Investor Road Show Presentation Q4 2021

Lund, February 3, 2022

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.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

Hansa Biopharma expressly disclaims any obligation to update or revise any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or otherwise, and disclaims any express or implied representations or warranties that may arise from any forward-looking statements. You should not rely upon these forward-looking statements after the date of this presentation.

Table of contents

Business update Q4’2021

HANSA BIOPHARMA

Solid progress across the business as Hansa concludes 2021

Highlights for the fourth quarter of 2021

- ✓ Launch and market access efforts in Europe progressing as planned
  - Market access procedures are ongoing in 14 countries
  - Health Technology Assessment dossier for Spain submitted during January 2022, which completes HTA filings in all of the five largest markets in Europe
- ✓ New commercialization partnership with Medison Pharma in certain countries in Central Eastern Europe and Israel
- ✓ First patients enrolled into the pivotal U.S. ConfIdeS study
- ✓ Clinical pipeline
  - Anti-GBM: New Phase 3 to commence in 2022 with 50 patients across U.S. and EU following a pre-IND meeting with the U.S. FDA
  - AMR: Patient enrollment on track for completion first half 2022 as previously guided
  - GBS: 15/30 patients enrolled in the GBS phase 2 study
- ✓ Year-end cash position of SEK 889 million (USD 98m)
  - Hansa financed into 2023, as previously guided

Events after the reporting period

- ✓ Agreement with AskBio (subsidiary of Bayer AG) to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease
- ✓ Hansa to explore allogeneic hematopoietic stem cell transplantation

Progress with commercial metrics; Market access procedures ongoing in fourteen countries

Pricing and Reimbursement processes on track; Completion of HTA filings in EU4+UK

ESOT workstream formed with leading experts to advance clinical guidelines in desensitization

Pricing and Reimbursement

4

✓ Agreements on funding obtained:

- Sweden
- Netherlands
- Finland (on a hospital basis)
- Greece (on a hospital basis)

✓ Additional milestones

- Preparing for market access in additional international markets beyond Europe and the U.S. (e.g. Israel)
- Pursuing select early access opportunities

Market access procedures

14

✓ Market access procedures are ongoing in fourteen countries

- Sweden
- Netherlands
- Finland
- Norway
- Denmark*
- France
- Belgium
- UK
- Germany
- Italy
- Scotland
- Israel
- Greece
- Spain

✓ Health Technology Assessment (HTA) dossier for Spain was submitted during January 2022, completing HTA filings in all of the five largest markets in Europe.

** In Denmark, the HTA has been pre-submitted*

Clinical readiness

10

✓ 10 priority centers ready to take on patients, including:

- Uppsala, Sweden
- Erasmus, Rotterdam
- University Hospital, Helsinki

✓ Hansa to continue to work closely with additional priority centers on clinical readiness

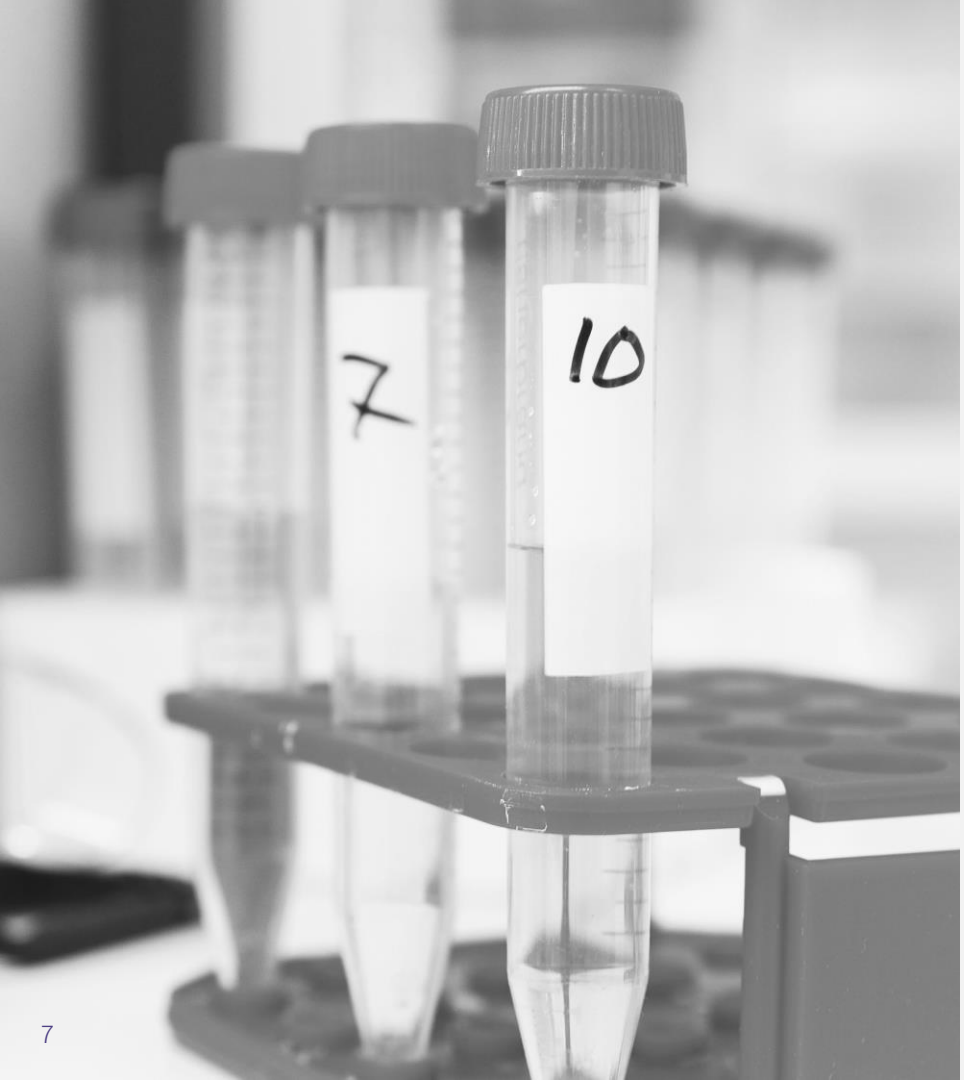
✓ Growing number of highly sensitized patient candidates identified and prioritized for incompatible kidney transplantations in the coming months

Awareness

✓ Over 30 experts engaged and committed to operationalizing HLA-incompatible kidney transplants for some of their highly sensitized patients.

✓ European Society for Organ Transplantation (ESOT) workstream formed and continuing its work on advancing clinical guidelines in the field of desensitization.

HANSA BIOPHARMA



New multiregional commercialization partnership with Medison Pharma

Partnership will cover Poland, Croatia, Hungary and Slovenia in addition to Israel

- Multiregional agreement for Medison to commercialize Idefirix® for kidney transplants in certain countries in Central Eastern Europe and Israel
- The commercialization is based on current conditional marketing authorization for Europe and pending marketing authorization by Israel's Ministry of Health
- An application for marketing authorization for desensitization treatment in kidney transplant was filed in Israel in June 2021; if granted would make Israel the first market outside of Europe where imlifidase is commercialized
- Hansa and Medison will be working together to obtain pricing and reimbursement as required depending on the country

MEDISON

HANSA BIOPHARMA

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

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

HANSA BIOPHARMA

Hansa's key resources and deliverables

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

+

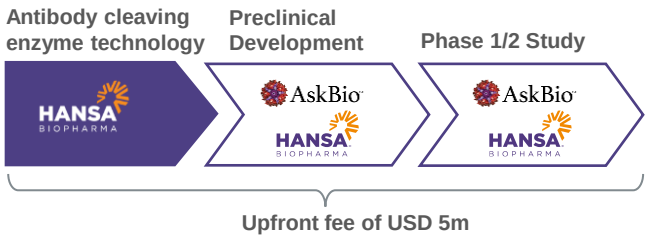
AskBio™

Fully owned subsidiary of Bayer AG

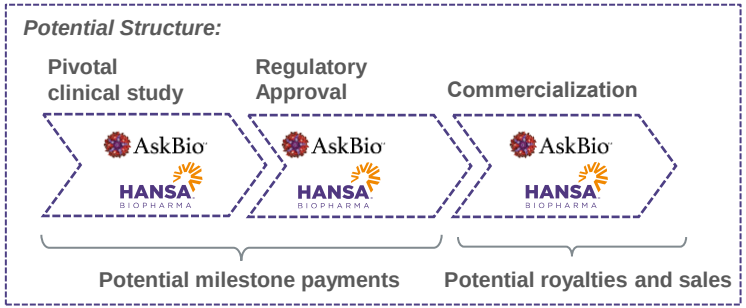
AskBio's key resources and deliverables

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

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



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



HANSA BIOPHARMA

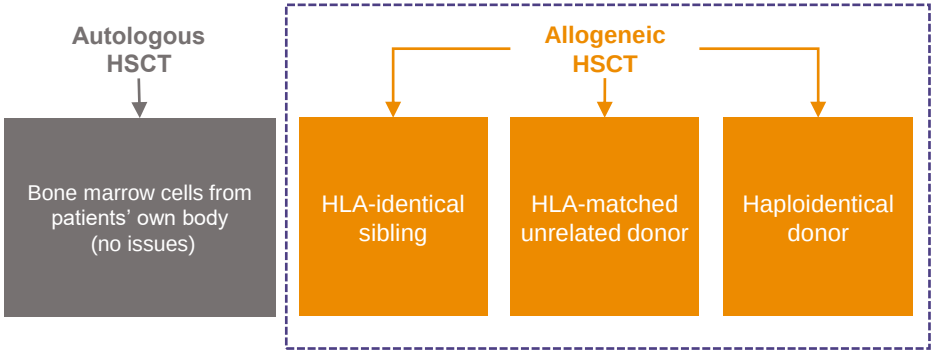
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge; Imlifidase may have the potential to inactivate DSAs prior to transplantation

Transplantations are often acutely needed, which reduces the time available to find an adequately matched donor

- Haploidentical donors (e.g. parents, children) are often available and transplant outcome is good (e.g. engraftment, graft survival, survival)
- However, presence of donor specific antibodies (DSAs) have a negative impact on transplant outcome[2] (e.g. graft failure and survival) Prevalence of DSAs in allogeneic HSCT is typically between 10-21%[1]
- There are currently no approved drugs to manage patients with high levels of DSAs and current desensitization methods are inadequate, thus preventing patients from having a potentially life-saving HSCT
- Consensus recommendations published[1] by the EBMT[3] on testing, monitoring and treatment of patients with donor specific antibodies recommend to desensitize all patients with DSAs
- Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation

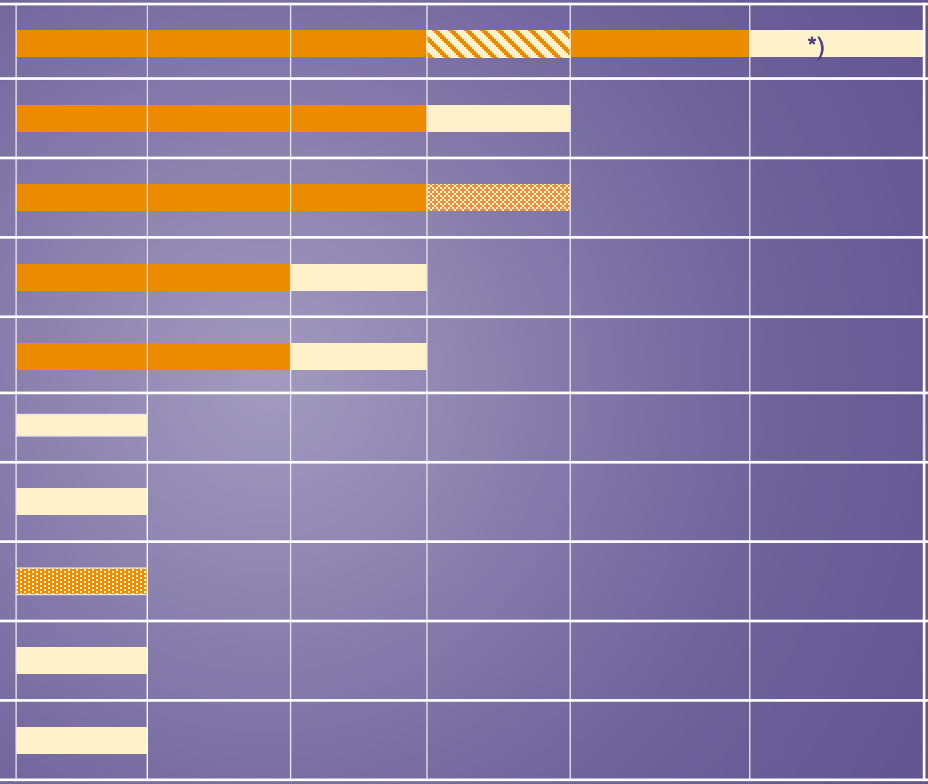
Pre-existing DSAs may result in primary graft failure and poor survival after allogeneic hematopoietic stem cell transplantations



[1] Ciurea et al., Bone Marrow Transplantation, 2018
[2] European Society for Blood and Marrow Transplantation

Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Program	Indication	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients [1,2]	EU: Additional agreements around reimbursement from H2'21
	US: Kidney transplantation in highly sensitized patients [1,2]	Completion of enrollment (64 patients) H2'22
	Anti-GBM antibody disease [3]	Pivotal Phase 3 study expected to commence in 2022 (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Completion of enrollment (30 patients) H1 2022
	Guillain-Barré syndrome (GBS)	Timeline guidance under review
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Preclinical phase
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Preclinical phase
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Preclinical phase
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Completion of GLP toxicology studies in 2022
EnzE	Cancer immunotherapy	Research phase



[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund
*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

Completed
Ongoing
Planned
Conditional approval based on Phase 2 data

Ongoing Clinical Programs

Fourth quarter highlights

- First patients enrolled in the pivotal U.S. ConfIdeS study in kidney transplant
- Alignment with FDA on a Phase 3 study of imlifidase in anti-GBM patients
- AMR: Patient enrollment on track for completion first half 2022, as previously guided
- GBS: Timeline for completion of enrollment under review due to the direct and indirect effects of the escalating pandemic

Enrollment status
Feb 2, 2022

- Patients enrolled
- Patients remaining

Antibody Mediated Rejection

- 23/30 patients enrolled in the AMR phase 2 study
- Completion of enrollment expected H1 2022* as previously guided
- First data read out expected in H2 2022*

- Patients enrolled
- Patients remaining

Guillain-Barré Syndrome

- 15/30 patients enrolled in the GBS phase 2 study
- GBS enrollment timeline under review given the difficulty of predicting enrollment due to the direct and indirect effects of the escalating pandemic
- Hansa expects to update its guidance for completion of enrollment in GBS in April 2022

