



Investor Presentation

Erik Penser Company Day
Stockholm

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VP, Head of Investor Relations

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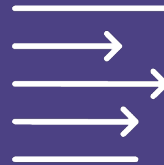
Hansa Biopharma today

A successful track record and a promising future...



A validated technology

- ✓ Commercial stage biotech company
- ✓ Approval in kidney transplantation (EU)
- ✓ Market Access in 13 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
- Planned clinical study in gene therapy
- Next generation IgG antibody-cleaving enzymes program in phase 1



Skilled and experienced team

- A high-performance organization with 20 years on average in life science
- Purpose driven culture
- Headquartered in Lund, Sweden with 162 employees (June 2023)
- Operations in both EU and the US



Financial position

- Hansa is financed into 2025
- Market cap (USD): ~228m (July 2023)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

Imlifidase

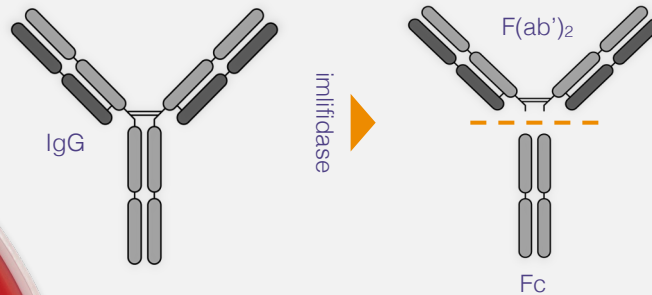
a novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

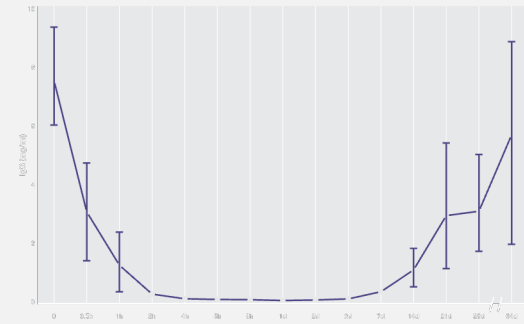
A unique IgG antibody-cleaving enzyme

- 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 pipeline with seven ongoing programs in clinical stage including three programs in late-stage development

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 randomization (64 patients) H2 2023
	Anti-GBM antibody disease ³							Complete enrollment (50 patients)
	Antibody mediated rejection in kidney transplantation (AMR)							Full data read out H2 2023
	Guillain-Barré syndrome (GBS)							Topline data H2 2023 / Comparative efficacy analysis 2024
	ANCA-associated vasculitis ⁴							Complete enrollment (10 patients)
	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 syndrome (Partnered with Genethon)							Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)							Completion of phase 1 (H2 2023)

 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 Mårten Segelmark, Professor at the universities in Linköping and Lund, Sweden

⁴ 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

Between 80,000 and 100,000 kidney transplant patients are waiting for a new kidney in both Europe and the U.S. Availability of organs remain a big challenge since only 1 in 4 patients are offered access to a lifesaving transplantation, while many highly sensitized patients are unlikely to be transplanted even under current prioritization programs

Low complexity transplants

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%)

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

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](#)

29-year-old woman transplanted at Erasmus, Rotterdam after being dialysis dependent since 2016 and experiencing two graft losses

[Link article in Amazing Erasmus from July 7, 2022](#)

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

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

1 Build the foundation for Idefirix®

Key activity matrix

- ✓ 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

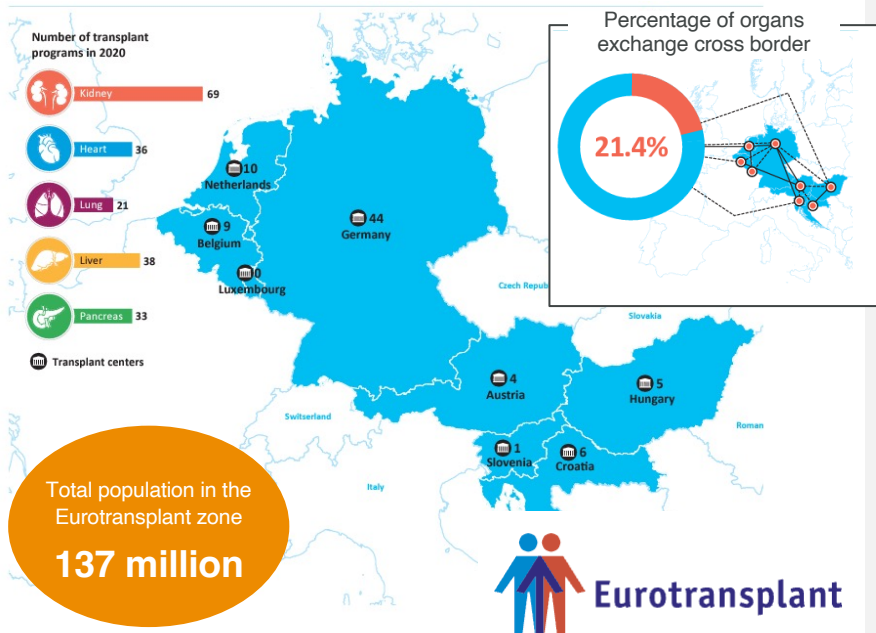
- Potentially expand into living donor transplantation
- Potentially expand into other solid organs

