Investor Presentation

Analyst Lunch Meeting
Stockholm

June 19, 2023

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 - Analyst lunch meeting

Agenda June 19, 2023, Stockholm

Introduction

Business update

Søren Tulstrup, President & CEO

Transplantation/Commercialization

Matthew Shaulis, CCO and US President Hansa Biopharma Inc

- Status of the commercial roll-out in Europe
- Eurotransplant and implementation of new imlifidase tier for HS patients
- US ConfIdeS and Hansa's strategy plan for building a presence in the US

Gene Therapy

Lena Winstedt, Global Franchise Lead Gene Therapy

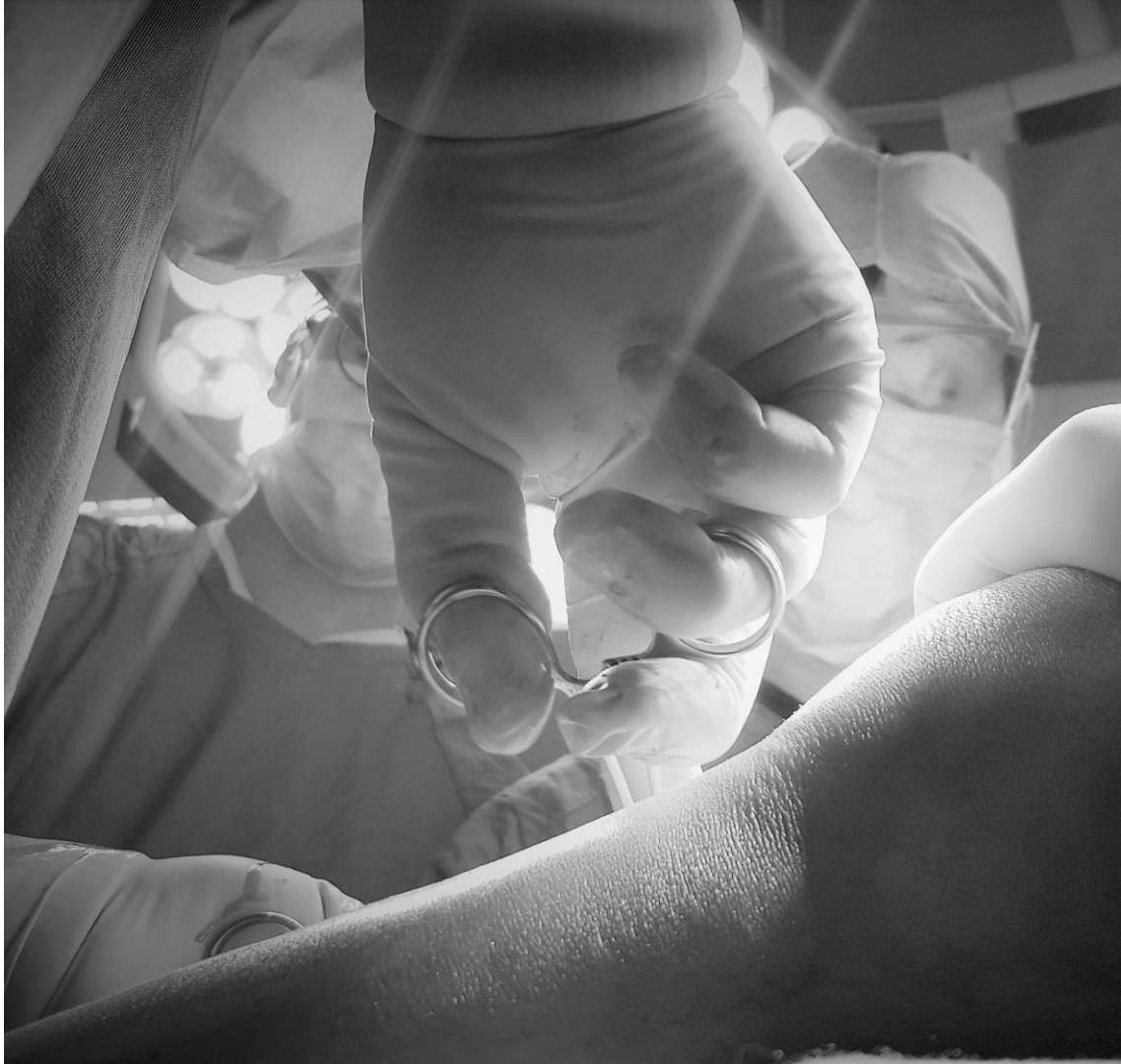
- Systemic gene therapy an emerging opportunity for Hansa Biopharma
- Deep dive into SRP-9001 (Sarepta in DMD) and imlifidase preclinical data in gene therapy
- Collaborations with Genethon and Askbio in Pompe disease and Crigler-Najjar

Concluding remarks and Q&A

Business Update

Søren Tulstrup

President & CEO



Solid progress on our key strategic deliverables

Our mission is to become a global leader in rare diseases

1 European launch of Idefirix® progressing as planned

- ✓ Market Access secured in 13 markets; More recently Spain completing access in the five of the largest European markets
- ✓ Expanded commercialization partnership with Medison Pharma in the Baltics
- ✓ US pivotal ConfIdeS trial continue to enroll. New centers added

2 Exciting pipeline advancing; Partnerships in Gene Therapy

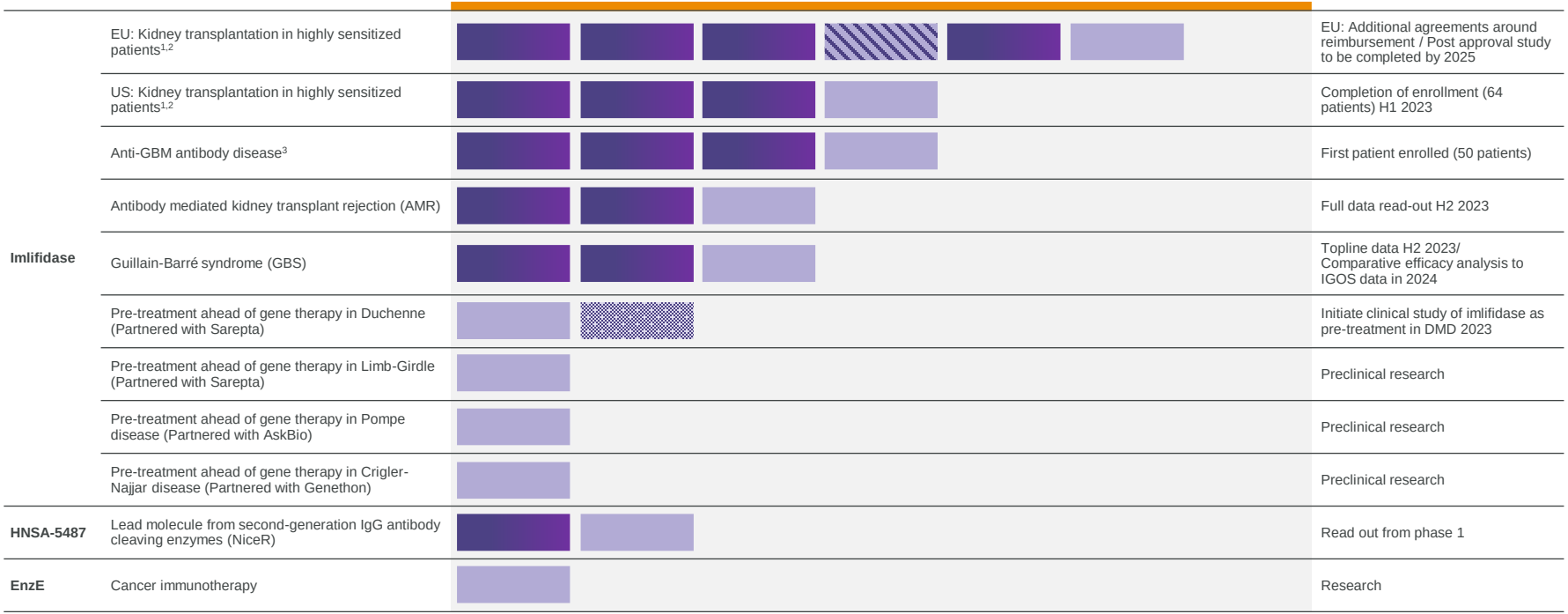
- ✓ Guillain-Barré Syndrome Phase 2 study enrollment completed. High-level data read-out H2 2023
- ✓ HNSA-5487: Clinical study initiated with our next generation enzyme in healthy volunteers
- ✓ Anti-GBM: First three patients enrolled in pivotal Phase 3 program
- ✓ New Partnership with Genethon in gene therapy in Crigler-Najjar