Enrollment status
Feb 2, 2022

- Patients enrolled
- Patients remaining

Anti-GBM

- Alignment with FDA on a pivotal Phase 3 study of imlifidase in anti-GBM patients
- The planned study will target approximately 50 patients with anti-GBM disease across the U.S. and Europe
- The first patient is expected to be enrolled in 2022*

- Patients enrolled
- Patients remaining

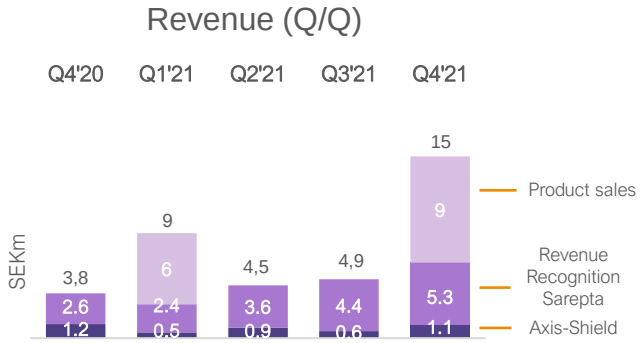
U.S. randomized control trial, “ConfIdeS”

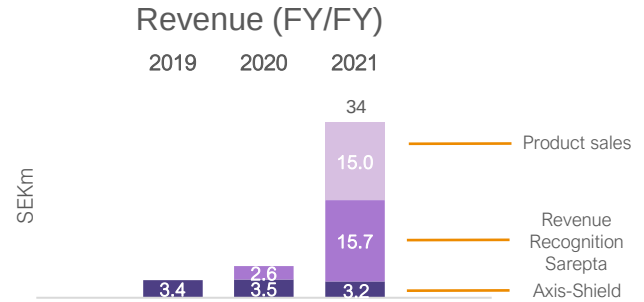
- 2/64 patients enrolled in the phase 3 “ConfIdeS” study
- First patients enrolled at Columbia University (NY) at the end of Dec 2021
- Five centers are active and open for enrollment
- Completion of enrollment expected H2 2022*
- Completion of 12 months follow-up expected H2 2023*

Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

HANSA BIOPHARMA

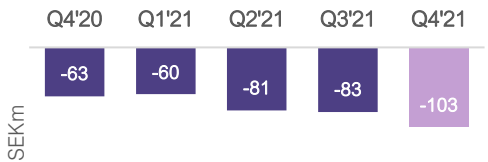
Revenue amounted to SEK 15m for Q4’21 and SEK 34m for FY’21



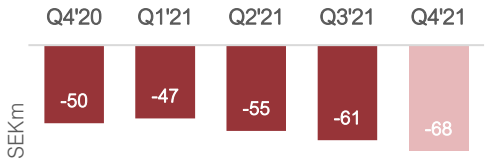


Continued investments in our commercialization and pipeline

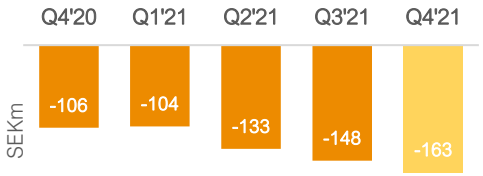
SG&A expenses (Q/Q)



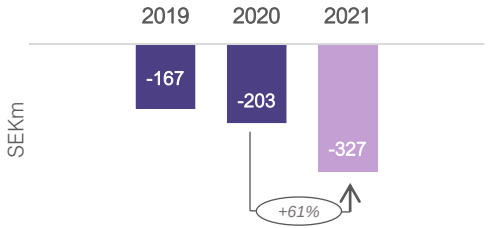
R&D expenses (Q/Q)



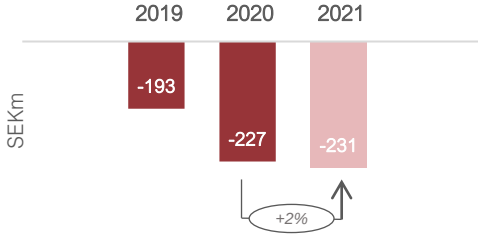
Net loss (Q/Q)



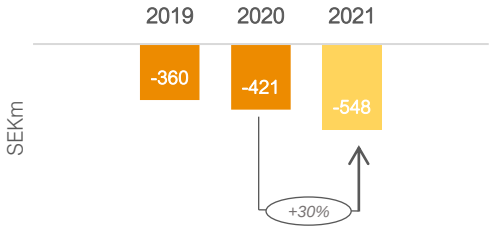
SG&A expenses (FY/FY)



R&D expenses (FY/FY)

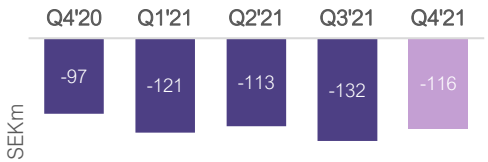


Net loss (FY/FY)

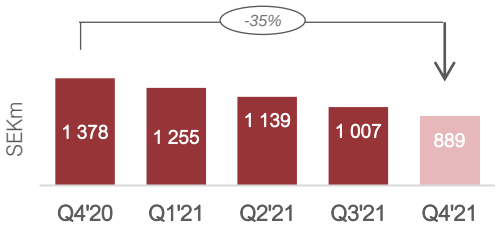


With current cash position and projected burn-rate, operations is financed into 2023

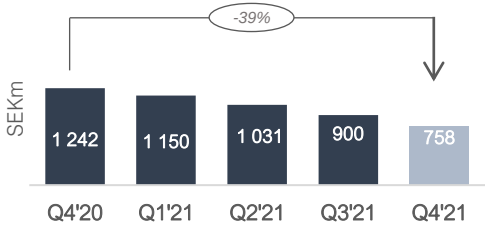
Operating cash flow (Q/Q)



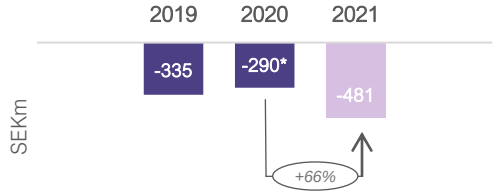
Cash & short-term investments (Q/Q)



Shareholders' equity (Q/Q)

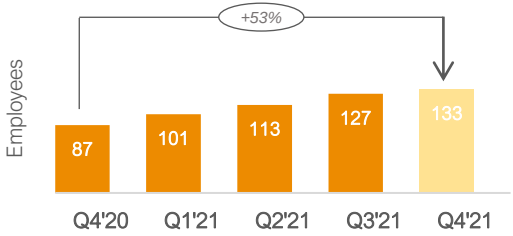


Operating cash flow (FY/FY)



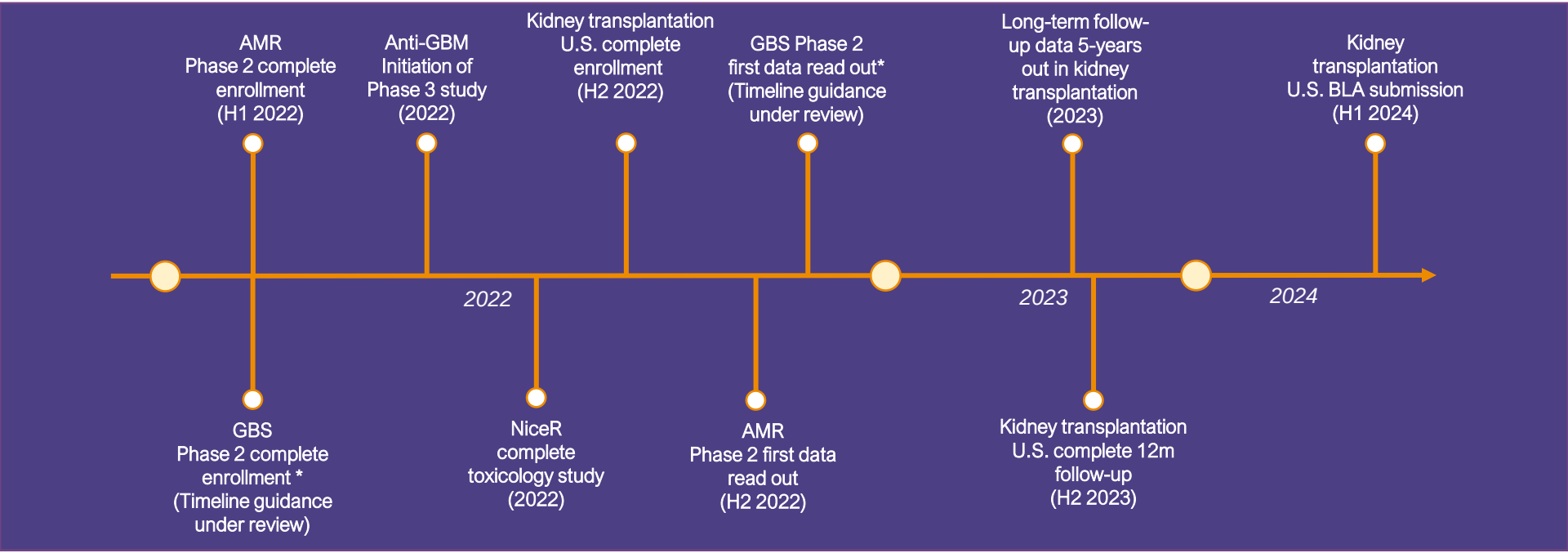
** incl. USD 10 mio (SEK ~90 mio) upfront from Sarepta*

Number of employees (Q/Q)



Upcoming milestones

Milestones subject to potential COVID-19 impact



Guidance assumes no persistent impact or further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.

**GBS: Given the current difficulty of predicting enrollment due to the direct and indirect effects of the persistent and even escalating pandemic, Hansa expects to update its guidance for completion of enrollment in GBS in April 2022*

HANSA BIOPHARMA

Company overview

HANSA BIOPHARMA

Hansa Biopharma today

Successful track record...
Strong momentum...
Promising future...

A validated technology

VALIDATION ACROSS THREE AREAS

- Approval in kidney transplantations
- Proof of concept in autoimmune diseases
- Partnerships to explore gene therapy (Sarepta & AskBio)

Idefirix® is our first approved drug in Europe*

EUROPE KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Broad pipeline in transplantation and autoimmunity

PROGRAMS IN CLINICAL DEVELOPMENT

US kidney transplants
Anti-GBM
Guillain-Barré syndrome (GBS)
Antibody mediated kidney transplant rejection (AMR)

Established a high-performance organization

NEW COMPETENCIES ADDED

133 employees December 2021 (~3x in 3 years)

Highly qualified team with 20 years on average in life science

Purpose driven culture

With recent capital injection Hansa is financed into 2023

FINANCIALS

SEK 889m in Cash (USD ~98m) December 2021

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~0.4bn

Listed on Nasdaq Stockholm

18,000 shareholders

Foreign ownership make up ~40% through leading international life science specialist funds

*Idefirix approved in EEA under conditional approval for kidney transplantation

**Actual patient has given consent to provide images

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 can lead long and healthy lives

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

Stock images

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.

Develop new therapies

- Desensitization in **kidney transplant** patients*
- Exploring treatment options in **anti-GBM****
- Exploring treatment options in **GBS****
- Exploring treatment options in **AMR****

Extend and improve human lives

Transplantation leads to dramatically better quality of life and life expectancy than dialysis

77% of transplanted patients are alive after 8 years vs 44% of patients on dialysis[1]

Deliver value to society

Transplantation is a cost-effective intervention vs. dialysis

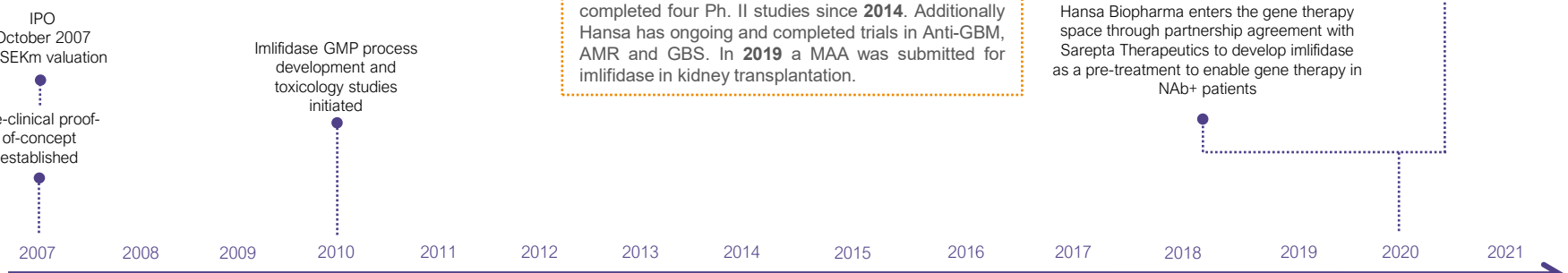
Idefirix was named in EMA report as Outstanding contribution to public health[3]

USD 115bn, equivalent to 20% of the US Medicare budget, relates to kidney diseases[2]

* Idefirix approved in EEA under conditional approval for kidney transplantation
** Imlifidase under investigation

[1] Orandi et al. N Engl J Med 2016;374:940-50
[2] https://www.hhs.gov/about/news/2019/07/10
[3] https://www.ema.europa.eu/en/documents/report/human-medicines-highlights-2020_en.pdf

Hansa Biopharma's history



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. In the first quarter of **2021**, Hansa recorded the first commercial sales of Idefirix and also entered into a pre-clinical collaboration with argenx.