Commercial sales uptake



Eurotransplant has recently initiated a new desensitization program for imlifidase-eligible patients

The Eurotransplant zone covers eight countries



New Pilot in the Acceptable Mismatch Priority Program

CURRENT

Acceptable Mismatch (AM) Program

Allocates organs to patients who are immunologically compromised because of current and/or historic HLA-sensitization

20 patients to be included in the Pilot program in rounds of five

NEW PILOT

Eurotransplant Desensitization Program

Imlifidase-eligible patients who are incompatible to a deceased donor

Inclusion criteria for new program

- No age limitation for patients
- Donor below 65 years
- A minimal waiting time of 3 years in the AM program
- Final transplant center CDC crossmatch must be negative.
- Informed consent form for a follow-up data

Idefirix receives provisional approval in Australia

First market to approve use in transplants from both living and deceased donors

Australian kidney disease and transplantation statistics

~15,200 patients suffer from ESRD and receive dialysis

1,338 patients were waitlisted for a kidney transplant from deceased donors in 2021

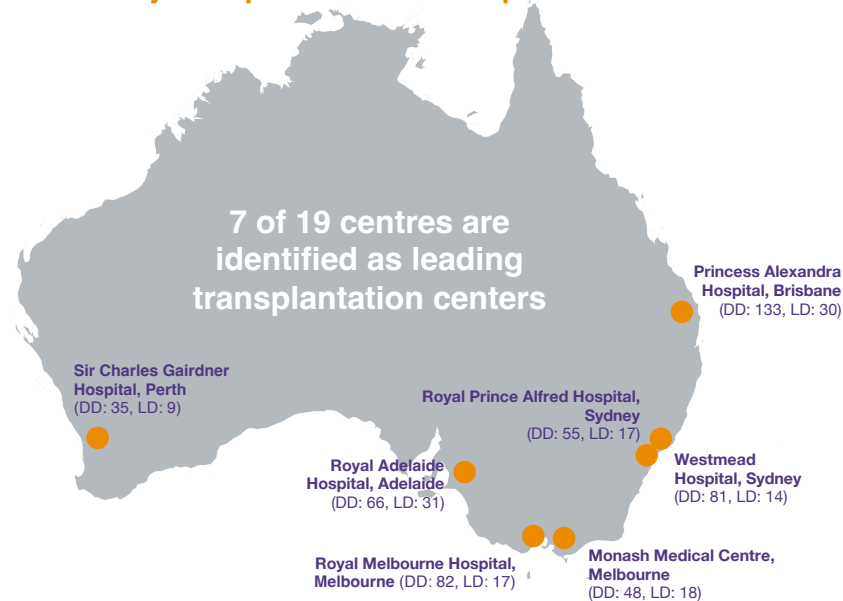
857 kidney transplantations were carried out in 2021

~21% of patients waitlisted have a cPRA score of 95 or higher

76/24 deceased vs living donor transplantations

Full approval in Australia will require submission to the TGA of further safety and efficacy data from studies that are currently underway (e.g. long-term follow-up, Post Approval Study and U.S ConfIdes study)

Kidney transplantation landscape in Australia



Sources:

1. ANZDATA. The Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) collects information about people receiving dialysis or kidney transplant for end-stage kidney disease in Australia and New Zealand.
2. ANZDATA 2022 Annual Report #45; available at: <https://www.anzdata.org.au/report/anzdata-45th-annual-report-2022-data-to-2021/>

Clinical development programs

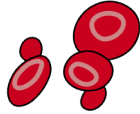


Autoimmune attacks

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



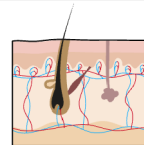
Lung

Wegner's granulomatosis



Skin

Psoriasis, Pemphigus



Over
100 different
types of
Autoimmune
disorders

Brain

Multiple sclerosis,
Neuromyelitis optica



Thyroid

Hashimoto's disease,
Graves' disease



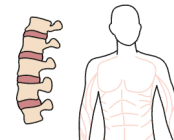
Kidney

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
~325 000*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.

