Lena Winstedt

Global Franchise Lead Gene Therapy

Pareto Securities' 14th Annual Healthcare Conference

September 14, 2023

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HANSA BIOPHARMA

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

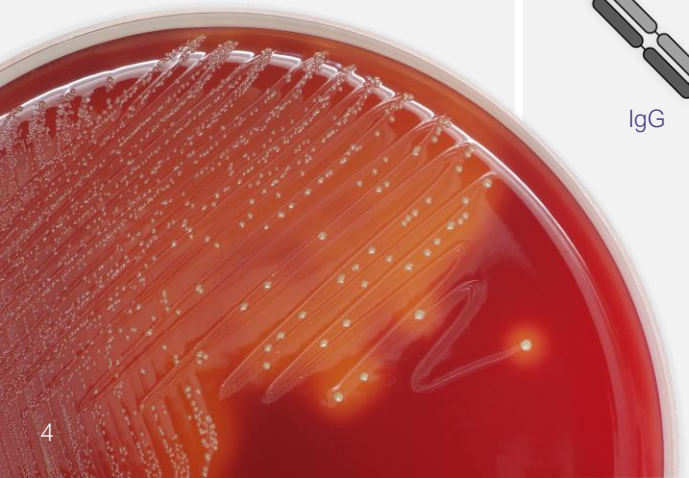
- Hansa is financed into 2025
- Market cap (USD): ~235m (Aug. 2023)
- Listed on Nasdaq Stockholm
- 20,000 shareholders
- Foreign ownership make up ~43%

Imlifidase

a novel approach to eliminate pathogenic IgG

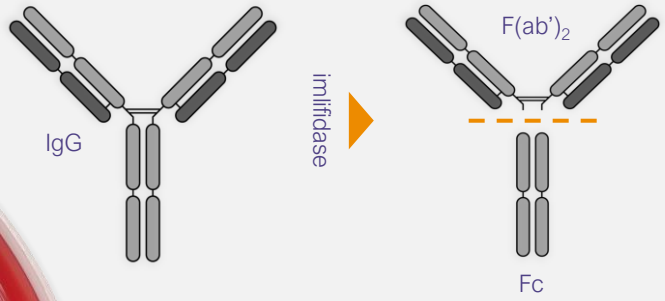
Origins from a bacteria *Streptococcus pyogenes*