Hansa Biopharma enters into three collaborations with argenx (combination therapies); Medison (commercial) and AskBio (gene therapy)

argenx

MEDISON
Delivering Innovative Healthcare

AskBio

HANSA BIOPHARMA

Many milestones achieved during the last 18 months

SEK 1.1bn
(USD 121m)
Hansa Biopharma strengthens its balance sheet with the successful completion of SEK 1.1bn (USD 121m) placement of newly issued shares. The share issue was multiple times oversubscribed due to high demand from US, European and Swedish institutional investors

July

Hansa Biopharma announces an exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as a pre-treatment to enable Sarepta gene therapy treatment in Duchenne muscular dystrophy and Limb-girdle muscular dystrophy

August

Positive high-level data from Phase 2 study in anti-GBM antibody disease

October

The EU Commission grants conditional approval for Idefirix® in highly sensitized kidney transplant patients in the European Union

November

December

2021

January

Healthcare Technology Assessment published by Swedish "TLV", with a favorable conclusion for using Idefirix® in highly sensitized patients incompatible with a deceased donor

February

Hansa Biopharma enters pre-clinical research collaboration with argenx BV to explore potential combination therapies with imlifidase and efgartigimod

March

Hansa Biopharma records first commercial sale of Idefirix®

April

May

First national market access agreement achieved for Idefirix® in Sweden and Finland

June

July

Positive 3-year follow-up data published in American Journal of Transplantation demonstrating graft survival of 84% after imlifidase treatment and transplantation

August

Full national reimbursement agreement achieved for Idefirix® in the Netherlands

Hansa Biopharma AB certified as a Great Place to Work® for second consecutive year

September

October

New multiregional commercialization partnership with Medison Pharma for imlidase in kidney transplant in Central Eastern Europe and Israel

November

December

First patient enrolled in the U.S. pivotal randomized controlled study "ConfIdeS" in highly sensitized kidney transplant patients

2022

January

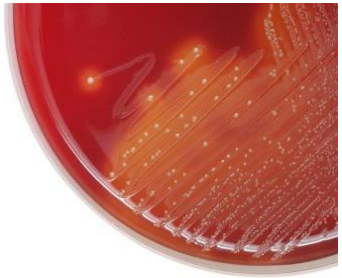
Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease

Imlifidase

a novel approach to eliminate pathogenic IgG

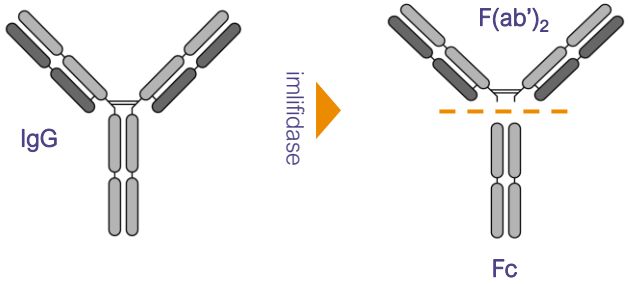
Origins from a bacteria *Streptococcus pyogenes*

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



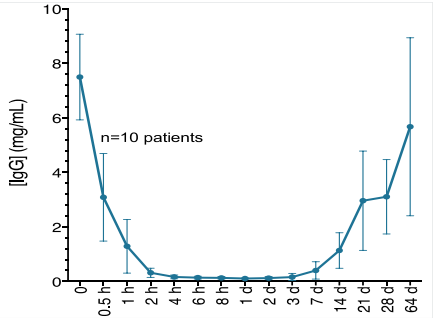
A unique IgG antibody-cleaving enzyme

- 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



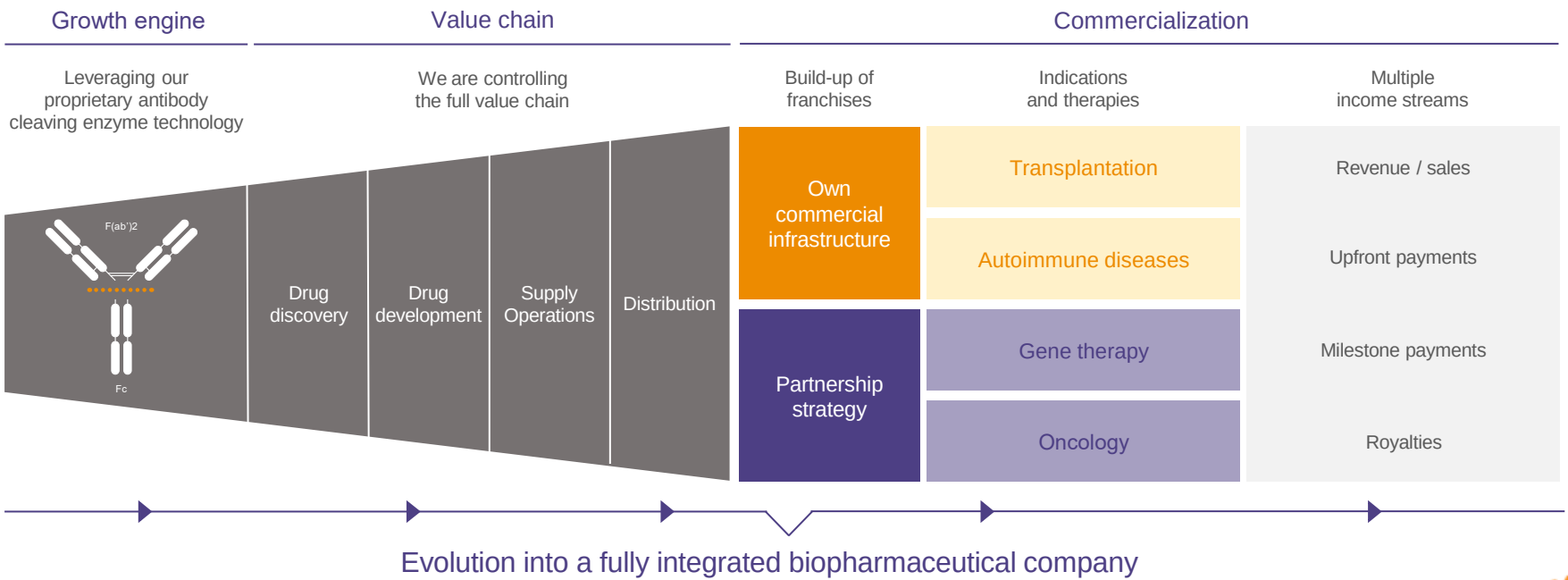
Inactivates IgG in 2-6 hours

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

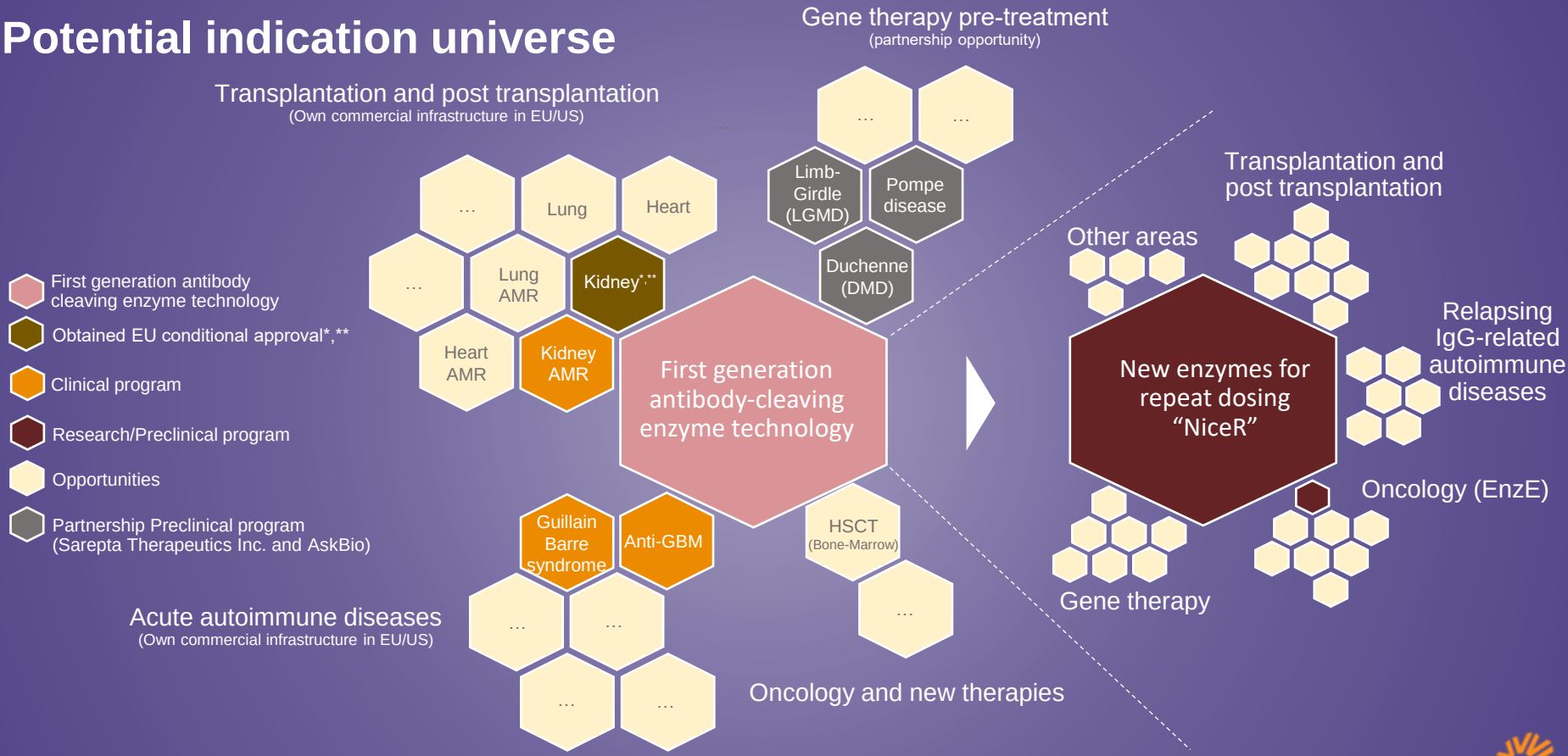


Our Business model

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



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 by H1 2024

HANSA BIOPHARMA

Our strategic priorities

Building tomorrow's Hansa Biopharma

Advance platform in new indications and therapeutic areas

BUILD NEW FRANCHIES TO CAPTURE FULL VALUE OF TECHNOLOGY PLATFORM

- Transplantation
- Autoimmunity
- Gene therapy
- Oncology

Commercialize Idefirix® in first markets and indications

SUCCESSFULLY LAUNCH IDEFIRIX® IN EUROPE*

Generate positive first experiences in key clinics and expand to targeted clinics with a patient focus

GEOGRAPHICAL EXPANSION

- Explore opportunities to commercialize Idefirix® beyond core markets

SECURE FDA APPROVAL AND LAUNCH IDEFIRIX IN THE US

- Complete Randomized Control Trial (RCT) and submit BLA under the accelerated approval pathway (H1 2024)

Build organizational capabilities and expand technology platform

BUILD A FIRST-CLASS COMMERCIAL ORGANIZATION

Build commercial team and competences in transplantation and autoimmune diseases

EXPAND R&D CAPABILITIES

Pursue innovation, further strengthen scientific expertise and capabilities in rare diseases

CREATE PARTNERSHIPS

Initially focused around gene therapy and potentially oncology

*Idefirix approved in EEA under conditional approval for kidney transplantation

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*
- Commercialisation
- First Market access and reimbursement obtained in Sweden, Finland and Netherlands
- 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

Experienced Board and Executive Committee

Extensive experience from the global healthcare industry

Executive Committee

Sören 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

Christian Kjellman

SVP & CSO/COO (2008)
+20 years in the Healthcare sector
Ex-Head of Research at Cartela
Ex-Senior Scientist at BioInvent,
MSc Chemical Biology, PhD in Tumour Immunology from Lund University

Donato Spota

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

Achim Kaufhold

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

Henk D. van Troostwijk

SVP & CCO (2016)
+20 years in the Healthcare sector
Ex-GM at Raptor Pharmaceuticals
Ex-BU Director at Genzyme Europe

Anne Säfström Lanner

SVP & CHRO (2019)
Ex-Head of HR European Spallation Source
Ex-Head of HR Cellavision

Board of Directors

Ulf Wiinberg

Chairman (2016)
+30 years in the Healthcare sector
Ex-CEO at Lundbeck (2008-14)
Ex-President at Wyeth of the global consumer heath care and European Pharma business

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)

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

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

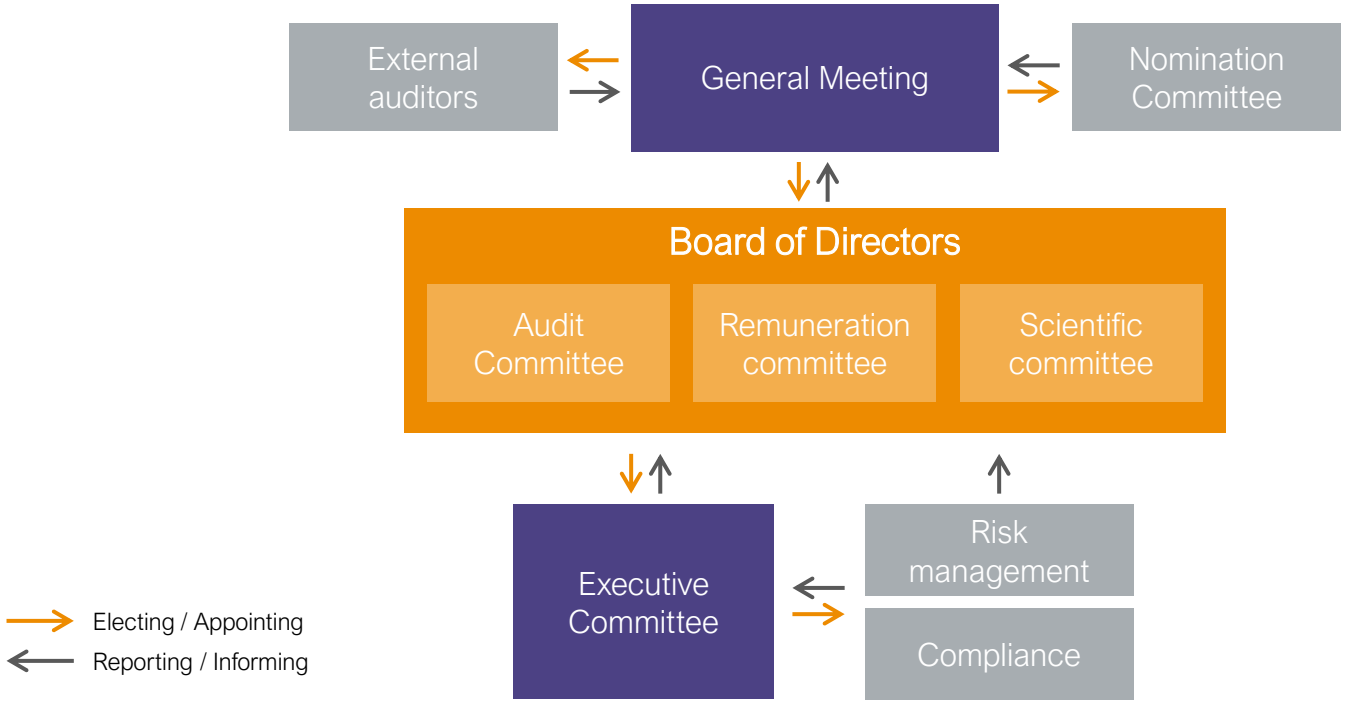
Mats Blom

Board Member (2019)
CFO of NorthSea Therapeutics
Ex-CFO Zealand Pharma
Member of Hansa Biopharma's Audit Committee

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

Hansa Biopharma's Governance Structure

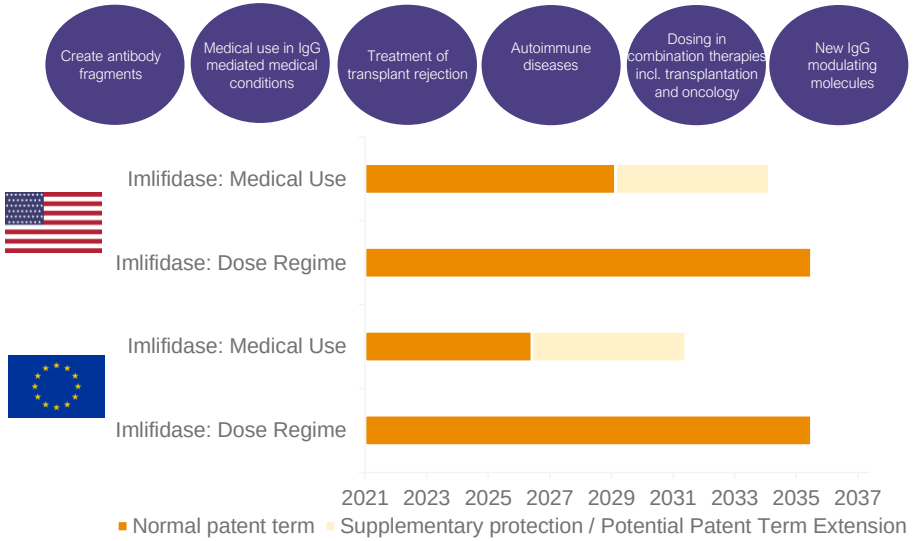


Strong technology protection

through patents and orphan drug designations

Patent coverage out to 2035 in key markets

- Hansa Biopharma's portfolio consist of 11 separate patent families incl. 7 patent families in relations to the use of imlifidase (granted/pending)
- Patents cover use of isolated imlifidase 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).
- Designation provides development and commercial incentives incl. 10 years market exclusivity in EU and 7 years in the US, when approved.