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.

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

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

⁷Chronic 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

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

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

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

¹³Litvinova, 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

New investigator-initiated phase 2 study in ANCA-associated vasculitis

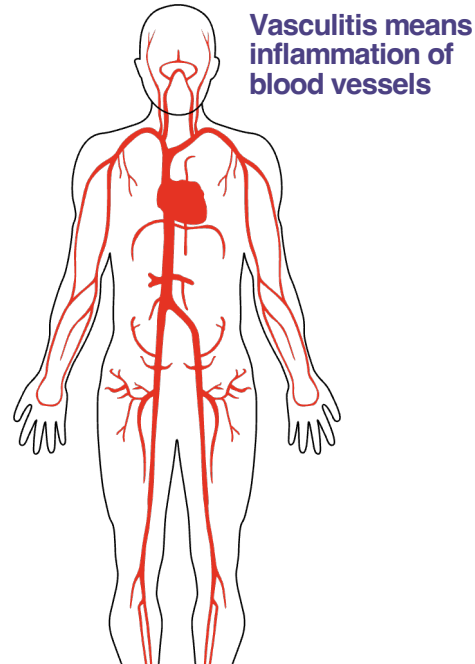
- a group of autoimmune diseases characterized by inflammation of blood vessels with very few treatment options today

Incidences

~3 in 100,000 annually across EU/US of which 8-36% are estimated to have Acute Respiratory Distress Syndrome due to pulmonary hemorrhage^{1,2}

Standard of Care

- Current protocol is Immunosuppression and Intensive support care



Indication

- Causes damage to small blood vessels in the body resulting in inflammation and damage to organs, such as the kidneys, lungs etc.³
- Progress of the disease results in end stage kidney disease in 25 percent of patients⁵
- Most severe cases involving lungs lead to respiratory failure⁴
- Few treatment options today

The investigator-initiated trial (IIT) is sponsored by Charité Universitätsmedizin, Berlin



Study design

- Single arm, single center, phase 2 study with the primary objective to evaluate efficacy and safety on top of SoC
- 10 patients with severe ANCA-associated vasculitis and Acute Respiratory Distress Syndrome will be treated with imlifidase on top of SoC
- First patient treated Q2 2023
- Trial led by Dr. Adrian Schreiber and Dr. Philipp Enghard at Charité

1. Bertl A, et al. Arthritis Rheum atol. 2017;69.
 2. Rathmann J, et al. RMD Open. 2023;9:e002949.
 3. Falk RJ, Jennette JC. The New England journal of medicine. 1988;318(25):1651-7.
 4. Flossmann O, et al. Annals of the rheumatic diseases. 2011;70(3):488-94.
 5. Booth AD, et al. American journal of kidney diseases. 2003;41(4):776-84.

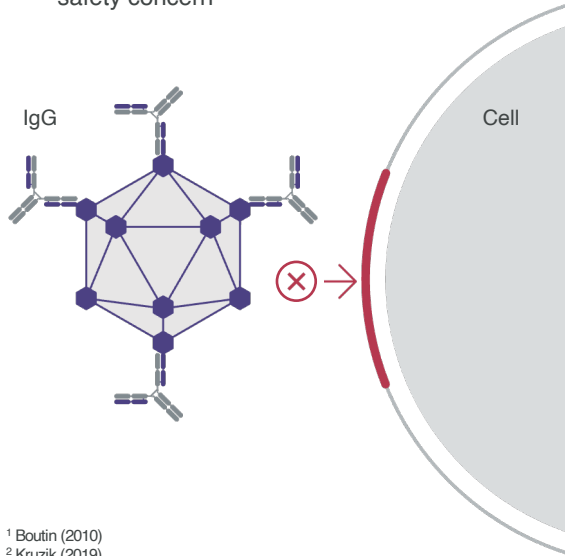
Gene Therapy



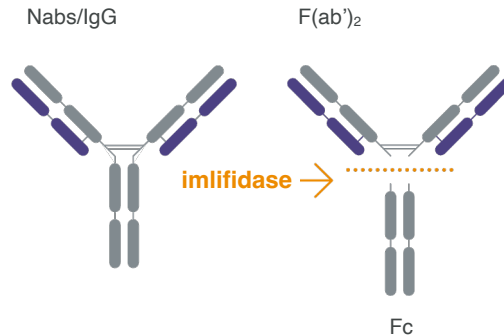
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