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



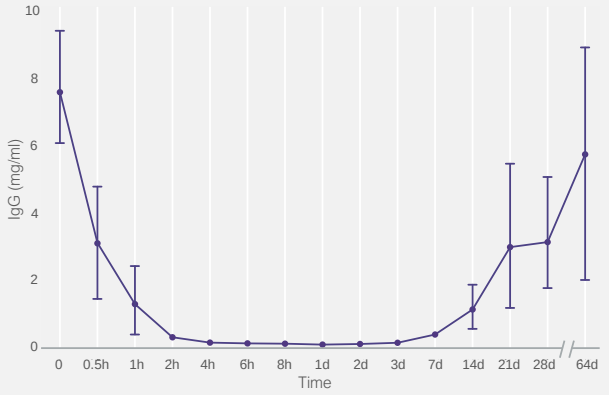
A unique IgG antibody-cleaving enzyme

- 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



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

Targeting rare IgG mediated diseases

Auto-immune diseases

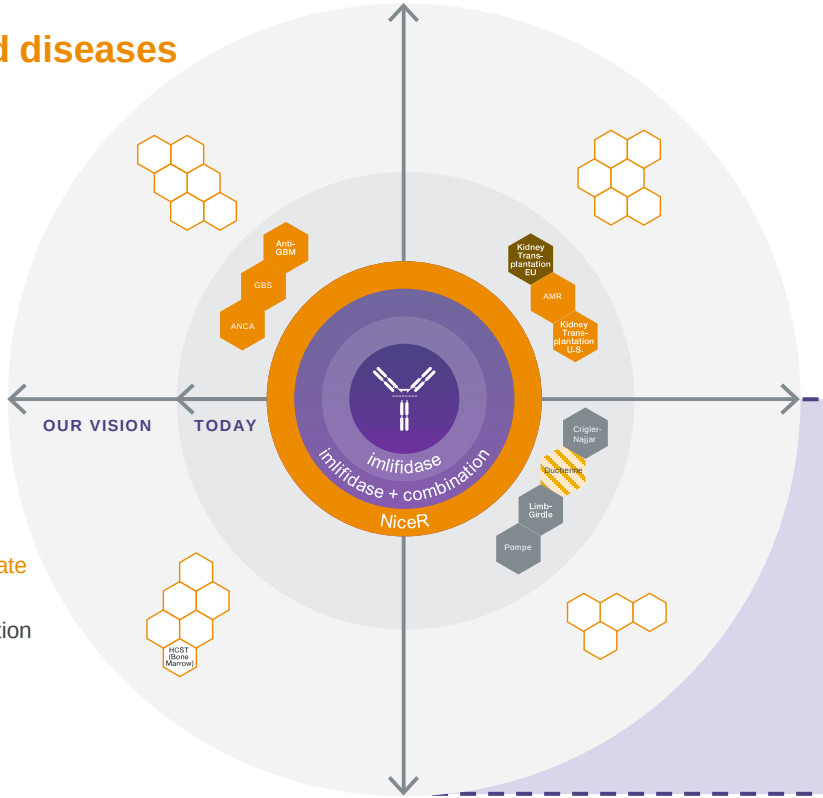
Anti-GBM disease paves the way for development in other autoimmune diseases

