HANSA BIOPHARMA

# Investor Presentation

Erik Penser bolagsdag Malmö

September 14, 2023

**Klaus Sindahl**

*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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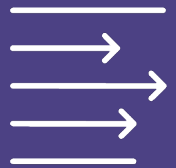
# Hansa Biopharma today

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%



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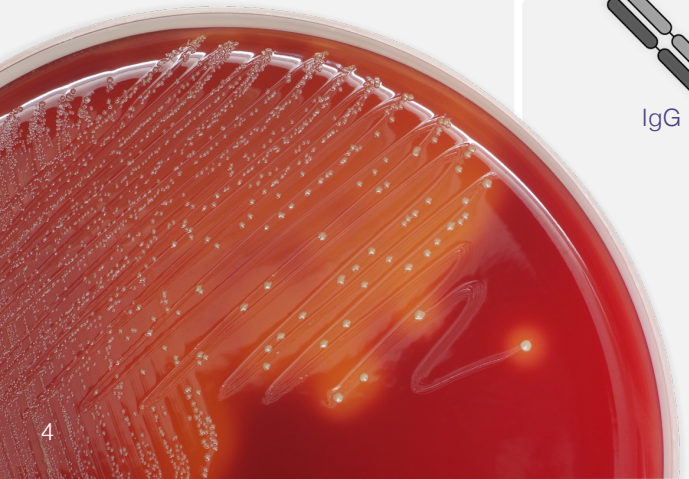
# Imlifidase

a novel approach to eliminate pathogenic IgG

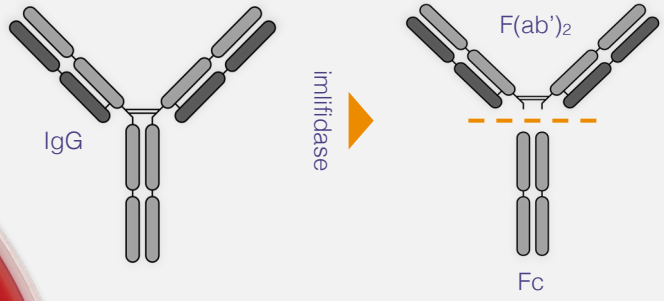
## Origins from a bacteria *Streptococcus pyogenes*

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



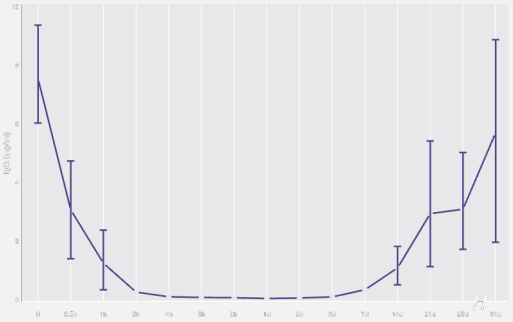
## A unique IgG antibody-cleaving enzyme