EMA

Marketing Approval with orphan drug designation

- Conditional marketing approval for imlifidase, for the prevention of graft rejection following solid organ transplantation, was achieved in 2020

Orphan drug designation

- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

FDA

Orphan drug designations

- 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)

Hansa Biopharma is financed into 2023

Capital injections in 2020 from new shares (SEK 1.1bn) and Sarepta (SEK 100m) will finance Hansa into 2023

*Including SEK 100m upfront payment from Sarepta

Our mid-term financial priorities

Fund a broad exploitation of our technology platform while securing a successful European launch

SEK ~889m
(USD ~98m)
in cash and short-term investments
(December 31, 2021)

…with current cash position and projected burn-rate, Hansa is financed into 2023

- **Fund commercial expansion across Europe, targeting mid-term product profitability**
- **Continue investments in kidney transplantation to approach US market**
- **Accelerate advancements in new therapeutic areas incl. autoimmunity, gene therapy and oncology**
- **Develop next generation enzymes for repeat dosing**

HANSA BIOPHARMA

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
- Obtain regulatory approval in anti-GBM, GBS and AMR
- Demonstrate PoC in our next gen enzymes (NiceR)
- Expand partnerships in gene therapy and oncology
- Advance clinical studies with imlifidase as pre-treatment in Limb-Girdle, Duchenne and Pompe Disease therapies with Sarepta and AskBio
- Show PoC in new indications such as oncology
- Advance combination treatment into the clinic with argenx to potentially enable new therapeutics in transplantation and autoimmune diseases

Our future

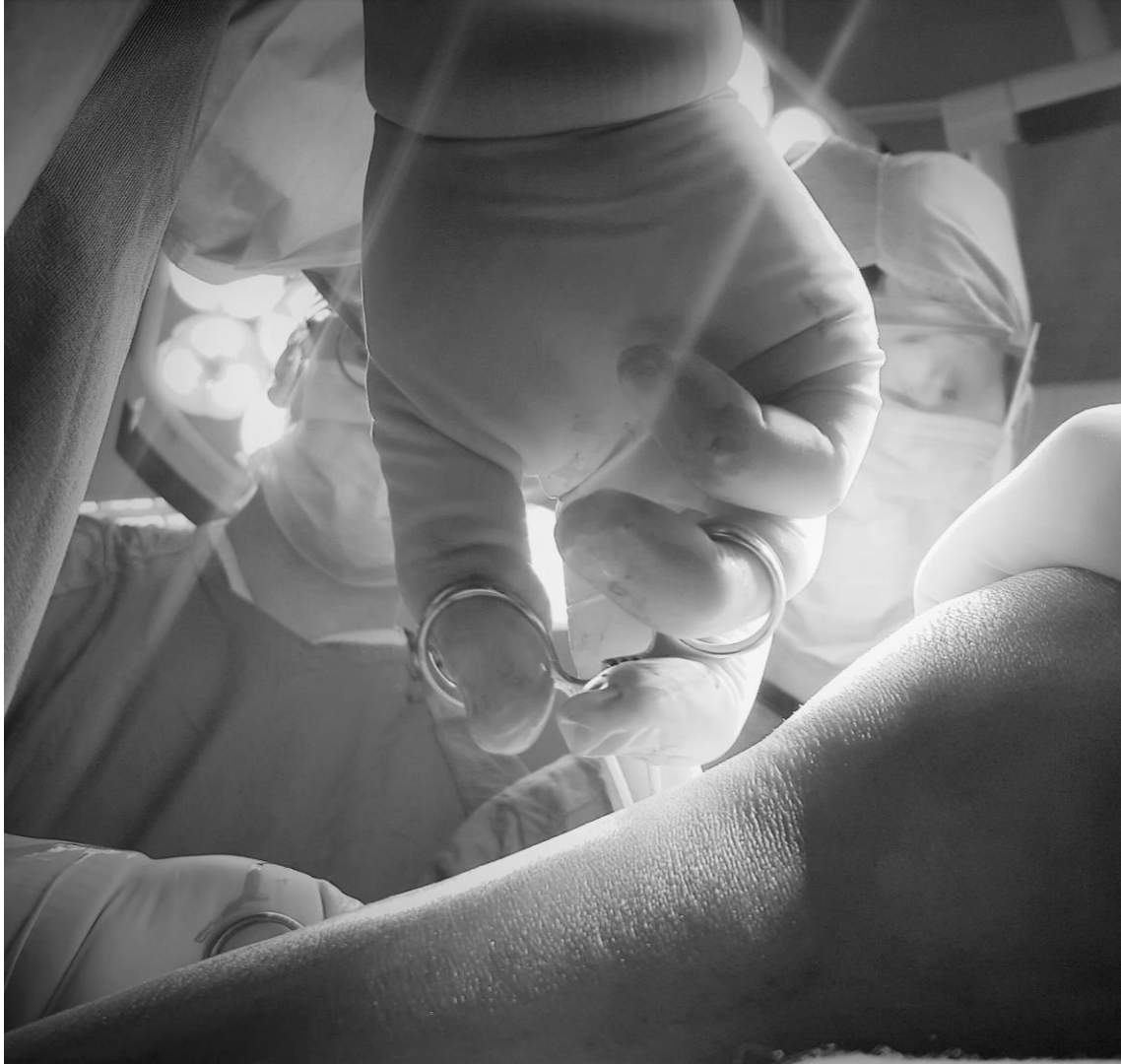
Hansa Biopharma is a recognized global leader in rare diseases across multiple broad therapeutic areas with several market leading products and a highly valuable pipeline of late stage drug candidates

Stock images

Idefirix approved in EU under conditional approval for kidney transplantation

Imlifidase in kidney transplantation

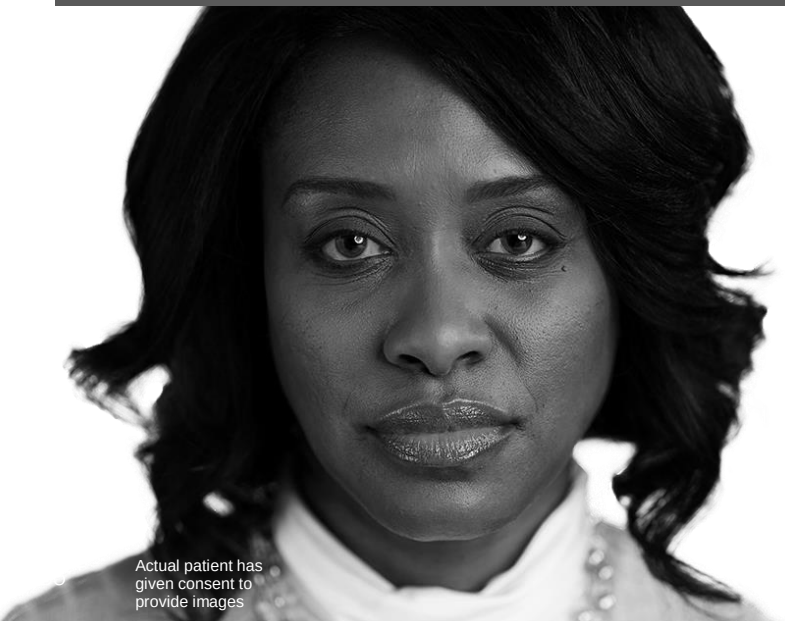
HANSA BIOPHARMA



Idefirix® (imlifidase) has received conditional approval in the European Union

Low complexity transplants ⟷ Higher 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%)
		Highly sensitized patients that are likely to be transplanted with a compatible donor
		Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs



Actual patient has given consent to provide images

Idefirix® is indicated for

desensitization treatment of highly sensitized 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 prioritization programs for highly sensitized patients

Potential patients

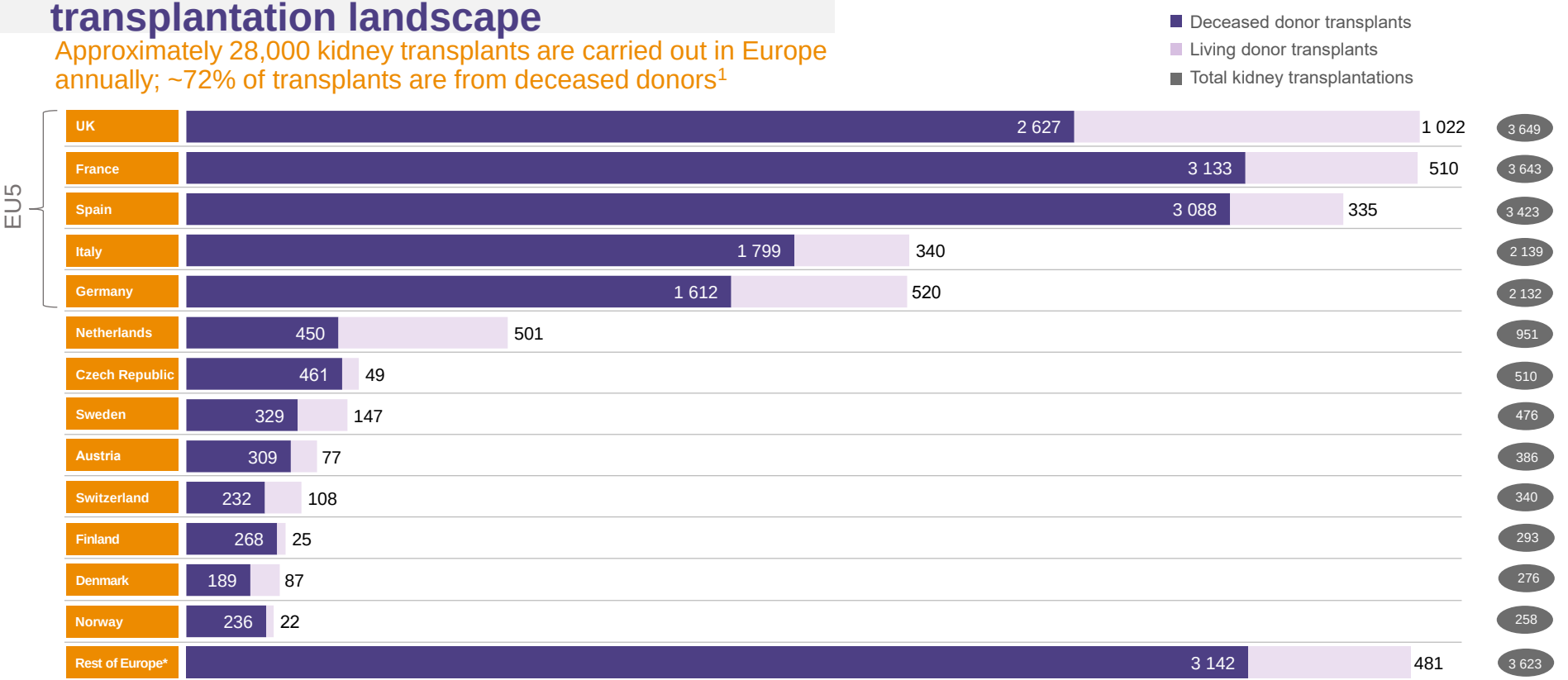
idefirix® imlifidase

HANSA BIOPHARMA

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

European kidney transplantation landscape

Approximately 28,000 kidney transplants are carried out in Europe annually; ~72% of transplants are from deceased donors[1]



[1] Transplant data from 2019.
*Belgium, Croatia, Cyprus, Greece, Hungary, Iceland, Ireland, Lithuania, Poland, Portugal, Romania, Slovakia, Slovenia
Source: Global Observatory on Donation & Transplantation, 2019

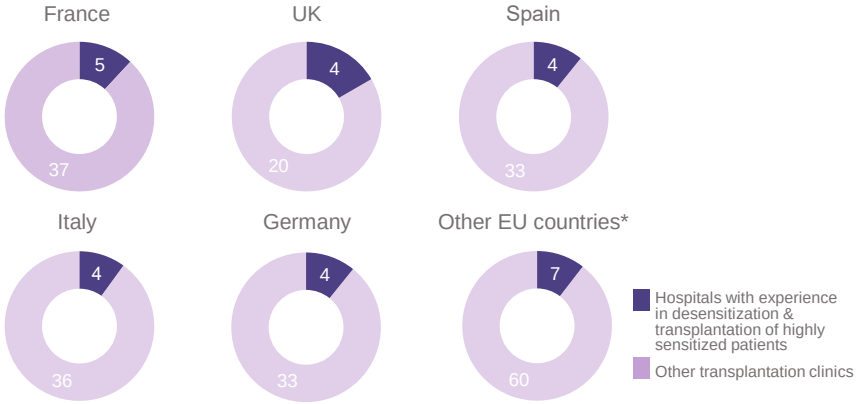
HANSA BIOPHARMA

Early launch in centres of excellence

First launch wave defined

1. Launch Idefirix® with kidney transplant specialists who have experience in desensitization
2. Create positive momentum with Idefirix as the new Gold Standard in desensitization protocols
3. Prepare post approval study to confirm filing data