- 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

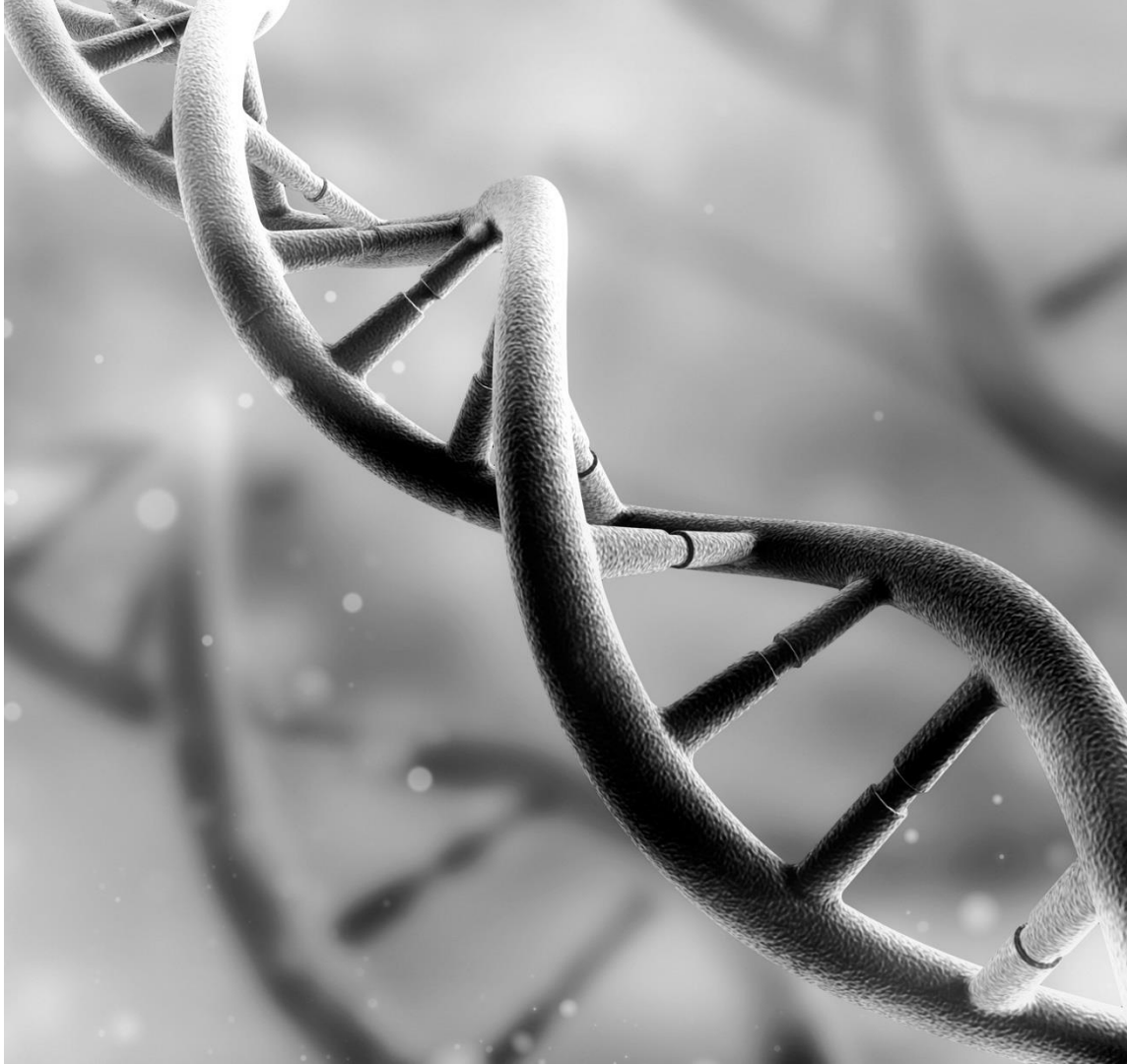
Gene therapy

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)

Gene Therapy

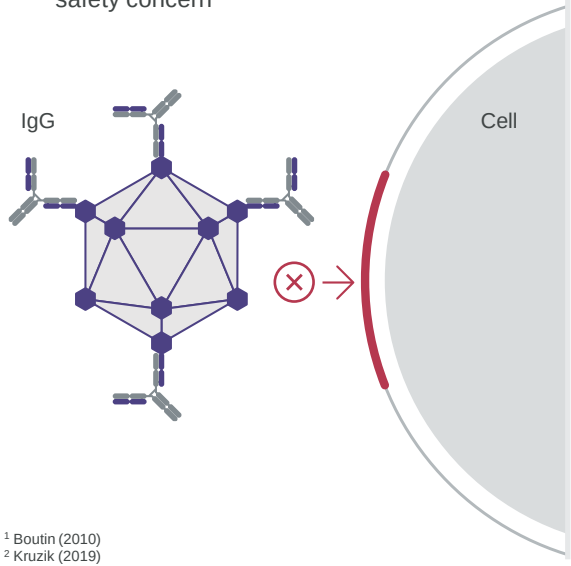


HANSA BIOPHARMA

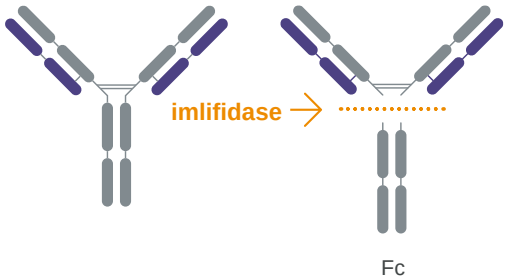
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

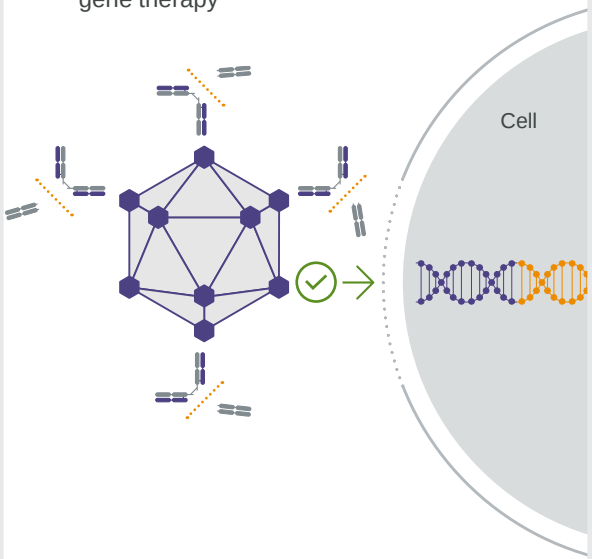
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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