- 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



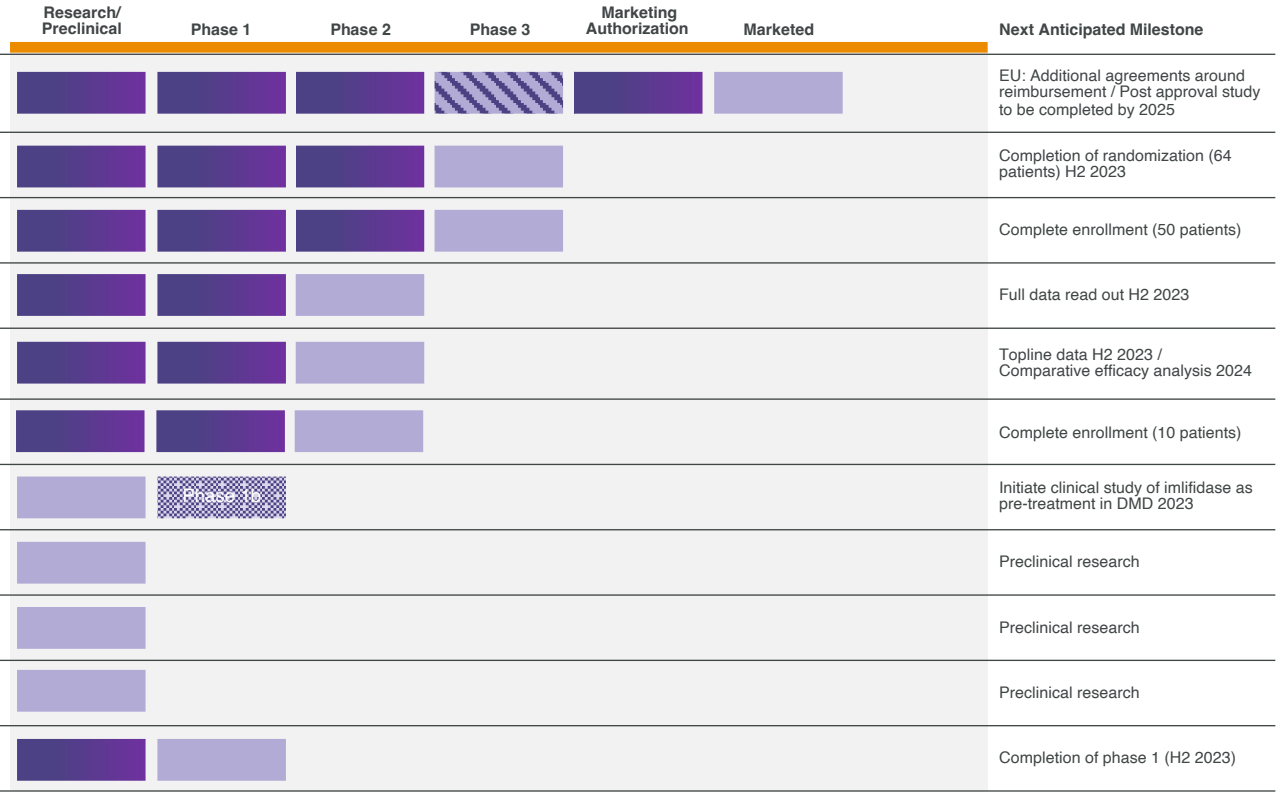

## Inactivates IgG in 2-6 hours

- 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

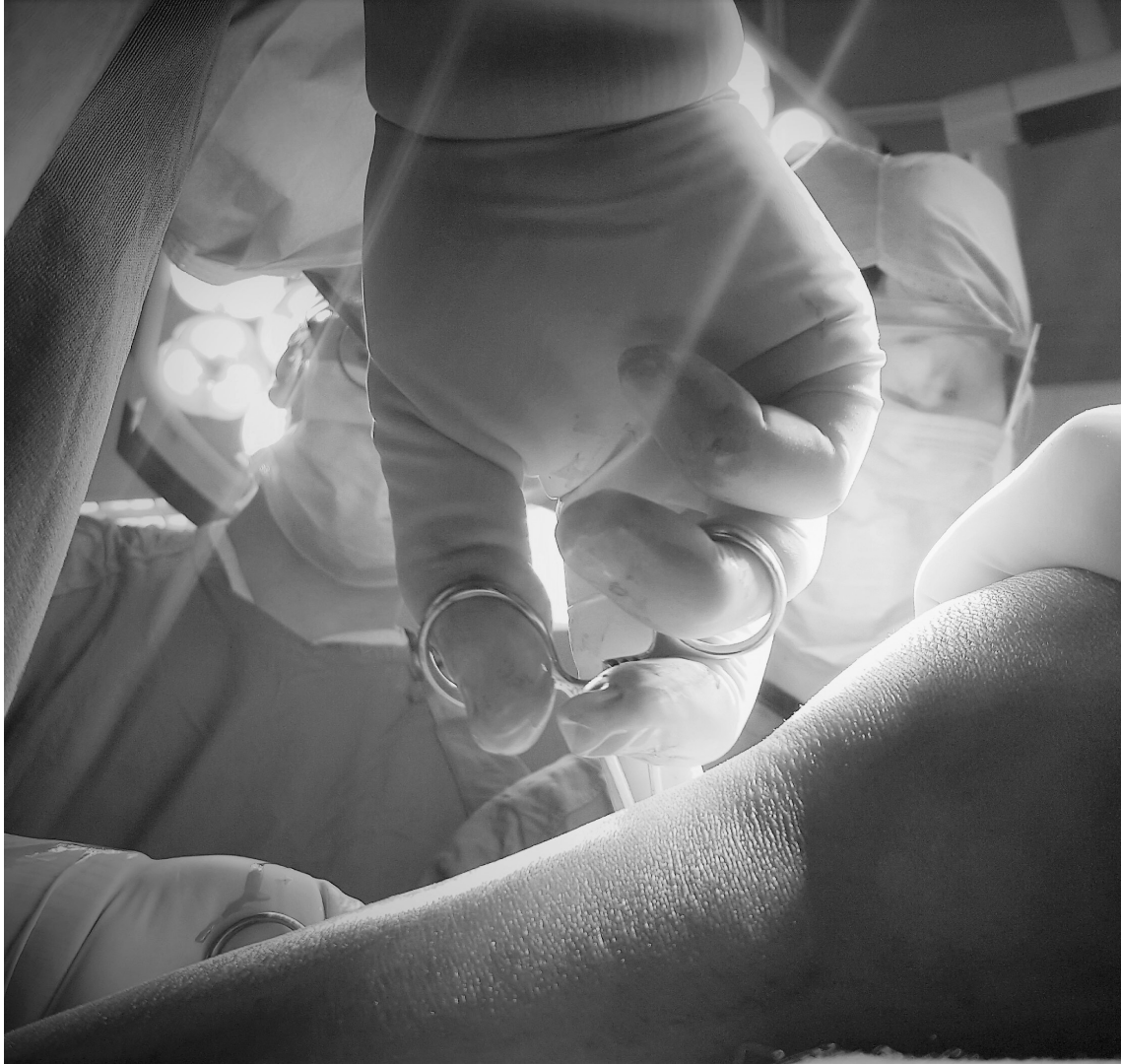
| Candidate/ Project | Indication | Next Anticipated Milestone |
|---|---|---|
| Imlifidase | EU: Kidney transplantation in highly sensitized patients[1,2] | EU: Additional agreements around reimbursement / Post approval study to be completed by 2025 |
| | US: Kidney transplantation in highly sensitized 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



