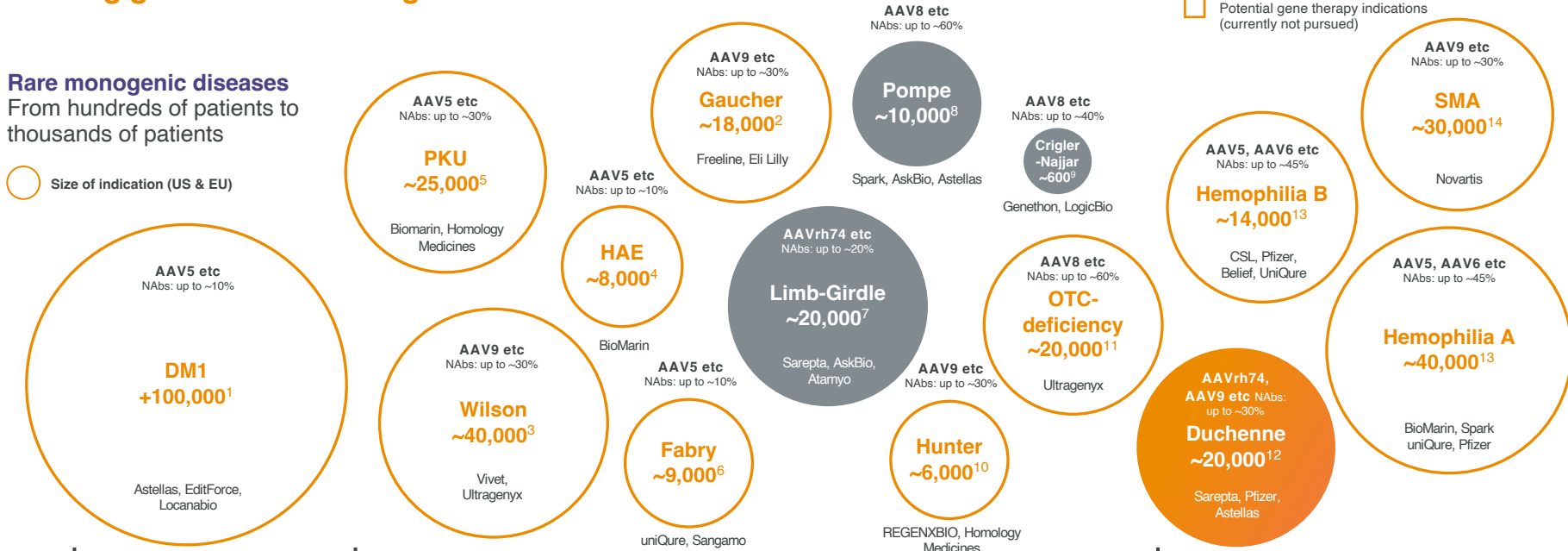
² Kruzik (2019)

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)