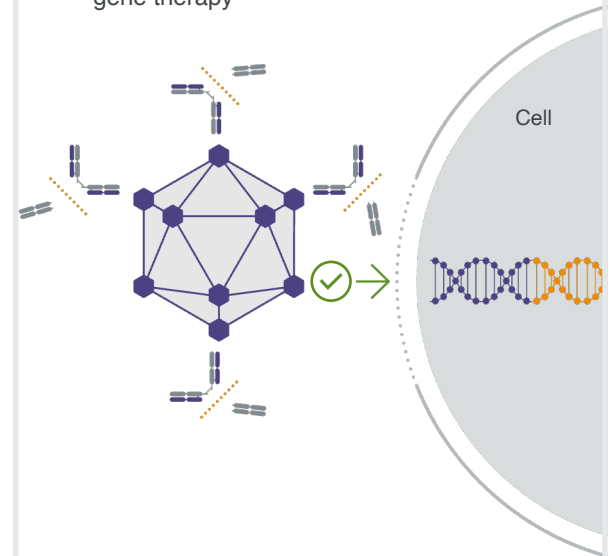
- 1** Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



- 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)

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 	Duchenne Muscular Dystrophy (DMD) 1/3,500 to 5,000 male births worldwide	Antibody cleaving enzyme technology ✓	Preclinical Development ✓	Planned 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
	<ul style="list-style-type: none"> 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)	Exclusive option for AskBio to negotiate a potential full development and commercialization agreement	
	<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) 	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)	The initial agreement is focused on research and development The companies will consider a subsequent agreement for commercialization at a later stage	

Duchenne muscular dystrophy (DMD) is progressive and causes irreversible muscle damage and loss of function

Incidences

1 in 3,500 to 5,000

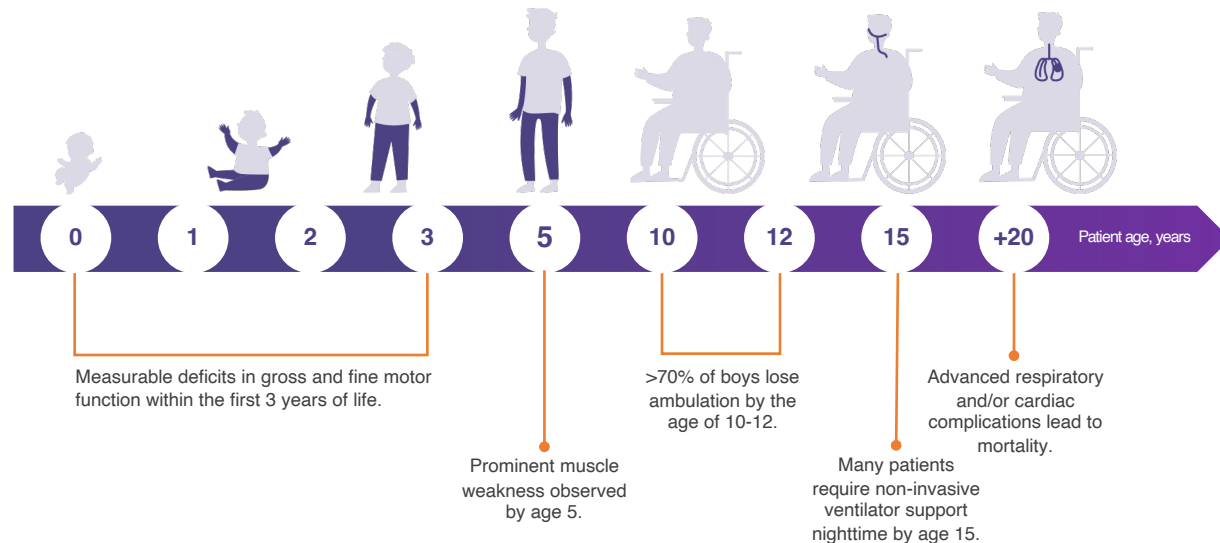
male births worldwide

~14% have pre-existing
IgG antibodies to rh74

High unmet need

- DMD is a rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3-5, and most patients use a wheelchair by the time they are 12, many require respiratory aid by late teens.
- Life expectancy 26-30 years