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# 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] | 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%) |

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

## 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

idefirix® imlifidase

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



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# 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

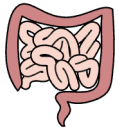
Commercial sales uptake

# Autoimmune attacks

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

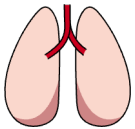
**Blood**
Autoimmune hemolytic anemia,
Immune thrombocytopenia

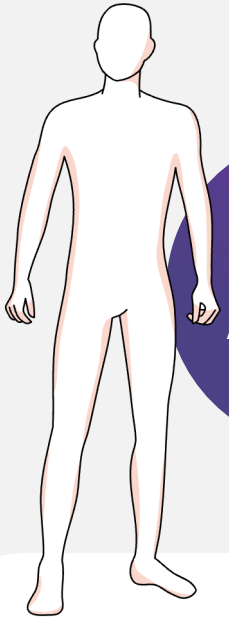
**GI tract**
Crohn's disease



**Nerves**
Guillain-Barré syndrome,
Myasthenia gravis

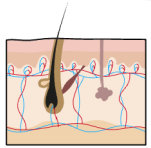
**Lung**
Wegner's granulomatosis





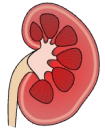
**Over 100 different types of Autoimmune disorders**

**Skin**
Psoriasis, Pemphigus

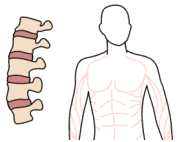


**Brain**
Multiple sclerosis,
Neuromyelitis optica

**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 ~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* 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

# 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

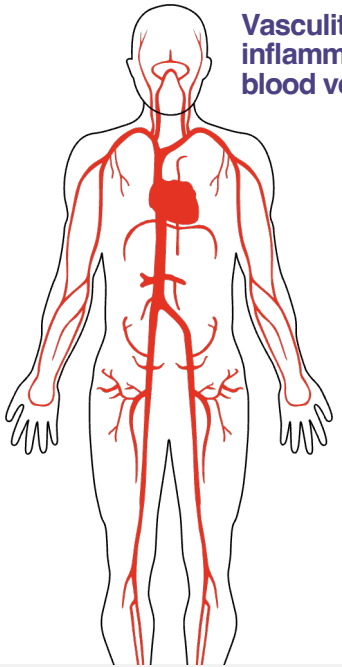
~3 in 100,000 annually across EU/US of which 8-36% are estimated to have Acute Respiratory Distress Syndrome due to pulmonary hemorrhage[1,2]

## 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 patients[5]
- Most severe cases involving lungs lead to respiratory failure[4]
- Few treatment options today