3 Performance continues at pace

- ✓ Total Q1 revenue - SEK 24m incl. SEK 14m in product sales; Product sales to be backend loaded in 2023
- ✓ Cash position - SEK 1.287m end of Q1’23; Hansa financed into 2025
- ✓ Matthew Shaulis - appointed new CCO and U.S. President

Broad clinical pipeline in transplantation and auto-immune diseases including three programs in phase 3

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 enrollment (64 patients) H1 2023
	Anti-GBM antibody disease[3]	First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)	Topline data H2 2023/ Comparative efficacy analysis to IGOS data in 2024
	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 disease (Partnered with Genethon)	Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)	Read out from phase 1
EnzE	Cancer immunotherapy	Research



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

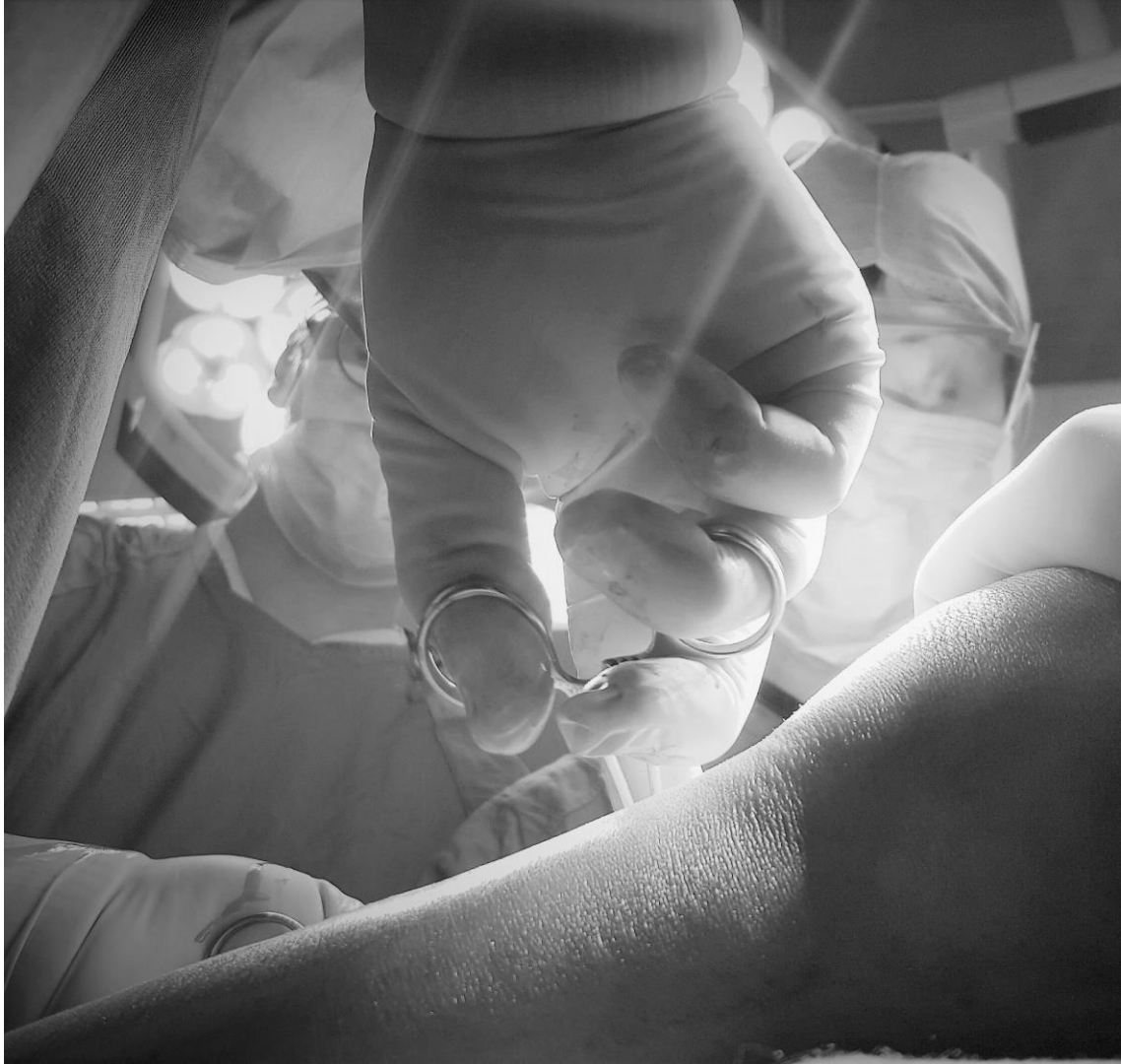
[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

Imlifidase in kidney transplantation

Matthew Shaulis

US President & CCO

HANSA BIOPHARMA



Matthew Shaulis Chief Commercial Officer and US President Hansa Biopharma Inc

Brings more than 20 years of international experience in life sciences

- Chief Commercial Officer and US President, Hansa Biopharma Inc
- Several senior executive roles at Pfizer
  - Senior Vice President responsible for the company's global commercial and medical go-to-market model transformation
  - President, Inflammation and Immunology for International Developed Markets
  - President, North America Oncology
- Prior to Pfizer, Matt held several commercial roles across multiple disease areas
  - TEVA
  - Cephalon
  - Johnson & Johnson

Matthew Shaulis

Our center focused and sequenced launch process designed to build the foundation for Idefirix® to become a new Standard of Care in transplantation

European launch activities and market access efforts progressing as planned

- ✓ Market Access secured in 13 European markets; most recently Spain and Belgium
  - Including five largest markets covering 2/3 of all kidney transplantations in Europe
  - Idefirix granted AP2 Early Access by French Transparency Commission and added benefit ASMR 3 rating
  - EuroTransplant intiating a new Desentization program for imlifidase-eligible patients this summer
- ✓ New medical guidelines implemented through ESOT
  - Guidelines represent first International consensus on a management pathway for highly sensitized patients and were published in *Transplant International*
- ✓ Increasing recognition and awareness on unmet medical need
  - KOL engagement, patient organizations and medical conferences (e.g. ATC)
  - Idefirix recognition: Prix Galien Award (UK) and “List of Technologies with a high level of innovation” (Poland)
- ✓ First Idefirix patient cases published with successful outcome at select clinics
- ✓ Repeat business of Idefirix at first clinics in Q1 2023
- ✓ Expanded commercialization partnership with Medison Pharma
  - Partnership covers Israel and select Eastern European markets; most recently the Baltics
- ✓ Post Approval Study continue to enroll; will support full marketing authorization in Europe, while generating valuable patient experience and long-term outcomes