Leading transplantation centres perform the majority of all transplantations in EU

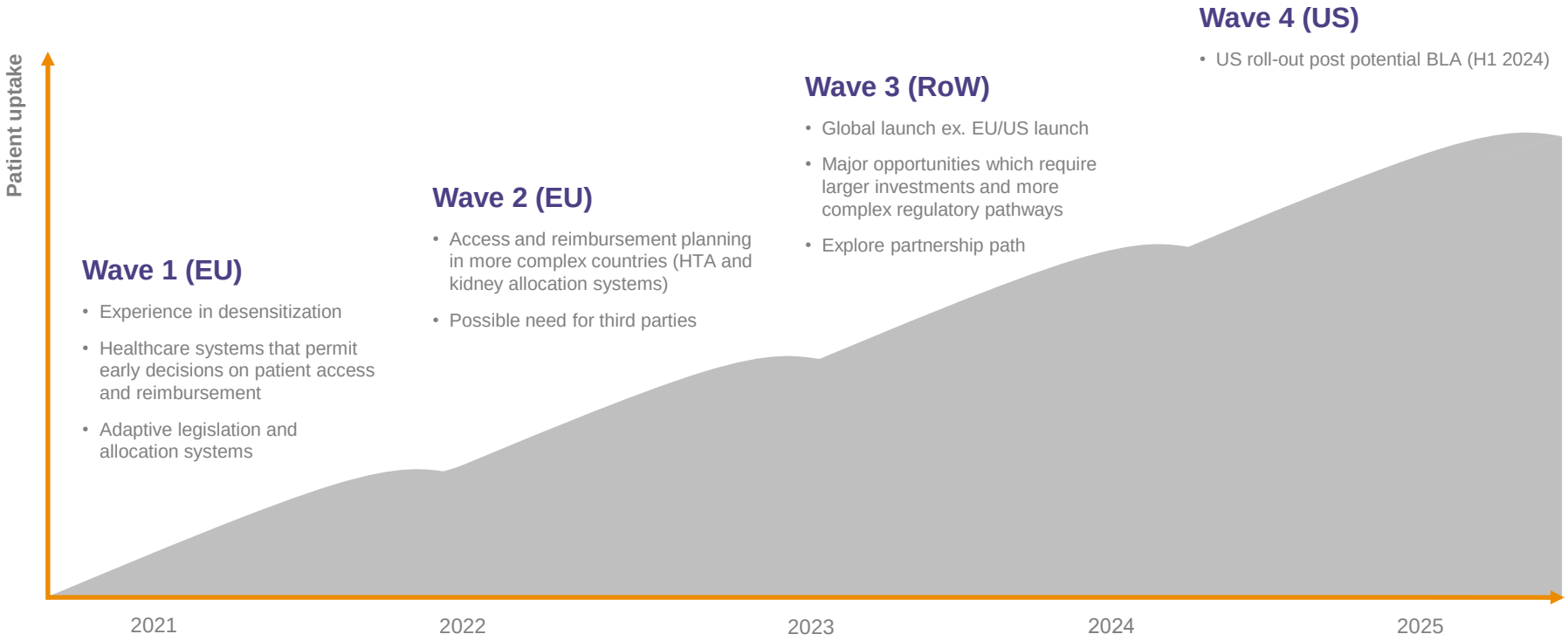


Idefirix approved in EU under conditional approval

*Other EU countries incl. Sweden, Denmark, Norway, Austria, Switzerland, Netherlands, Belgium, Poland, Czech Rep. and Portugal

Plans for global expansion

Launching in overlapping waves with a centre-by-centre approach in Europe



Approximately 10-15% of patients on wait list are highly sensitized

Highly sensitized patients are difficult to match with an available kidney

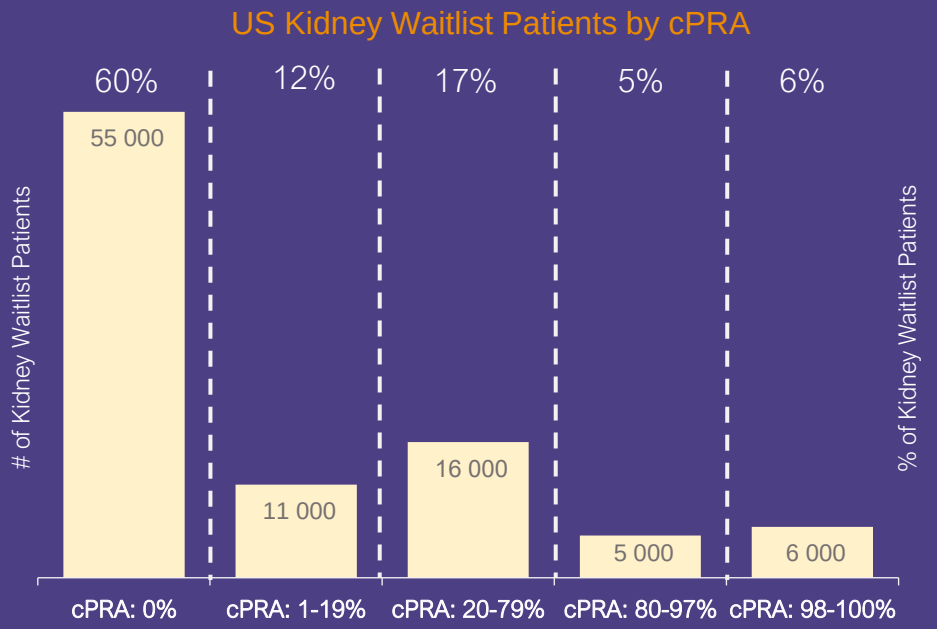
Causes of sensitization include

Pregnancy

Blood transfusion

Previous transplantations

- 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



Source: Organ Procurement and Transplant Network

Imlifidase is set out to help highly sensitized patients

who cannot access a kidney through the allocation system

Creating equity for highly sensitized patients

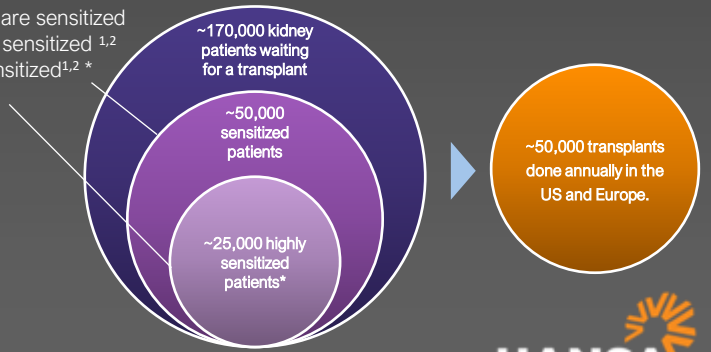
- Allocation systems increase transplantation rates, however the rates for highly sensitized patients are still very low compared with average or non-sensitized patients
- Imlifidase may potentially:
  - Complement allocation systems (e.g. KAS, Euro-transplant) to reduce time to transplant in highly sensitized patients
  - Reduce the need for antibody matching and give sensitized patients access to a larger pool of organs
  - Reduce the risk for co-morbidities and mortality associated with dialysis and waiting time
  - Increase transplant rates in highly sensitized patients
  - Help reduce the number of discarded kidneys
    (1,000 donated kidneys are discarded in the U.S. alone every year[3])

[1] Jordan et al. British Medical Bulletin, 2015, 114:113–125
[2] Orandi et al. N Engl J Med 2016;374:940-50
[3] Organ Procurement and Transplantation Network (OPTN)
[4] Jordan et al. British Medical Bulletin, 2015, 114:113-125

Delilah, a 23 years old highly sensitized kidney transplant patient from California

U.S. + EU Kidney Transplant Waitlist Breakdown

>30% of waitlist patients are sensitized
- 15-20 % moderately sensitized [1,2]
- Up to 15% highly sensitized[1,2] *



*Patients with sensitivity above cPRA 80%
Source: The U.S. Department of Health and Human Services and .irodat.org

HANSA BIOPHARMA

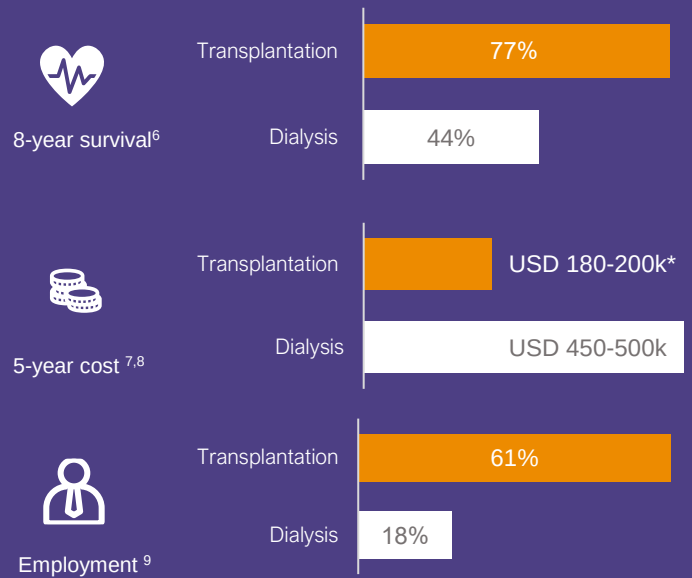
Transplantation leads to better outcomes

Saves lives, reduce costs and increase quality of life, incl. gains for the society

Several complications and risks with dialysis

- Undergoing dialysis treatment is associated with many complications and side effects incl. cardiovascular diseases[1]. In the long term, patients may also eventually lose access to dialysis as a result of failed ports, bad veins, and other factors[2]
- In general, patients on the kidney transplant waiting list and who are on dialysis have a lower quality of life than non-dialysed patients or patients who have been transplanted[3]
- First study in Europe on labor market outcomes demonstrates societal gains of enabling transplantation with three times as many transplant patients employed compared to dialysis patients.
- Lastly, extended dialysis is also a high-risk factor for removal from the transplant wait list[6]

Better outcomes for transplantation patients



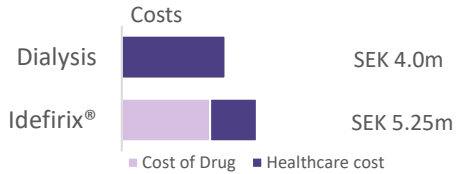
*Cost of kidney transplantation and 5 years of immuno-suppression treatment[6,7]

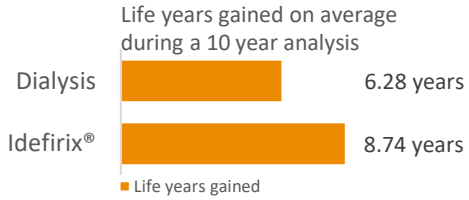
[1] Cozzolino et al., 2018
[2] Sinnakirouchenan and Holley, 2011 Shenoy, 2017
[3] Wyld et al., 2012
[4] Jarl et al. Transplantation, 2018, 102:1375-1381
[5] NHS blood and transplant, 2018.
[6] Orandi et al. N Engl J Med 2016;374:940-50
[7] www.usrds.org
[8] Shehata et al, Transfus Med Rev 201, 24 Suppl 1: S7-S27
[9] Jarl et al. Transplantation, 2018, 102:1375-1381

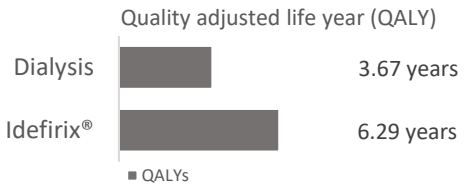
First HTA report (TLV) published in Sweden favourable to the use Idefirix® in highly sensitized patients incompatible to a deceased donor

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

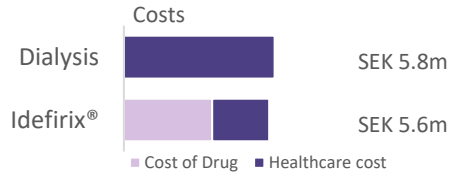


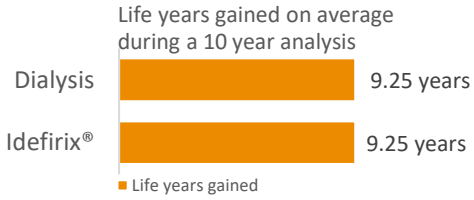


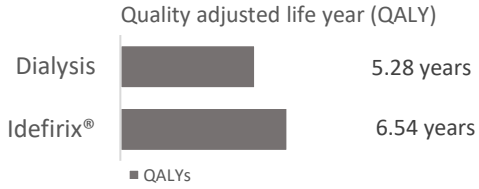


Costs per quality adjusted life year (QALY)
SEK 460k
(EUR 45k)

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

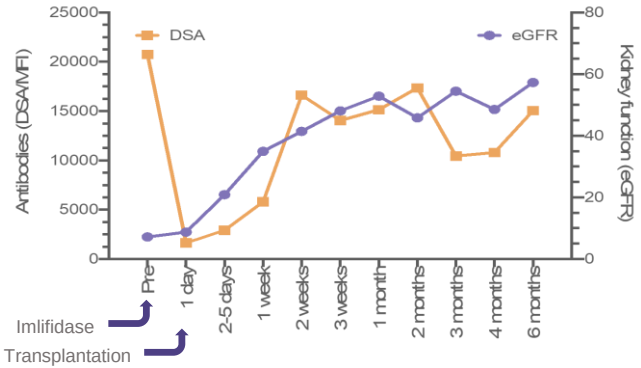
Completed and ongoing studies in kidney transplantation

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



Study design of our four Phase 2 trials

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

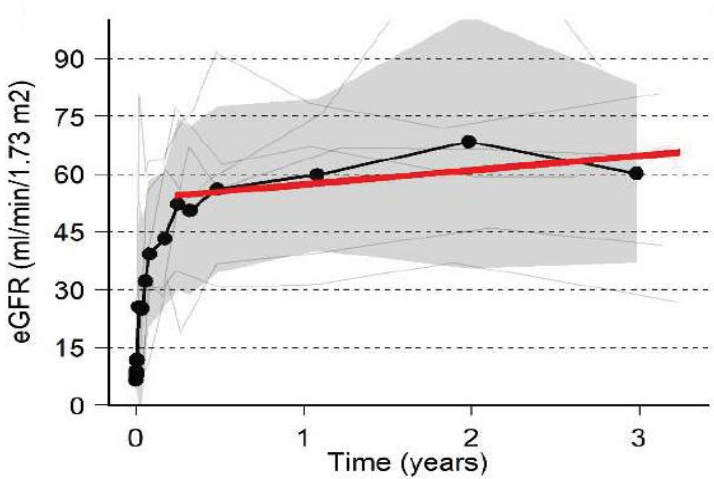
3-year follow up demonstrate graft survival of 84% after imlifidase treatment and transplantation

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

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)

U.S. ConfIdeS study: First patient enrolled Dec'21; BLA submission expected H1 2024

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

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

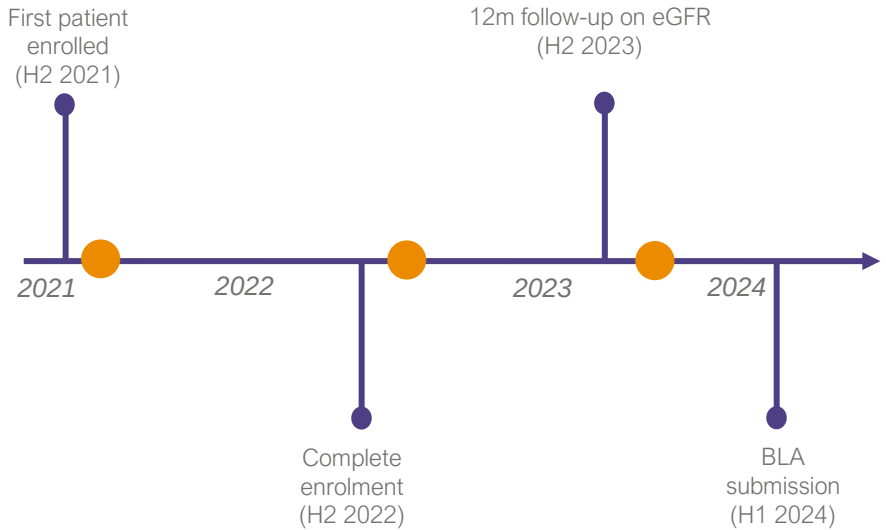
Secondary endpoint

- Patient survival at 12 months

12-15 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
- Five clinics are open for recruitment as of February 2, 2022

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

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 is expected to commence in 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

Study 01
Phase 1

The 01 study results

Data showed complete removal of IgG and a good tolerability profile

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

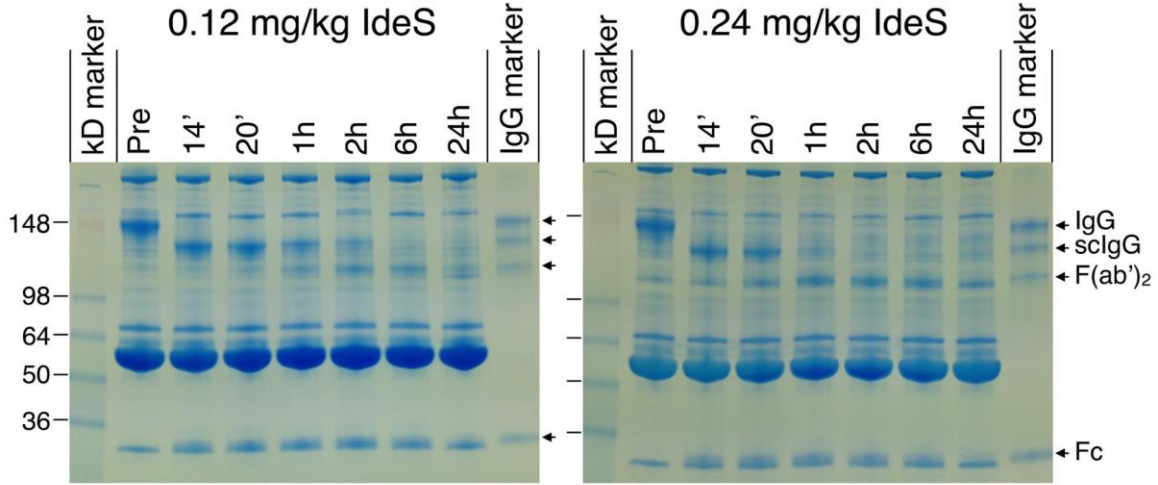
- The 01 study showed complete removal of IgG and that Imlifidase was considered safe to use

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)

HANSA BIOPHARMA

Study 02
Phase 2

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]

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

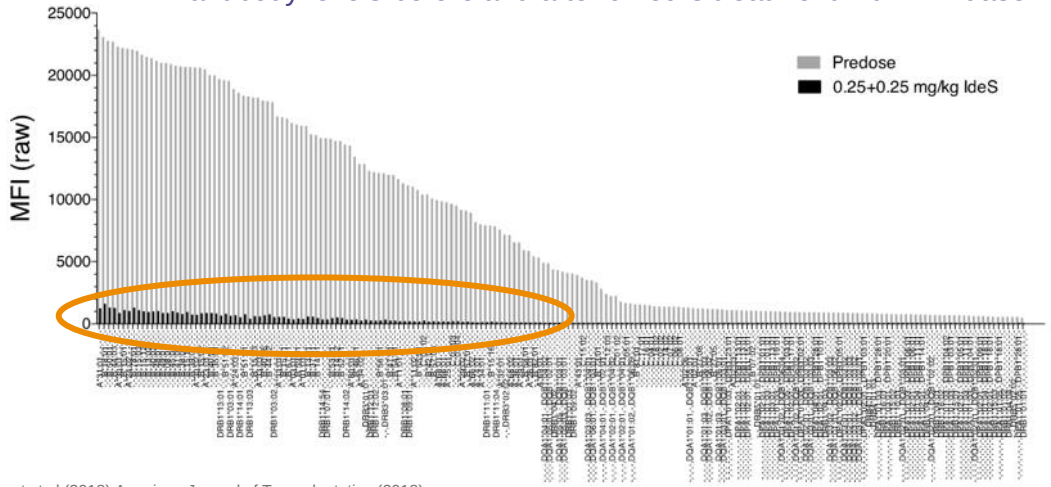
STATUS

Completed

- Primary efficacy endpoint reached
- Safe and well tolerated

- ✓ 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

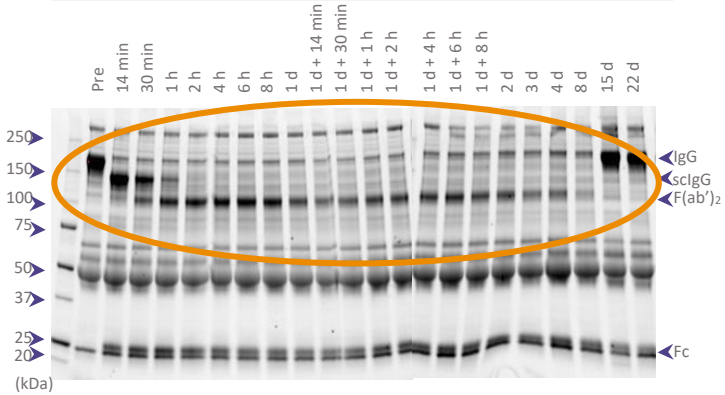
- ~~Single center, single arm, open label~~, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

~~Completed~~

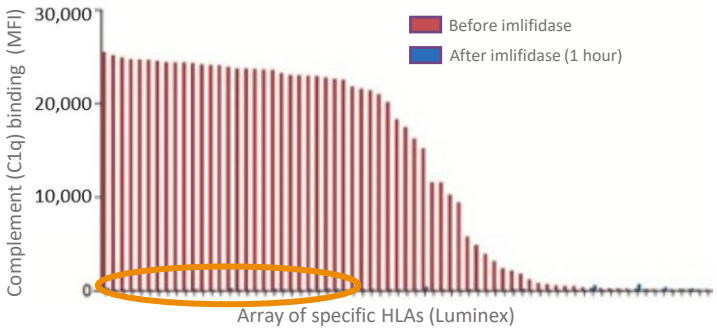
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

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.

HANSA BIOPHARMA

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

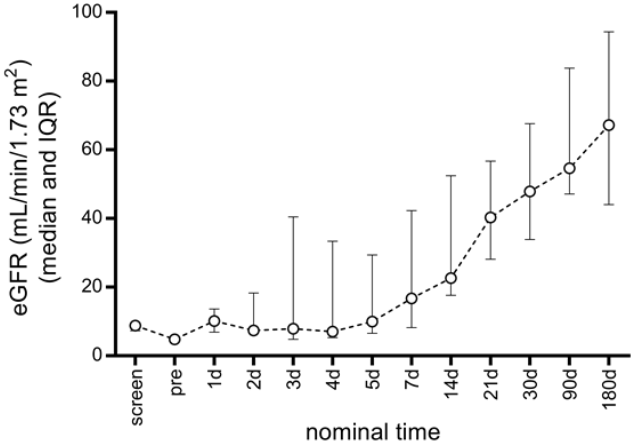
STUDY DESIGN

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

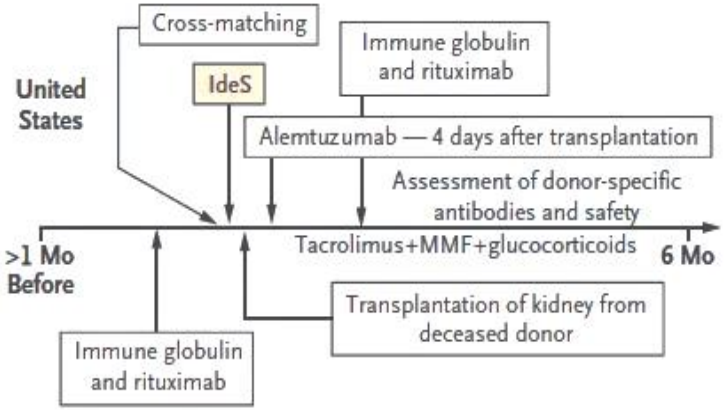
STATUS

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

Study 06
Phase 2

The 06 study results

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

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

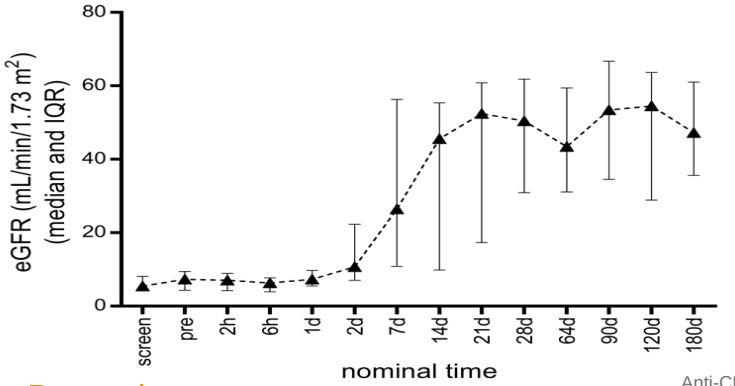
STUDY DESGIN

- 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

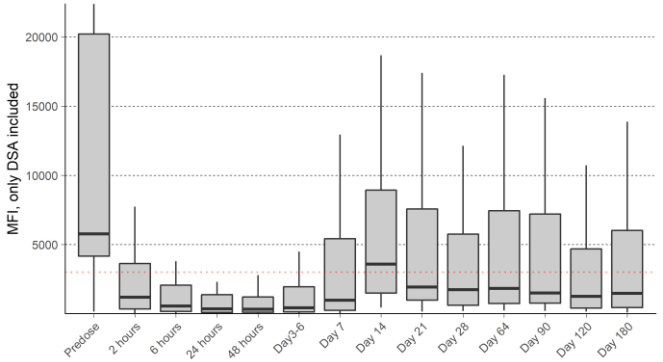
STATUS

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.

HANSA BIOPHARMA

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

[1] Winstedt el 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

Medical Advisory Board in kidney transplantation

Professor Stanley Jordan

(Chairman) M.D., Ph.D., Director of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and Director of Division of Pediatric and Adult Nephrology, Cedars-Sinai Medical Center, Los Angeles, California

Professor Robert Montgomery

M.D., Ph.D., FACS, Director at NYU Langone Transplant Institute, New York, NY, USA

Professor Christophe Legendre

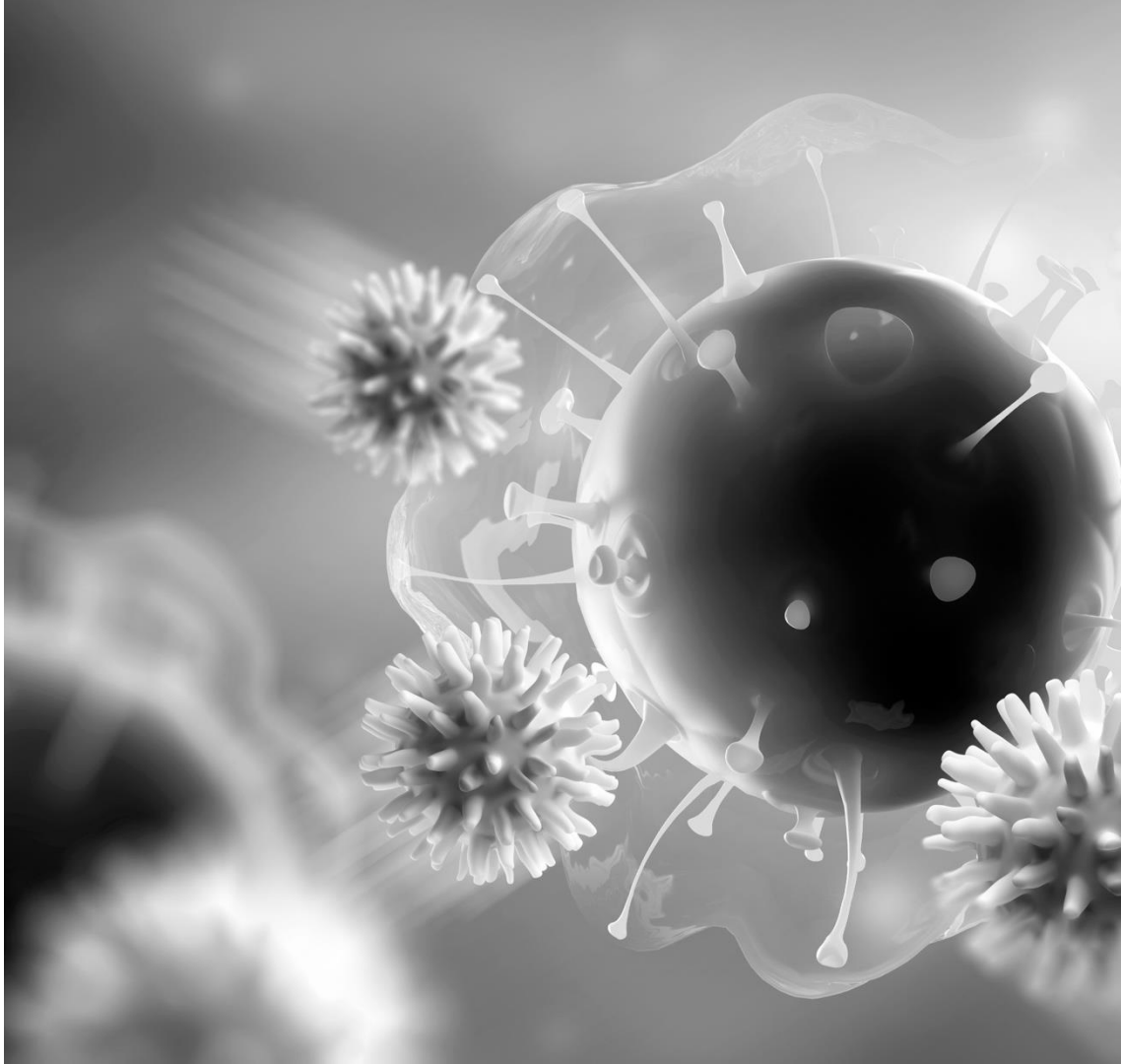
M.D., Ph.D. Professor at Paris Descartes University and Head of the Adult Nephrology and Transplantation unit at Necker Hospital in Paris.

Professor Kathryn Wood

Ph.D. Fellow of the Academy of Medical Sciences, Professor of Immunology in the Nuffield Department of Surgical Sciences, University of Oxford, England, runs the Transplantation Research Immunology Group

Our antibody cleaving enzyme technology

HANSA BIOPHARMA



Broad clinical pipeline in transplantation and auto-immune diseases

[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund
*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients. A post-approval study will commence in parallel with the launch

Completed
Ongoing
Planned
Conditional approval based on Phase 2 data

HANSA BIOPHARMA

Ongoing Clinical Programs

Fourth quarter highlights

- First patients enrolled in the pivotal U.S. ConfIdeS study in kidney transplant
- Alignment with FDA on a Phase 3 study of imlifidase in anti-GBM patients
- AMR: Patient enrollment on track for completion first half 2022, as previously guided
- GBS: Timeline for completion of enrollment under review due to the direct and indirect effects of the escalating pandemic

Enrollment status
Feb 2, 2022

- Patients enrolled
- Patients remaining

Antibody Mediated Rejection

- 23/30 patients enrolled in the AMR phase 2 study
- Completion of enrollment expected H1 2022* as previously guided
- First data read out expected in H2 2022*

- Patients enrolled
- Patients remaining

Guillain-Barré Syndrome

- 15/30 patients enrolled in the GBS phase 2 study
- GBS enrollment timeline under review given the difficulty of predicting enrollment due to the direct and indirect effects of the escalating pandemic
- Hansa expects to update its guidance for completion of enrollment in GBS in April 2022

Enrollment status
Feb 2, 2022

- Patients enrolled
- Patients remaining

Anti-GBM

- Alignment with FDA on a pivotal Phase 3 study of imlifidase in anti-GBM patients
- The planned study will target approximately 50 patients with anti-GBM disease across the U.S. and Europe
- The first patient is expected to be enrolled in 2022*

- Patients enrolled
- Patients remaining

U.S. randomized control trial, “ConfIdeS”

- 2/64 patients enrolled in the phase 3 “ConfIdeS” study
- First patients enrolled at Columbia University (NY) at the end of Dec 2021
- Five centers are active and open for enrollment
- Completion of enrollment expected H2 2022*
- Completion of 12 months follow-up expected H2 2023*

**Guidance assumes no further escalation of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down again.*

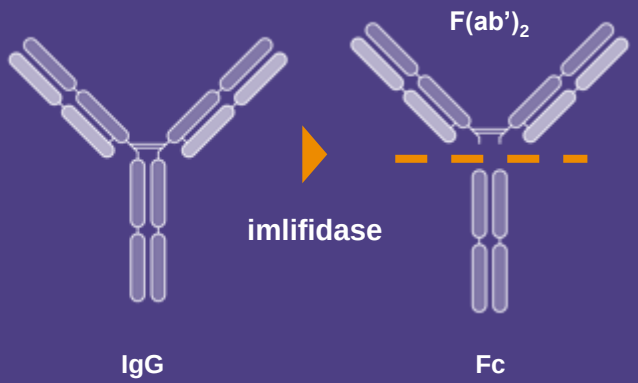
HANSA BIOPHARMA

Imlifidase mode of action

Novel approach to effectively eliminate pathogenic IgG

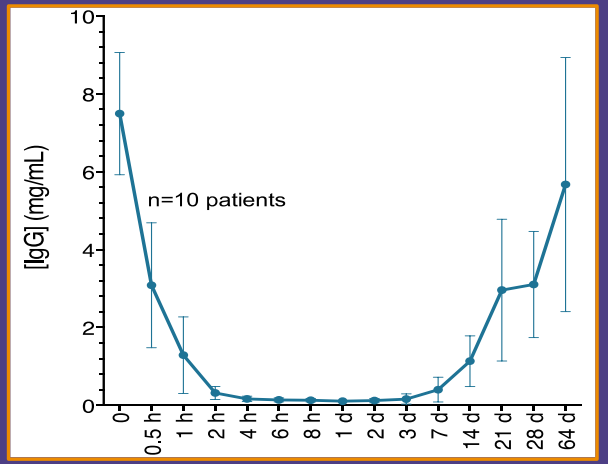
Proven mechanism of action

- 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

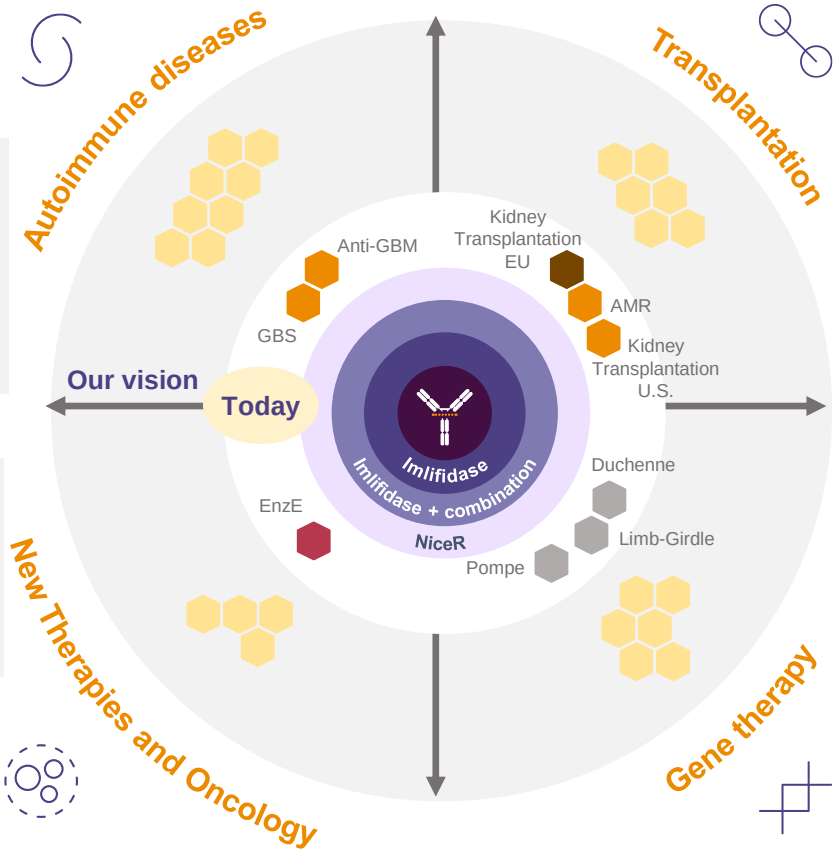
Targeting rare IgG mediated diseases

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

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

IgG-cleaving enzymes to enable or even potentiate cancer therapy

- Allogenic stem cell (bone marrow) transplantation (HSCT)
- Enzyme-based antibody Enhancement (EnzE)



Expanding our commercial franchises

- Regulatory approval (conditional)
- Clinical development
- Partnership (preclinical development)
- Preclinical development

Shaping a new standard for desensitization will help enable new indications in transplantations

- Antibody mediated rejection (AMR) in kidney transplantation
- Other transplantation types

Exploring opportunities in gene therapy

- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta and AskBio
- Wide indication landscape beyond

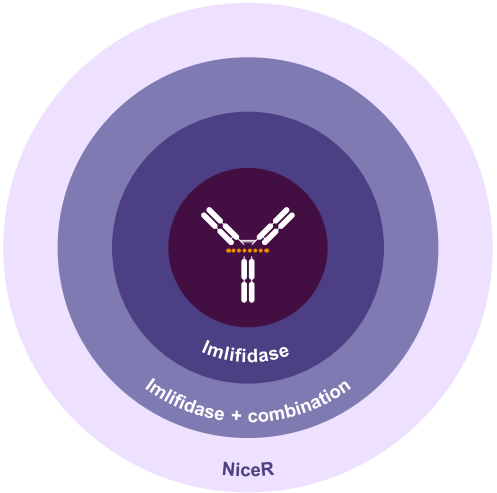
HANSA BIOPHARMA

The technology platform is the primary basis for our evolution

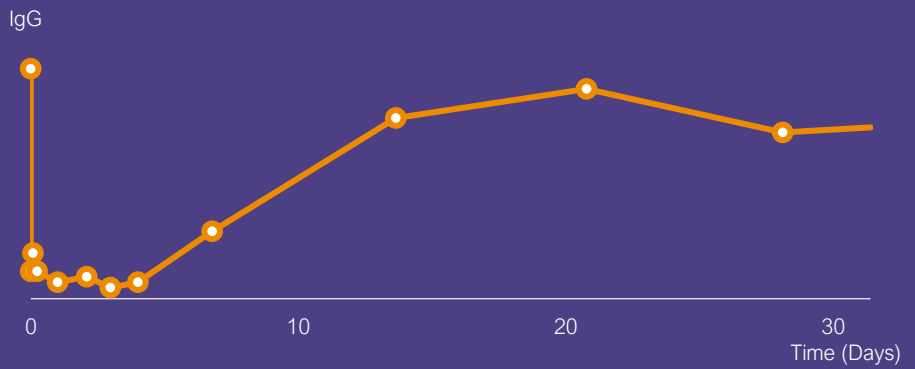
Targeting rare IgG mediated diseases and conditions

Key opportunities:

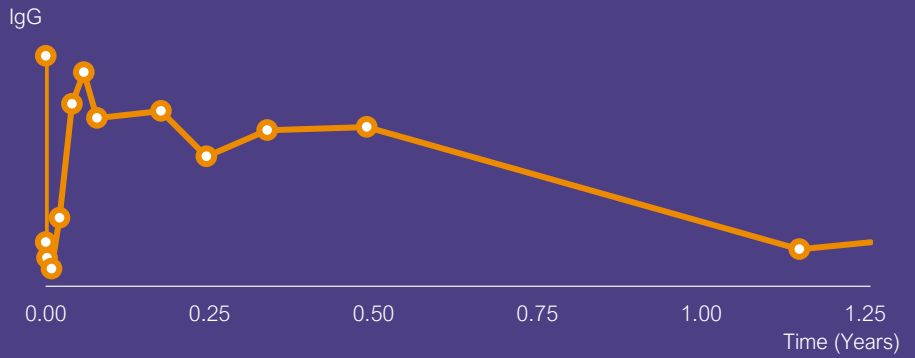
- Expanding into **new indications**
- Reduce immune response to IgG-cleaving enzyme, i.e. allow **repeated treatment**
- **Combination therapy**, i.e. induction and maintenance therapy



IgG levels after imlifidase treatment in humans – First 30 days



IgG levels after imlifidase treatment in humans – 1 year and beyond



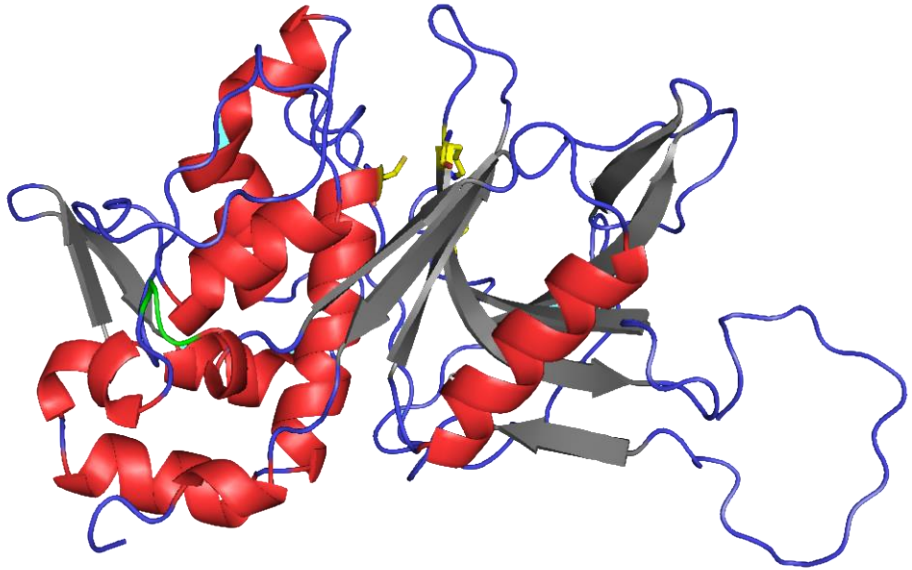
HANSA BIOPHARMA

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



HANSA BIOPHARMA

Imlifidase is a lyophilized product formulation

Shelf life of 18 months at 2-8º Celsius storage

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

Supply Chain

Imlifidase in kidney transplantation

Drug Development

Drug substance Manufacturer (API)

Logistics of bulk product
- handling of drug substance product

Final product (packaging and labelling)

Distribution

Clinics and hospitals

Patients

Drug product manufacturer (upscaling)

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

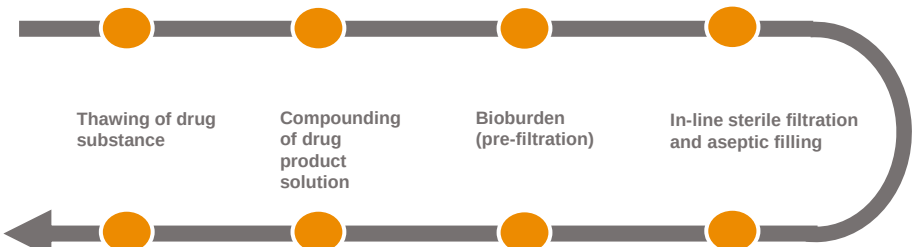
Protein purification
- Cell Disruption
- Protein Release