**Vasculitis means inflammation of blood vessels**

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

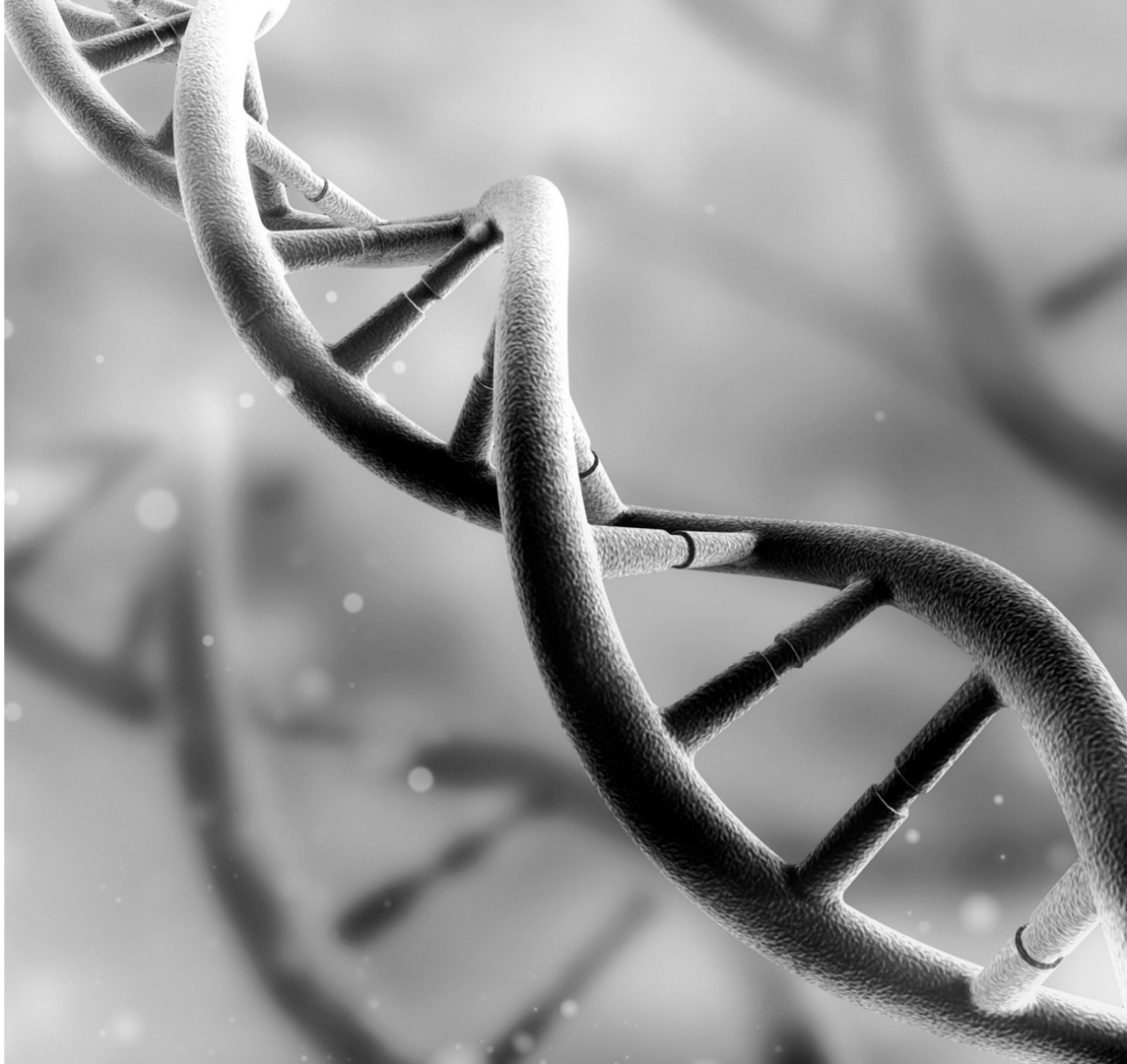
CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

## 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. Berti 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



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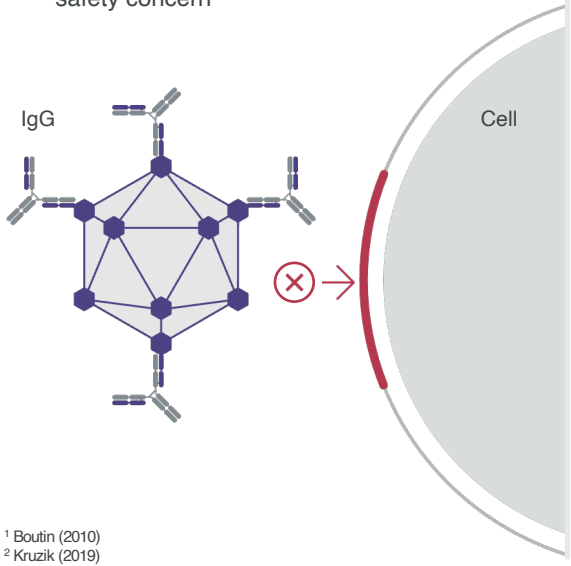
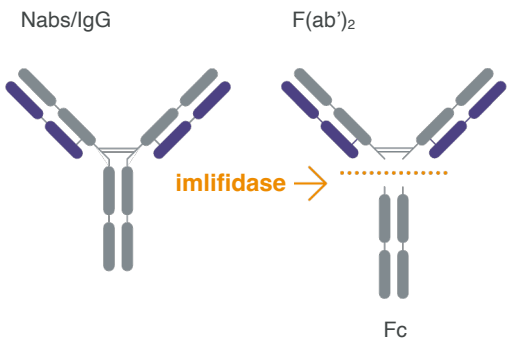
# Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