Late Preclinical Clinical Market

Numbers are estimated based on population and prevalence

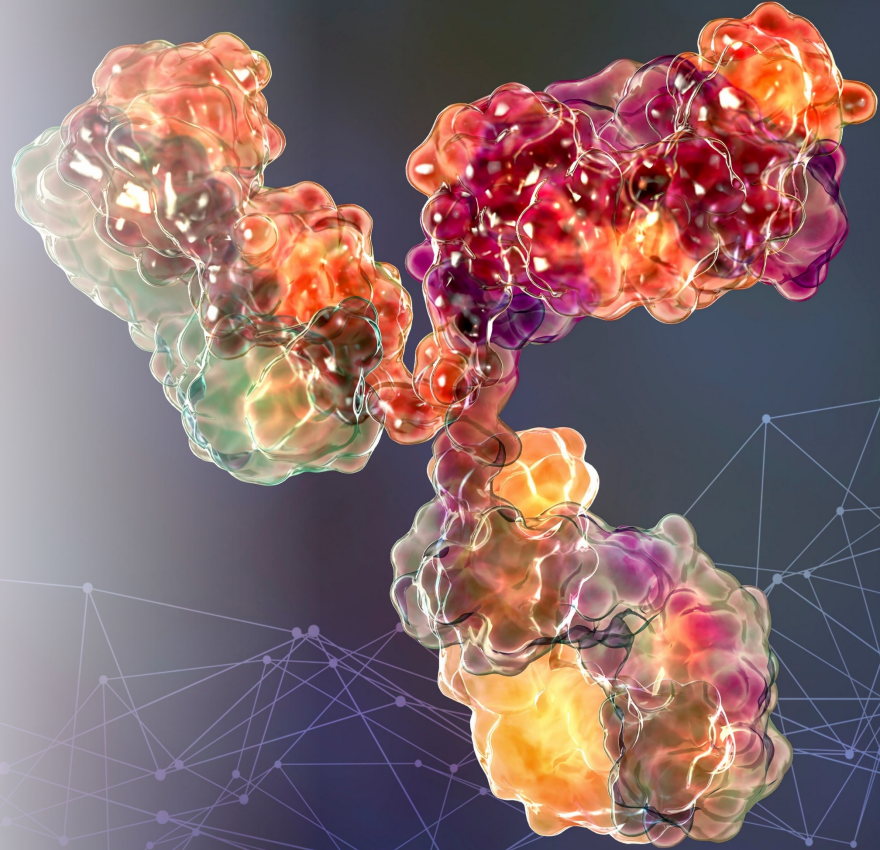
17
1. RareDiseases.org, <https://rare-diseases.org/entry/duchenne-muscular-dystrophy/> [Accessed 2023-06-28]
2. Medlineplus.gov, <https://medlineplus.gov/duchenne-muscular-dystrophy.html> [Accessed 2023-06-28]
3. Santali TD, Lauren TL, Munk DE, Vitting H, Weiss HA, Orr P. The Prevalence of Wilson's Disease: An Update. *Hepatology*. 2020 Feb;71(2):722-732. doi: 10.1002/hep.23911. Epub 2020 Jan 31. PMID: 31449670.
4. Grant A, Grant JA. Hereditary angioedema: epidemiology, management, and role of ecallinert. *Biologics*. 2013;7:1103-13. doi: 10.2147/BTT.257568. Epub 2013 May 3. PMID: 2360243; PMCID: PMC3647445.
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11. RareDiseases.org, <https://rare-diseases.org/entry/hemophilia-a/> [Accessed 2023-07-12]
12. Cristallini S, et al. Global epidemiology of Duchenne muscular dystrophy: an updated systematic review and meta-analysis. *Orphanet J Rare Dis*. 2020 Jun 5;15(1):141. doi: 10.1186/s13023-020-01433-8. PMID: 32625595; PMCID: PMC7273023
13. GlobalData [Accessed 2023-12-15]
14. Verhaert, I.E.C., Rutgersen, A., Wilson, L.J. et al. Prevalence, incidence and carrier frequency of Sq-linked spinal muscular atrophy - a literature review. *Orphanet J Rare Dis* 12, 124 (2017). <https://doi.org/10.1186/s13023-017-0671-8>

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
	<ul style="list-style-type: none"> 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 	<p>Duchenne Muscular Dystrophy (DMD) 1/3,500 to 5,000 male births worldwide</p> <p>Limb-Girdle Muscular Dystrophy Global prevalence of ~1.6 per 100k individuals</p>	 
	<ul style="list-style-type: none"> Early innovator in gene therapy Conducts pre-clinical and clinical trials (Phase 1/2) 	<p>Pompe disease Approximate incidence is 1 per 40,000 births, or ~200 per year in the US + EU</p>	 <p>Exclusive option for AskBio to negotiate a potential full development and commercialization agreement</p>
	<ul style="list-style-type: none"> A pioneer in the discovery and development of gene therapies Conducts pre-clinical and clinical trials (Phase 1/2) 	<p>Crigler-Najjar syndrome Approximately incidence is 0.6-1 case per one million people or 600 patients in Europe and the U.S</p>	 <p>The initial agreement is focused on research and development The companies will consider a subsequent agreement for commercialization at a later stage</p>

Next generation enzymes



Advancing HNSA 5487 – a high potential next-gen enzyme for repeat dosing

HNSA-5487



Engineered for lower immunogenicity



Short and long-term interval dosing



Broad range of indications
(prolonged or intermittent IgG-free window)

Broaden the IgG free window

Rapidly cleaves IgG and could potentially create a longer IgG-low period

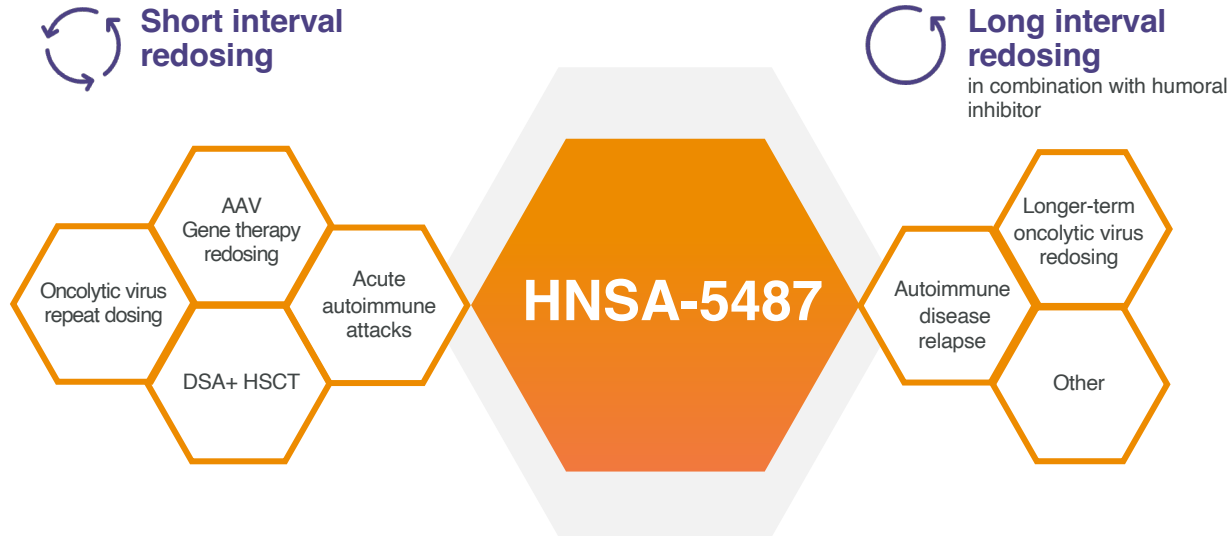
Address unmet need in autoimmune disease

Powerful 5487 IgG cleaving in combination with humoral inhibitor could result in greater control of disease in variety of autoimmune diseases

Enable re-dosing in gene therapy

Could provide solutions to enable re-dosing in AAV gene therapy and prolonged dosing of oncolytic viruses

Potential indication landscape for HNSA-5487 and reasons to believe



First in Human Study Results

- ✓ Administration was safe and well tolerated
- ✓ PD showed a fast and complete cleavage of IgG to F(ab')₂ and Fc-fragments with ascending doses; PK in line with expectations
- ✓ Further analysis around endpoints and immunogenicity to be completed in 2024 incl. selection of lead indication

Key strategic priorities



Commercialize Idefirix® in first indication and markets

1

- Successfully launch Idefirix® in Europe
- Secure FDA approval and launch Idefirix® in the U.S.
- Geographic expansion



Advance our ongoing clinical programs

2

- Achieve approval/usage of imlifidase in follow-on indications
- Broaden the Idefirix® label beyond kidney transplantation



Expand our IgG-cleaving enzyme technology

3

- Expand IgG-cleaving enzyme technology platform into gene therapy
- Develop next gen IgG-cleaving enzymes for repeat usage



HANSA

BIOPHARMA

2023 achievements and upcoming milestones 2024/25

2023	2024	2025
Q4 2023		
<ul style="list-style-type: none"> ✓ 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 	<ul style="list-style-type: none"> - GBS Phase 2: Outcome of comparative efficacy analysis - 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 	<ul style="list-style-type: none"> - 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

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

March 6, 2024 Life Sciencedagen, Sahlgrenska University Hospital, 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