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

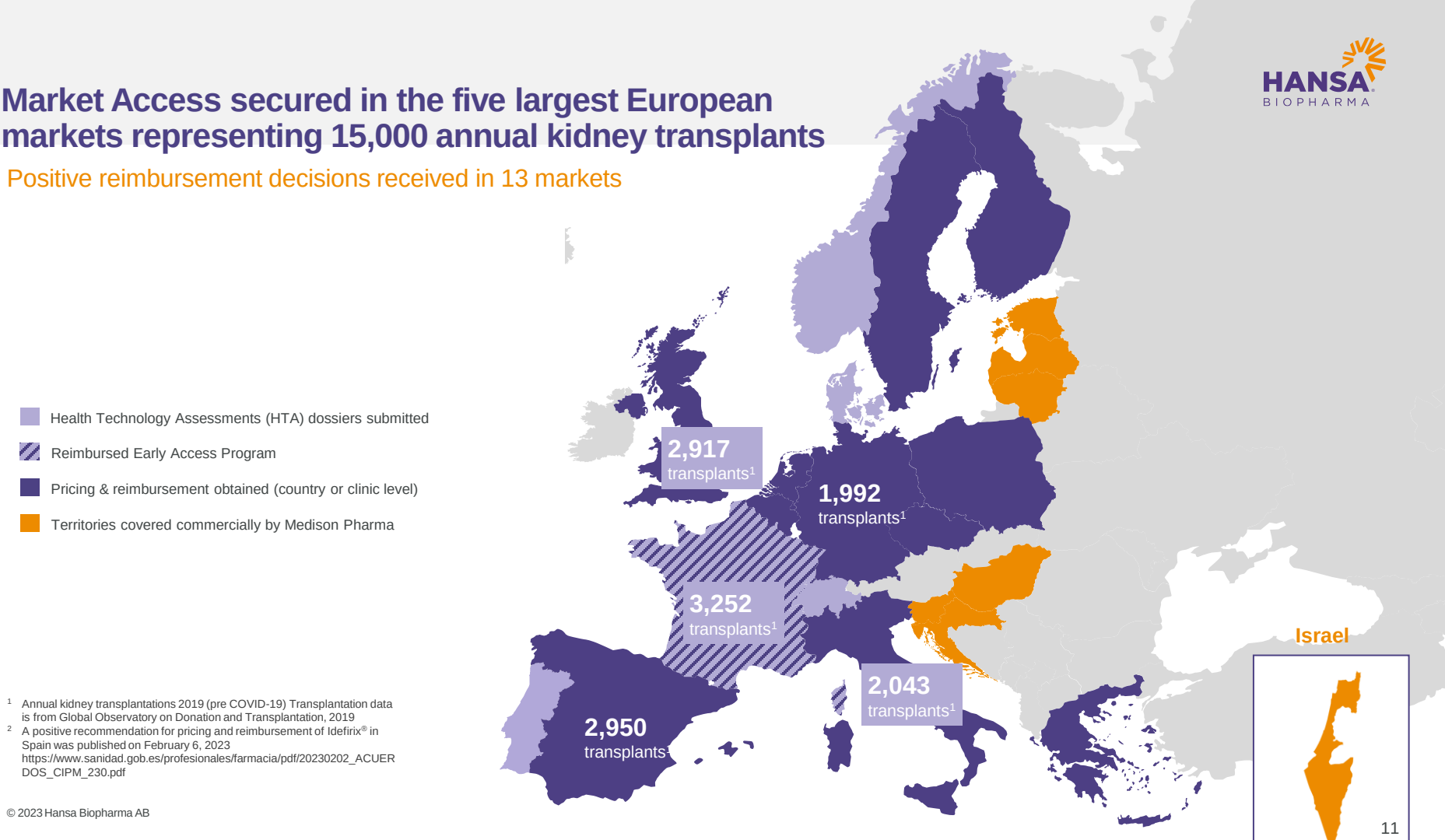
3 Potential label expansion

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

Commercial sales uptake

Market Access secured in the five largest European markets representing 15,000 annual kidney transplants

Positive reimbursement decisions received in 13 markets



[1] Annual kidney transplantations 2019 (pre COVID-19) Transplantation data is from Global Observatory on Donation and Transplantation, 2019

[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

Idefirix (imlifidase) supports the scientific community pioneering kidney transplants in highly sensitized patients

ESOT ENGAGE I

2020/21

Stratifying the humoral risk of candidates to a solid organ transplantation: A proposal from the ENGAGE working group

ESOT Guidelines shaping the framework

2021/22

First European Guidelines for management of highly sensitized kidney transplant paitents published in *Transplant International*

PanEU Expert Delphi Project

"How to integrate Imlifidase into clinical practice"

2021/23

Publication planned for Q4 2023

Recommendations implemented in first countries

2022 -

Recommendations underway in additional eight coutnries including: NL, SE, GE, ES, IT, CZ, CH and AU

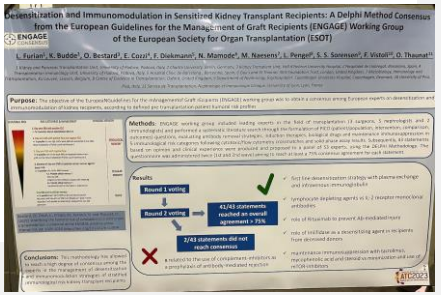
ESOT ENGAGE II

Desensitization immunomodulation in highly sensitized kidney transplant patient

Publication in *Transplant International* planned for Q3 2023

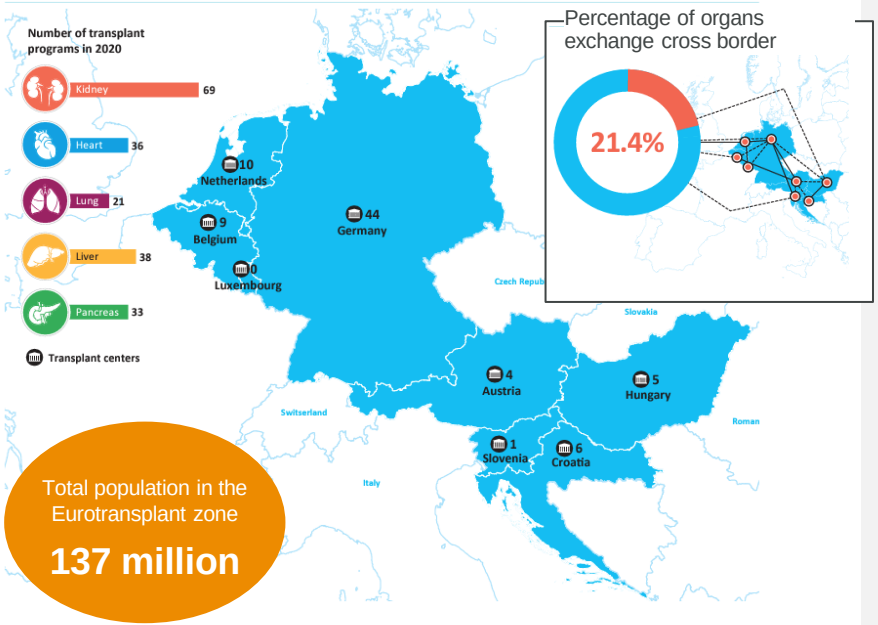
2022/23

Poster from ATC 2023 San Diego, CA



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

The Eurotransplant zone covers eight countries



Eurotransplant and the Eurotransplant network

- Eurotransplant is an international non-profit organization, that acts as a mediator between donor hospitals and transplant centers between its member states
- Eurotransplant is responsible for the allocation of donor organs in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia
- The Eurotransplant network has facilitated organ allocation (deceased) and cross-border exchanges for more than 50 years
- The network has one common aim: *”Ensure best possible match”*
- Today patients with a high level of donor specific antibodies are eligible for a special priority list ”Acceptable Mismatch” program
- Within the Acceptable Mismatch program, a new desentization program is established for an imlifidase-tier of patients (June’23)

The new Eurotransplant desensitization program will be included as a pilot in the Acceptable Mismatch program

Inclusion criteria for new Eurotransplant desensitization program

- No age limitation for patients
- Donor below 65 years
- A minimal waiting time of 3 years in the AM program (At the start of the project only patients that are waiting at least 3 years in the AM program are eligible)
- Preferable negative T-cell crossmatch towards Acceptable Antigens for the ET desensitization program (positive flow cross match on HLA DSA), final transplant center CDC crossmatch must be negative.
- Informed consent form for a follow-up data

20 patients to be included in the Pilot program

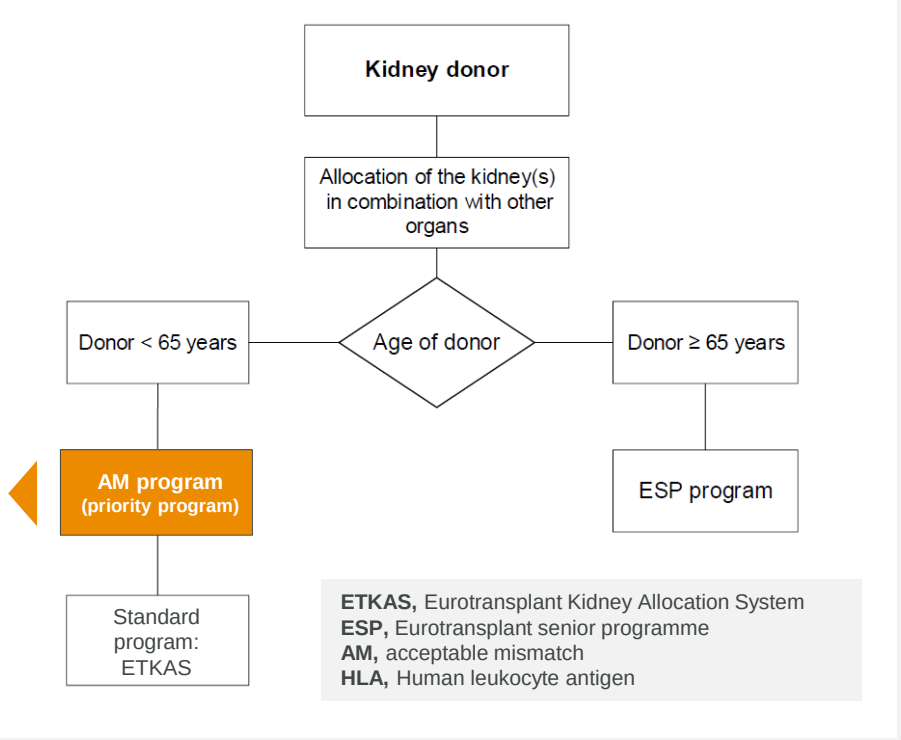
Priority Program

Acceptable Mismatch (AM) program

- Allocate organs for patients who are immunologically compromised because of current and/or historic HLA-sensitisation
- To increase chances of an organ allocation

New Eurotransplant desensitization program

- Imlifidase-eligible patients who are incompatible to a deceased donor



ETKAS, Eurotransplant Kidney Allocation System
ESP, Eurotransplant senior programme
AM, acceptable mismatch
HLA, Human leukocyte antigen

U.S. kidney transplantation landscape

U.S. kidney transplantation landscape

~25,000[1] annual kidney transplantations

~71%[1] deceased donor

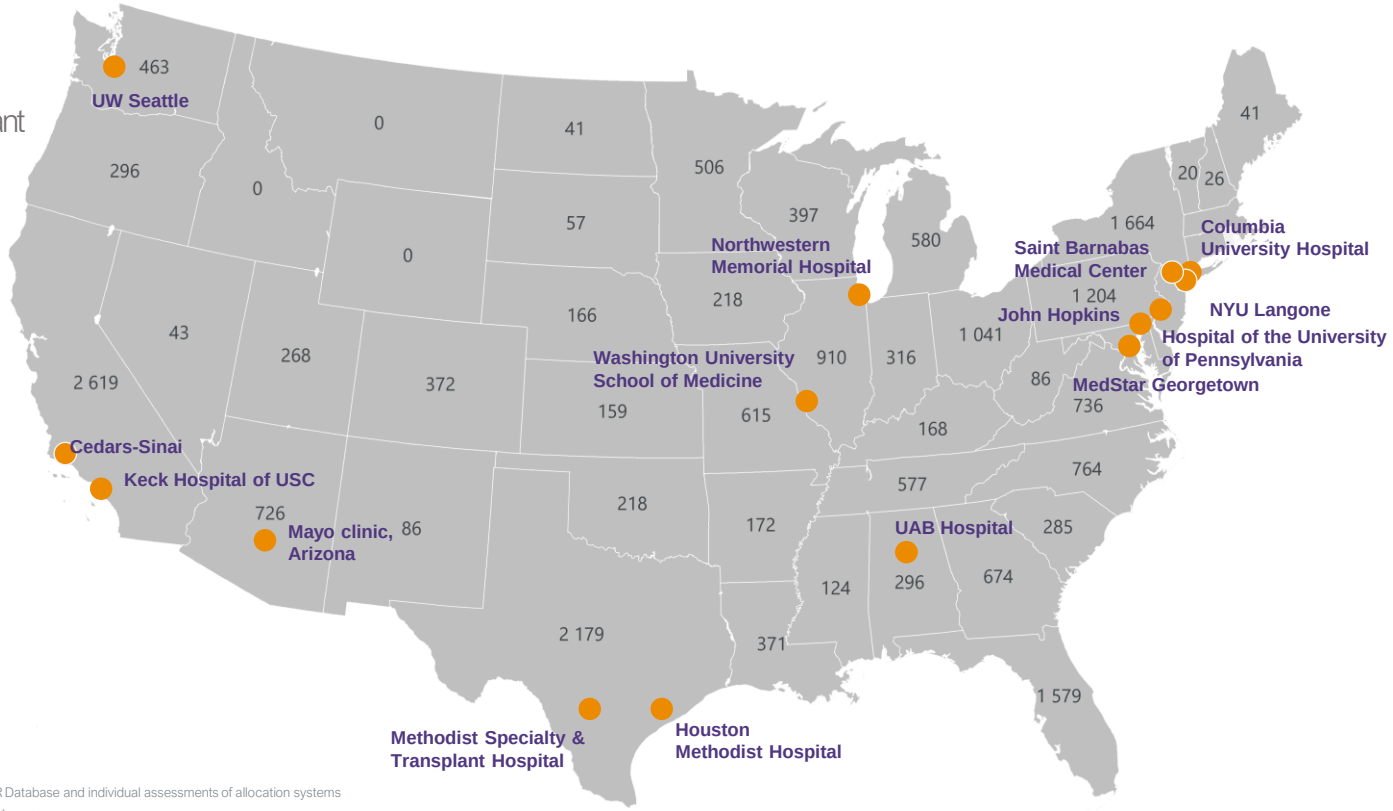
~90,000[2] waiting for a kidney transplant

10-15%[3] of waitlisted patients are highly sensitized

Phase 3

U.S. ConfIdeS

- 71 patients screened and enrolled
- 14 centers open for enrollment; Hansa expects to add additional centers up to a total of 20
- Randomization expected to be completed H2 2023, as previously guided



[1]2019 data from Organ Procurement & Transplantation Network
[2]United Network for Organ Sharing
[3]EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems

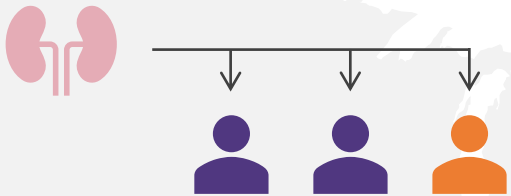
Imlifidase may complement the US Kidney Allocation System, as thousands of patients are still unlikely to find a match

Factors impacting the KAS score[1]
- Waiting time
- Age
- Transplantation history
- Sensitization (cPRA score)
- Distance and recipient
- Quality of donor kidney (KDPI)

KAS gives patients points with regards to levels of sensitization, increasing the likelihood of finding a match for sensitized patients

Transplantation of highly sensitized patients has increased since the introduction of KAS.

However, thousands of patients are still unlikely to find a match



Highly sensitized patients are less likely to find a matching organ from a deceased donor through KAS

Degree of sensitization	cPRA%	Est. no. of organs to find match[2]	Estimated number of patients on waitlist (U.S)[3]
Less or moderate	0-20	1-2	~66,000
	20-80	2-14	~16,000
Highly sensitized	80-98	14-300	~5,000
	98-99.9	300-3,000	~3,500
	>99.9	3,000-300,000	~2,500

KAS was revised in the U.S. in 2014 to increase equity of transplantation.

However, thousands of highly sensitized patients are still not treated

idefirix (imlifidase)

If approved, Idefirix® may address highly sensitized kidney transplant patients, who are incompatible to a deceased donor in the US Kidney Allocation System

[1] OPTN, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf
[2] p=95%, Clinical Journal of the American Society of Nephrology, 2016
[3] Company estimates, OPTN and Global Observatory on Donation and Transplantation

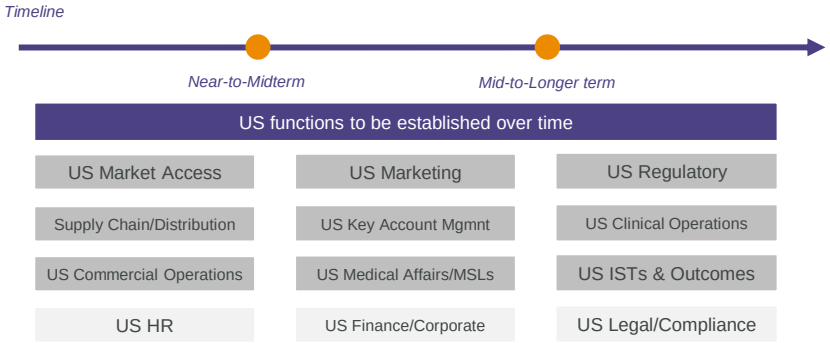
Strategic plan to build US presence ahead of potential regulatory approval and commercial launch of imlifidase in the US

Three shots on goal to enter important US market

1. US pivotal phase 3 study in kidney transplantation
2. Pivotal phase 3 study in anti-GBM disease
3. Pre-treatment to SRP-9001 in Gene Therapy (DMD)

Critical functions to be established

- Small and agile team with deep clinical and US marketplace expertise
- Comprehensive functional coverage with dedicated US based and experienced team members
- Strength of global strategy and key global functions



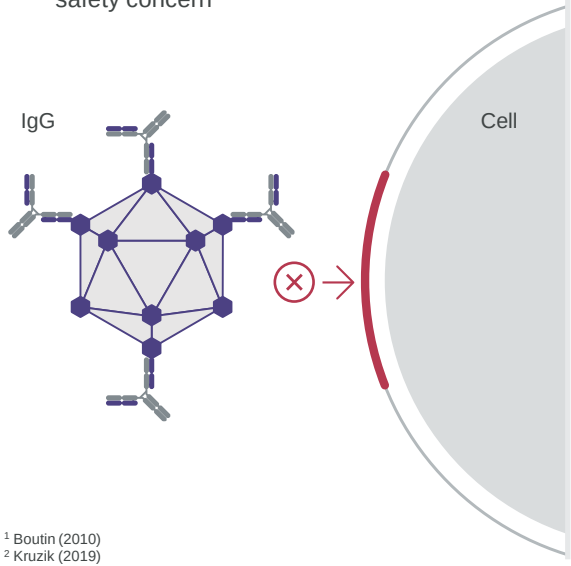
Gene Therapy

Lena Winstedt
Global Franchise Lead, Gene Therapy

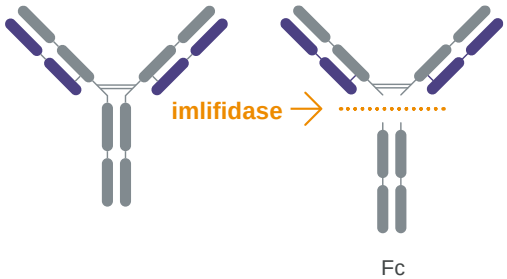
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

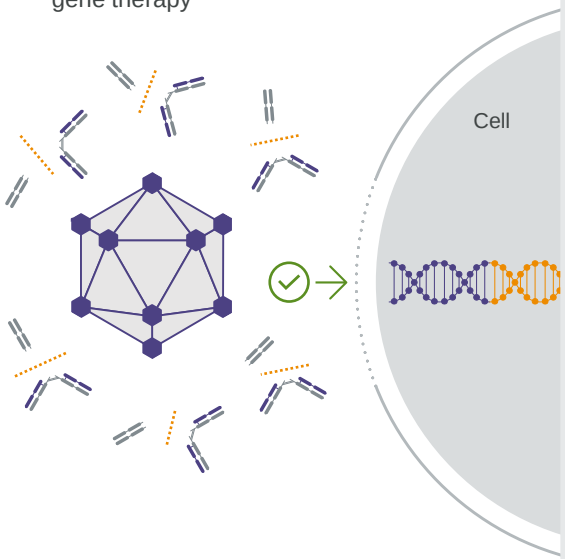
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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



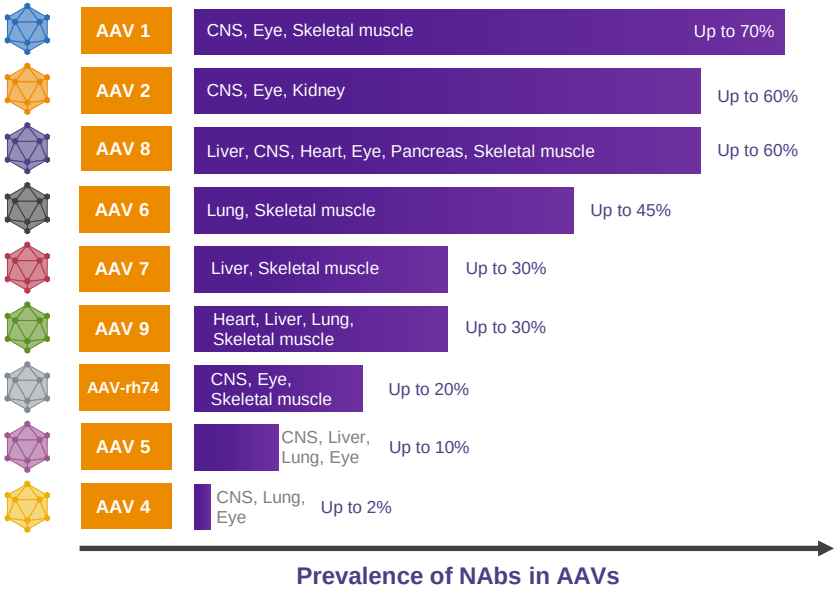
[1] Boutin (2010)
[2] Kruzik (2019)

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)

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 ▪ SRP-9001 PDUFA June 2023	**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)

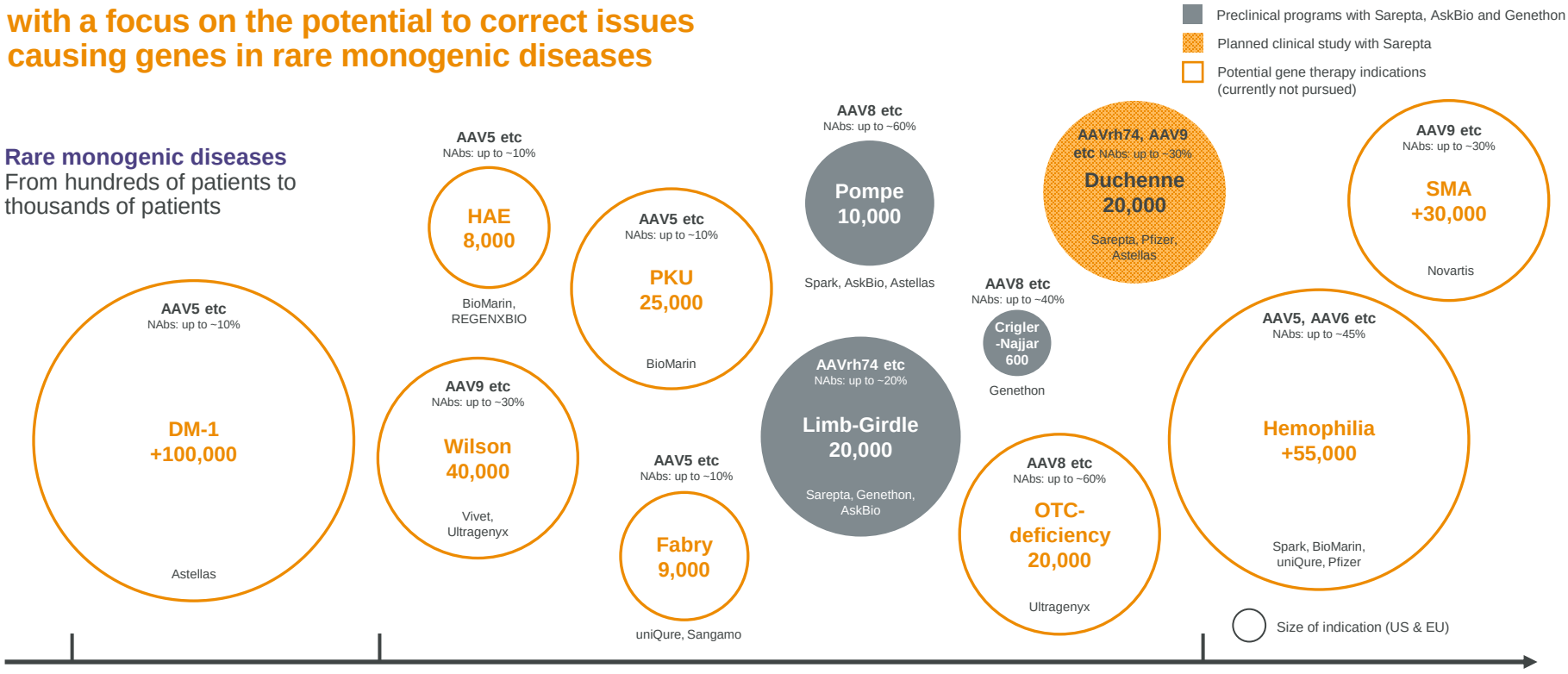
Exclusive option for AskBio to negotiate a potential full development and commercialization agreement