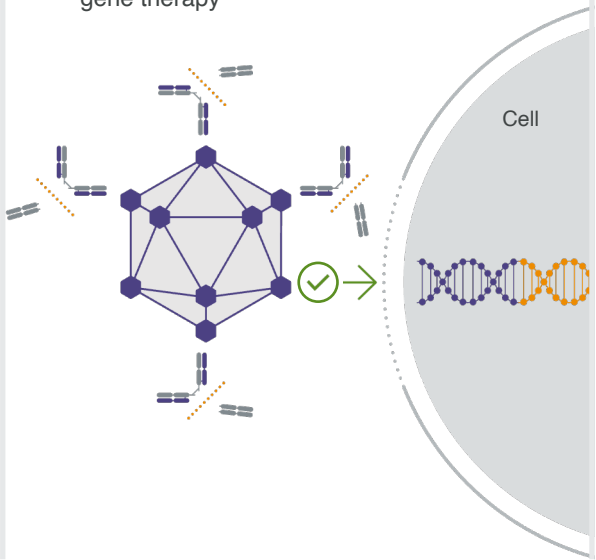
**1** Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern




**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<br>▪ Pre-clinical and clinical plan<br>▪ Regulatory<br>▪ Promotion<br>▪ FDA approval in 4–5-year-old kids suffering with DMD | **Duchenne Muscular Dystrophy (DMD)**<br>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**<br>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<br>▪ Conducts pre-clinical and clinical trials (Phase 1/2) | **Pompe disease**<br>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<br>▪ Conducts pre-clinical and clinical trials (Phase 1/2) | **Crigler-Najjar syndrome**<br>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**

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

## Targeting rare IgG mediated diseases

### Auto-immune diseases

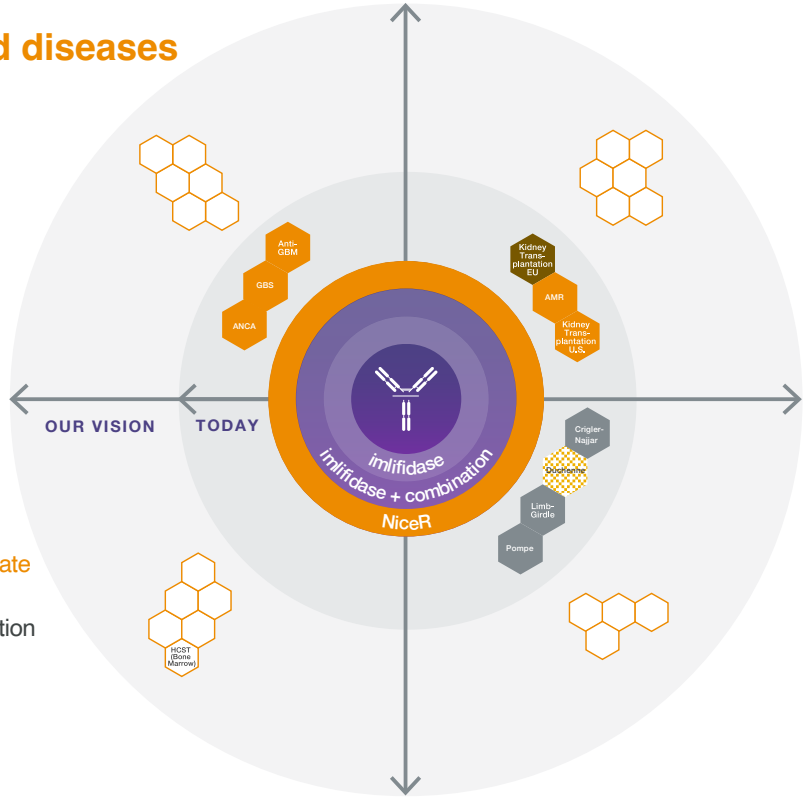
Anti-GBM disease paves the way for development in other autoimmune diseases

- 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)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# Achieved and upcoming milestones

## 2023

### H1 2023

- ✓ **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

### H2 2023

- **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

## 2024

- **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 |