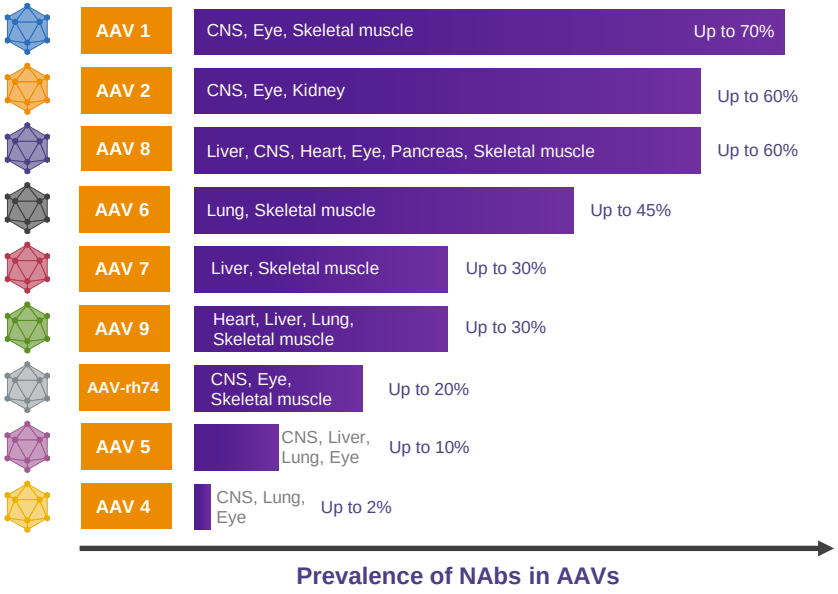
[1] Boutin (2010)
[2] Kruzik (2019)

Introducing Adeno Associated Virus (AAVs)

AAVs, the delivery system of Gene Therapy

- Wildtype Adeno Associated Viruses (AAV) belong to the family of parvoviruses
- AAVs come in many serotypes with different tissue distribution
- They carry their genetic information as DNA and normally do not integrate into the host genome but remains in the cells as episomes
- Recombinant AAV is commonly used for gene delivery, resulting in safe and long-term expression of the transgene

Pre-existing antibodies towards AAVs are a limiting factor in Gene Therapy and excludes patients from clinical trials.



Source: Boutin et al. (2010), Griffin et al. (2019), Wang et al. (2018), Calcedo & Wilson (2013), Falese et al. (2017), Haiyan et al. (2017), Ellsworth et al. (2018), Greig et al. (2017)

Systemic gene therapy is an emerging opportunity

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

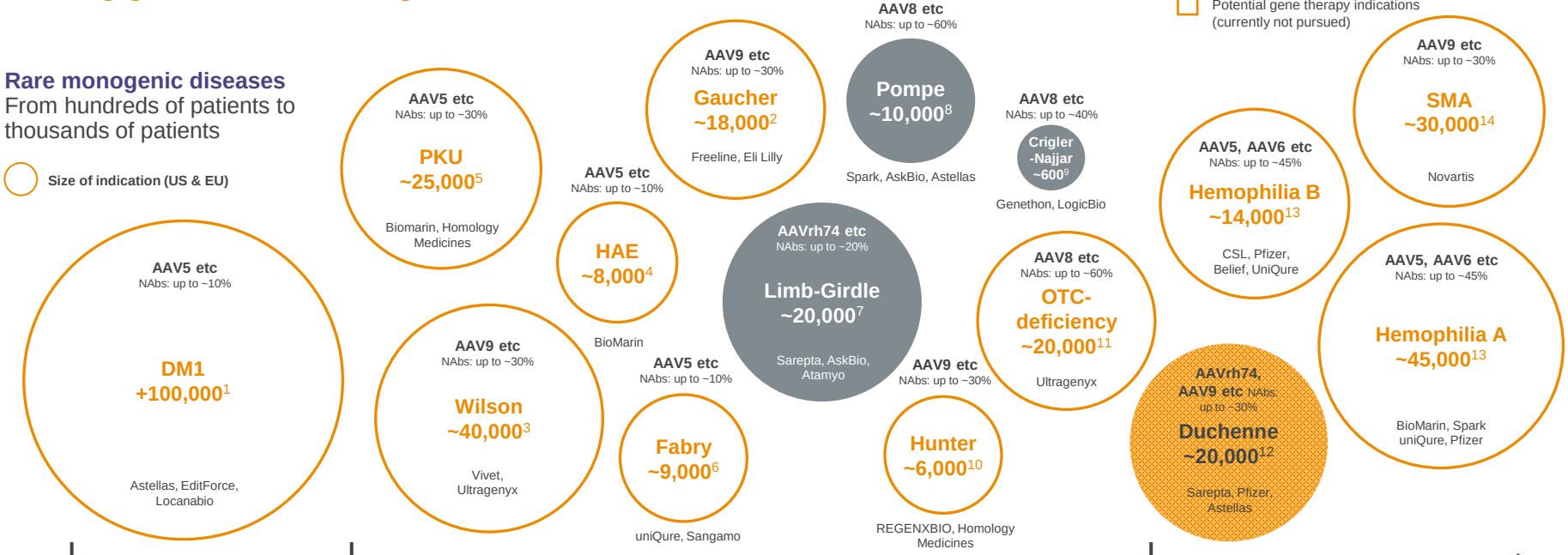
Rare monogenic diseases
From hundreds of patients to thousands of patients

Size of indication (US & EU)

Preclinical programs with Sarepta, AskBio and Genethon

Planned clinical study with Sarepta

Potential gene therapy indications (currently not pursued)



Numbers are estimated based on population and prevalence

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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 ✓ → 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
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)

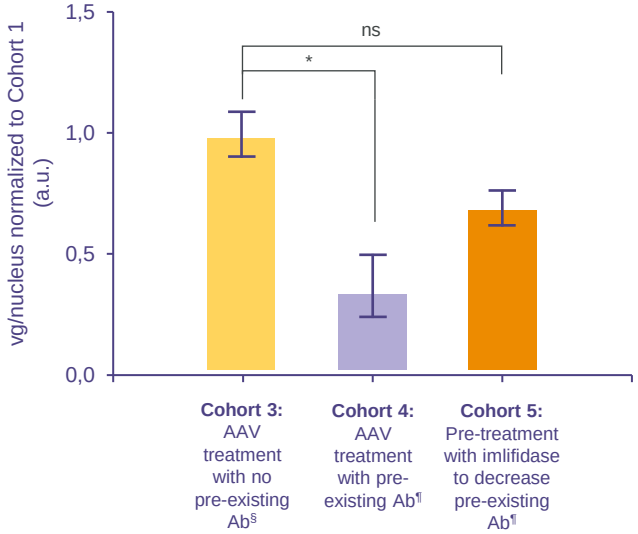
Exclusive option for AskBio to negotiate a potential full development and commercialization agreement

The initial agreement is focused on research and development

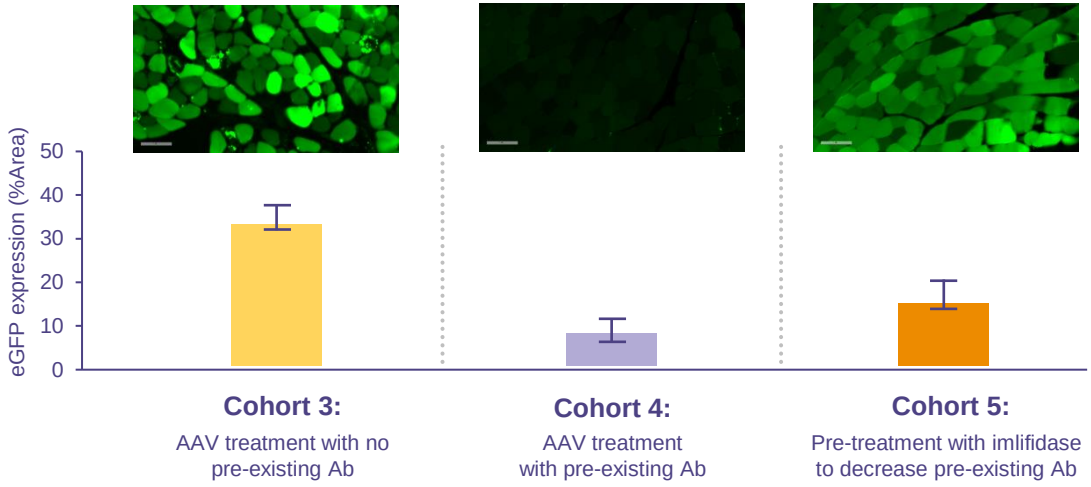
The companies will consider a subsequent agreement for commercialization at a later stage

Imlifidase pre-treatment decreases pre-existing antibodies and enhances transduction and transgene expression in NHPs

Transduction†



Expression in Skeletal Muscle‡



*P<0.05. †Data are represented as mean ± SEM and analyzed by one-way ANOVA followed by post-hoc analysis with Dunnett's multiple comparison test . ‡Data are represented as the mean ± SEM for the percent area for all of the muscle tissues analyzed at terminal necropsy. §AAVrh74 titer ≤1:400. ¶AAVrh74 titer 1:800–1:1600.