DMD signs at early age, with most patients using a wheelchair by age 12



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

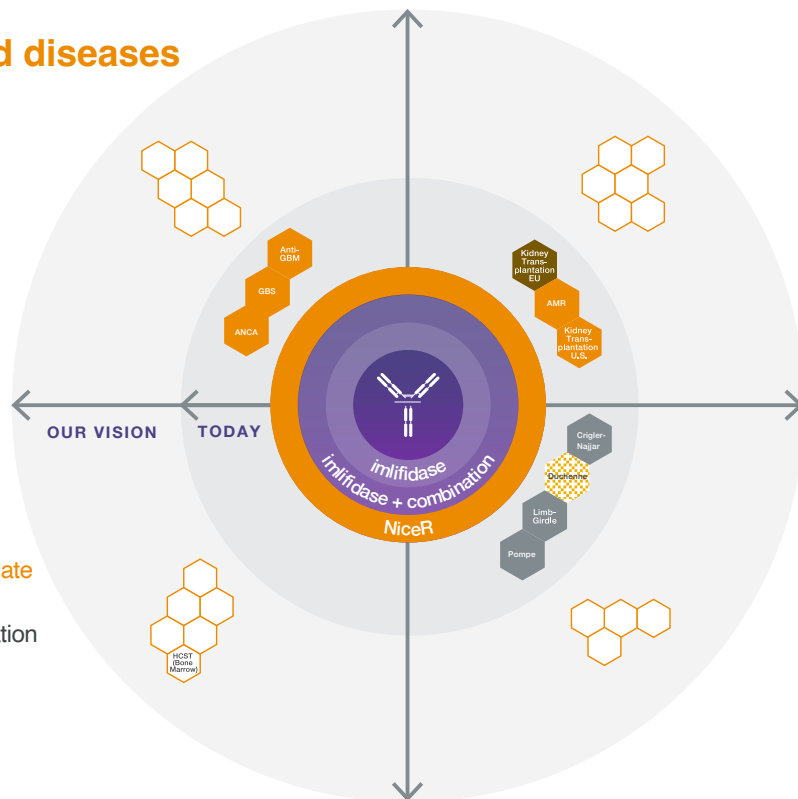
- Rapidly progressive glomerulonephritis
- Neurological disorders
- Skin and blood disorders



New therapies and oncology

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogeneic 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



Achieved and upcoming milestones

2023		2024
H1 2023	H2 2023	
<ul style="list-style-type: none"> ✓ U.S. ConfideS (Kidney tx) Phase 3: Complete enrollment ✓ Anti-GBM disease Phase 3: First patient enrolled ✓ GBS Phase 2: Complete enrollment ✓ ANCA-associated vasculitis Phase 2: First patient enrolled ✓ HNSA-5487 (Lead NiceR candidate): Initiate Phase 1 study ✓ Genethon Crigler-Najjar: Initiate preclinical study with imlifidase prior to GNT-0003 	<ul style="list-style-type: none"> - U.S. ConfideS (Kidney tx) Phase 3: Complete randomization - GBS Phase 2: First data readout - AMR Phase 2: Full data readout - Long-term follow-up (Kidney tx): 5-year data readout - Sarepta DMD pre-treatment Phase 1b: Commence clinical study - HNSA-5487 (Lead NiceR candidate): Completion of Phase 1 study 	<ul style="list-style-type: none"> - U.S. ConfideS (Kidney tx) Phase 3: BLA submission - 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

Contact our Investor Relations and Corporate Affairs team

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Calendar and events

Aug 31, 2023	HC Andersen – Life Science seminar (virtual)
Sept 11, 2023	HC Wainwright Annual Global Investment Conference, NYC
Sept 11, 2023	MorganStanley Global Healthcare Conference, NYC
Sept 14, 2023	Pareto Annual Healthcare Conference, Stockholm
Sept 14, 2023	Erik Penser Company Day, Malmö
Oct 2, 2023	Redeye: Autoimmune and inflammatory disease, Stockholm
Oct 5-6, 2023	Cowen US non-deal road show
Oct 12, 2023	Redeye: Afterwork, Malmö
Oct 19, 2023	Interim Report for January-September 2023
Nov 21, 2023	SEB Healthcare Seminar 2023, Stockholm
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen