HANSA BIOPHARMA

Investor Road Show Presentation Q2 2023

Lund, July 20, 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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Business update Q2’2023

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Solid commercial performance in Q2 and advancements across all four franchises

1 Advancing the EU launch

- ✓ Solid sales performance in Q2'23; Sales doubled vs. Q1'23
- ✓ Desensitization clinical guidelines in five countries and Eurotransplant program
- ✓ Provisional approval in Australia in both living and deceased donor

2 Accelerating science across all franchises

- ✓ 76 patients enrolled in US ConfIdeS phase 3 trial
- ✓ First patients treated in ANCA-associated vasculitis phase 2 trial and anti-GBM phase 3 trial
- ✓ Gene therapy collaboration with Genethon in Crigler-Najjar syndrome
- ✓ Enrollment completed in HNSA-5487 phase 1 trial

3 Total Q2 revenue: 36.7m; Hansa financed into 2025

- ✓ SEK 29.6m in product sales
- ✓ SEK 7.1m in revenue recognition from partnerships
- ✓ Cash position: SEK 1.1bn (Q2'23)
- ✓ Write-up of SEK 1.4bn in intangible assets related to Idefirix®; Will increase Shareholder Equity

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

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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

Eurotransplant pilot program set to transform desensitization and increase clinical experience with imlifidase

Acceptable Mismatch Priority Program

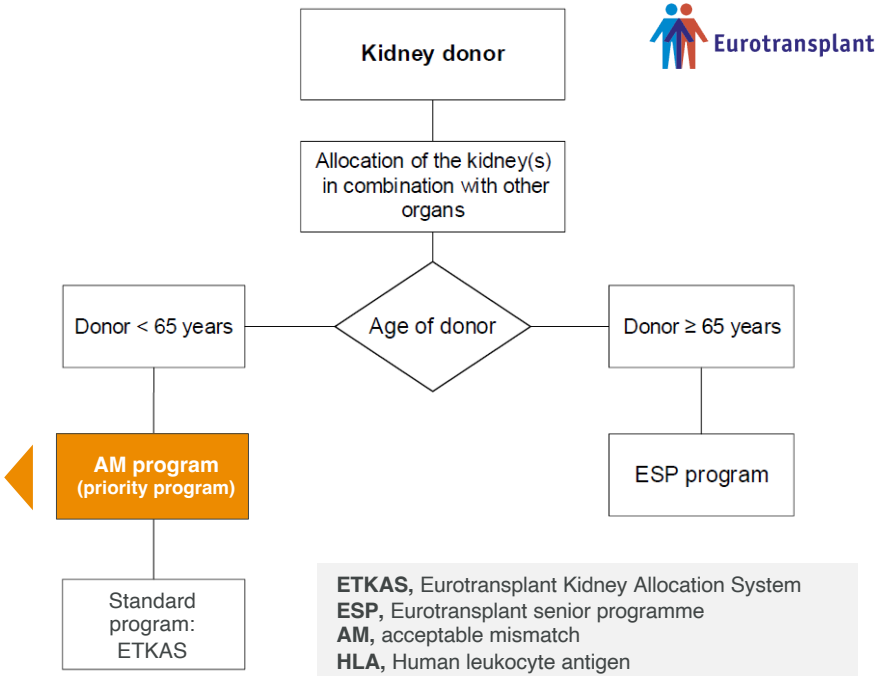
CURRENT
Acceptable Mismatch (AM) Program
Allocates organs to patients who are immunologically compromised because of current and/or historic HLA-sensitization

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



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

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

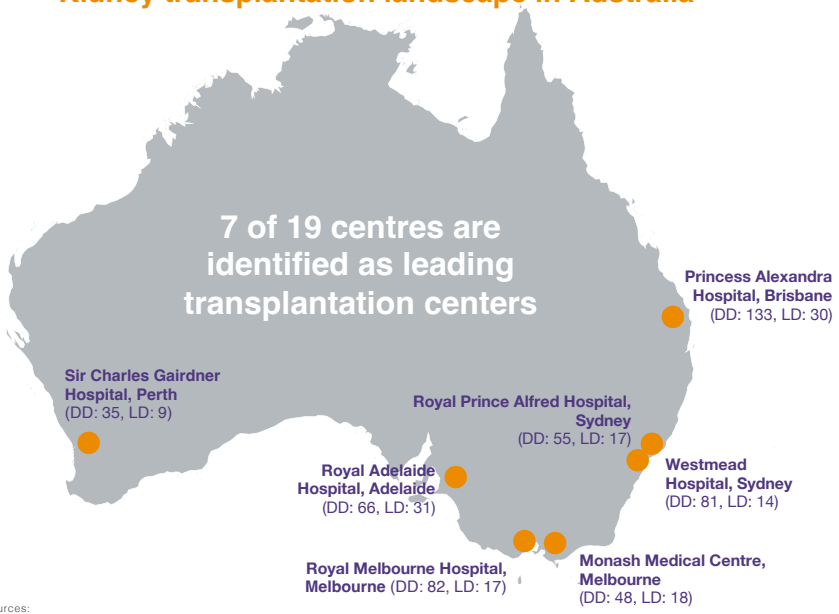
857 kidney transplantations were carried out in 2021

~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/

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

Complex allocation system with limited clinical innovation

25,000 annual kidney transplants

71% diseased donors

~90,000 patients on the waitlist

10-15% of waitlisted patients are highly sensitized

~6,000 highly sensitized patients with cPRA of 98% or above (hereof ~2,500 with cPRA of 99.9% and above)

U.S. ConfIdeS

Phase 3

- 76 patients screened and enrolled
- Plans to expand no of sites from currently 14 to 20 or more to accelerate randomization
- Randomization expected to be completed H2 2023, as previously guided

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

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

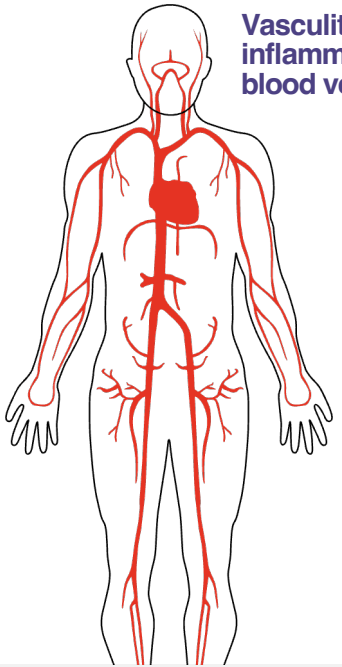
~3 in 100,000 annually across EU/US of which 8-36% are estimated to have ARDS due to pulmonary hemorrhage[1,2]

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

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.

Solid progress in our valuable pipeline of drug candidates across our franchises

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U.S. ConfIdeS kidney tx

Phase 3

- 76 patients enrolled for randomization
- Plans to expand number of centers from currently 14 to 20 or more sites to accelerate randomization
- Randomization expected to be complete H2 2023

Anti-GBM disease

Phase 3

- 4/50 patients enrolled
- Open-label, randomized controlled study
- 50 patients to be treated with imlifidase and SoC or SoC, alone
- First patient treated in Q2

Guillain-Barré Syndrome (GBS)

Phase 2

- 30/30 patients enrolled
- Topline data expected H2 2023
- Full data following comparative efficacy analysis with the IGOS database expected 2024

Antibody Mediated Rejection (AMR)

Phase 2

- 30/30 patients enrolled
- Topline data showed statistical significance in rapidly reducing DSAs levels vs SoC
- Full data read-out expected H2 2023

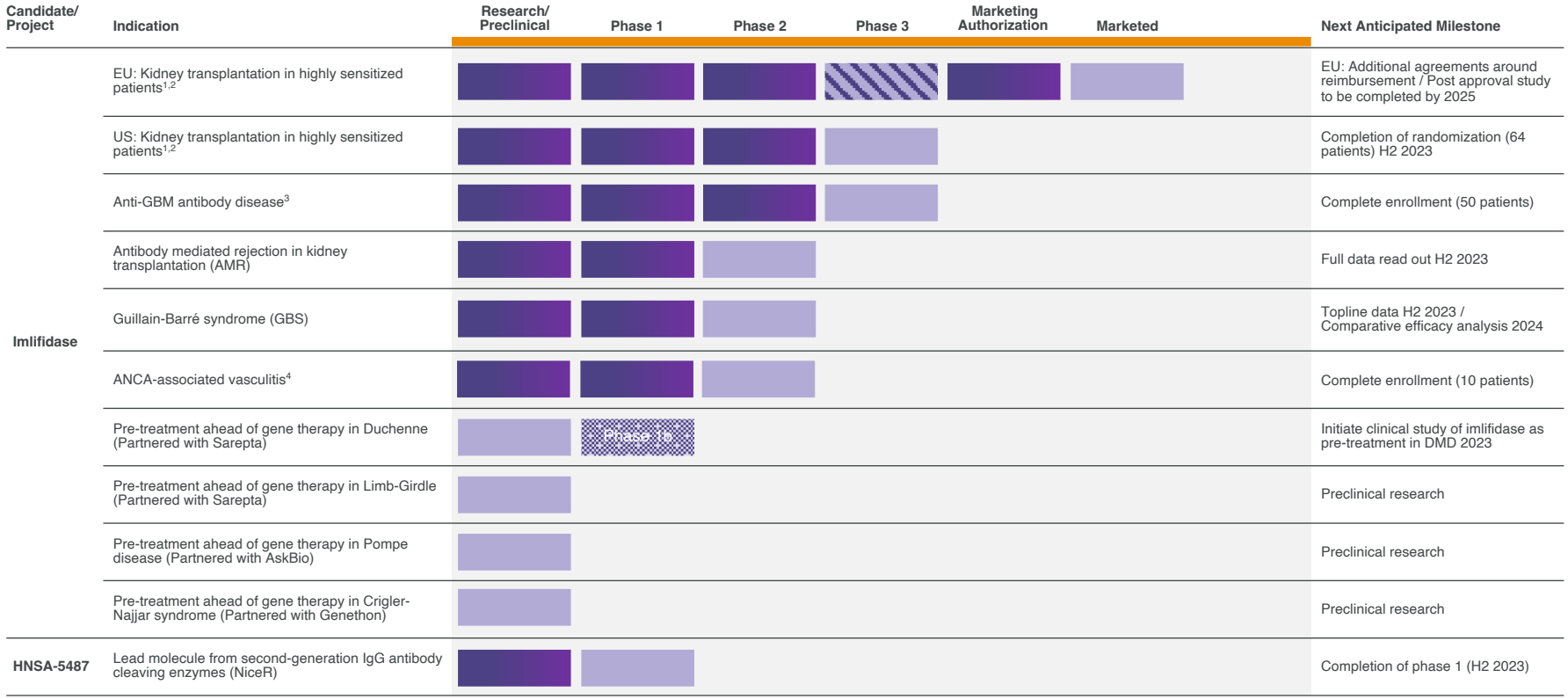
ANCA associated vasculitis

Phase 2

- 10 patients with severe ANCA-associated vasculitis will be treated with imlifidase on top of SoC.
- Study is single center, single arm to evaluate efficacy and safety
- First patient treated Q2'23

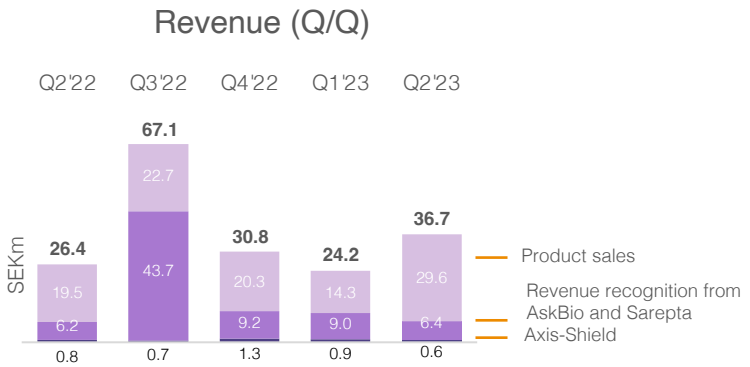
- Patients enrolled
- Patients remaining

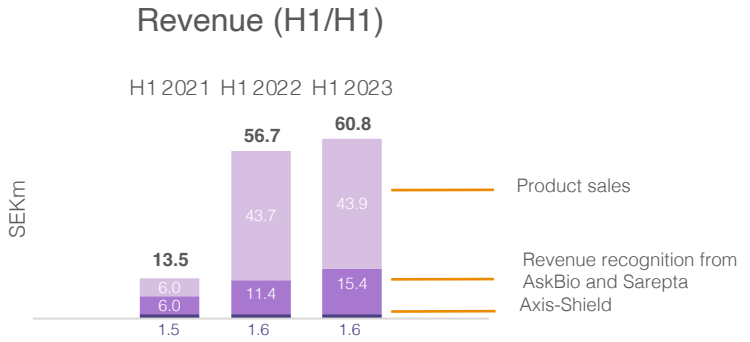
Broad clinical pipeline in transplantation and autoimmune diseases



[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

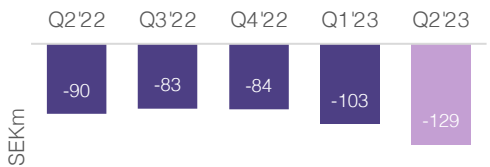
Q2 2023 Revenue amounted to SEK ~37m including SEK ~30m in product sales



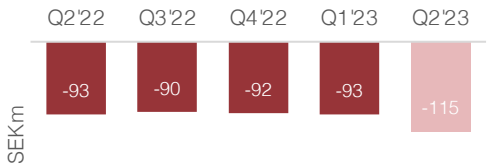


Continued investments in commercialization and R&D activities

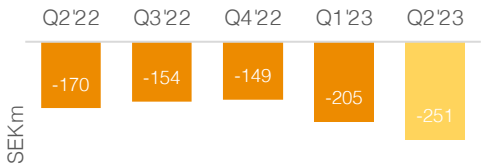
SG&A expenses (Q/Q)



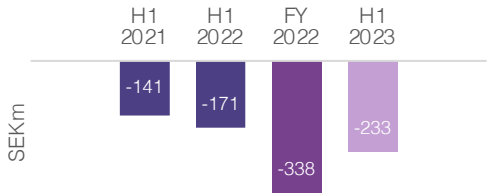
R&D expenses (Q/Q)



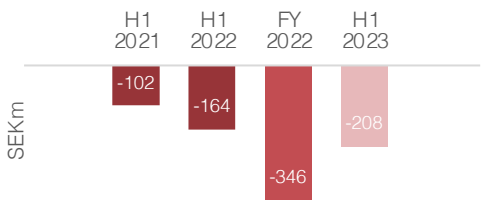
Net loss (Q/Q)



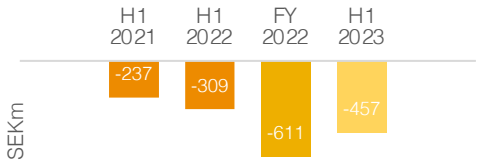
SG&A expenses (H1/H1)



R&D expenses (H1/H1)

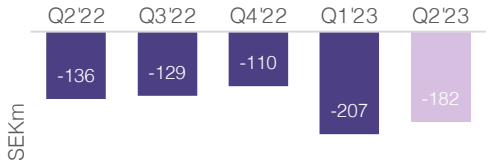


Net loss (H1/H1)

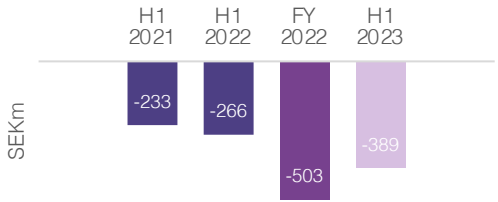


With current cash position and projected burn-rate, Hansa's operations are financed into 2025

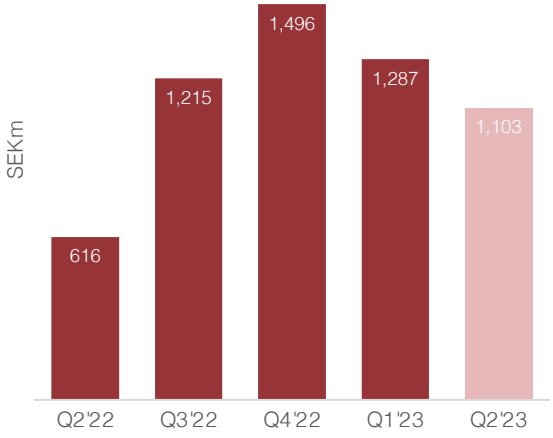
Operating cash flow (Q/Q)



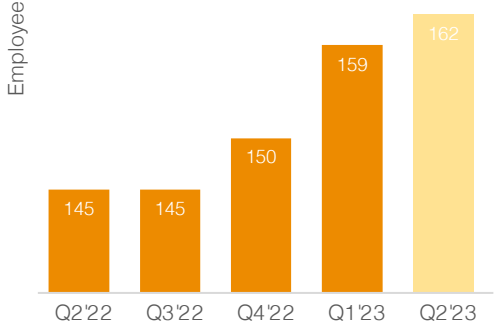
Operating cash flow (H1/H1)



Cash & short-term investments (Q/Q)



Number of employees (Q/Q)



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

Company overview

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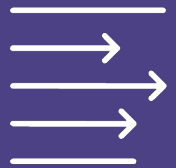
Hansa Biopharma today

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 (March 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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We are building a global leader in rare diseases

Today

We are launching our first commercially approved product for enablement of kidney transplantation in Europe*

Tomorrow

We envision a world where patients with rare immunologic diseases and conditions can lead long and healthy lives

* European Economic Area incl EU plus Iceland, Liechtenstein and Norway

Stock images

Hansa Biopharma's history

IPO
October 2007
39 SEKm
valuation

Pre-clinical proof-of-concept established

Imlifidase GMP process development and toxicology studies initiated

2. Clinical development

After the first-in-man study in **2013**, Hansa has completed four Ph. II studies since **2014**. Additionally Hansa has ongoing and completed trials in Anti-GBM disease, AMR, GBS and ANCA-associated vasculitis. In **2019** a MAA was submitted for imlifidase in kidney transplantation.

Hansa Biopharma enters the gene therapy space through partnership agreement with Sarepta Therapeutics to develop imlifidase as a pre-treatment to enable gene therapy in NAb+ patients

The EU Commission grants conditional approval for Idefirix® in highly sensitized kidney transplant patients in Europe

Market access secured in 13 countries

2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

Discovery, proof of concept and pre-clinical research | Clinical development | Commercialization

1. Turning foe into friend

The therapeutic potential in using a bacterial enzyme with specificity for IgG-antibodies, to neutralize pathogenic antibodies was discovered around **2006**. The original enzyme, IdeS, has been developed by *Streptococcus pyogenes* over thousands of years and by transferring a majority of the IdeS coding nucleotide into harmless *E. coli*-bacteria, the IgG-cleaving part of the IdeS molecule can be expressed and purified, resulting in the Hansa Biopharma drug imlifidase, i.e., turning a former foe to a friend.

First-in-man study

First Ph. II study of imlifidase in kidney transplantation

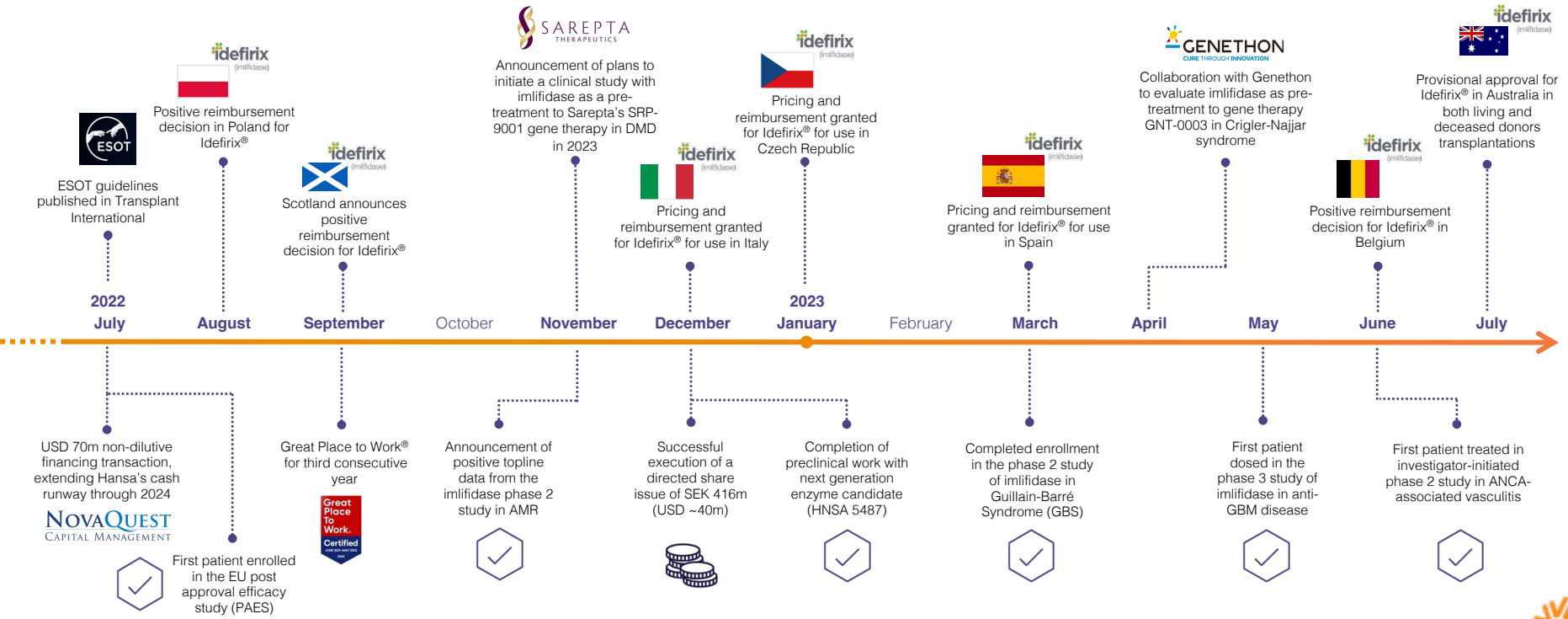
Starts trading on NASDAQ Stockholm main board

3. Commercialization

In august **2020**, Hansa received conditional approval for Idefirix (imlifidase) in kidney transplantation. Additionally, Hansa entered into the gene therapy field through a commercial partnership with Sarepta Therapeutics. Thus far, Hansa achieved market access in 13 European markets including the five largest markets. Market access procedures are ongoing in additional countries.

Hansa Biopharma enters into collaborations Medison (commercial), AskBio and Genethon (both gene therapy)

Key milestones achieved during the last 12 months

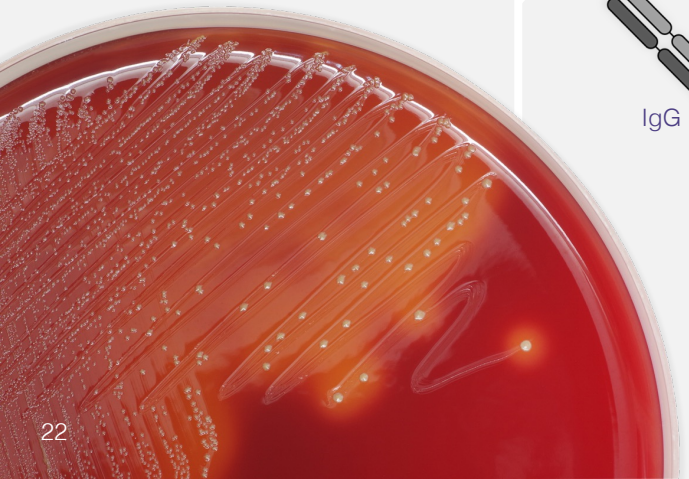


Imlifidase

a novel approach to eliminate pathogenic IgG

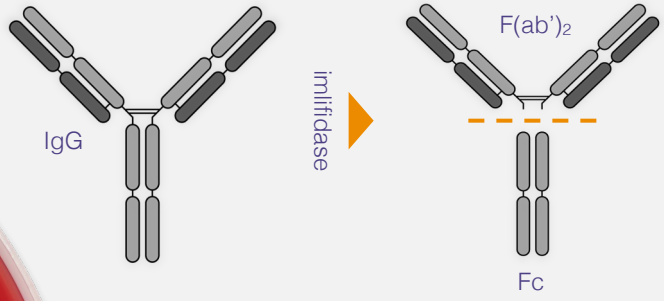
Origins from a bacteria *Streptococcus pyogenes*

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



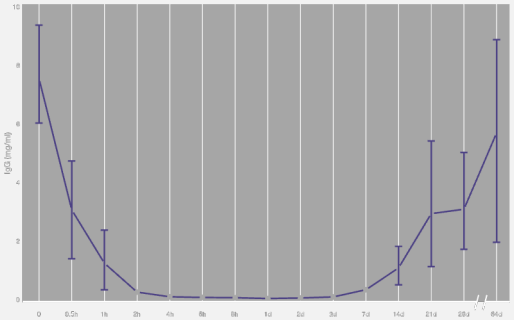
A unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one F(ab')2 fragment and one homo-dimeric Fc-fragment



Inactivates IgG in 2-6 hours

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

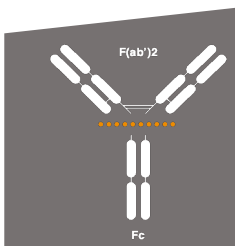


Our Business model

Leveraging our technology platform to develop new therapies targeting rare diseases with unmet medical need across a range of indications

Growth engine

Leveraging our proprietary antibody cleaving enzyme technology



Value chain

We are controlling the full value chain

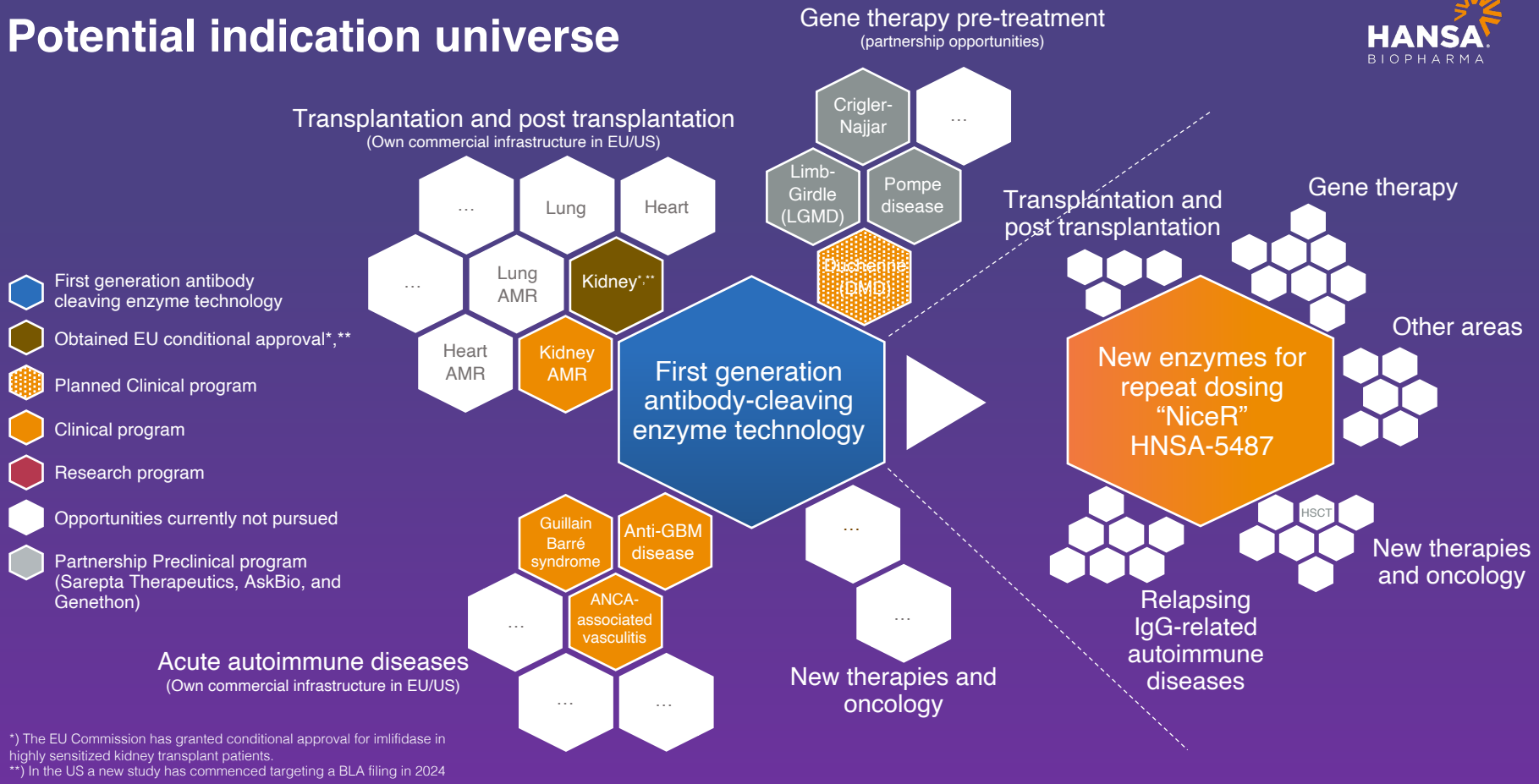
- Drug discovery
- Drug development
- Supply Operations
- Distribution

Commercialization

Build-up of franchises	Indications and therapies	Multiple income streams
Own commercial infrastructure	Transplantation	Revenue / sales
	Autoimmune diseases	Upfront payments
Partnership strategy	Gene therapy	Milestone payments
	Oncology	Royalties

Evolution into a fully integrated biopharmaceutical company

Potential indication universe



*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.
**) In the US a new study has commenced targeting a BLA filing in 2024

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

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Becoming a fully integrated commercial stage biopharmaceutical company

while expanding our technology and global footprint

We are here!

Pre-clinical | Early-stage clinic | Late-stage clinic | Commercial stage

1 Creating a scientific platform

- Advanced imlifidase from preclinical models through to approval
- Initiated clinical studies in transplantation in EU and the US
- Built the R&D organization
- Validated through peer-reviewed publications (e.g. NEJM and AJT)

2 Preparing the company for commercial success

- Completion of four phase 2 studies in transplantation
- Development of GMP process
- Expanded the pipeline to post-transplantation and autoimmunity
- Established corporate and medical functions
- Expanding the footprint in EU and US

3 Building and capturing value in new indications and markets

- First drug approval in kidney transplantation in EU*
- Commercialization
- Market Access secured in 13 countries, including the five largest European markets
- Expanding commercial teams and adding territory management
- Securing supply chain management
- Progressing pipeline and advancing our technology footprint

* Idefirix approved in EEA under conditional approval for kidney transplantation

Our culture is driven by people passionate about making changes

Purpose driven culture

Helping patients with rare diseases serves as a **strong purpose** for our colleagues to **go the extra mile**

Diverse and international

~45%

Internationals across ~30 nationalities

~55/45

Male/female gender split in the leadership team

Skilled and experienced team

>50%

With relevant PhD in R&D

~20 years*

of life science experience on average from Big Pharma, Biotech and Academia

**covers Management, R&D, and Commercial functions*

Motivated workforce

For second consecutive year Hansa is certified as a **"Great Place to Work"** with **100%** participation rate in the survey

Great Place To Work. Certified JUNE 2021–MAY 2022 SWE

Experienced Board and Executive Committee

Extensive experience from the global healthcare industry

Executive Committee

Søren Tulstrup

President & CEO (2018)
+30 years in the Healthcare sector
Ex-CEO at Vifor Pharma
Ex-SVP at Shire Pharmaceuticals
Ex-CEO at Santaris Pharma
Shareholding: 26,541

January 30, 2023, it was announced that CSO/COO Christian Kjellman had decided to leave the company in 2024.

Achim Kaufhold will assume an interim role as CSO, while a search is underway for a new Chief Scientific Officer.

Donato Spota

SVP & CFO (2019)
+20 years in the Healthcare sector
Ex-CFO Basilea Pharmaceutica
Senior Finance roles at Roche
Shareholding: 5,673

Achim Kaufhold

SVP & CMO (2020) and interim CSO
+40 years in the Healthcare sector
Ex-CMO Basilea Pharmaceutica
Ex-CEO Affitech (merged with Pharmexa A/S)
Ex-CMO Chiron (acquired by Novartis)
Shareholding: 0

Matthew Shaulis

CCO & US President (2023)
+20 years in the Healthcare sector
Ex-SVP Global Commerical and Medical Go-To-Market model transformation at Pfizer Inc.
Shareholding: 0

Anne Säfström Lanner

SVP & CHRO (2019)
Ex-Head of HR European Spallation Source
Ex-Head of HR Cellavision
Shareholding: 3,565

Board of Directors

Peter Nicklin

Chairman (2022)
+30 years in the Healthcare sector
Chairman of Tunstall Healthcare, Sciensus & Versantis
Held senior executive roles at Baxter, Bayer, Novartis & Bristol-Myers Squibb
Shareholding: 14,500

Hilary Malone

Board Member (2021)
COO at Valo Health (US).
Chief Regulatory Officer & Head of Global Regulatory Affairs at Sanofi (2013-2019)
SVP & Head of Worldwide Regulatory Strategy at Pfizer (2009-2011)
Shareholding: 0

Anders Gersel Pedersen

Board Member (2018)
+30 years in the Healthcare sector
Ex-EVP R&D H.Lundbeck
Chairman of Hansa Biopharma's Scientific Committee
Shareholding: 2,500

Eva Nilsagård

Board Member (2019)
Board member of several companies, e.g. Addlife, Bufab, Irras, Xbrane
Ex-CFO of Vitrolife and Plasta
Chairman of Hansa Biopharma's Audit Committee
Shareholding: 3,000

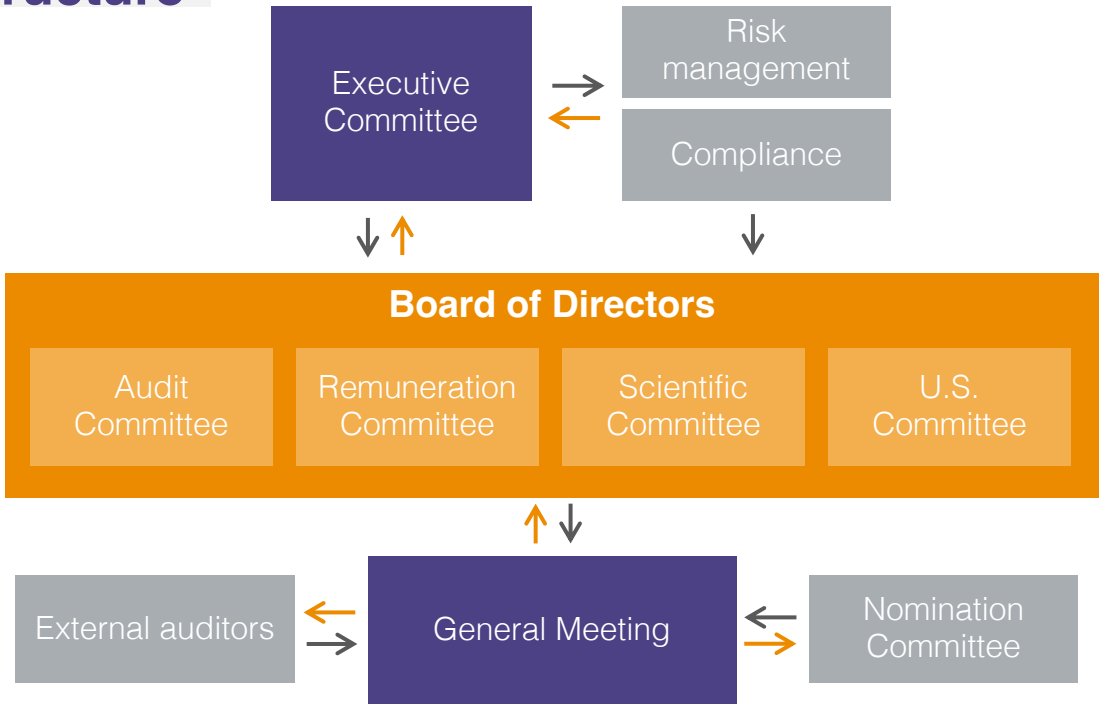
Mats Blom

Board Member (2019)
CFO of NorthSea Therapeutics
Ex-CFO Zealand Pharma
Member of Hansa Biopharma's Audit Committee
Shareholding: 1,000

Andreas Eggert

Board Member (2018)
Ex- SVP at H. Lundbeck A/S
Ex-VP Wyeth/Pfizer in the U.S.
Member of Hansa Biopharma's Audit Committee and Renumeration Committee
Shareholding: 5,500

Hansa Biopharma's Governance Structure



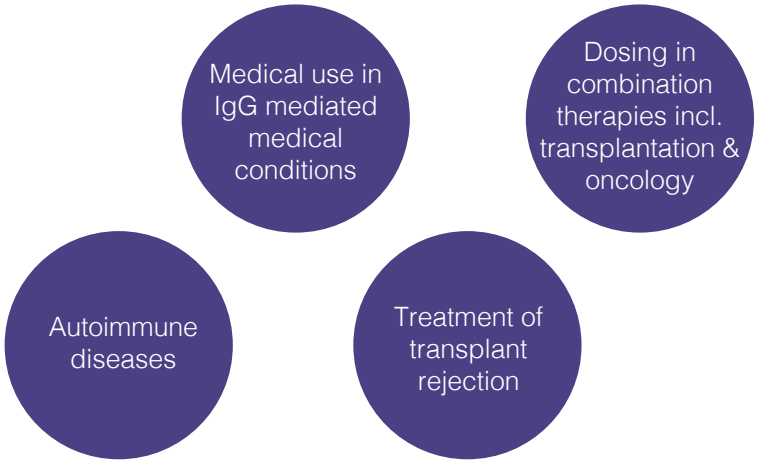
Electing / Appointing

Reporting / Informing

Strong technology protection through patents and orphan drug designations

Patent coverage out to 2035 in key markets

- Our lead product, imlifidase, is protected by six patent families including both granted patents and pending applications and cover the use of isolated imlifidase
- Patents cover use of isolated imlifidase at least in:



Orphan drug designation

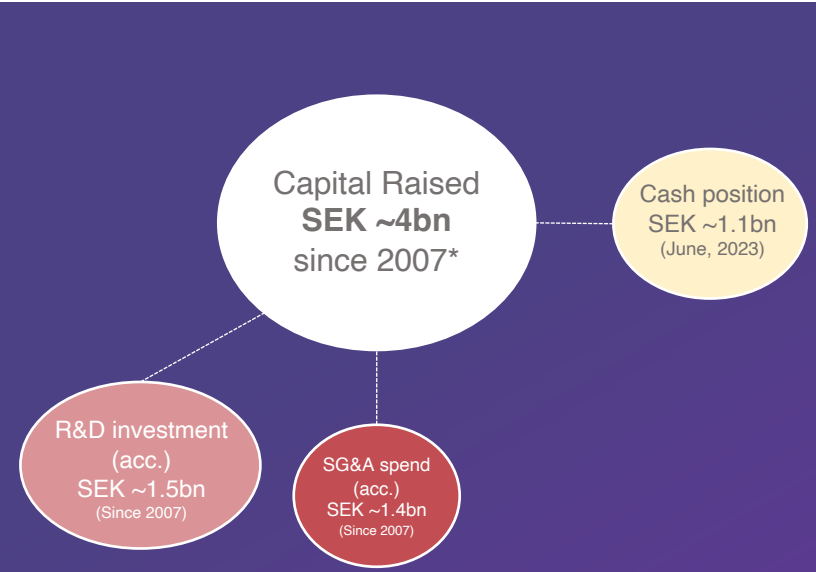
- Orphan drug designation is granted to drugs intended for rare diseases (affecting max 5 patients in 10,000 persons in EU or affecting less than 200,000 patients in the US)
- The designation provides development and commercial incentives, including ten years of market exclusivity in the EU and seven years in the U.S., protocol assistance on the development of the drug, including clinical studies and certain exemptions from or reductions in regulatory fees

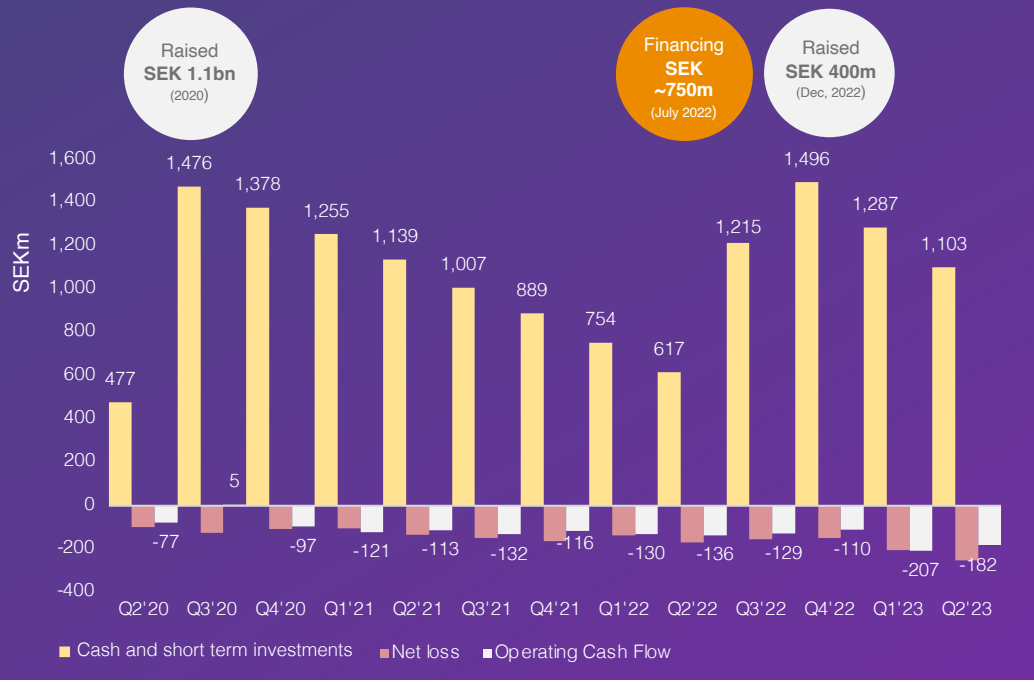
	Orphan drug designation & marketing authorization	Orphan drug designations
EMA/EC	ODD for the prevention of graft rejection following solid organ transplantation. Conditional marketing authorization for imlifidase was granted in 2020[1].	
	Orphan drug designation	
	Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)	
FDA		Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
		Imlifidase for the treatment of Guillain-Barré Syndrome (2018)
		Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

[1]Idefirix is indicated for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of Idefirix should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.

Hansa Biopharma is financed into 2025

Financing to support the continued development of Hansa's antibody-cleaving enzyme technology platform and commercial preparations toward regulatory approval in the U.S.





*Including SEK ~750m from NovaQuest financing agreement
& SEK ~100m upfront payments from Sarepta

HANSA BIOPHARMA

Mid-term financial priorities

Our key financial priorities over the coming years will be focused on ensuring a successful European launch of Idefirix®, while targeting mid-term product profitability

With the recent financing Hansa is fully financed into 2025
We expect to use our current cash position to:

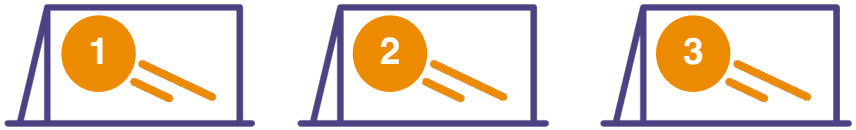
SEK ~1.1bn
(USD ~101m)
in cash and short-term investments post recent financing

- Fund the launch and commercial expansion of Idefirix® in kidney transplantation across Europe and start preparations for a potential launch in the U.S.
- Complete our EU post-approval commitments and patient enrollment in our ConfIdeS study as well as advance in our long-term follow-up study to the five-year data readout in 2023
- Strengthen ongoing product development activities and expand the Company's R&D pipeline, including AMR, GBS, and anti-GBM disease
- Advance our next generation enzymes (HNSA-5487) into clinical development as well as our initiatives in our other indications such as gene therapy and oncology
- Fund working capital and general corporate purposes

HANSA BIOPHARMA

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

Three shots on goal to enter important US market



US pivotal phase 3 study in kidney transplantation

Pivotal phase 3 study in anti-GBM disease

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

Timeline

Near-to-Midterm — Mid-to-Longer term

US functions to be established over time		
US Market Access	US Marketing	US Regulatory
Supply Chain/Distribution	US Key Account Mgmnt	US Clinical Operations
US Commercial Operations	US Medical Affairs/MSLs	US ISTs & Outcomes
US HR	US Finance/Corporate	US Legal/Compliance

An exciting journey ahead!

This is just the beginning!

- Clinical validation
- External validation
- Regulatory validation
- Validated manufacturing
- Strong IPR
- Exciting pipeline
- Strong team

Key milestones to be achieved

- Expand Idefirix® label in transplantation and in other solid organs
- Expand our platform and obtain regulatory approval in indications beyond kidney transplantation
- Advance our lead second generation molecule HNSA-5487 successfully through phase 1 and identify first relevant indication area
- Expand partnerships in gene therapy and oncology
- Advance imlifidase as pre-treatment into Limb-Girdle, Duchenne, Pompe Disease and Crigler-Najjar syndrome in gene therapy
- Show PoC in new indications such as oncology
- Advance potential combination treatment into the clinic

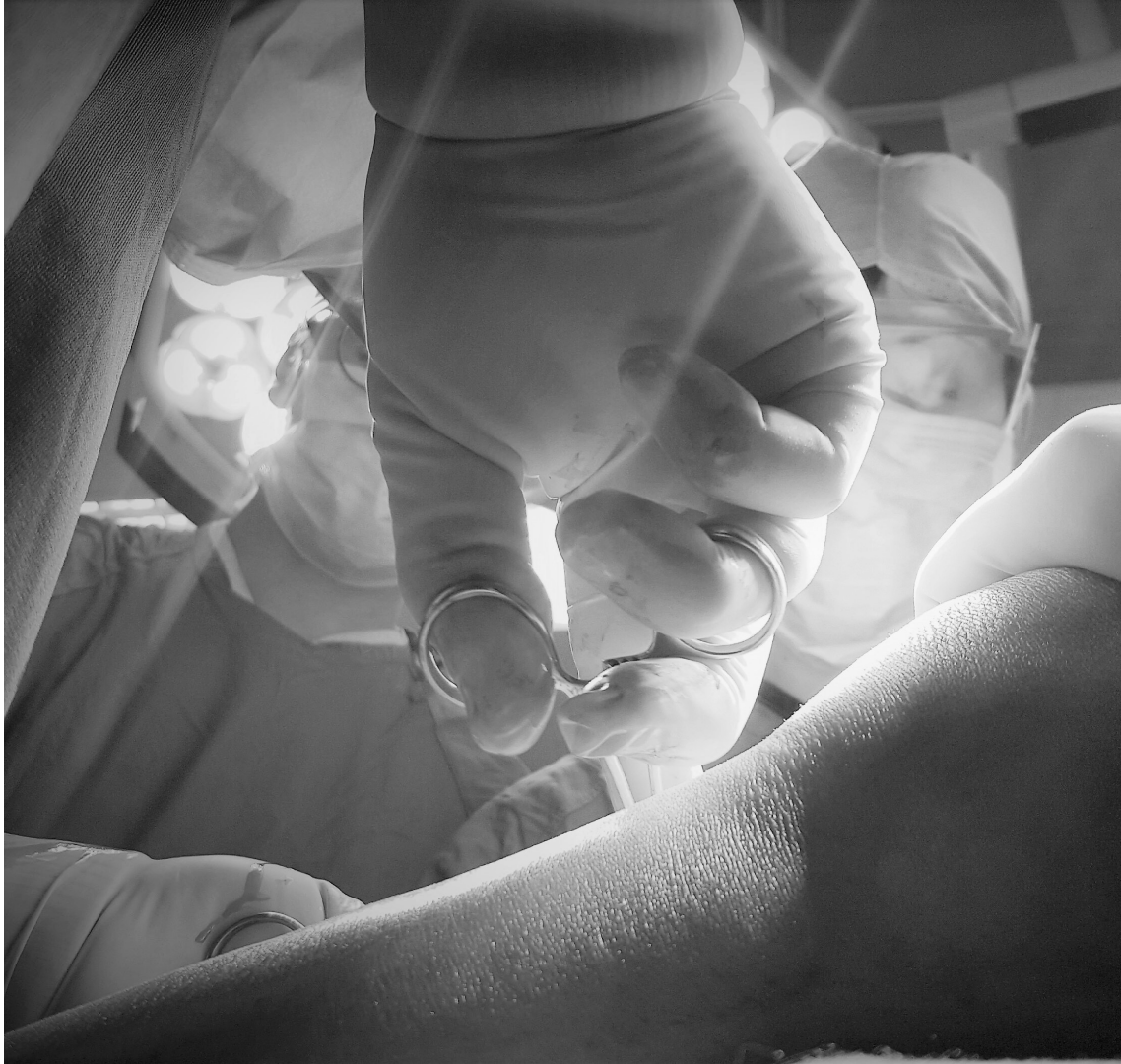
Idefirix® approved in EU under conditional approval for kidney transplantation

Our future

Hansa Biopharma is a recognized global leader in rare diseases across multiple broad therapeutic areas with several market leading products and a highly valuable pipeline of late stage drug candidates

Stock images

Imlifidase in kidney transplantation



HANSA BIOPHARMA

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

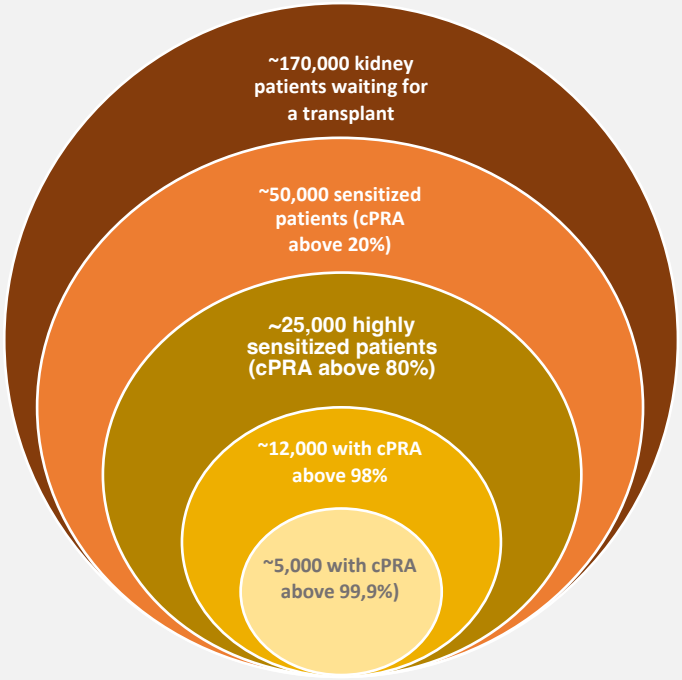
idefirix® imlifidase

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

The kidney transplantation landscape in Europe and the U.S.

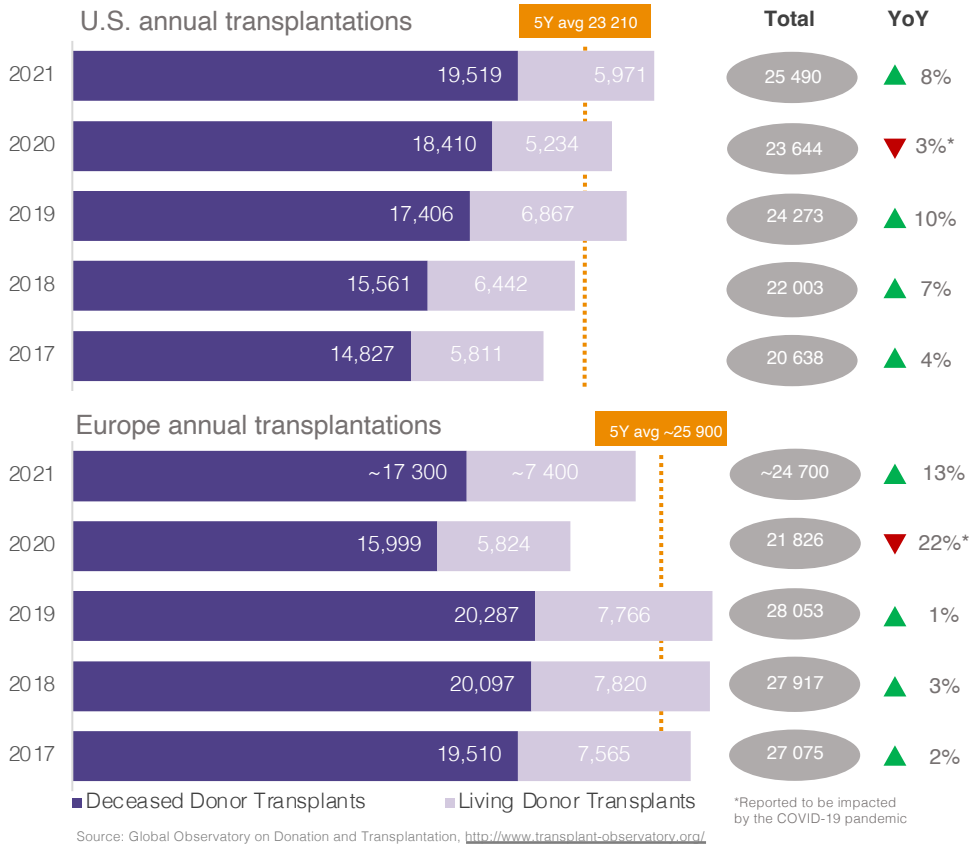
Up to 15% of patients waiting for a new kidney are highly sensitized

Breakdown of the kidney transplant waitlist in U.S. and EU



Source: The U.S. Department of Health and Human Services and irodat.org

~50,000 transplants done annually in the U.S. and Europe

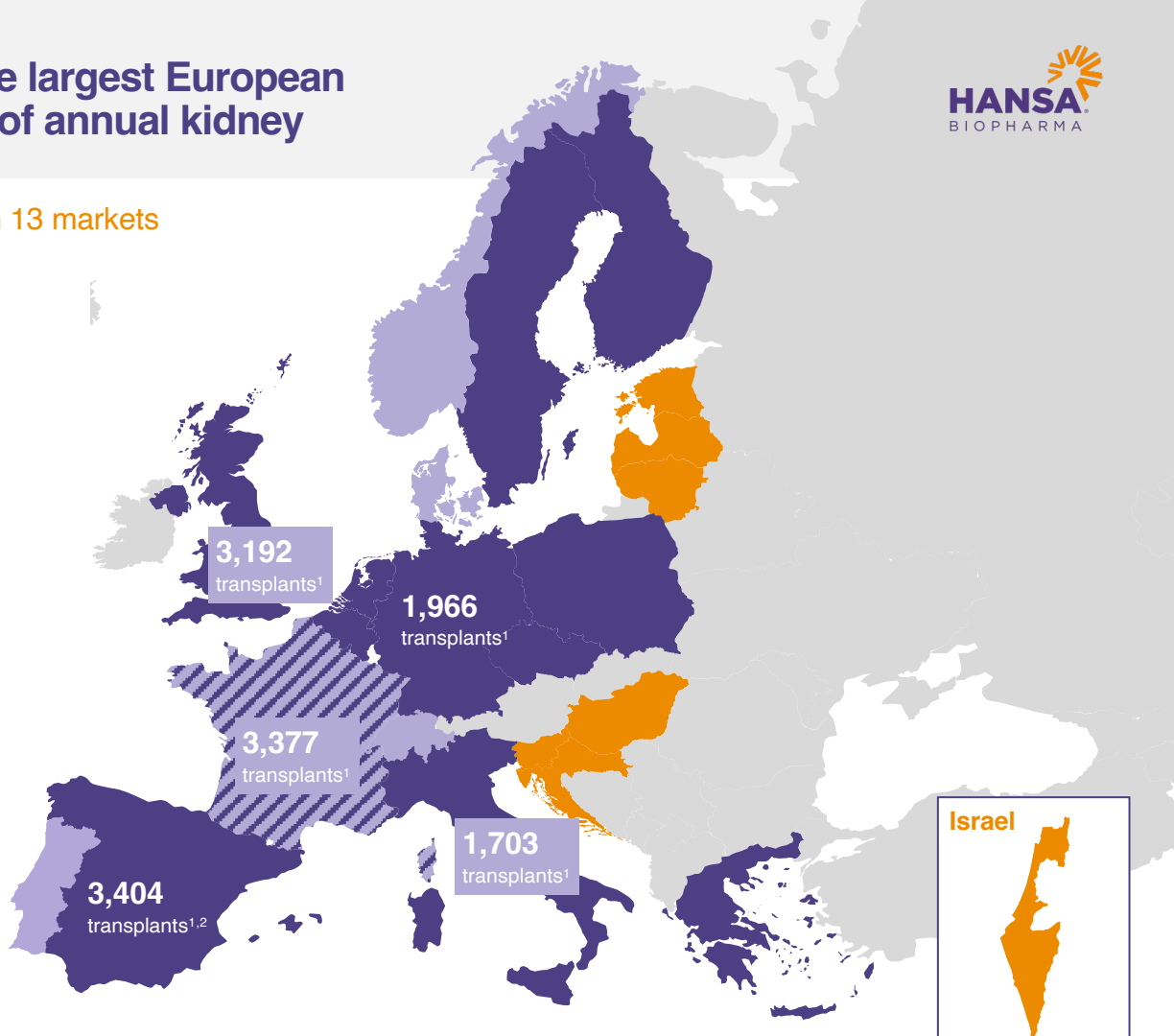


Source: Global Observatory on Donation and Transplantation, http://www.transplant-observatory.org/

Market Access secured in the five largest European markets representing two thirds of annual kidney transplants in Europe

Positive reimbursement decisions received in 13 markets

- Health Technology Assessments (HTA) dossiers submitted
- Reimbursed Early Access Program
- Pricing & reimbursement obtained (country or clinic level)
- Territories covered commercially by Medison Pharma



[1] Annual kidney transplantations 2022. Transplantation data is from Global Observatory on Donation and Transplantation, https://www.transplant-observatory.org/ [Accessed 2023-07-10]

[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

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

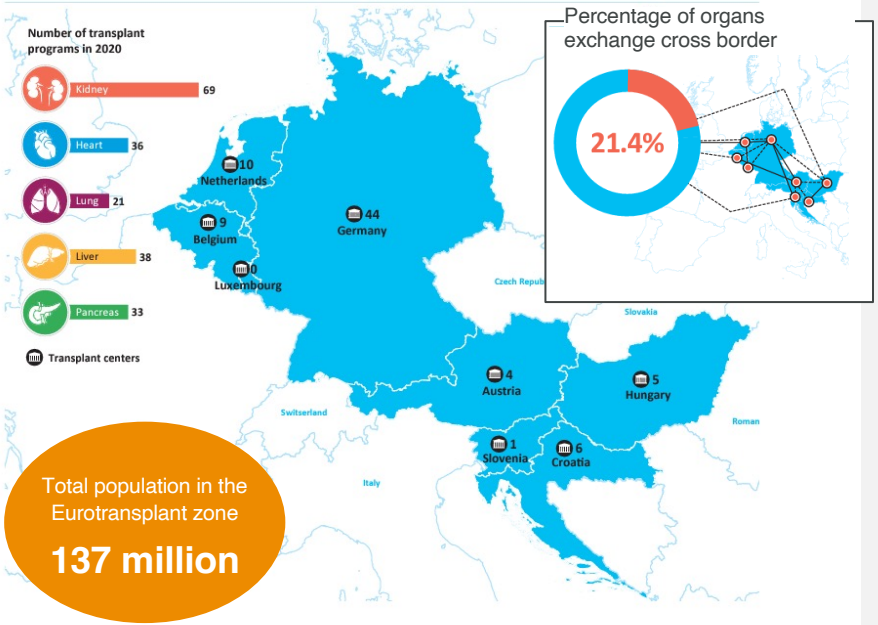
3 Potential label expansion

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

Commercial sales uptake

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)

Eurotransplant

Eurotransplant pilot program set to transform desensitization and increase clinical experience with imlifidase

Acceptable Mismatch Priority Program

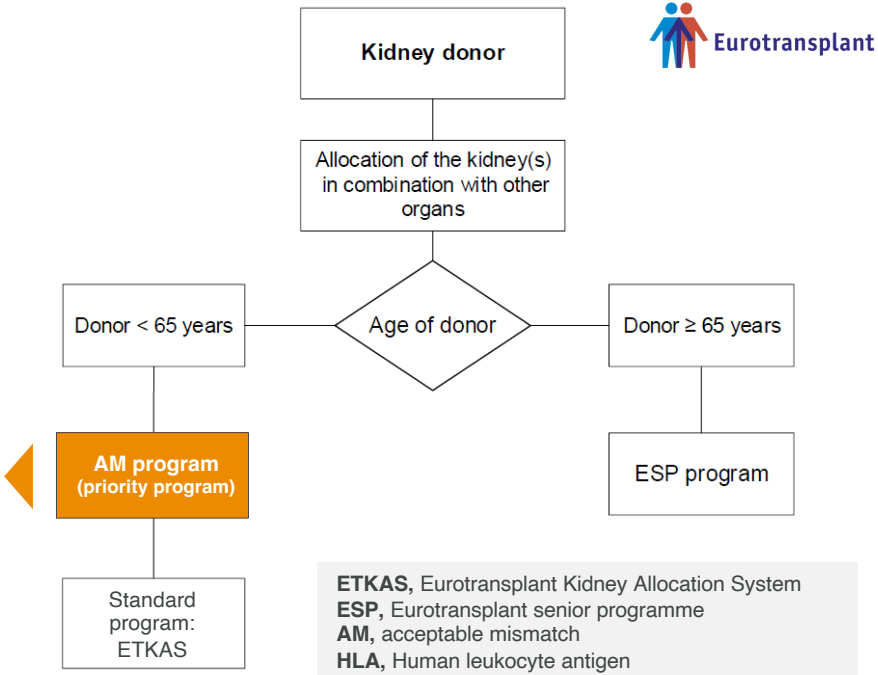
CURRENT
Acceptable Mismatch (AM) Program
Allocates organs to patients who are immunologically compromised because of current and/or historic HLA-sensitization

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



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

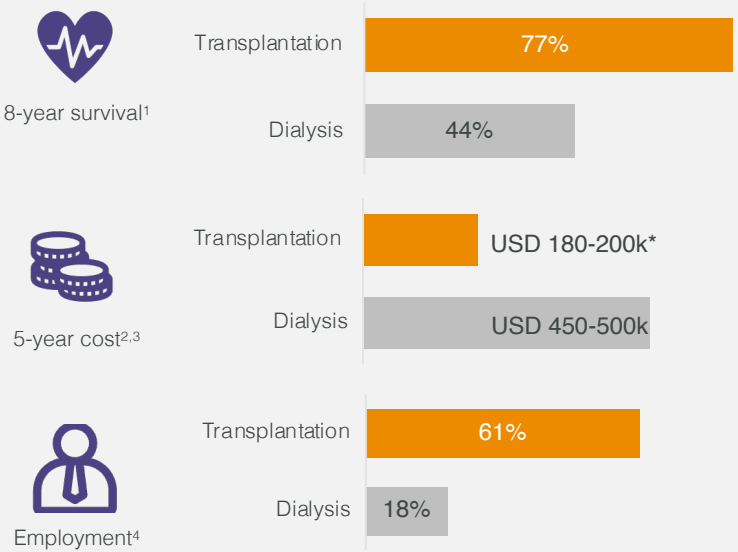
Highly sensitized patients are difficult to match with an available kidney

Transplantation leads to better outcomes, saves lives and increase quality of life for patients

Causes of sensitization include:

- Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization
- Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients
- Allocation Systems such as KAS and Eurotransplant rely on cPRA score to characterize patients for transplant

Better outcomes with transplantation



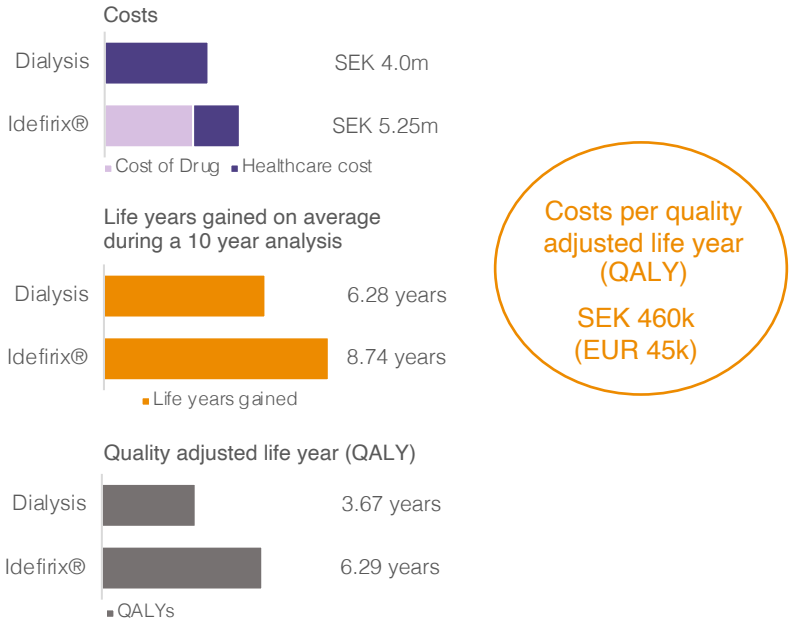
*Cost of kidney transplantation and 5 years of immuno-suppression treatment[6,7]

[1] Orandi et al. N Engl J Med 2016;374:940-50
[2] www.usrds.org
[3] Shehata et al, Transfus Med Rev 201, 24 Suppl 1: S7-S27
[4] Jarl et al. Transplantation, 2018, 102:1375-1381

First HTA report (TLV) published in Sweden favourable to the use Idefirix® in highly sensitized patients incompatible to a deceased donor

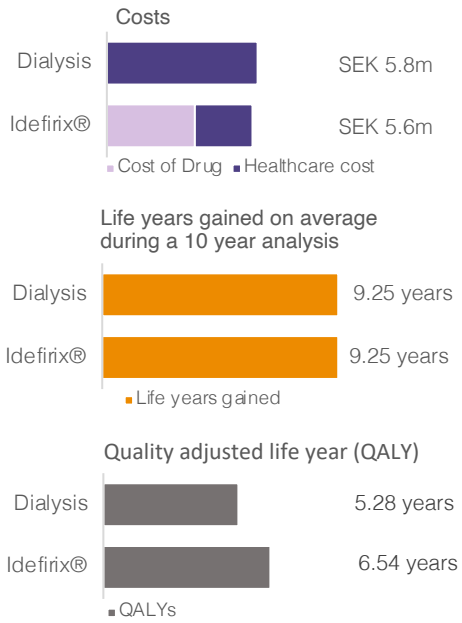
Two cost-effectiveness scenarios presented – both within the accepted threshold for costs related to new drugs
One scenario even concluding Idefirix treatment would lead to an overall cost saving – rare for orphan drugs

Scenario 1
High dialysis mortality



Costs per quality adjusted life year (QALY)
SEK 460k
(EUR 45k)

Scenario 2
Low dialysis mortality



Scenario 2 supports Idefirix® as a cost saving drug

Costs per quality adjusted life year (QALY)
SEK -170k
(EUR -17k)

Source: TLV https://www.tlv.se/download/18.1d0e11ca17750df902370541/1614947000269/bed210127_idefirix.pdf

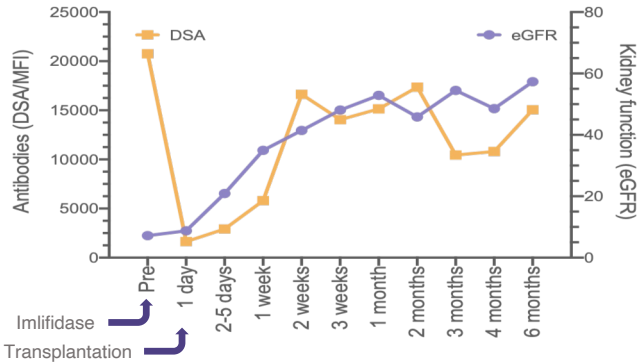
Completed and ongoing studies in kidney transplantation

HANSA BIOPHARMA

Imlifidase enabled kidney transplantation in 46 highly sensitized patients during clinical trials

Pooled analysis from four Phase 2 trials

- Analysis included 46 patients
  - 50% had a cPRA of 100% (Average 99%)
  - 85% were crossmatch positive
  - 70% were retransplanted
- Donor Specific Antibody (DSA) levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation in all patients
- At study completion, all patients alive and graft survival at 94% six months post transplantation
- 5 year follow-up data expected in 2023



Study design of our four Phase 2 trials leading to the approval in EU

Study 02 Phase 2

Subjects	8 patients
Design	Single-center, single-arm, open-label
Main objective	Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours

Study 03 Phase 2

Subjects	10 patients
Design	Single-center, single-arm, open-label, no prior desensitization
Main objective	Safety in the transplantation setting and efficacy defined as HLA antibody levels acceptable for transplantation

Study 04 Phase 2

Subjects	17 patients
Design	Investigator initiated, single-center, single-arm, open-label. All patients had prior desensitization with IVIG and/or PLEX
Main objective	Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patient

Study 06 Phase 2

Subjects	18 patients
Design	Multicenter, multinational, single-arm, open-label
Main objective	Efficacy in creating a negative crossmatch test

3-year follow up demonstrate graft survival of 84% after imlifidase treatment and transplantation

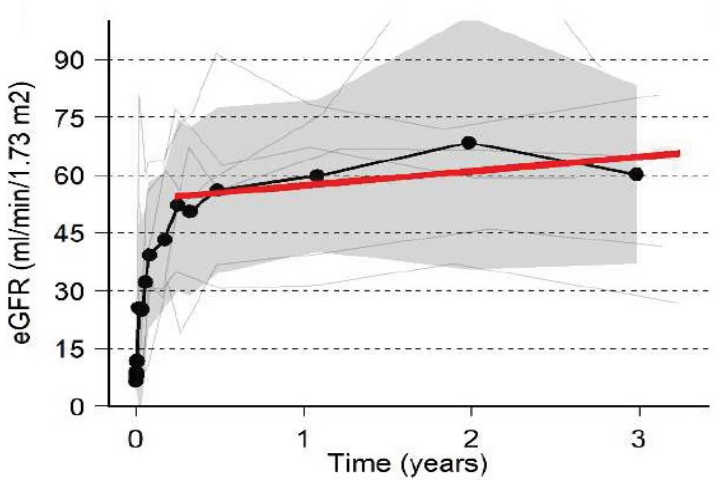
Data accepted for publication in the American Journal of Transplantation[1] Link AJT article

30 patients participating in follow-up study at year three

AMR frequency in line with other desensitization protocols

- Three-year follow-up data shows graft survival of 84% after imlifidase treatment and transplantation and a mean eGFR of 55 mL/min/1.73 m^2 (61 ml/min/m^2 for those without AMR)
- For a subgroup of patients (n=13) with cPRA of ≥ 99.9% graft survival was 92% and improved kidney function for patients with a mean eGFR at 60ml/min/1.73 m^2 after year three
- 38% of the patients experienced active antibody mediated rejection episodes (AMR) within the first six months, which compares with 25-60% of patients in the literature for highly sensitized patients[2]
- Only two AMR episodes were reported beyond the first 6 months. All AMRs were treated with standard therapies and no graft losses were attributed to AMR
- Patient survival 90% (three deaths unrelated to imlifidase)
- Long-term safety profile indicates no increase in the rates of infection or malignancy
- Next milestone expected in H2 2023 on the 5-year follow-up data

Improved kidney function for patients with cPRA ≥ 99.9%



Median eGFR at 60ml/min/1.73 m^2 after year 3

[1] American Journal of Transplantation - Outcomes at 3 years post-transplant in imlifidase-desensitized kidney transplant patients (AJT16754)
Link to AJT article https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16754

[2] Vo et al. 2013; Colvin 2007; Gloor et al. 2008; Haas et al. 2014; Jordan et al. 2010; Lefaucheur et al. 2010; Solez et al. 2007; Riella et al. 2014)

HANSA BIOPHARMA

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

Complex allocation system with limited clinical innovation

25,000 annual kidney transplants

71% diseased donors

~90,000 patients on the waitlist

10-15% of waitlisted patients are highly sensitized

~6,000 highly sensitized patients with cPRA of 98% or above (hereof ~2,500 with cPRA of 99.9% and above)

U.S. ConfIdeS

Phase 3

- 76 patients screened and enrolled
- Plans to expand no of sites from currently 14 to 20 or more to accelerate randomization
- Randomization expected to be completed H2 2023, as previously guided

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

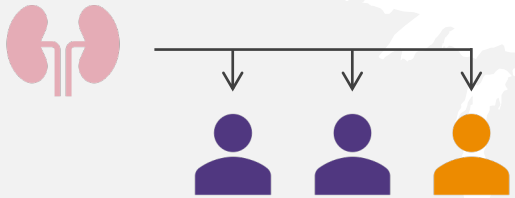
Imlifidase may complement the US Kidney Allocation System, as thousands of patients are still unlikely to find a match

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
Less or moderate	20-80	2-14	~16,000
Highly sensitized	80-98	14-300	~5,000
Highly sensitized	98-99.9	300-3,000	~3,500
Highly sensitized	>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

U.S. ConfIdeS study: Randomized controlled study in 64 highly sensitized patients with highest unmet medical need

U.S. trial design

64 highly sensitized kidney patients with the highest unmet medical need

- Patients with a cPRA score of ≥99.9% will be enrolled
- First patients enrolled at Columbia University, NYC
- 76 patients enrolled across fourteen sites as of July 20, 2023
- 1:1 Randomization
- When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase or to a control arm, where patients either remain waitlisted for a match or receive experimental desensitization treatment*

Primary endpoint

- Mean estimated glomerular filtration rate (eGFR) “kidney function” at 12 months.
- For randomized patients who do not undergo transplantation, lose their graft or die before 12 months, eGFR will be set to zero, consistent with kidney failure

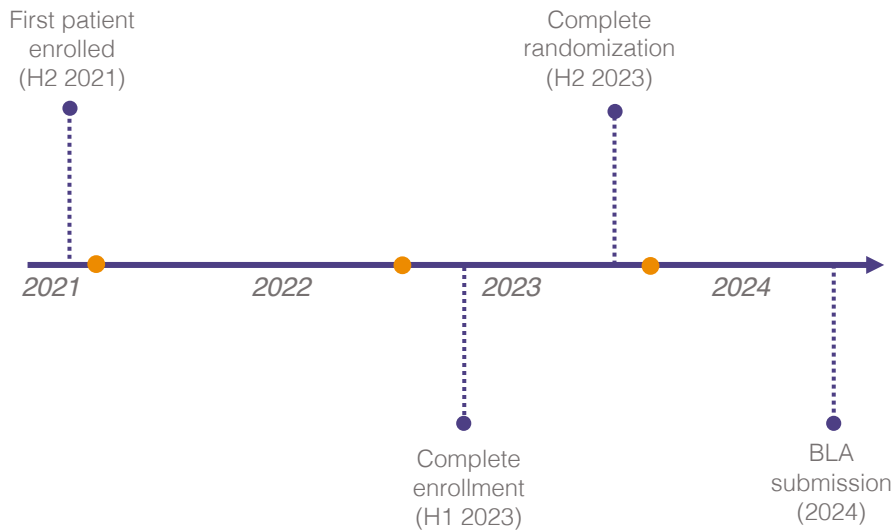
Secondary endpoint

- Patient survival at 12 months

Up to 20 leading transplantation centers in the U.S. will be engaged in the study

- Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, NYC is appointed to be the principal investigator

Timeline



*Experimental desensitization treatment can include any combination of plasma exchange (PLEX), intravenous IVIg, anti-CD20 antibody, and eculizumab. Link to the full protocol at ClincalTrials.gov

First patient treated in post-authorization efficacy study (PAES) of Idefirix® (imlifidase) in highly sensitized kidney transplant patients

The study will provide further important insights regarding Idefirix® desensitization treatment of highly sensitized kidney transplant patients

An open-label Phase 3 study in 50 patients

- First patient was treated by Dr. Oriol Bestard, Chair of Nephrology and Kidney Transplantation at Vall d'Hebron University Hospital in Barcelona
- Study will enroll 50 highly sensitized patients with positive crossmatch against an available deceased donor across multiple countries and centers in Europe
- The study is an obligation under the conditional marketing authorization for Idefirix® granted by EMA in August 2020, in order to complete a full marketing authorization in the EU. Study is expected to be complete in 2025
- The aim will be to confirm the long-term efficacy and safety of Idefirix® with the primary objective to determine the one-year graft failure-free survival of the Idefirix® treated and transplanted patients.
- In addition, a total of 50-100 patients undergoing compatible kidney transplantation at the participating centers will be included and serve as a non-comparative concurrent reference cohort, with no formal comparison, to contextualize the one-year graft failure-free survival of the Idefirix® treated patients

Study to assess imlifidase in combination to optimize patient outcome

in highly sensitized patients with donor specific antibodies (DSA) rebound and antibody mediated kidney transplant rejection

Trial design (ClinicalTrials.gov ID: NCT05049850)

The study is designed to assess if imlifidase in combination with bortezomib[1], belatacept[2], rituximab[3] and IVIg[4] can suppress donor specific antibodies (DSA) and the occurrence of antibody-mediated rejection (AMR) in transplant patients with a positive crossmatch towards their living donor.

Open label, single arm study

- Imlifidase is administered within the 24-hour prior to a living donor transplantation

Primary endpoint

- Proportion of patients with DSA rebound (up to 3 months after transplantation)
- Rebound of DSA may cause AMR and is thus a risk for graft loss

Secondary endpoint

- Proportion of patients with AMR (up to 6 months after transplantation)

The study will be run at the NYU Langone Transplant Institute and was commenced end of 2022

[1] bortezomib, a proteasome inhibitor which has activity against mature plasma cells, the source of DSA
[2] belatacept, a fusion protein which is crucial in blocking T-cell co-stimulation and which is effective in reducing de novo DSA generation in humans
[3] rituximab, an anti-CD20 monoclonal antibody that targets B-cells and which is an immunomodulatory agent
[4] intravenous immunoglobulin (IVIg) which is commonly used in desensitization regimens and for the treatment of AMR
Link to the full protocol at ClincalTrials.gov

The 01 study results

Data showed complete removal of IgG and a good tolerability profile

Study 01
Phase 1

CLINICALTRIALS.GOV ID

NCT01802697 (2013/2014)

SUBJECTS

29 (20 active plus 9 placebo) healthy subjects (Sweden)

DOSES/FOLLOW UP TIME

The starting dose was 0.01 mg/kg BW and the highest dose group received 0.24 mg/kg BW

MAIN OBJECTTIVES

- The objectives were to assess safety, efficacy in IgG cleavage, pharmacokinetics and immunogenicity of imlifidase following intravenous administration

STUDY DESIGN

- Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects

STATUS

Completed

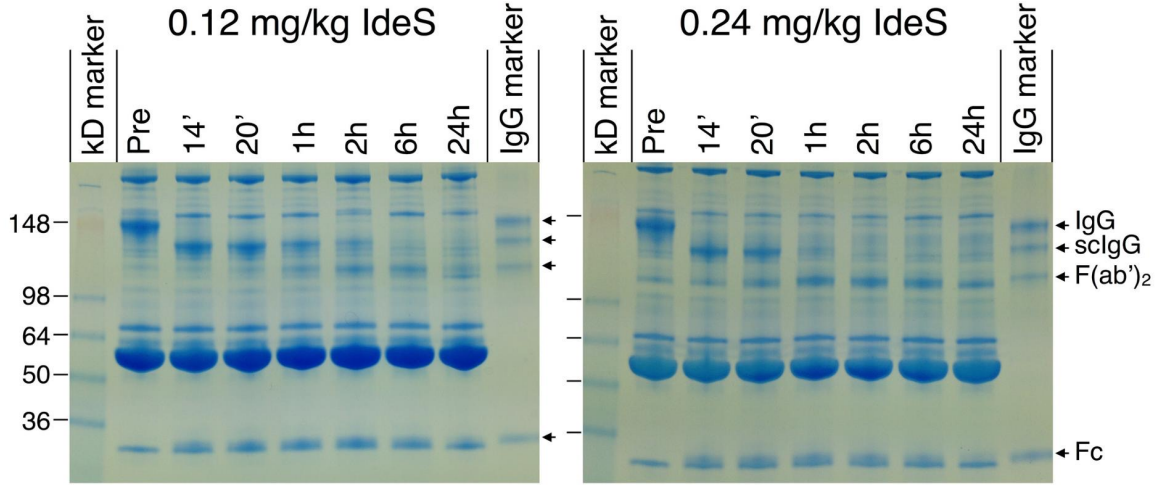
- The 01 study showed that Imlifidase was considered safe to use

Efficacy

✓ Rapid degradation of IgG in serum in subjects dosed with 0.12 and 0.24 mg/kg imlifidase. Imlifidase had full effect within 6 hours. The entire IgG pool was converted into F(ab')$_2$ and Fc-fragments. Maximal effect was accomplished 2-6 hours after dosing.

Safety

✓ Newly synthesized intact IgG was clearly detectable in all subjects after 1-2 weeks after dosing. After 3 weeks the level of intact IgG constituted the main IgG fraction in serum



Winstedt el al., PLOS ONE 2015, 10(7)

Study 02
Phase 2

CLINICALTRIALS.GOV ID

NCT02224820

SUBJECTS

8 Patients with chronic kidney disease (Sweden)

DOSES/FOLLOW UP TIME

0.12 & 0.25 mg/kg BW given once or twice within 48 hours

MAIN OBJECTTIVES

- Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours from dosing
- Safety

STUDY DESIGN

- Single-center, Single arm with ascending doses, open-label
- Transplantation not part of protocol

STATUS

Completed

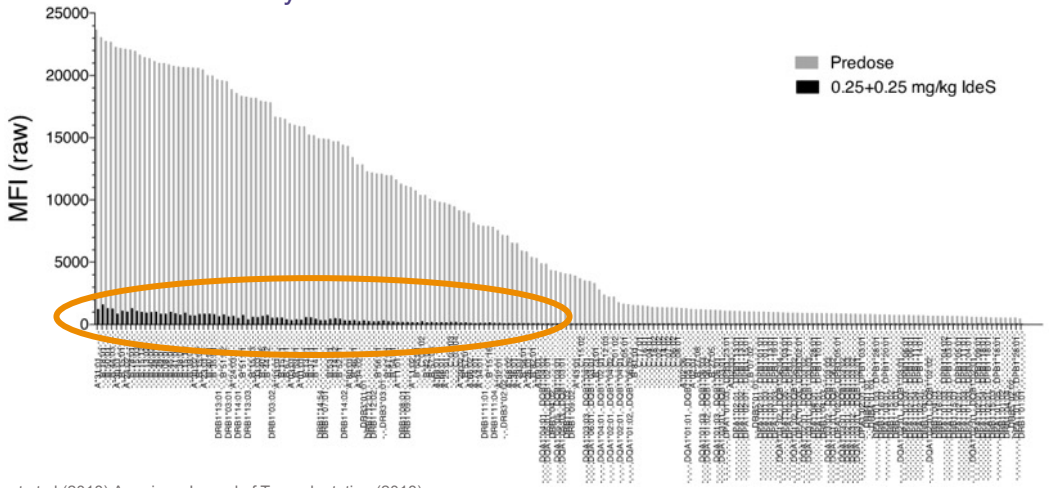
- Primary efficacy endpoint reached
- Safe and well tolerated

The 02 study results

Data showed that 1-2 doses of imlifidase at 0.25 mg/kg BW resulted in HLA antibody levels acceptable for transplantation[1]

- ✓ Imlifidase is well tolerated in patients with chronic kidney disease
- ✓ Efficacy results strongly support further development in the patient population
- ✓ The first HLA-incompatible transplantation ever after desensitization with imlifidase was performed in one of these patients (2014)

HLA-antibody levels before and after 6 hours treatment with imlifidase



[1] Lorant et al (2018) American Journal of Transplantation (2018)

HANSA BIOPHARMA

The 03 study proved safety and efficacy

HLA antibodies at acceptable levels; enabling transplantation in all patients

Study 03
Phase 2

CLINICALTRIALS.GOV ID

NCT02475551

SUBJECTS

10 Patients (Sweden)

DOSES/FOLLOW UP TIME

0.25 and 0.50 mg/kg during 180 days

MAIN OBJECTTIVES

- Safety in the transplantation setting
- Efficacy defined as HLA antibody levels acceptable for transplantation

STUDY DESIGN

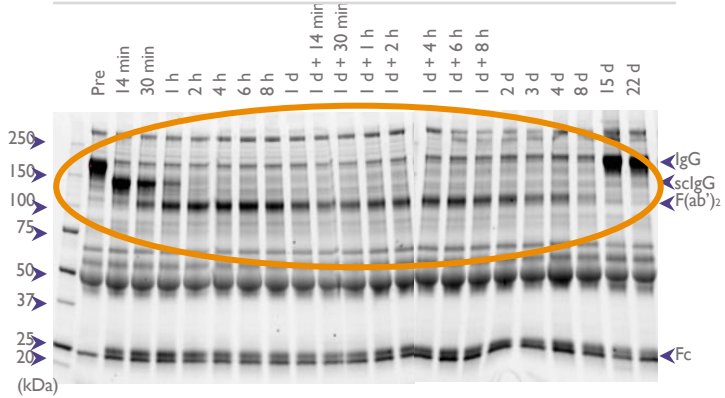
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

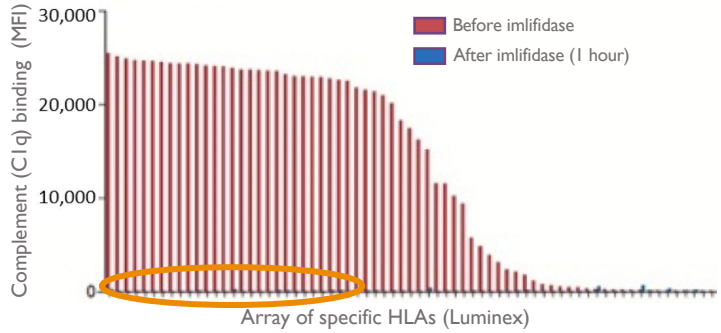
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment



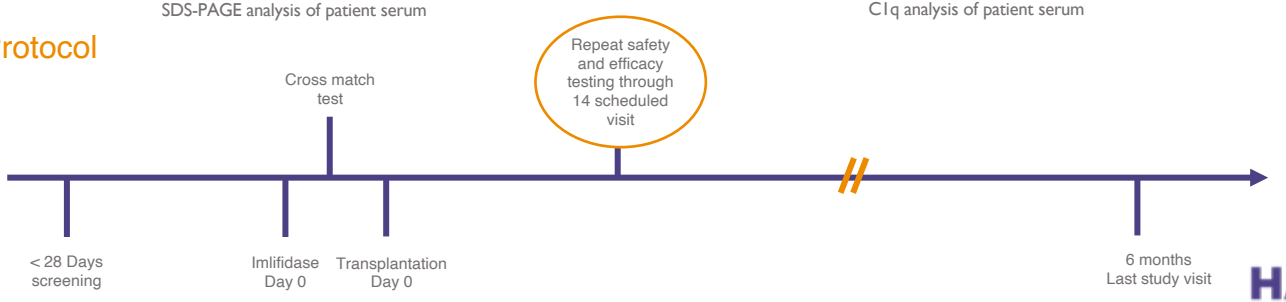
SDS-PAGE analysis of patient serum

Analysis of complement binding HLA antibodies before and after imlifidase



C1q analysis of patient serum

Protocol



Jordan SC, *et al.* (2017) NEJM Aug 3;377(5):442-453.

Study 04
Phase 2

The 04 study results

Study proved safety and efficacy with Cedar Sinai's standard protocol (rituximab and IVIg)

CLINICALTRIALS.GOV ID

NCT024226684

SUBJECTS

17 Patients (US)

DOSES/FOLLOW UP TIME

0.24 mg/kg 180 days

MAIN OBJECTTIVES

- Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patients
- Efficacy in preventing AMR

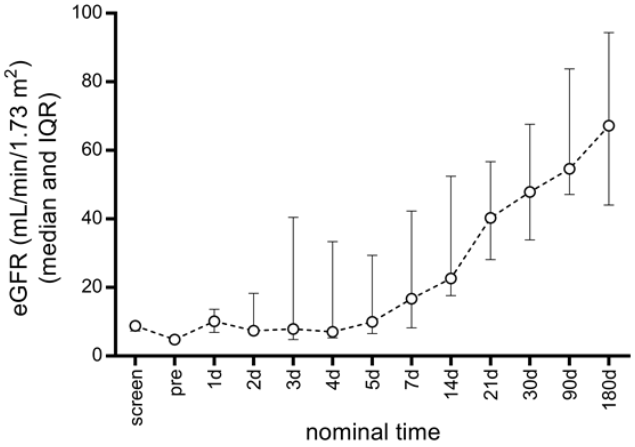
STUDY DESIGN

- Investigator initiated study
- Investigator sponsored IND
- Imlifidase to desensitize patients previously treated with rituximab and IVIg
- Deceased donors only

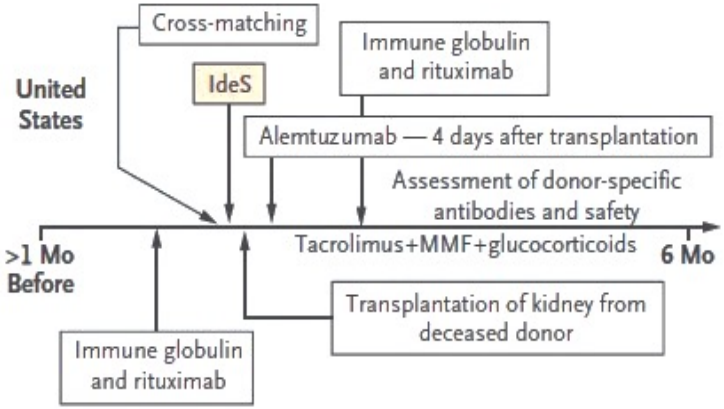
STATUS

Completed

Graft function (eGFR) post six months



Cedar's desensitization protocol in combination with imlifidase



Jordan SC, *et al.* (2017) NEJM Aug 3;377(5):442-453.
Huang E, *et al.,* (2019). Three-year outcomes of highly-sensitized kidney transplant recipient desensitized with imlifidase (IdeS). Abstract at ATC.

HANSA BIOPHARMA

The 06 study results

Study showed proved safety and efficacy in making highly sensitized patients eligible for kidney transplantation

Study 06
Phase 2

CLINICALTRIALS.GOV ID

NCT02790437

SUBJECTS

18 Patients (US+Sweden+France)
19 safety set, 18 efficacy set

DOSES/FOLLOW UP TIME

0.25 mg/kg 180 days

MAIN OBJECTTIVES

- Efficacy in creating a negative crossmatch test

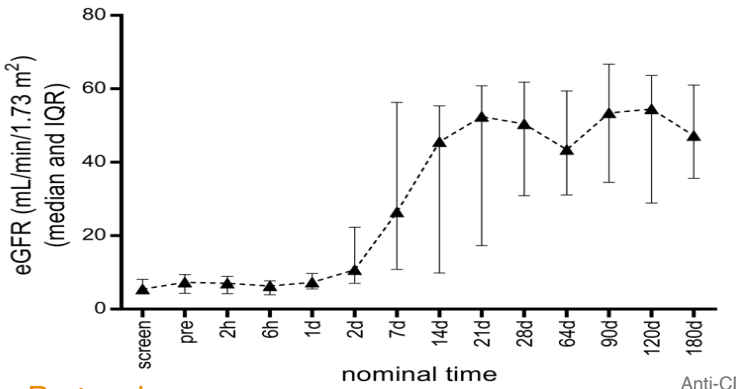
STUDY DESGIN

- Multicenter, multinational, single-arm, open-label Included patients who may have had prior unsuccessful desensitization or patients in whom it was unlikely to be effective

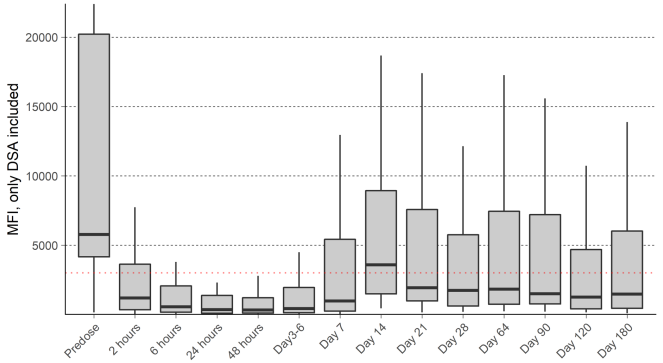
STATUS

Completed

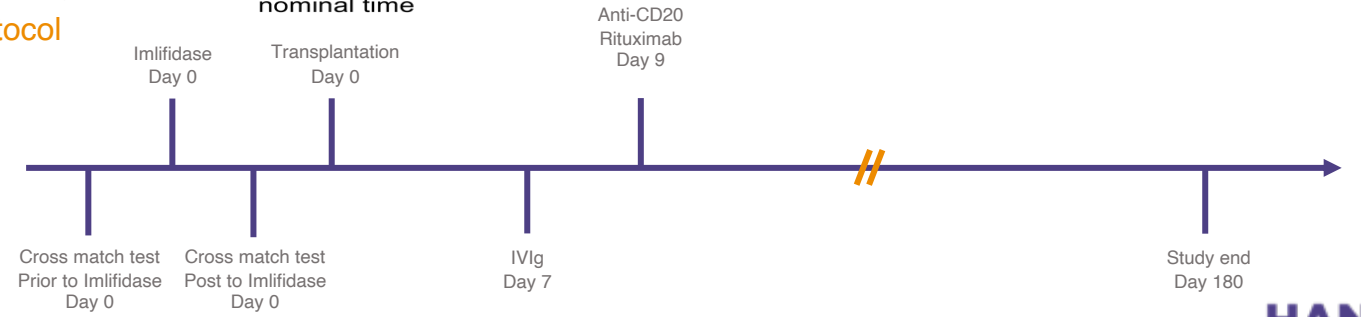
Graft function (eGFR) post imlifidase



DSA level pre-dose and post imlifidase



Protocol



Jordan SC, *et al.* (2019).
Results from the international phase II study on the safety and efficacy of imlifidase in highly-sensitized kidney transplant patients. Abstract presented at ATC.

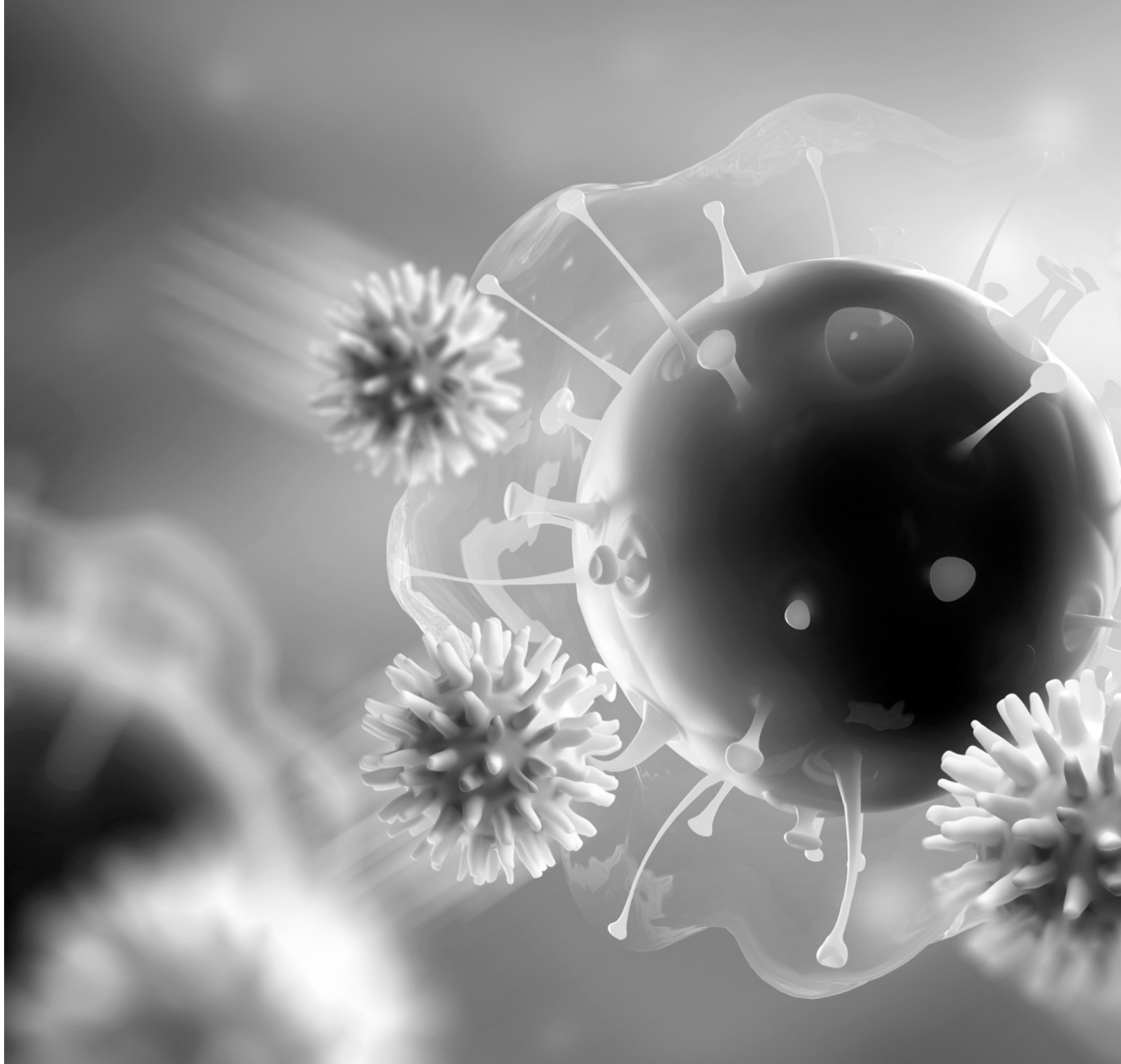
Completed studies with imlifidase in transplantation

STUDY	SUBJECTS/ COUNTRY	STUDY DESIGN	PRIMARY ENDPOINT	SECONDARY ENDPOINTS	STATUS/ PUBLICATION
Study 01 Phase 1	29 subjects	• Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects	• Safety and tolerability	• Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase	Complete PLOS ONE (2015)[1]
Study 02 Phase 2	8 subjects	• Single-center, single-arm, open-label	• Dosing resulting in HLA-antibody reduction (MFI<1100)	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete Lorant et al (2018) American Journal of Transplantation[2]
Study 03 Phase 2	10 subjects	• Single-center, single-arm, open-label • No prior desensitization	• Safety: AEs, clinical laboratory tests, vital signs, ECGs	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete The New England Journal of Medicine (2017)[3]
Study 04 Phase 2	17 subjects	• Investigator initiated study, Single-center, single-arm, open-label • All patients had prior desensitization with IVIG and/or plasmapheresis	• Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients • Assessment of safety • Assessment of efficacy/kidney function	• Serum creatinine (0-6 months) • Proteinuria (0-6 months) • DSA at multiple timepoints posttransplant (day 0, D30, D90, D180)	Complete The New England Journal of Medicine (2017)[3]
Study 06 "Highdes" Phase 2	18 subjects	• Multicenter, multinational, single-arm, open-label Included pts who may have had prior unsuccessful desensitization or pts in whom it was unlikely to be effective	• Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD	• DSA reduction at multiple timepoints (2, 6, 24, 48 h after imlifidase) • Time to create negative CDC XM test and/or flow cytometry (FACS) XM test • Safety	Complete Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019)[4]
Long-term follow-up study	Up to 46 subjects	• A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation	• Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration	• Patient survival, kidney function, comorbidity, treatments and QoL • Safety • DSA • Immunogenicity	Ongoing 5 year long-term data read-out (2023)

[1] Winstedt et al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)
[2] Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762
[3] Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation", N Engl J Med 2017;377:442-53.
[4] Montgomery et al., "Safety And Efficacy Of Imlifidase In Highly-sensitized Kidney Transplant Patients: Results From A Phase 2 Study" ATC Abstract, 2019

HANSA BIOPHARMA

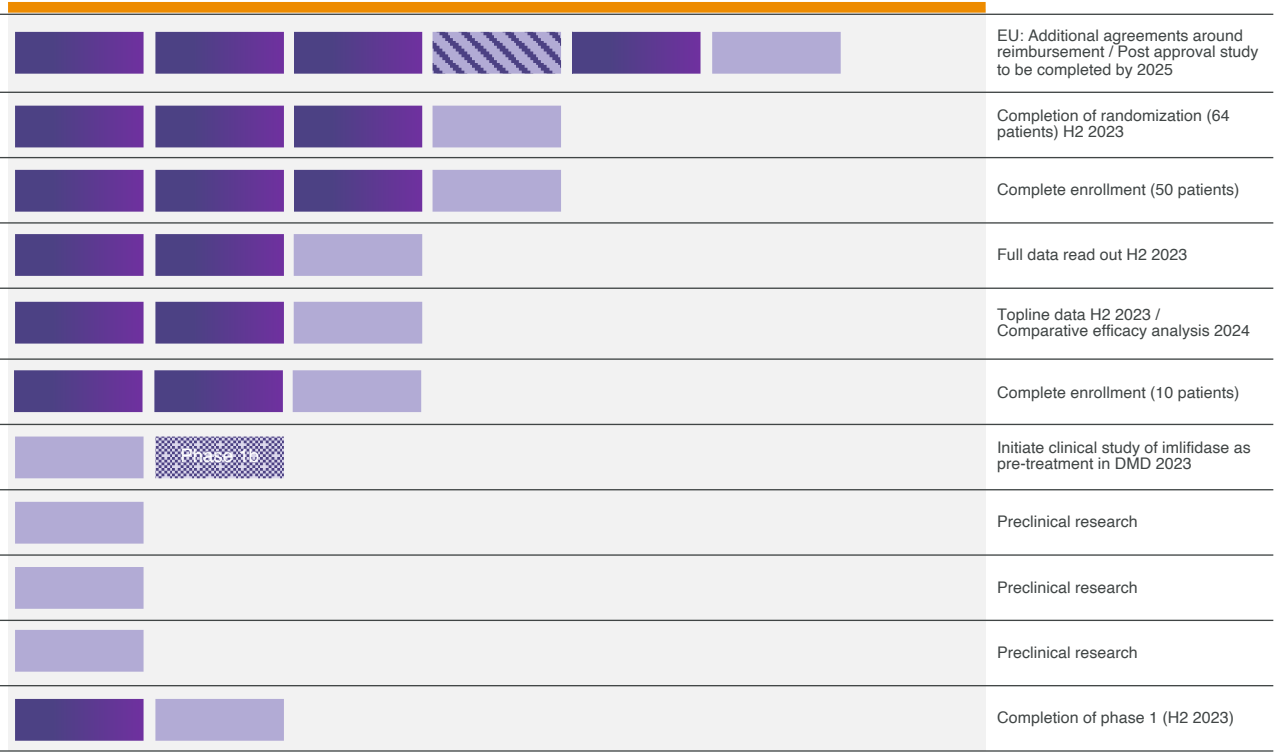
Our antibody cleaving enzyme technology



HANSA BIOPHARMA

Broad clinical pipeline in transplantation and autoimmune diseases

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)



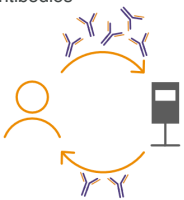
Completed | Ongoing | Planned | Post approval study running in parallel with commercial launch

[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

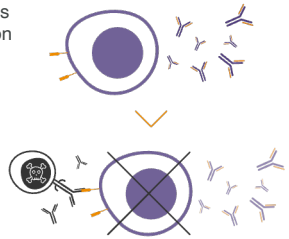
Development of IgG-modulating technologies

Mechanisms can be both complementary and competing

PLEX, plasmapheresis, immunoadsorption
Mechanically removes antibodies from circulation



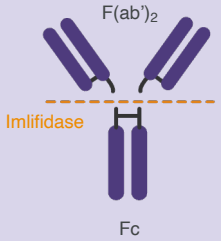
B-cell depleting mAbs
Lowering antibody levels through B-cell elimination



Imlifidase – IgG-cleaving enzyme

Deactivates IgG within 2-6 hours through enzymatic cleavage. IgG-free window for approximately one week

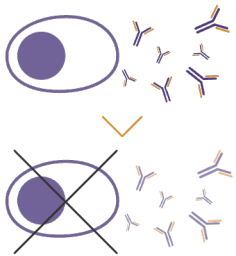
Unique mechanism-of-action is the basis for competitive advantage vs other IgG-modulating therapies



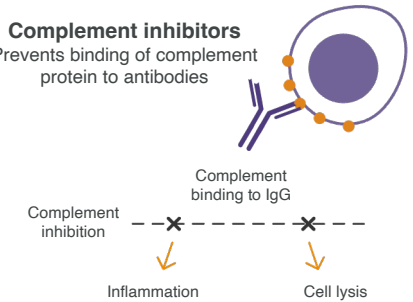
1950s | 1980s | 1990s | 2000s | 2010s | 2020s

IV/SC immunoglobulins
IVIg/SCIg contains healthy antibodies that replaces pathogenic antibodies

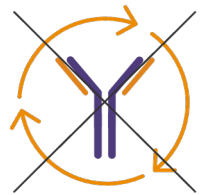
Proteasome inhibitors
Depletes antibody producing long-lived plasma cells and lowers overall immunoglobulin levels



Complement inhibitors
Prevents binding of complement protein to antibodies



FcRn-inhibitors
Lowering IgG through blocking of antibody recycling

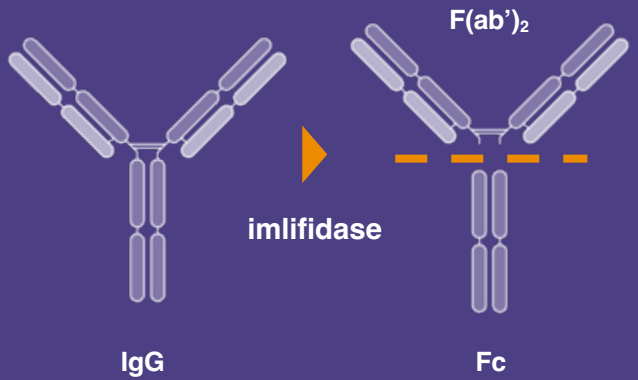


Imlifidase mode of action

Novel approach to effectively eliminate pathogenic IgG

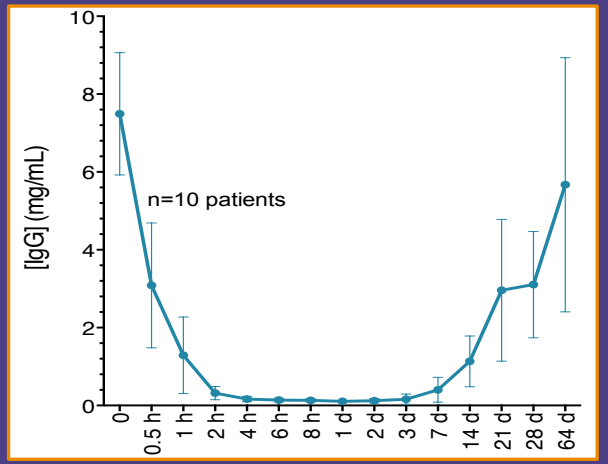
Proven mechanism of action

- 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



Inactivation of IgG in human serum

- Rapid onset of action that takes down IgG below detectable level in 2-6 hours post 15 min infusion
- 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

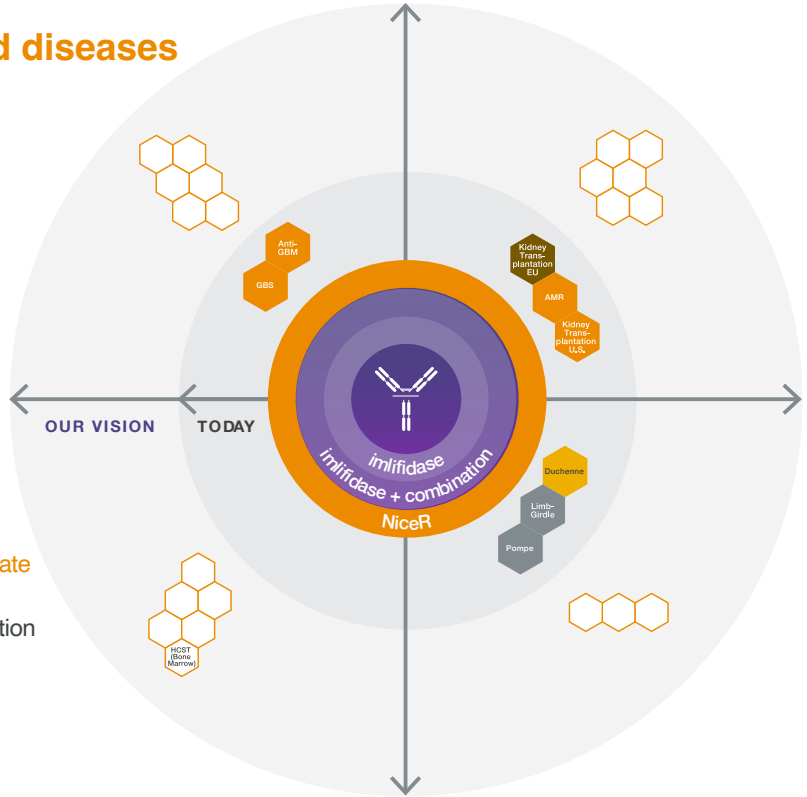
Anti-GBM paves the way for development in other autoimmune diseases

- 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 and AskBio
- Wide indication landscape beyond

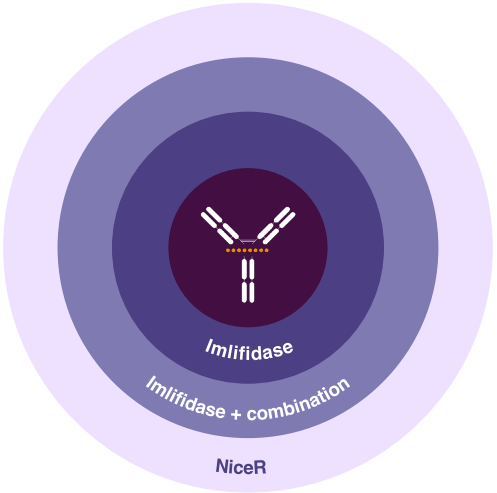
Regulatory approval (conditional) | Clinical development | Planned clinical trial | Partnership (preclinical development) | Preclinical development | Potential indications (currently not pursued)

The technology platform is the primary basis for achieving our vision

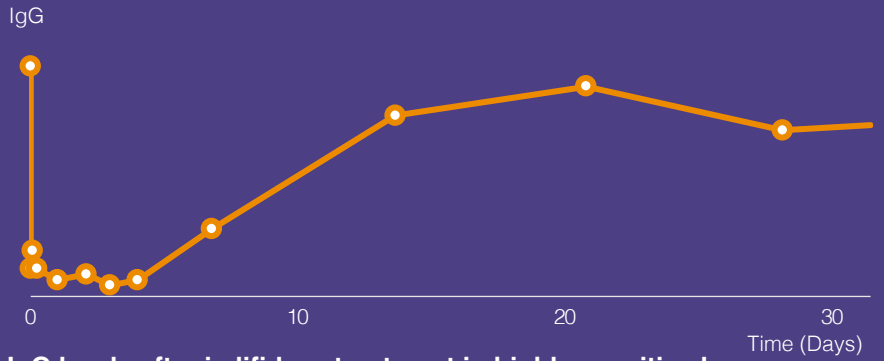
Targeting rare IgG mediated diseases and conditions

Key opportunities:

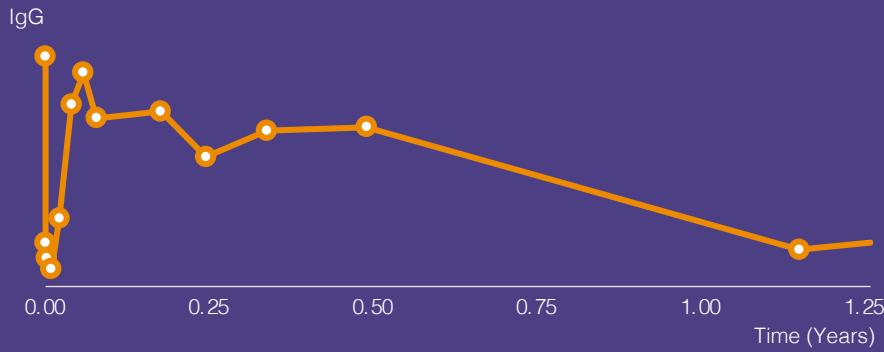
- Expanding into **new indications**
- Reduce immune response to IgG-cleaving enzyme, i.e. allow **repeated treatment**
- **Combination therapy**, i.e. induction and maintenance therapy



IgG levels after imlifidase treatment in in highly sensitized patients – First 30 days



IgG levels after imlifidase treatment in highly sensitized patients – 1 year and beyond



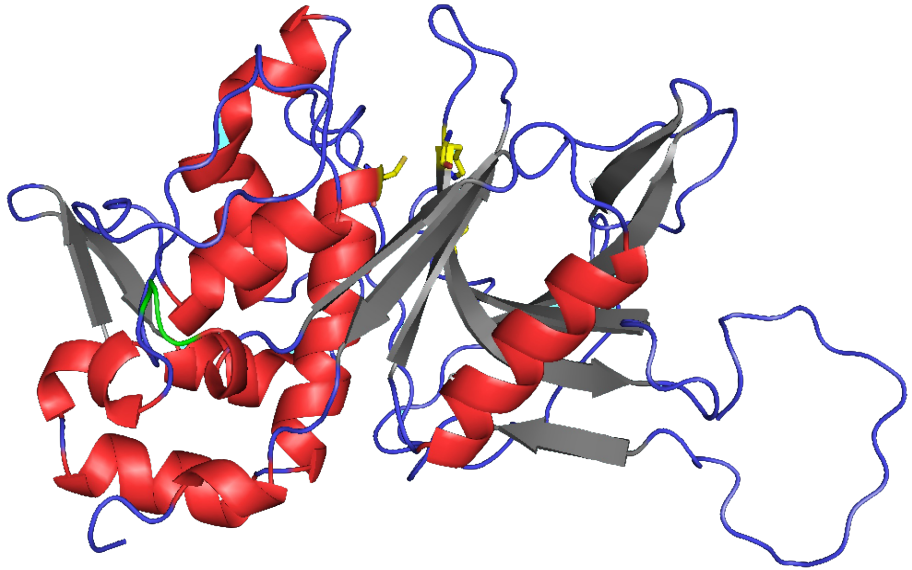
HANSA BIOPHARMA

Our IgG antibody-cleaving enzyme, imlifidase

Origins from Streptococcus pyogenes

- Cysteine protease derived from an Immunoglobulin G (IgG)-degrading enzyme of Streptococcus pyogenes
- Contains only one cysteine - no disulfide bridges
- Monomeric protein with a molecular mass of 35 Kilo Dalton
- Isoelectric point of 6.1
- The coding gene for imlifidase is cloned and expressed in Escherichia coli

Imlifidase consists of 311 amino acids



Imlifidase is a lyophilized product formulation

Shelf life of 18 months at 2-8º Celsius storage; Ongoing stability studies indicate a shelf life of at least 24 months.

Imlifidase will be infused in 15 minutes

- The product for commercial supply will be a lyophilized (cold chain) powder concentrate (11 mg solution) for infusion currently with a claimed shelf life of 18 months at 2-8ºc storage. Ongoing stability studies indicate a shelf life of at least 24 months.
- Each vial is filled with 1.2 mL of a 10 mg/mL solution before freeze drying (=12 mg). Extractable volume after reconstitution with 1.2 mL sterile water is 1.1 mL of 10 mg/mL solution - resulting in 11 mg product
- The protein concentration,10 mg/mL, has desirable characteristics with respect to not form aggregates
- Continuous stability programs ongoing to study changes in protein characteristics and performance.
- Imlifidase dose is clinically set to 0.25 mg/kg bodyweight (11 mg / 0.25 mg/kg = 44 kg (BW) / vial content) 2R vial size is suitable for the content

Manufacturing process

Hansa has close collaborations with highly experienced European based third party CMOs

Drug substance production process (API)

Northway Biotech

Fermentation/ harvesting
- Working Cell Bank
- Pre-Cultivation
- Main Cultivation
- Cell Harvest

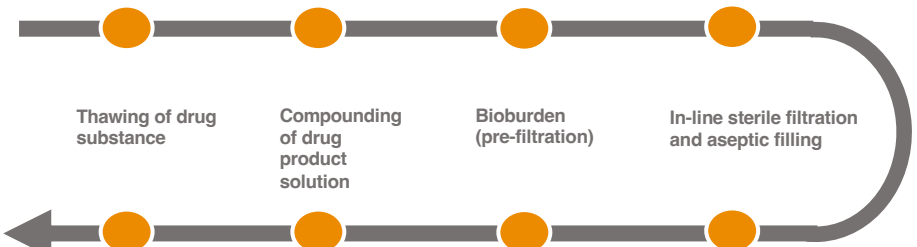
Protein purification
- Cell Disruption
- Protein Release

Protein purification cont.
- Ion Exchange Chromatography
- Ceramic Hydroxy Apatite Chromatography
- Hydrophobic Interaction Chromatography
- Ultrafiltration/ Diafiltration

Filling
- Formulation, filtration, filling and storage (-80°C)

Drug product production process (upscaling)

Baxter



Thawing of drug substance

Compounding of drug product solution

Bioburden (pre-filtration)

In-line sterile filtration and aseptic filling

Lyophilization (14 h + 7.5 h)

Capping, outer decontamination

Packaging

Storage 2-8°C

NORTHWAY BIOTECH

Facts
- **Based in Vilnius, Lithuania**
- **Start-up Year: 2004**
- **Capacity: 300 L fermentor (1000 L fermentor in 2020)**
- **Certifications: GMP compliance, Manufacturing authorization license**
- **Inspections: National regulatory agency (EU), EU/US customer inspections, FDA mock inspection**

Baxter

Facts
- **Based in Halle/Westfalen Germany**
- **Start-up Year: 2001 (contract manufacturing)**
- **Capacity: 6-35 L drug product solution per batch (5,000-30,000 vials)**
- **Certifications: GMP compliance, Manufacturing authorization license**
- **Inspections: National regulatory agency (EU), FDA, EU/US customer inspections**

HANSA BIOPHARMA

Clinical development programs

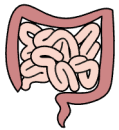
HANSA BIOPHARMA

Autoimmune attacks

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

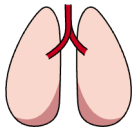
Blood
Autoimmune hemolytic anemia,
Immune thrombocytopenia

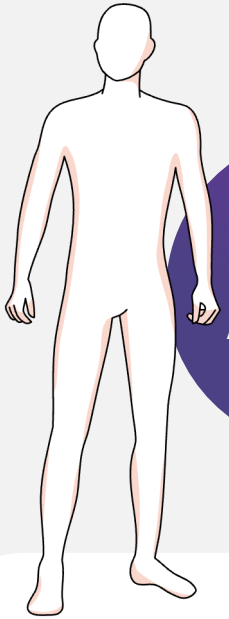
GI tract
Crohn's disease



Nerves
Guillain-Barré syndrome,
Myasthenia gravis

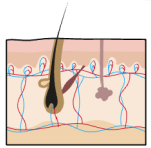
Lung
Wegner's granulomatosis





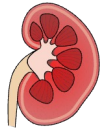
Over 100 different types of Autoimmune disorders

Skin
Psoriasis, Pemphigus

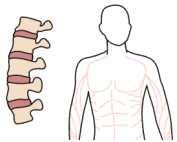


Brain
Multiple sclerosis,
Neuromyelitis optica

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

Anti-GBM, a rare acute autoimmune disease

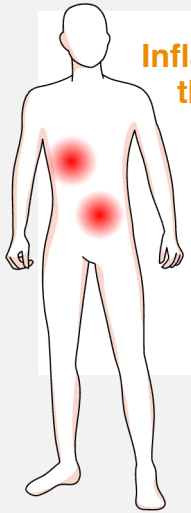
Incidences

1.6

in a million affected annually[1,2]

Standard of Care

- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids



Inflammation in the glomeruli

Early symptoms are unspecific…

…but can lead to rapid destruction of the kidney and/or the lung

Data published in JASN

CLINICAL RESEARCH www.jasn.org

Endopeptidase Cleavage of Anti-Glomerular Basement Membrane Antibodies *in vivo* in Severe Kidney Disease: An Open-Label Phase 2a Study

Fredrik Uhlin,[1,2] Wladimir Sapir,[3] Andreas Kronbichler,[4] Annette Bruchfeld,[1,5] Inga Sowerby,[6] Lionel Rostaing,[7] Eric Daugas,[8] Arnaud Lionet,[9] Nassim Kamar,[10] Cédric Rafat,[11] Marek Myslwiec,[12] Vladimir Tesar,[13] Anders Fernström,[14] Christian Kjellman,[15] Charlotte Elfving,[16] Stephen McAdoo,[17] Johan Mölne,[15] Ingeborg Bajema,[18] Elisabeth Sonesson,[19] and Mårten Segelmark[1,17]

Due to the number of contributing authors, the affiliations are listed at the end of this article.

ABSTRACT

Background The prognosis for kidney survival is poor in patients presenting with circulating anti-glomerular basement membrane (GBM) antibodies and severe kidney injury. It is unknown if treatment with an endopeptidase that cleaves circulating and kidney bound IgG can alter the prognosis.

Methods An investigator-driven phase 2a one-arm study (EudraCT 2016-004082-39) was performed in 17 hospitals in five European countries. A single dose of 0.25 mg/kg of imlifidase was given to 15 adults with circulating anti-GBM antibodies and an eGFR <15 ml/min per 1.73m². All patients received standard treatment with cyclophosphamide and corticosteroids, but plasma exchange only if autoantibodies rebounded. The primary outcomes were safety and dialysis independency at 6 months.

Results At inclusion, ten patients were dialysis dependent and the other five had eGFR levels between 7 and 14 ml/min per 1.73m². The median age was 61 years (range 19-77), six were women, and six were also positive for anti-neutrophil cytoplasmic antibodies. Then 6 hours after imlifidase infusion, all patients had anti-GBM antibodies levels below the reference range of a prespecified assay. At 6 months 67% (ten out of 15) were dialysis independent. This is significantly higher compared with 18% (nine out of 50) in a historical control cohort (P<0.001, Fisher's exact test). Eight serious adverse events (including one death) were reported, none assessed as probably or possibly related to the study drug.

Conclusions In this pilot study, the use of imlifidase was associated with a better outcome compared with earlier publications, without major safety issues, but the findings need to be confirmed in a randomized controlled trial.

Clinical Trial registration number: EUDRACT 2016-004082-39 https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-001377-28/results

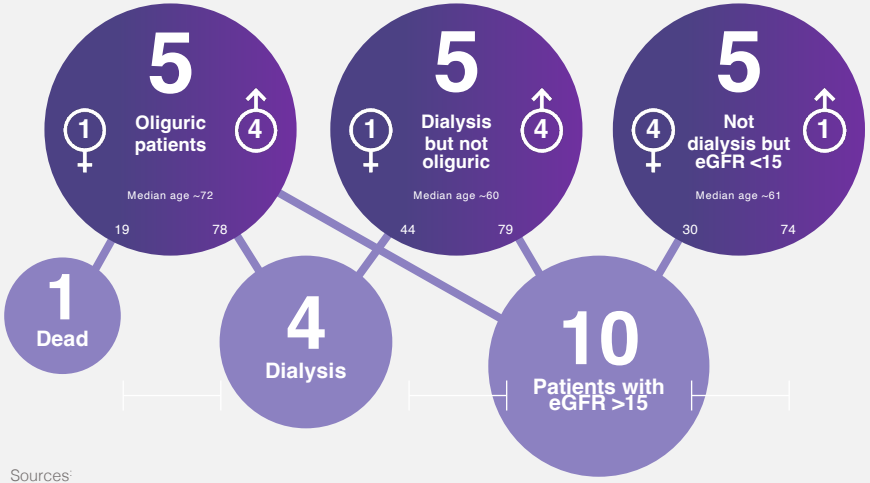
JASN 33: ••• ••, 2022. doi: https://doi.org/10.1681/ASN.2021111440

Kidney survival is poor in patients presenting with circulating anti-glomerular basement membrane (anti-GBM) antibodies and advanced kidney failure.[1,2] Most anti-GBM

Received November 12, 2021. Accepted February 1, 2022.

Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)[3]

10 out of 15 patients were dialysis independent after six months vs. the historical cohort[4], where only 18% had functioning kidney



Sources:
[1] Wang et al., J. Intern. Med., 2015
[2] Desai et al., Front. Endocrinol., 2019
[3] Uhlin et al. JASN (2022)
[4] McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. Kidney Int 92: 693–702, 2017

New pivotal phase 3 trial with imlifidase in 50 anti-GBM patients to evaluate kidney function after six months

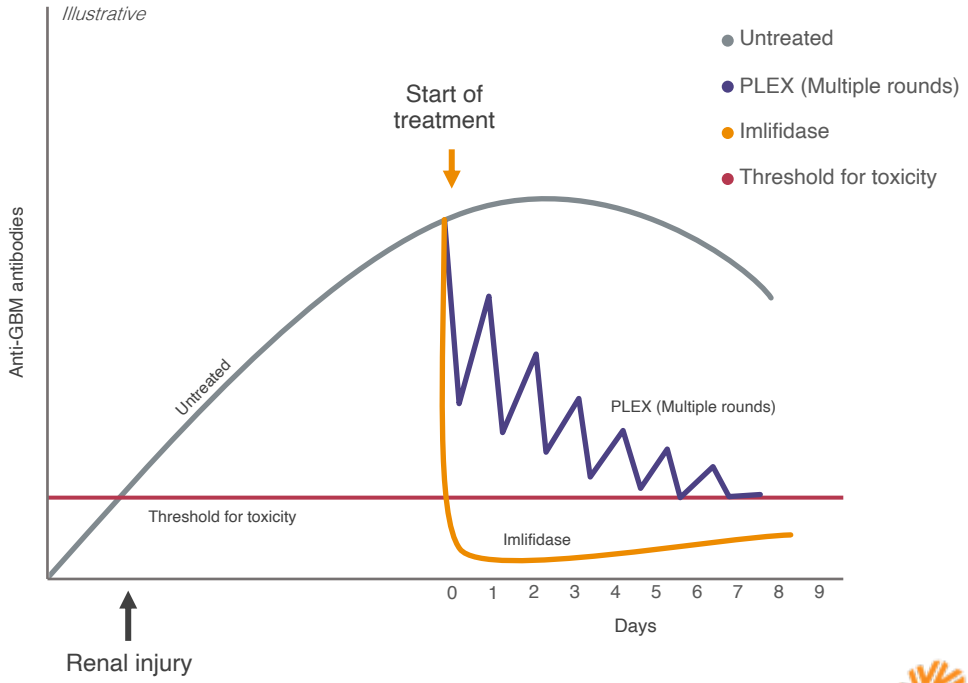
Study Design
- Open-label, controlled, randomised, multi-centre Phase 3 trial evaluating renal function in patients with severe anti-GBM disease imlifidase + SoC vs. SoC

Subjects
- 50 anti-GBM patients to be enrolled
- Patients will be followed for six months
- Recruitment at 30-40 clinics across US/UK/EU

Doses/Follow up time
- Dosage 0.25mg/kg with 180 days follow up

Main Objectives
- Renal function is evaluated by estimated glomerular filtration rate (eGFR) at 6 months
- Dialysis need at 6 months

Status
- First patients enrolled in May 2023



1 Wang et al., J. Intern. Med., 2015
2 Desai et al., Front. Endocrinol., 2019

HANSA BIOPHARMA

Guillain-Barré Syndrome (GBS) is an aggressive acute autoimmune attack on the peripheral nervous system

Incidences

~10,000

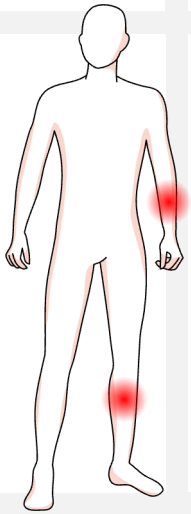
in 100,000 annually in 7 major markets

Standard of Care

- Intravenous immune globulin (IVIG) or
- Plasma Exchange (PLEX)

Indication

- Rapidly and progressively weakens extremities
- Triggered frequently by viral infections



High unmet need

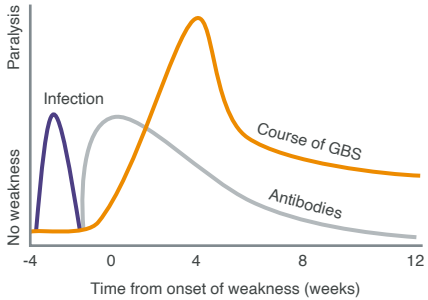
- 1/3 of hospitalized patients require mechanical ventilation
- Remaining long lasting symptoms in ca 40% of patients

FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

Phase 2 study to evaluate safety and effectiveness of imlifidase in patients diagnosed with GBS

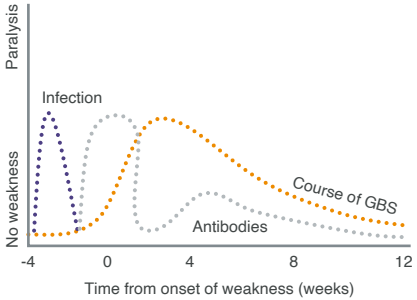
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



Study design: Study is an open-label, single arm, multi-center trial in 30 patients

Data read-out: Topline data expected H2'2023; Comparative efficacy analysis to a match cohort (IGOS data base at Erasmus, Rotterdam) expected 2024

Sources:

1) McGrogan et al. Neuroepidemiology 2009:32(2): 150-63.

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

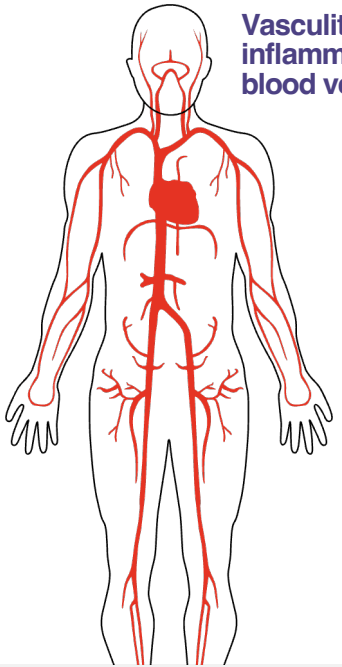
~3 in 100,000 annually across EU/US of which 8-36% are estimated to have Acute Respiratory Distress Syndrome due to pulmonary hemorrhage[1,2]

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.

Positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation

Incidences

Acute AMR episodes occur in

5-7%

of annual kidney transplants[1]
(2,500-3,500 patients across US/EU)

Standard of Care

- Intravenous immune globulin (IVIg) or
- Plasma Exchange (PLEX) or
- Steroids

High unmet need

- AMR is one of the most challenging adverse events after kidney transplantation leading to graft dysfunction and loss
- There is no approved treatment for AMR

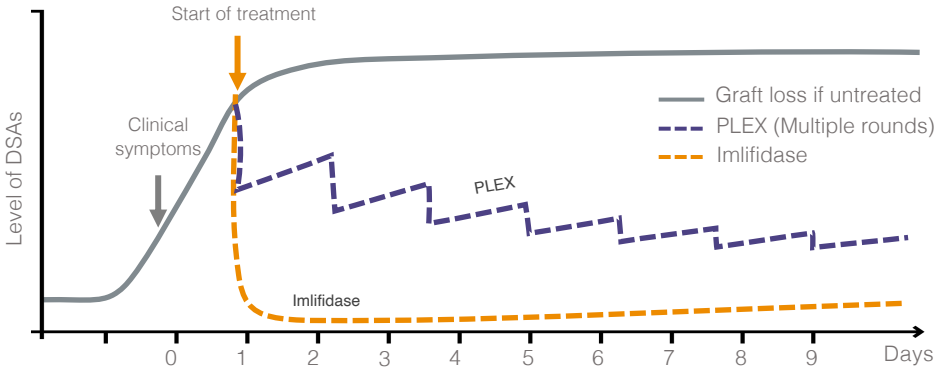
Phase 2 study design

30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled and randomized 2:1 to imlifidase vs. SoC

Full data read out from phase 2 study expected to be published in H2'23

Top-line data readout from phase 2 trial demonstrates a significant superior capacity of imlifidase to rapidly reduce levels of DSAs vs. PLEX (SoC) in the five days following the start of the treatment

Potential with imlifidase vs. PLEX in AMR
Illustrative



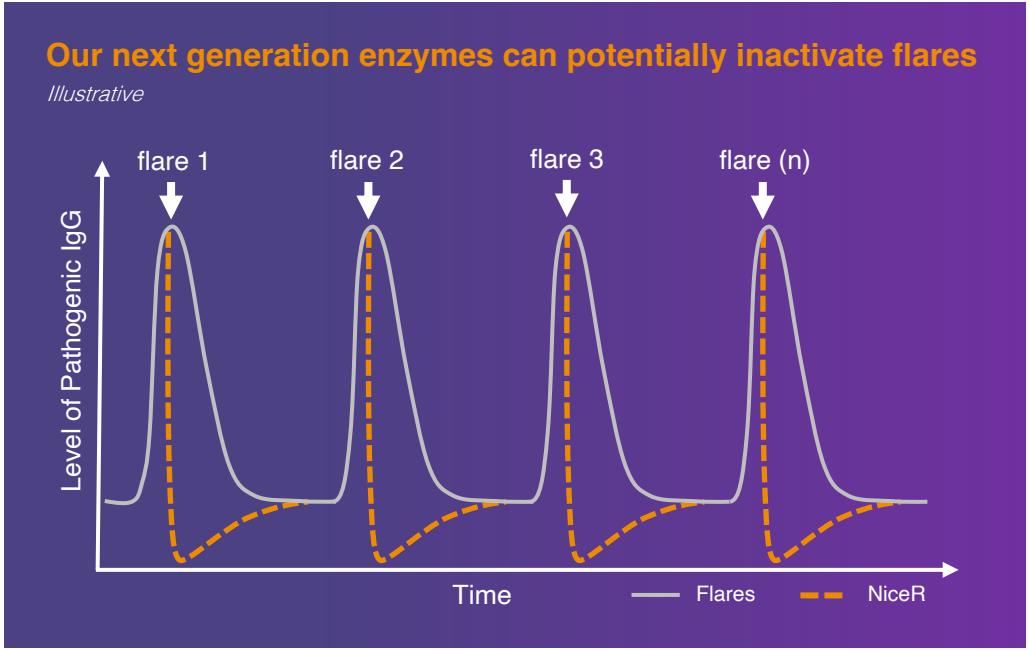
[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.

HNSA-5487, Hansa's next generation enzymes

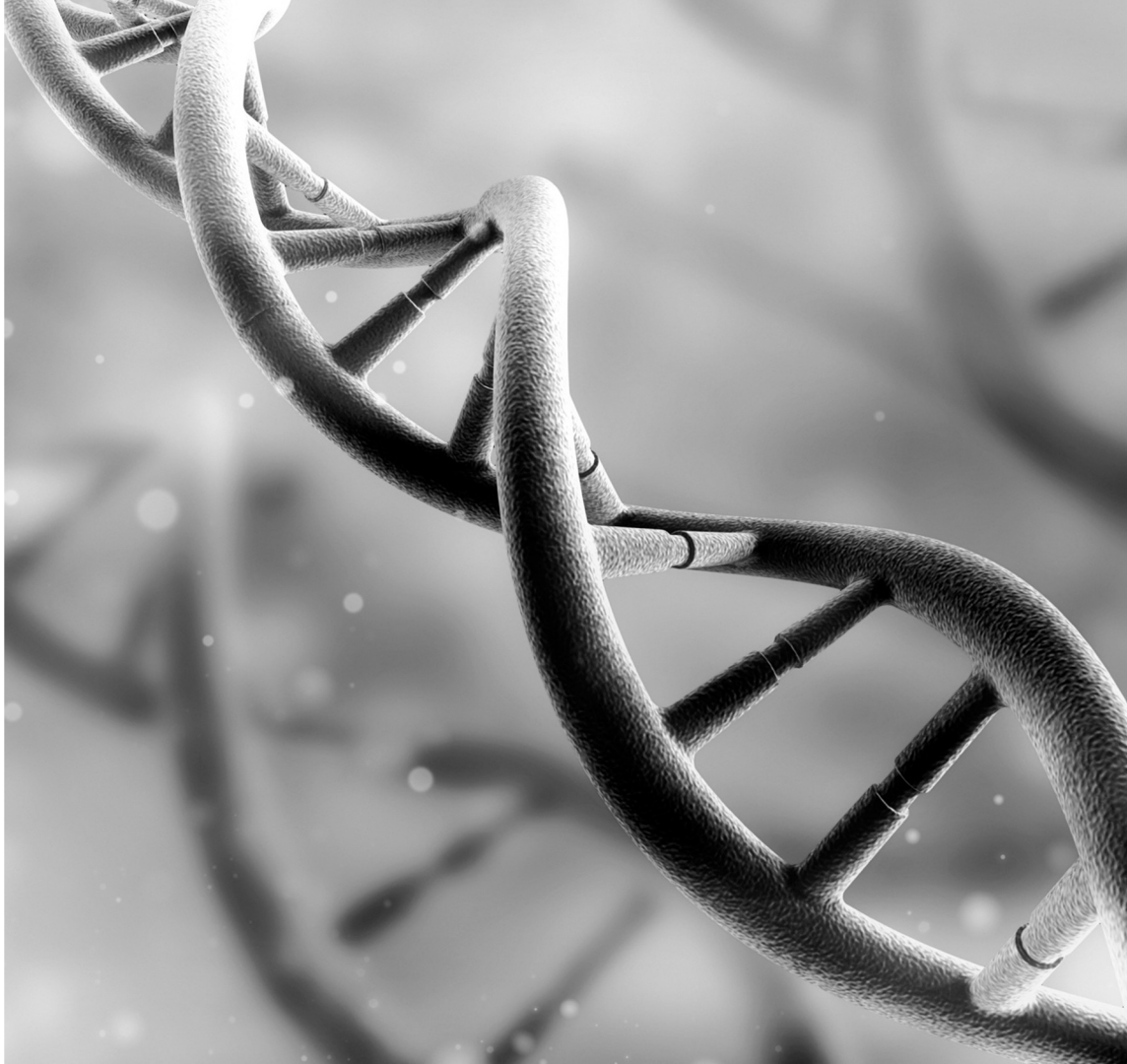
Objective to potentially enabling repeat dosing in autoimmune conditions, oncology, gene therapy and transplantation, where patients may benefit from more than one dose of an IgG-modulating enzyme

NiceR - Novel Immunoglobulin Cleaving Enzymes for Repeat dosing with lower immunogenicity

- Potential application for a broad array of indications, including reoccurring AMR, relapsing autoimmune diseases, gene therapy and oncology
- HNSA-5487, part of the Company's NiceR program, has been selected as the lead IgG-eliminating enzyme
- HNSA-5487 is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with lowered immunogenicity
- Enrollment in the phase I study in healthy volunteers is completed. Data analysis is underway to evaluate relevant indications to pursue in clinical development.



Gene Therapy



HANSA BIOPHARMA

Exploring opportunities in gene therapy

Exploring the opportunities in systemic administration of gene therapy for our unique antibody cleaving enzyme platform to potentially enable gene therapy treatment in NAb+ patients

A revolutionary approach

Significant unmet need

Encouraging pre-clinical data

Partnership strategy

Stock images

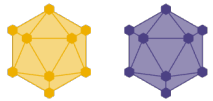
Tropism and target tissue

AAV subtypes targets different tissues

AAV 1, 2 & 5

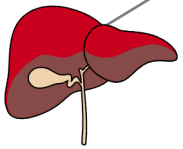
Eye (local target)
~1x10^{11} vg

Brain (local target)
~1x10^{12} vg

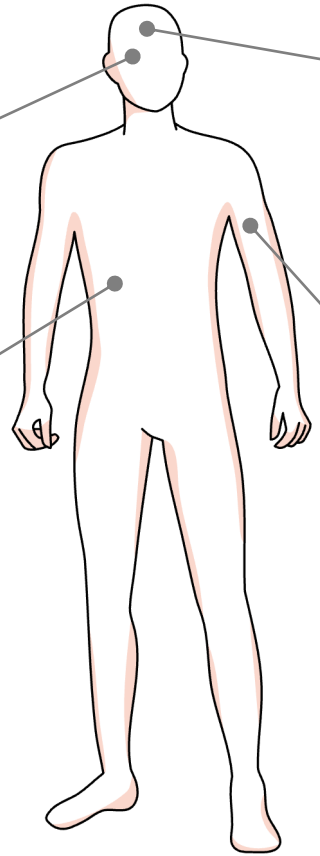


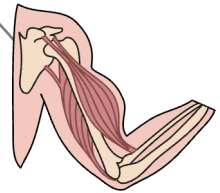
AAV 4 & 8

AAV 3, 7 & 8

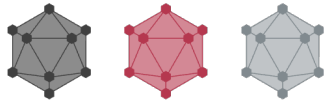


Liver (systemic)
~1x10^{14} vg





Muscle (systemic)
~1x10^{15} vg



AAV 6, 7, rh74

Target tissues
Dose of gene therapy (vg)

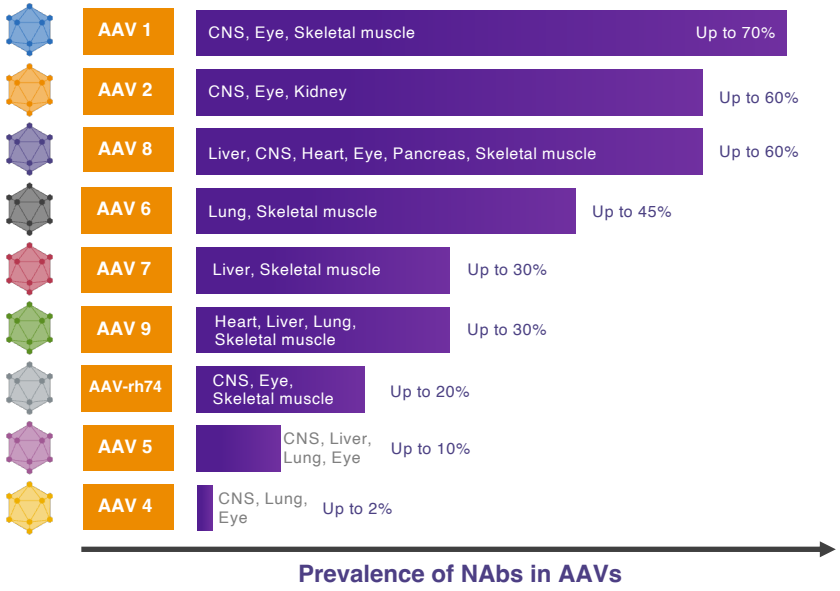
HANSA BIOPHARMA

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.

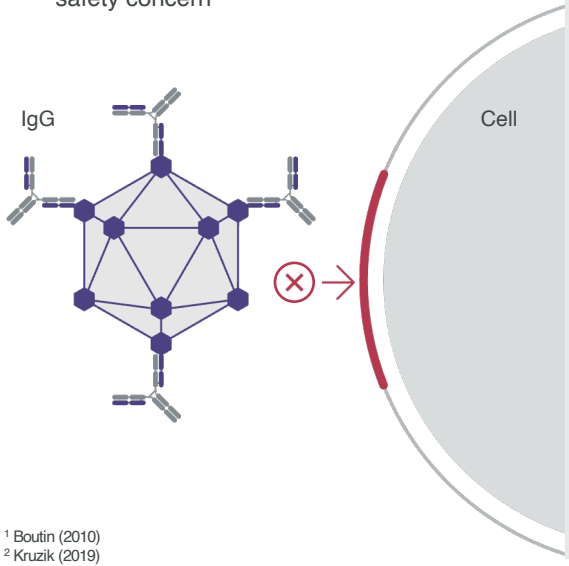


Source: Boutin et al. (2010), Griffin et al. (2019), Wang et al. (2018), Calcedo & Wilson (2013), Falese et al. (2017), Haiyan et al. (2017), Ellsworth et al. (2018), Greig et al. (2017)

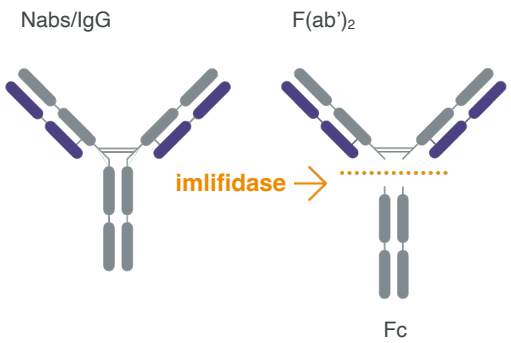
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

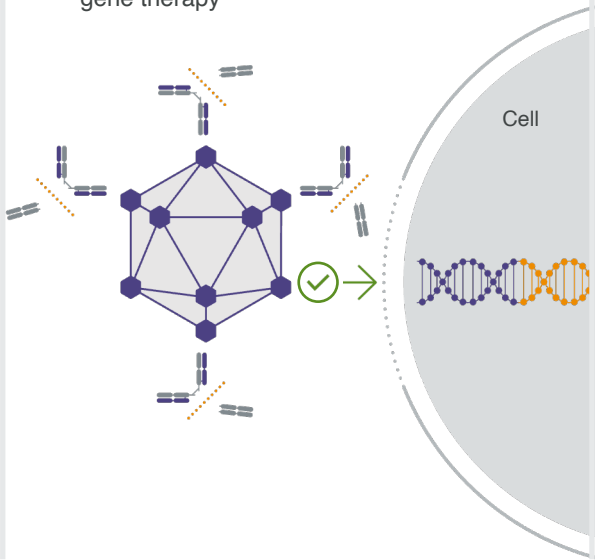
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



2 Imlifidase is a unique IgG antibody-cleaving enzyme that cleaves IgG at the hinge region with extremely high specificity



3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



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

Systemic gene therapy is an emerging opportunity

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

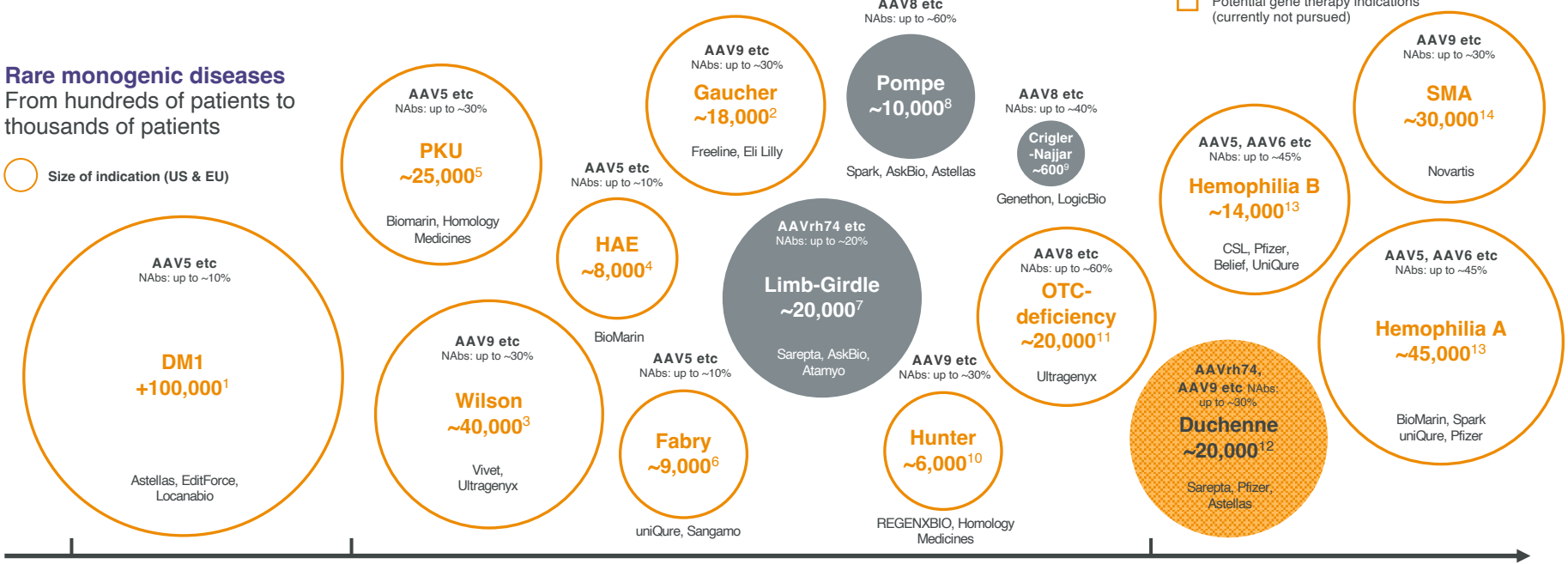
Rare monogenic diseases
From hundreds of patients to thousands of patients