The initial agreement is focused on research and development

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

Systemic gene therapy is an emerging opportunity

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



Numbers are estimated based on population and prevalence

Global and exclusive agreement with Sarepta Therapeutics

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

Indication exclusivity:

- Duchenne Muscular Dystrophy (DMD)
- Limb-Girdle Muscular Dystrophy (LGMD)

Hansa's key resources

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval
- Positive preclinical data published in *Nature*
- Clear path to U.S. approval (kidney transplant)

+

Sarepta's key resources

- World leader within gene therapy targeted at muscular dystrophies
- Pre-clinical plan: PoC and IND-tox
- Clinical / Regulatory
- Promotion

Collaborative research, development and commercialization – working together at every stage

Upfront payment
USD 10 million upfront

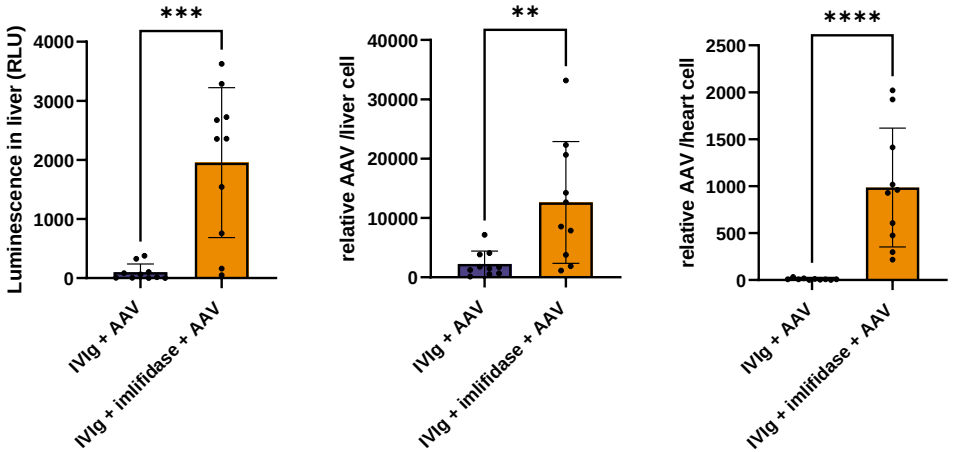
Milestones
Hansa is eligible for up to USD 397.5 million in development, regulatory and sales milestones

Royalties & Sales
Hansa to receive high single-digit to mid-teens royalties on Sarepta's gene therapy sales enabled with imlifidase in Nabs positive patients and also book all sales of imlifidase

Imlifidase facilitates transduction of AAV8 in a mouse model

Imlifidase treatment neutralises the inhibitory effect of IgG and facilitates AAV8 transduction in target cells

In severe combined immunodeficient mice pre-immunised with human IgG, the AAV transduction is significantly improved in the presence of imlifidase compared to without imlifidase



Mice administrated with IVIg and AAV8 viral vectors in the absence or presence of imlifidase. Transgene luciferase expression is measured in liver lysates as relative luminescence units (RLU) (a). Transduction was measured in both liver (b) and heart (c) by qPCR analysis of total DNA and calculated as the relative AAV8 genomes/cell using primers specific for viral genomes (ITR) and normalised against a mice reference gene (actin). Mann-Whitney test were performed to evaluate the significance of the difference between the two groups, **p<0.01, ***p<0.001, ****p<0.0001. Data is presented as mean ± SD, n=10.

Imlifidase has previously been highlighted in Nature Medicine[1] with encouraging outcome

Leborgne et al. Nat Med (2020)

[1] Nature Medicine https://doi.org/10.1038/s41591-020-0911-7

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

Incidences

1 in **3,500** to **5,000**

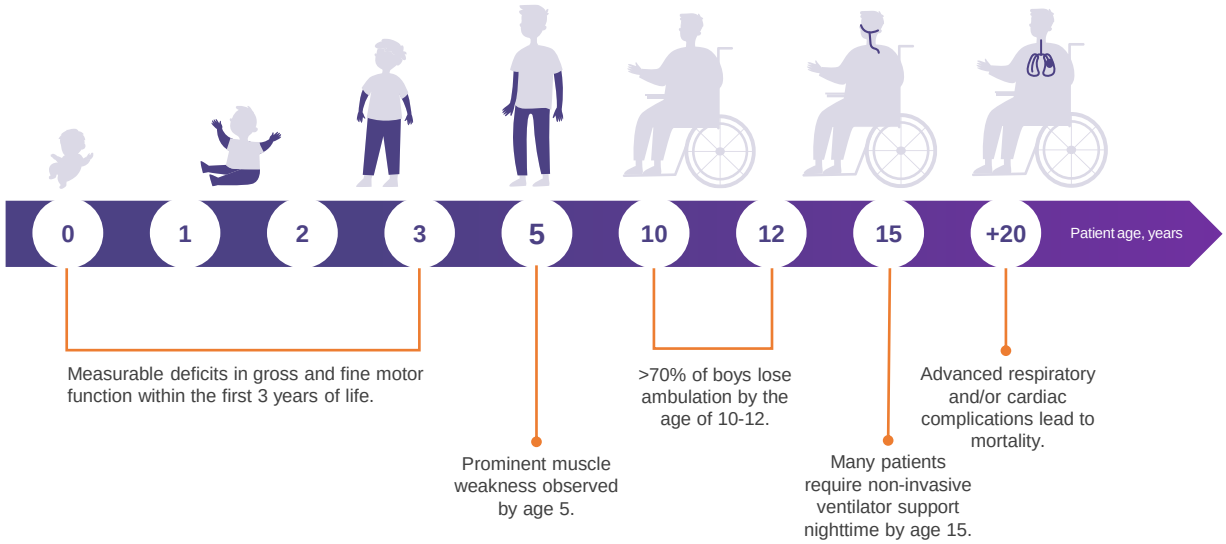
male births worldwide

~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



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

SRP-9001 has been rationally designed to maximize expression in tissues most affected by Duchenne

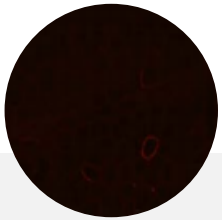
SRP-9001 gene therapy treatment

- SRP-9001 (delandistrogene moxeparvovec) AAVrh74 vector with a micro-dystrophin transgene
- Functional benefit as well as micro-dystrophin expression demonstrated

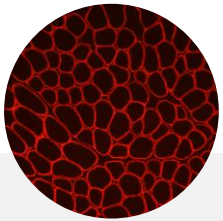
PDUFA date for SRP-9001 in DMD June 22

SRP-9001 treatment leads to restoration of DAPC, reduced CK, and improved histopathology

Pre-treatment



Post-treatment



4- to 5-year-old group showed significant improvement in North Star Ambulatory Assessment (NSAA) vs. placebo at week 48

For more details and data regarding Sarepta's gene therapy programs, please refer to www.sarepta.com

Limb-girdle muscular dystrophy (LGMD) is a group of diseases that cause weakness and wasting of the muscles

Incidences

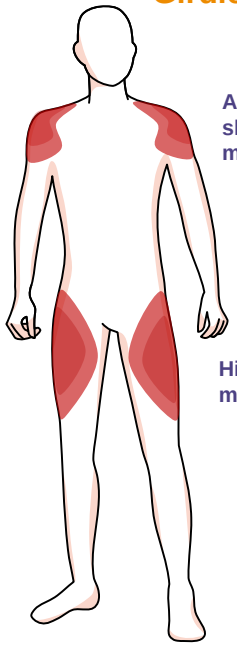
1.63 per **100,000** individuals; over 30 subtypes exist, and both genders are affected equally.

~15% of patients have pre-existing IgG antibodies to rh74

Indication

- Limb-Girdle can be caused by a single gene defect that affects specific proteins within the muscle cell
- Symptoms may appear at any age. Patients may have trouble getting out of chairs or climbing stairs. Eventually, they may need a wheelchair to get around.

Girdle Muscles



SRP-9003 β-sarcoglycan (SGCB) gene therapy for treatment of LGMD2E

Initiation of VOYAGENE

On Feb 17, 2023, Sarepta announced that it had commenced dosing in the VOYAGENE study (Study SRP-9003-102) a Phase 1 trial of SRP-9003,

VOYAGENE is a U.S.-only study that will enroll ambulant patients aged 18 years or older and non-ambulant patients, ages 4-50 years, using clinical process SRP-9003 material.

Following positive results in the initial Phase 1 study SRP-9003-101 exploring two different doses, the VOYAGENE study will allow gathering additional data on the intended dose of SRP-9003 in a broader population of patients while finalizing plans for a global Phase 3 study (SRP-9003-301) that utilizes commercially representative material.

More information on the study is available at https://genesislgmd.com/study/voyagene

Source: www.sarepta.com

Pompe disease, an ultra-rare disease is caused by the deficiency of an enzyme called alpha-glucosidase (GAA)

Incidences

An ultra-rare indication impacting

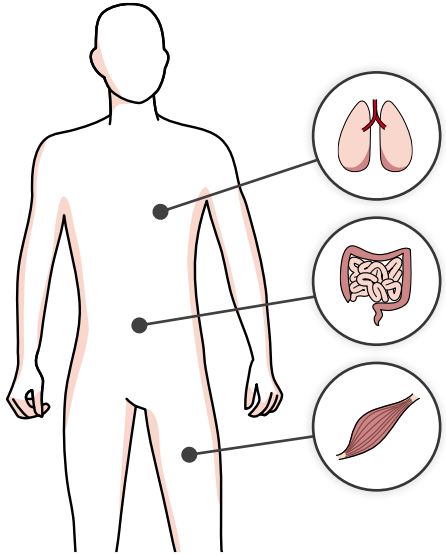
1 in **40,000** births or **~200** cases per year across US and Europe

~40-60% patients have pre-existing IgG antibodies to AAV8

Indication

- Defect in a gene making an enzyme called acid alpha-glucosidase (GAA), which is used to break down glycogen
- Accumulation of glycogen result in severe impact on the normal organ and muscle function

Late Onset Pompe Disease



Respiratory

- Respiratory failure
- Diaphragm weakness, sleep-disordered breathing
- Orthopnoea, dyspnea, aspiration

Gastrointenstinal

- Difficulty chewing/jaw muscle fatigue
- Poor weight gain/maintenance
- Swallowing difficulties/weak tongue

Musculoskeletal

- Proximal muscle weakness, muscle pain
- Frequent falls, gait abnormalities, difficulty walking/climbing stairs/getting up
- EMG abnormalities, elevated CK, MRI changes

Sources:
1. AskBio.com, www.askbio.com
2. Rarediseases.org https://rarediseases.org/rare-diseases/pompe-disease/

Collaboration with AskBio to evaluate imlifidase in gene therapy targeting Pompe disease

Feasibility program to evaluate imlifidase as pre-treatment ahead of gene therapy in Pompe disease for patients with pre-existing neutralizing antibodies (NAbs) to adeno-associated virus (AAV)

HANSA BIOPHARMA

Hansa's key resources and deliverables

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval and clear path to U.S. approval
- Significant know-how around antibody cleaving enzymes
- Hansa supplies material and provides additional support

+

AskBio™

Fully owned subsidiary of Bayer AG

AskBio's key resources and deliverables

- Early innovator in the Gene Therapy space with AAV platform and ongoing clinical stage Pompe disease program
- Conducts pre-clinical and clinical trials according to agreed plan

AskBio's AAV2/8-LSPhGAA gene therapy

- AAV2 vector genome cross-packaged as AAV8
- Liver-specific promoter to express GAA enzyme
- Open label Phase I/II study ongoing
- Study in 13 late-onset Pompe Disease patients

Current agreement scoped around a feasibility program

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

HANSA BIOPHARMA

Crigler-Najjar (CN) syndrome is an ultra-rare hereditary disorder caused by deficiency in UGT1A1 (liver enzyme)

Incidences

An ultra-rare indication impacting

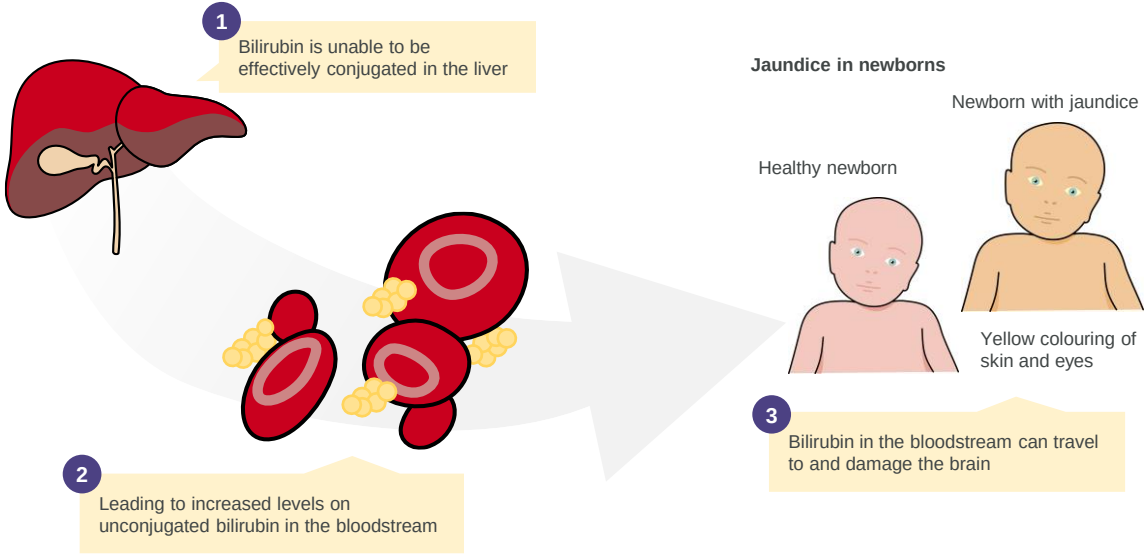
0.6-1 per **1,000,000** newborns around the world[1,2]

~30% of patients have pre-existing IgG antibodies to AAV8

Indication

- Build-up of free bilirubin in serum and body tissues, which can become toxic in the brain[3]
- Severity can vary from mild to severe, no medication approved for treatment so far

Build-up of free bilirubin in serum and tissue can become toxic in the brain



Sources:
[1] Collaud F, Bortolussi G, Guianvarc'h L, Aronson SJ, Bordet T, Veron P, Charles S, Vidal P, Sola MS, Rundwasser S, Dufour DG, Lacoste F, Luc C, Wittenberghe LV, Martin S, Le Bec C, Bosma PJ, Muro AF, Ronzitti G, Hebben M, Mingozzi F. Preclinical Development of an AAV8-hUGT1A1 Vector for the Treatment of Crigler-Najjar Syndrome. Mol Ther Methods Clin Dev. 2019 Mar 15;12:157-174.
[2] Ebrahimi A, Rahim F. Crigler-Najjar Syndrome: Current Perspectives and the Application of Clinical Genetics. Endocr Metab Immune Disord Drug Targets. 2018;18(3):201-211.
[3] American Liver Foundation, https://liverfoundation.org/liver-diseases/pediatric-liver-information-center/pediatric-liver-disease/crigler-najjar-syndrome/ [Accessed 2023-06-13]

Collaboration with Genethon to evaluate imlifidase in gene therapy targeting Crigler-Najjar Syndrome

HANSA BIOPHARMA

Hansa's key resources and deliverables

- Imlifidase validated with positive clinical efficacy and safety data as well as European approval and clear path to U.S. approval
- Significant know-how around antibody cleaving enzymes
- Hansa supplies material and provides additional support

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GENETHON
CURE THROUGH INNOVATION

Genethon's key resources and deliverables

- A pioneer in the discovery and development of gene therapies
- A not-for-profit organization
- Conducts pre-clinical and clinical trials (Phase 1/2)

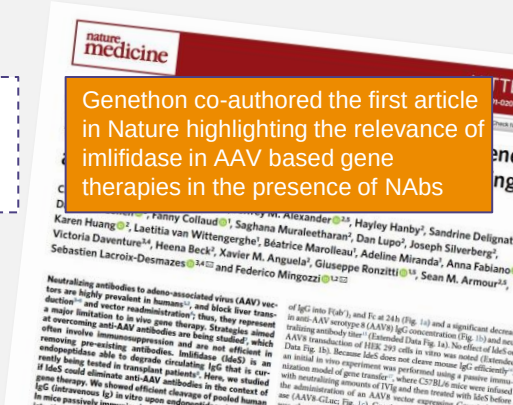
Initial agreement focused on research and development

HANSA BIOPHARMA
Antibody cleaving enzyme technology

GENETHON CURE THROUGH INNOVATION
HANSA BIOPHARMA
Preclinical Development

GENETHON CURE THROUGH INNOVATION
HANSA BIOPHARMA
Clinical Development
Phase 1/2 study (feasibility)

Upon completion the two companies will consider a subsequent agreement for commercialization


nature medicine

Genethon co-authored the first article in Nature highlighting the relevance of imlifidase in AAV based gene therapies in the presence of NAbs

Feasibility program to evaluate imlifidase as pre-treatment to Genethon's gene therapy in patients with severe Crigler-Najjar syndrome

Study design and timeline

- Study expected in a small patient population
- GNT0003: 5E12 vg/kg
- Imlifidase: 0.25 mg/kg (possible with two doses)

Timeline

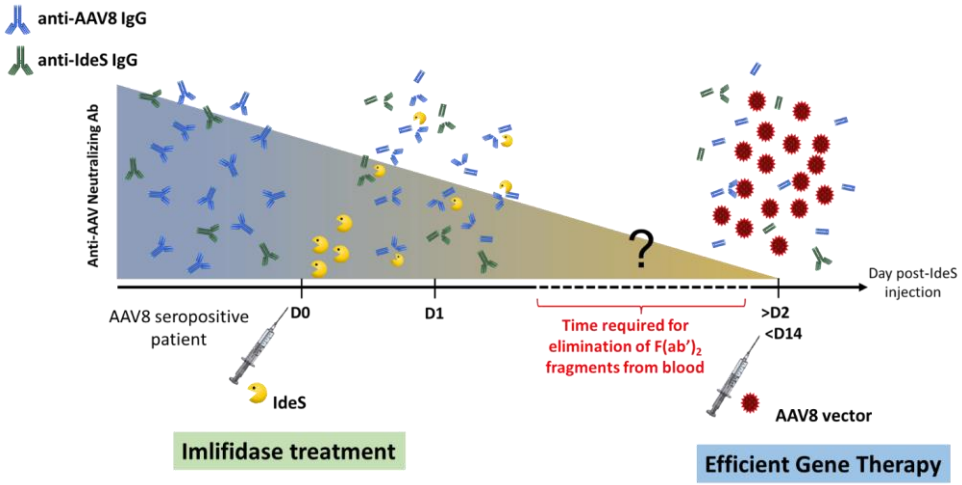
January 2023
Genethon launches pivotal clinical trial of Gene Therapy for Crigler-Najjar Syndrome

April 2023
Hansa and Genethon signs collaboration

Initiation of pre-clinical study with imlifidase as pre-treatment to GNT0003

2024
Initiate clinical study with imlifidase as pre-treatment to GNT0003

Evaluation of safety and efficacy of "GNT0003" in seropositive to AAV8 patients pre-treated with imlifidase

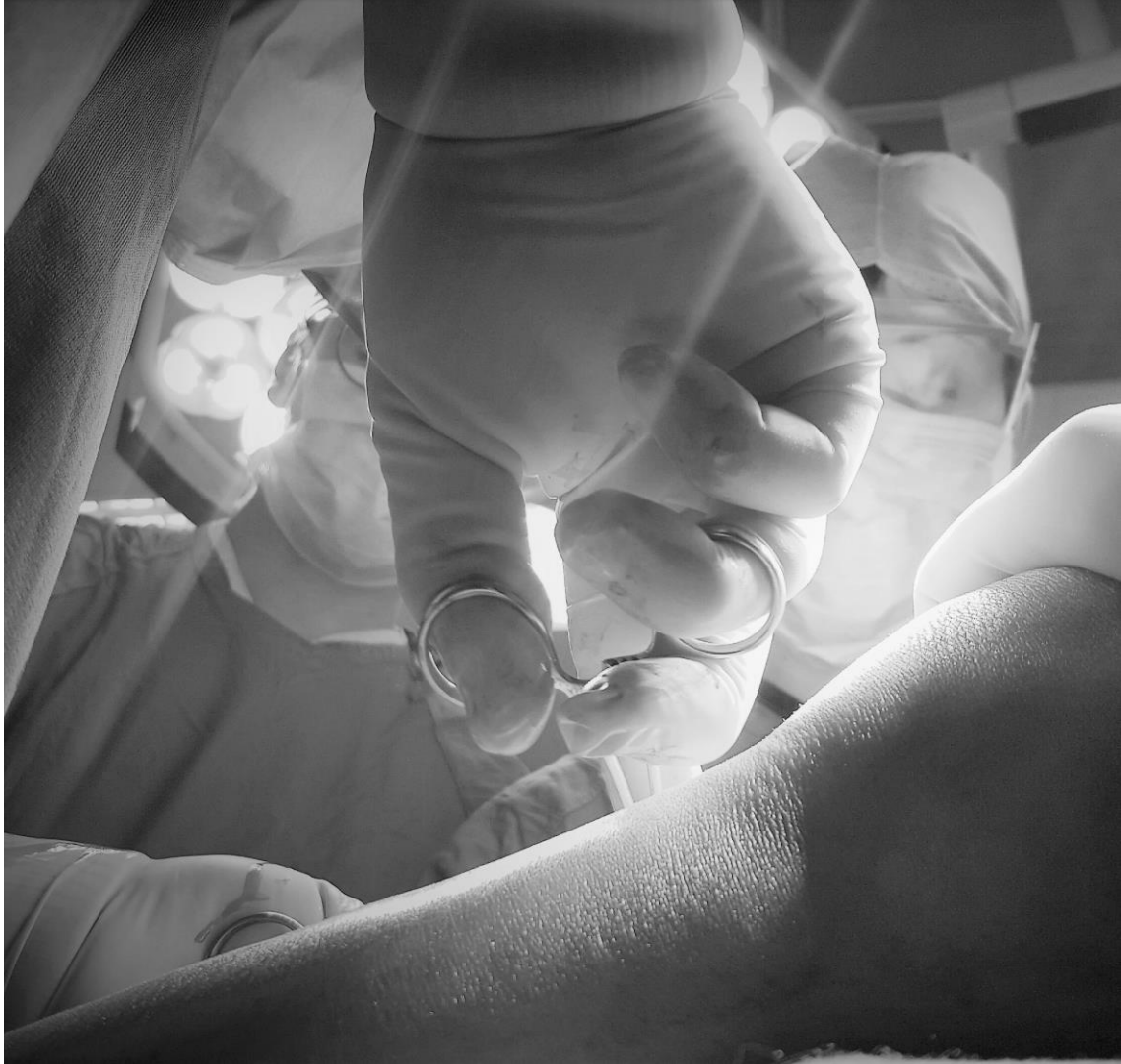


Source: https://www.genethon.com/

Concluding remarks and Q&A

Søren Tulstrup

President & CEO



Our strategic priorities

Our mission is to become a global leader in rare diseases

Commercialize Idefirix® in first indications and markets

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

Advance ongoing imlifidase clinical programs in transplantation and autoimmune diseases

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

Expand IgG-cleaving enzyme technology platform into new disease areas and indications

- Explore gene therapy opportunity
- Explore opportunities in Oncology and stem cell transplantation (HSCT)
- Develop our next generation IgG-cleaving enzymes to allow for recurring treatment

Build focused, integrated, agile and empowered international organization and seek partnerships to accelerate growth and reduce risk


HANSA
BIOPHARMA