AAV, adeno-associated virus; AAVrh74, adeno-associated virus rhesus isolate serotype 74; Ab, antibody; a.u., arbitrary units; eGFP, enhanced green fluorescent protein; NHP, non-human primate; ns, not significant; vg, viral genome.

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

Incidences

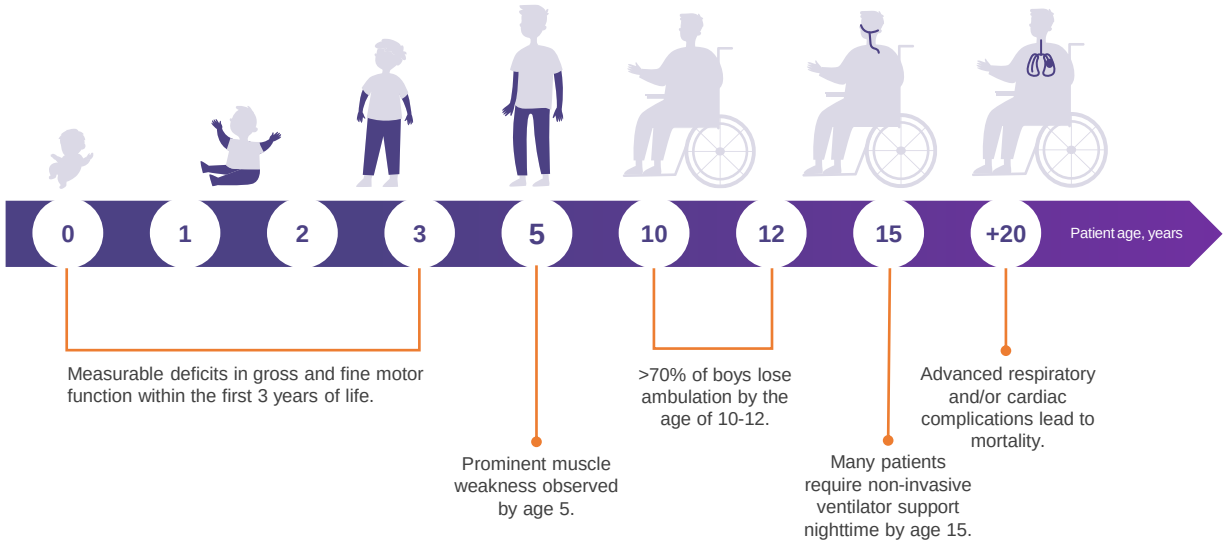
1 in **3,500** to **5,000**
male births worldwide

~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



Source:
Sarepta Therapeutics, https://www.sarepta.com/ [Accessed 2023-06-13]

Systemic Gene Therapy is an emerging opportunity for Hansa

Global exclusive agreements with three partners in select indications

- ✓ Data in non-human primates confirms the ability of imlifidase to remove antibodies towards AAVrh74
- ✓ Sarepta's Elevidys received FDA approval in children aged 4 through 5 years suffering from DMD
- ✓ Clinical study with imlifidase to commence in a small Duchenne patient population in H2 2023

- ✓ Pre-clinical research ongoing with AskBio in Pompe disease with the aim to conclude by year end
- ✓ Next step to enter clinical feasibility study (Phase I/II)
- ✓ Exclusive option to enter into a full development and commercialization agreement

- ✓ Pre-clinical research ongoing with Genethon in Crigler-Najjar (C-N) syndrome
- ✓ GNT-0003 is currently being evaluated in a pivotal study in Europe
- ✓ Clinical study with imlifidase planned for 2024 in patients with C-N syndrome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Calendar and events

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