Size of indication (US & EU)

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

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* (2020) and at *ASGCT* (May 2023)
- 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
- FDA approval in 4–5-year-olds suffering with DMD

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

Upfront payment
USD 10 million upfront

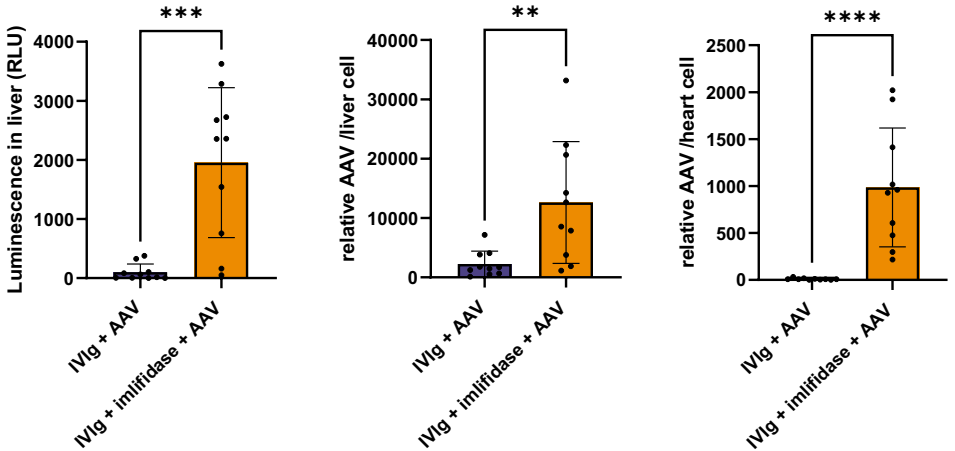
Milestones
Hansa is eligible for up to USD 397.5 million in development, regulatory and sales milestones

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

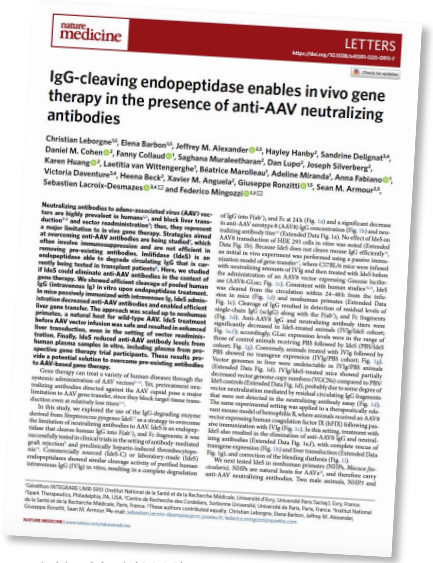
Imlifidase treatment neutralises the inhibitory effect of IgG and facilitates AAV8 transduction in target cells

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

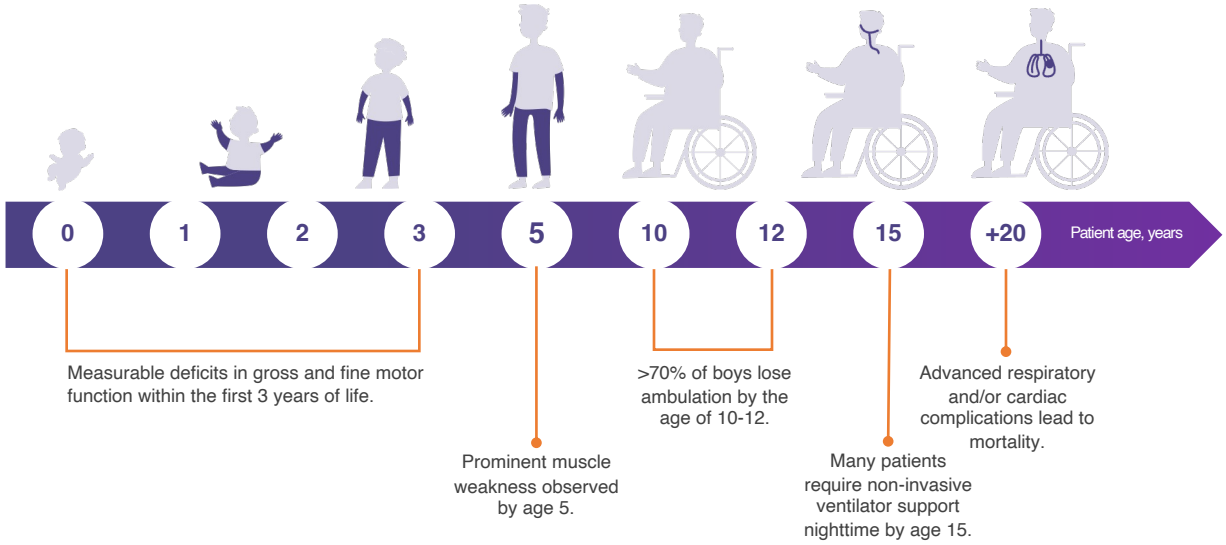
1 in **3,500** to **5,000**
male births worldwide

~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



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

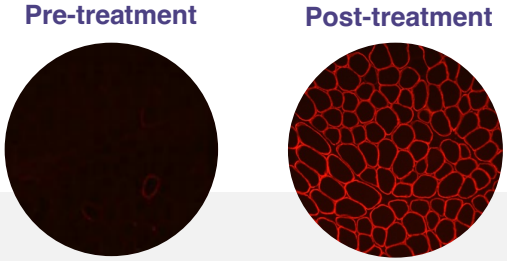
SRP-9001 has been rationally designed to maximize expression in tissues most affected by Duchenne

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

FDA approval in 4-5 year olds suffering with DMD

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



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

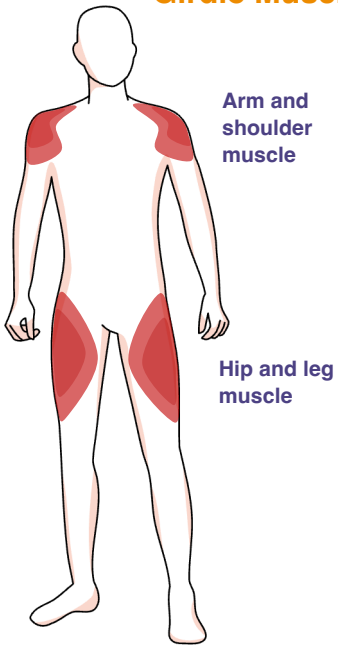
1.63 per **100,000** individuals; over 30 subtypes exist, and both genders are affected equally.

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

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's key resources and deliverables

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

Current agreement scoped around a feasibility program which covers preclinical work and a Phase 1/2 study

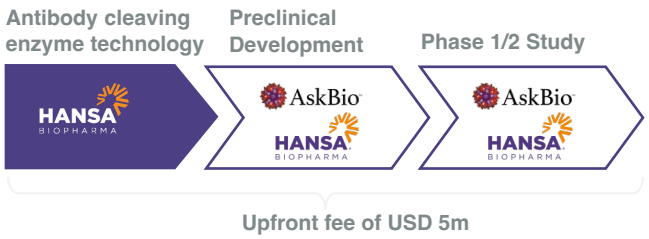
AskBio™

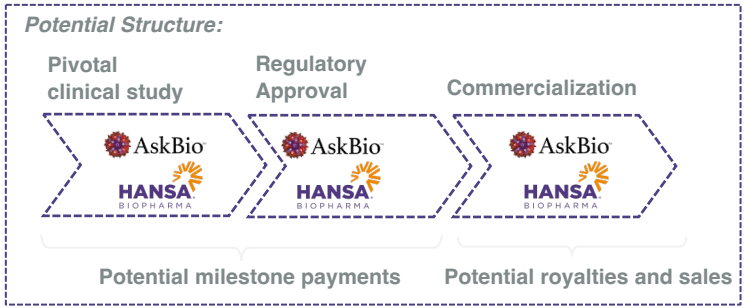
Fully owned subsidiary of Bayer AG

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

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





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

Incidences

An ultra-rare indication impacting

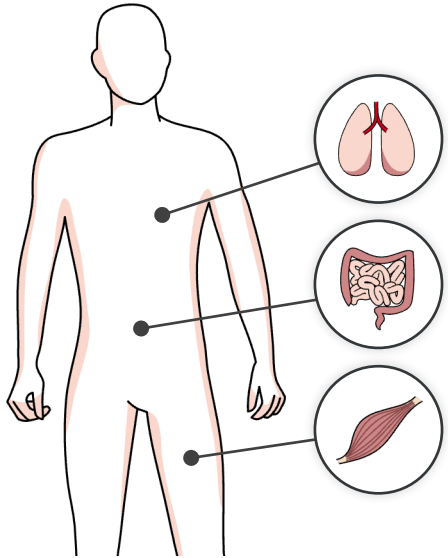
1 in **40,000** births or **~200** cases per year across US and Europe

~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]Pompe Disease, https://rarediseases.org/rare-diseases/pompe-disease/ [accessed 2023-05-15]

[2]Calculated by Hansa on the basis of incidence numbers from https://rarediseases.org/rare-diseases/pompe-disease/ and life expectancy estimates from https://pompediseasenews.com/late-onset-pompe-disease/, as well as population statistics for the United States and European Union/Europe.

[3]ESGCT 27th Annual Congress Abstracts, Sensitivity of different AAV serotypes to pre-existing NAbs, https://www.esgct.eu/home/Barcelona%202019/NEW_All%20Barcelona%20Abstracts.pdf

[4]Boutin et al. Prevalence of serum IgG and neutralizing factors against adeno-associated virus (AAV) types 1, 2, 5, 6, 8, and 9 in the healthy population: implications for gene therapy using AAV vectors. Hum Gene Ther. 2010. https://pubmed.ncbi.nlm.nih.gov/20095819/

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

HANSA BIOPHARMA

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

+

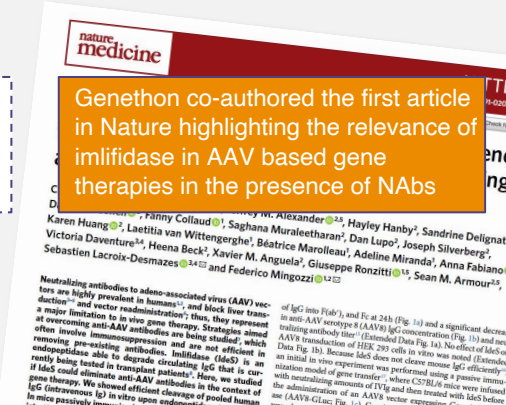
GENETHON
CURE THROUGH INNOVATION

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

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



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

Incidences

An ultra-rare indication impacting

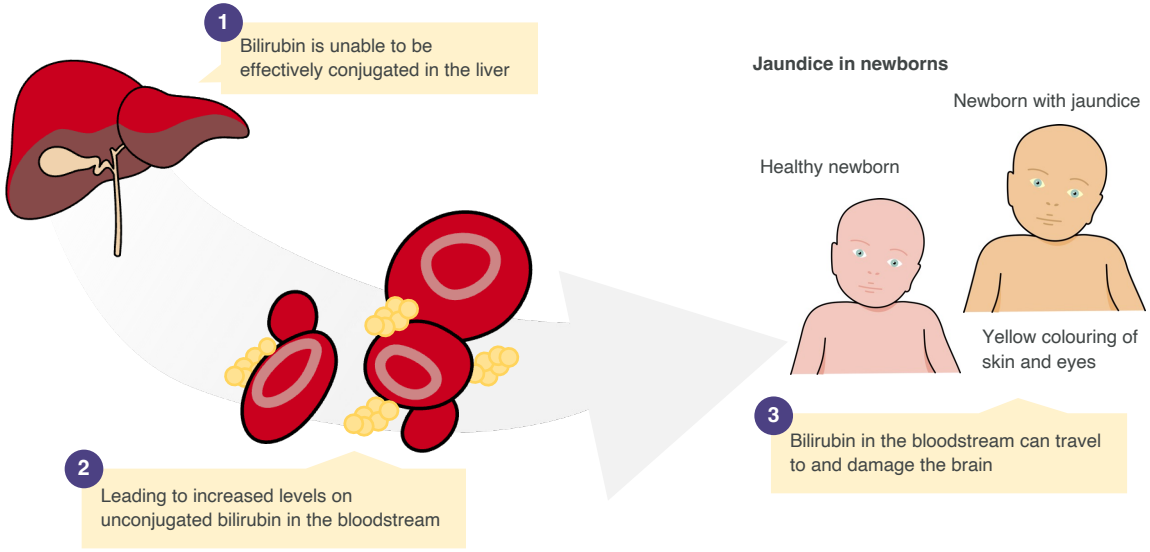
0.6-1 per **1,000,000** newborns around the world[1,2]

~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]

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

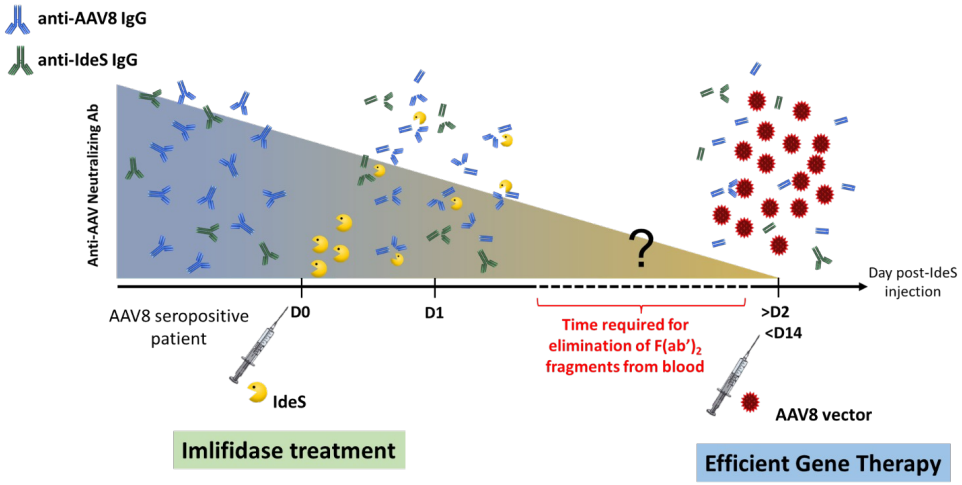
April 2023
Hansa and Genethon signs collaboration

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

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

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

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



ESG Overview

At Hansa we are committed to driving our business forward in a sustainable way guided by three strategic ESG principles

Healthy people

Address unmet medical need and ensure equitable access to care

Healthy business

Make a difference by operating an ethical, transparent and responsible business and cultivate an engaged culture of collaboration, inspiration and innovation

Healthy planet

Embrace sustainable decision making and environment stewardship

94

Formalising our ESG approach

At Hansa, we have always strived to achieve sustainable business practices. We are now formalizing our approach to sustainability and ESG issues, starting with identifying our key material focus areas.

Our mission: We leverage our unique enzyme technology platform to develop innovative, lifesaving and life altering immunomodulating therapies, bring these to the patients with rare diseases who need them, and generate value to society at large.

Our key ESG material aspects

Environment

Climate & waste impacts of production and logistics

Hansa's environmental impact is small because our production is limited in volume. However, as we grow, we need to be transparent about, and make efforts to limit, our climate and waste impacts.

Social

Unmet needs and equity in health

Patients with rare conditions in general, and highly sensitized patients in particular, have many unmet needs which our therapies help address. These unmet needs can also be reinforced by ethnic or socio-economic status, particularly regarding access to organ transplants. Collaboration with patient groups can help us reach even more patients who can benefit from our treatments.

Putting patients first

In the biopharma industry, there is a risk that patient access to innovative treatment is delayed. Hansa can therefore provide bridge financing on a case-by-case basis to benefit patients who have limited treatment options.

Employee wellbeing, diversity and inclusion

Ensuring employee wellbeing, diversity and inclusion is a fundamental commitment at Hansa. It is also essential for attracting talent in a fast-growing organization and delivering on our strategy.

Third-party risks

We diligently select new business partners, as well as monitor our existing partners and require them to comply with all laws and regulations and our Code of Conduct.

Pricing

In Europe, value-based pricing and universal health coverage is common, but in other countries access is a pressing issue. We can expand access to unfunded patients through collaboration with patient groups.

Governance

Safety, efficacy and ethics

To build a successful company and achieve our mission to extend and enhance the lives of the patients we serve, we must hold ourselves to the very highest standards. Trust is at the core of everything we do.

Return to investors

Biopharma companies need to remain economically attractive as an investment, so as to continue to secure capital and develop new treatments.

HANSA BIOPHARMA

UN Sustainable Development Goals

The Sustainable Development Goals (SDGs) were adopted by all UN Member States in 2015 as a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity by 2030. They have since become a gold standard for sustainability across businesses, and each of our recommended factors have been developed to align with relevant goals.

HANSA BIOPHARMA

Capital Markets

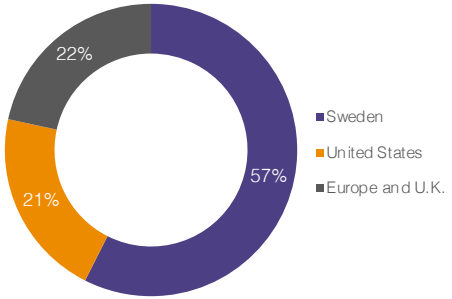
Ownership in Hansa Biopharma

Top 10 shareholders as per June 30, 2023

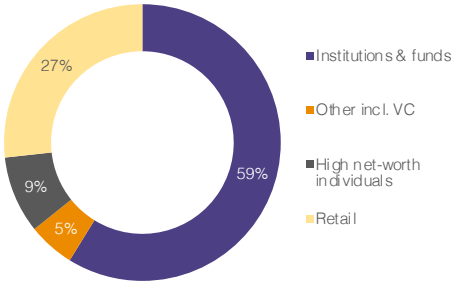
Name	No. of shares	Ownership
Redmile Group, LLC	10,626,131	20.3%
Försäkrings AB Avanza Pension	2,382,092	4.5%
Fjärde AP-Fonden (AP 4)	2,207,397	4.2%
Nexttobe AB	2,155,379	4.1%
Olausson, Thomas	1,917,000	3.7%
Tredje AP-Fonden (AP 3)	1,389,650	2.6%
Handelsbanken Asset Management	879,183	1.7%
Jeansson, Theodor	860,000	1.6%
C WorldWide Asset Management	799,749	1.5%
VOB & T Trading AB	644,800	1.2%
Other	28,582,581	54.6%
Total	52,443,962	100.0%

Classification of ownership as per June 30, 2023

Ownership by region



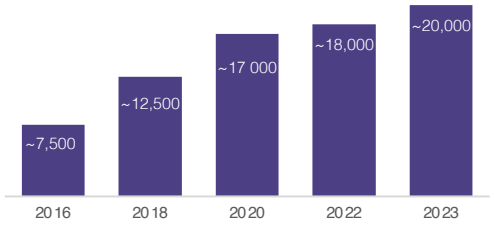
Ownership by type



Capital Raises

Capital raised:
SEK ~4bn
since 2007

No. of shareholders



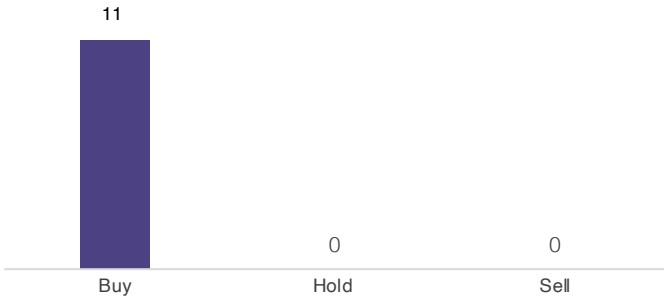
Company collected consensus

Consensus is based on a collection of analyst estimates pre-Q2 2023 report (July 2023)

	Price Target, SEK	WACC	Patient uptake, EU				Revenue, SEKm			
			Q2'23e	FY'23e	FY'24e	FY'25e	Q2'23e	FY'23e	FY'24e	FY'25e
Average	200	12%	9	53	114	195	36	212	378	1,013
Median	215	12%	9	52	101	182	33	214	350	738
High	244	13%	10	69	180	246	43	258	525	2,902
Low	135	8%	8	44	93	150	33	163	273	568
Number of contributions	*7*	*7*	*5*	*8*	*8*	*7*	*5*	*8*	*8*	*8*

	EBIT, SEKm				Operating Cash Flow, SEKm				Cash position, SEKm			
	Q2'23e	FY'23e	FY'24e	FY'25e	Q2'23e	FY'23e	FY'24e	FY'25e	Q2'23e	FY'23e	FY'24e	FY'25e
Average	-172	-633	-551	-251	-160	-607	-515	-273	1,121	974	860	973
Median	-171	-637	-587	-352	-160	-590	-569	-365	1,121	925	622	645
High	-169	-471	-149	808	-130	-530	-180	816	1,147	1,610	2,054	2,958
Low	-176	-737	-757	-639	-191	-732	-690	-590	1,095	760	110	-425
Number of contributions	*5*	*8*	*8*	*8*	*2*	*8*	*8*	*8*	*2*	*8*	*8*	*8*

Analyst recommendations



Bank/Research Institution	Analyst	Location	E-mail
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Calendar and events

July 20, 2023	**Half-year Report for January-June 2023**
Aug 23, 2023	Carnegie non-deal road show, Stockholm
Aug 24, 2023	Erik Penser Company Day, Stockholm
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


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