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

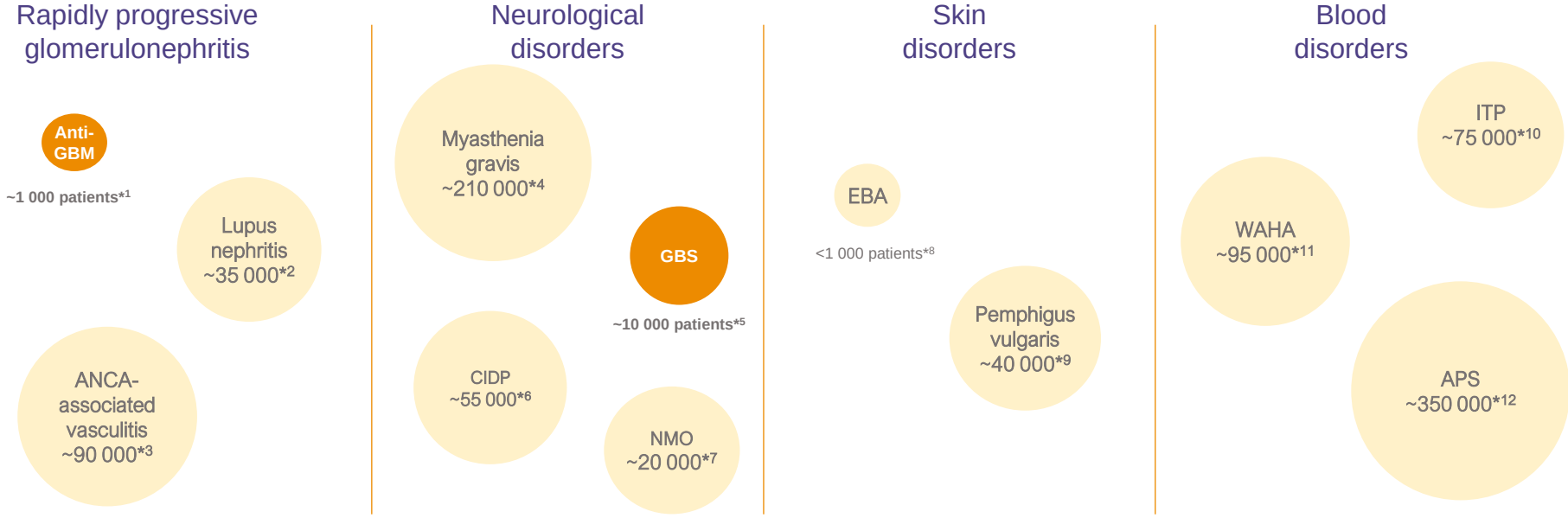
Hansa's antibody cleaving enzyme technology

may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

Clinical programs

Potential autoimmune indications

*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

[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.

Anti-GBM, a rare acute autoimmune disease

Positive read-out from phase 2 study with 2/3 of anti-GBM patients achieving dialysis independence six months after treatment

Anti-GBM

- Indication: Antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM) causing acute injury of kidney and/or lung
- Anti-GBM affects 1.6 in a million people annually with majority of patients losing their kidney function[1,2], requiring chronic dialysis and kidney transplantation
- Phase 2 study concludes that imlifidase leads to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysis independence six months after treatment
- Plans to initiate a Phase 3 study of imlifidase to treat 50 anti-GBM patients following a successful pre-IND meeting with the U.S. FDA. The first patient is expected to be enrolled in 2022
- Our Anti-GBM program obtained Orphan Drug designation from both FDA and European Commission in 2018

1 Kluth et al . J Am Soc Nephrol. 1999 Nov;10(11):2446-53
2 Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

Anti-GBM Phase 2

Imlifidase in Anti-GBM

The idea is that imlifidase in anti-GBM patients may cleave IgG bound to the GBM within a few hours and prevent further renal damage

Today only a fraction of the total IgG antibodies are removed with plasma exchange and IgG in the interstitial tissue and bound to the GBM remains

CLINICALTRIALS.GOV ID

NCT03157037 (Since March 2017)

SUBJECTS

15 patients targeted. Patients will be monitored for six months
Recruitment at 15 clinics

DOSES/FOLLOW UP TIME

Dosage 0.25mg/kg 180 days follow up

MAIN OBJECTTIVES

- Primary objective is to evaluate the safety and tolerability of imlifidase on background of standard of care, and assess efficacy based on renal function at six months after treatment

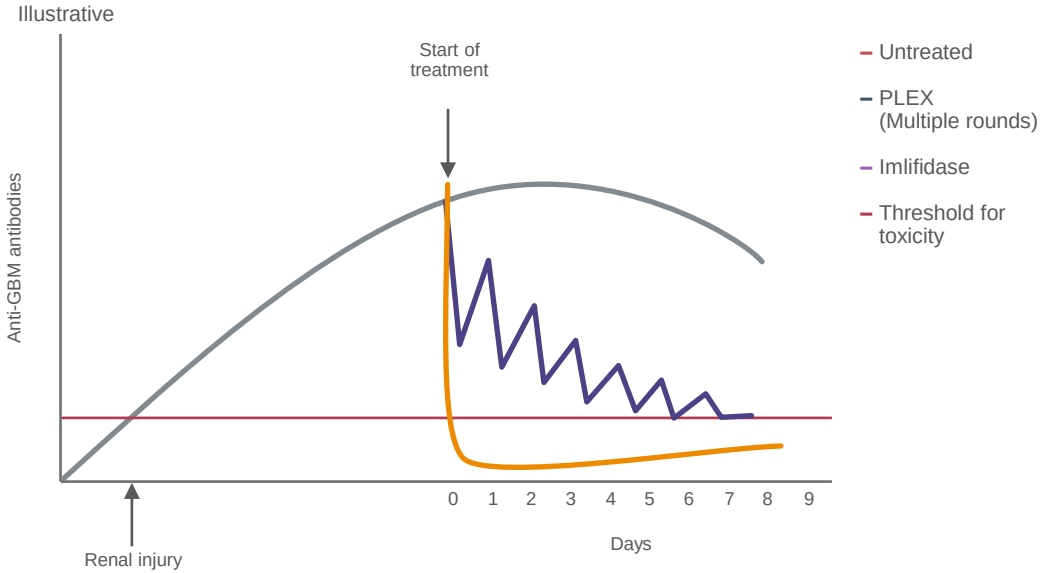
STUDY DESIGN

- Open label, multicenter, single arm Phase 2 study with adverse renal prognosis
- Investigator initiated study

STATUS

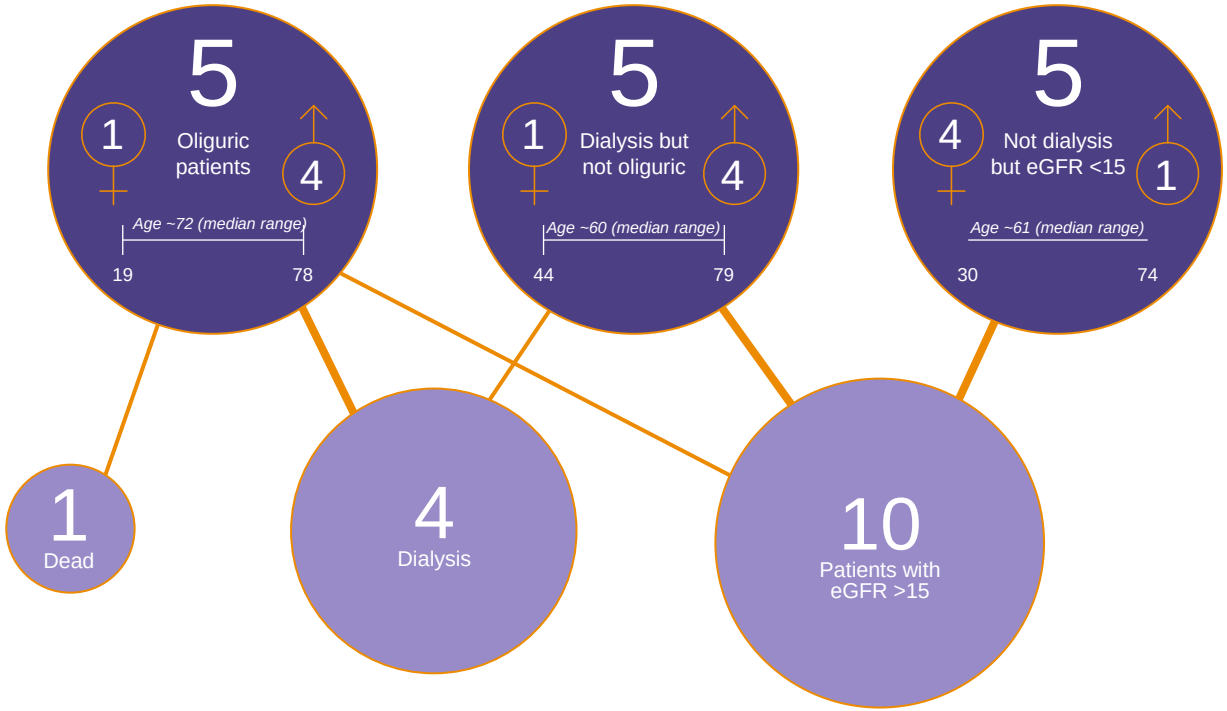
Plans to initiate a Phase 3 study of imlifidase to treat 50 anti-GBM patients (FPI 2022)

Potential of using imlifidase vs. PLEX in anti-GBM



Positive high-level data from Phase 2 study in anti-GBM antibody disease

marks an important milestone for Hansa's expansion of imlifidase outside transplantation with 2/3 of patients achieved dialysis independence six months after treatment



High-level data read out

- Study concludes that imlifidase leads to rapid clearance of anti-GBM antibodies
- 2/3 of patients achieving dialysis independence six months after treatment. Normally 2/3 will lose kidney function and progress into dialysis after six months or die
- Next step: Initiation of Phase 3 study in 2022

Guillain-Barré syndrome

GBS is an acute autoimmune attack on the peripheral nervous system

GBS can affect anyone at any age

- GBS is an acute autoimmune attack on the peripheral nervous system, which rapidly and progressively weakens extremities.
- Only parts of the patients fully recover from GBS, thus a high unmet medical need for new treatments; 40% lose strength and have pain while mortality is 3-7%
- Addressable population of ~10,000[1] per year in 7MM[2]
- Current Standard of Care is treatment with IVIG or PLEX
- The new Phase 2 study is an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg)
- 15/30 patients enrolled. Ongoing recruitment of patients at 10 centers across France, UK and the Netherlands
- Given the difficulty of predicting enrollment, due to the direct and indirect effects of the pandemic, Hansa is currently reviewing its timeline guidance related to the GBS. Update is expected in April, in connection with the publication of its Q1 report
- In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

[1] McGrogan et al. Neuroepidemiology 2009;32(2):150-63.
[2] 7MM = Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

GBS
Phase 2

New Phase 2 study initiated in GBS to evaluate safety, tolerability and efficacy of imlifidase in GBS patients

CLINICALTRIALS.GOV ID

NCT03943589 (2019)

SUBJECTS

30 patients targeted
Recruitment at ten clinics in Europe (France, U.K. and the Netherlands)

DOSES/FOLLOW UP TIME

Dosage 0.25mg/kg follow up 180 days and 12 months

MAIN OBJECTTIVES

- safety and effectiveness of imlifidase in patients diagnosed with GBS

STUDY DESIGN

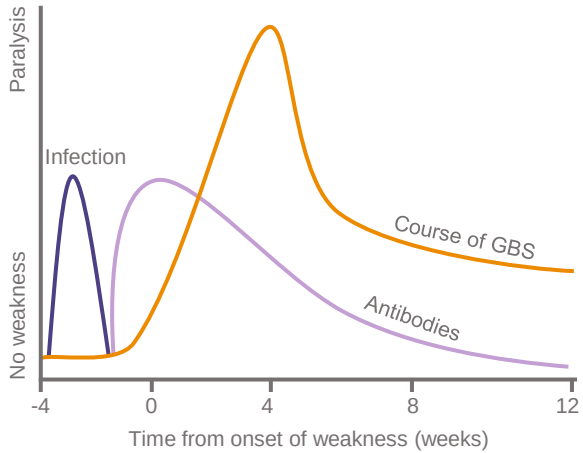
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing recruitment

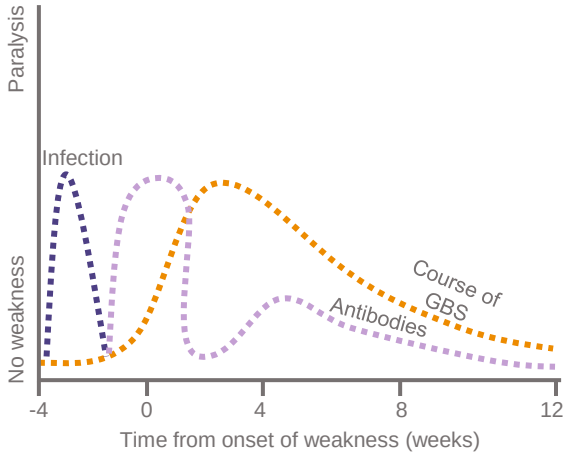
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



HANSA BIOPHARMA

Antibody Mediated Rejection

Long term graft survival is challenged by AMR post transplantation

There is no approved treatment for AMR

- Active antibody mediated rejection after transplantation occurs in ~10% of kidney transplants[1] annually[4] and is a significant challenge to long term graft survival
- Today's standard of care include plasma exchange, and treatment with steroid and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist
- The AMR Phase 2 study is a randomized, open-label, multi-center, active control study designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients.
- 23/30 patient treated with imlifidase in AMR. Ongoing recruitment of patients at 14 centers across the US, Europe and Australia
- A first data read-out is expected in the H1 2022, as previously guided. Guidance assumes no further escalation or sustained negative impact of the COVID-19 pandemic potentially forcing trial centers to reprioritize patient recruitment or even shut down
- First data read out still expected in H2 2022

[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.
[2] Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

AMR Phase 2

Ongoing AMR Phase 2 study

New AMR Phase 2 study initiated to test imlifidase ability to reduce the amount of DSA in AMR patients post transplantation

CLINICALTRIALS.GOV ID

NCT03897205 (2019)

SUBJECTS

30 patients targeted (20 patients will be treated with imlifidase and 10 with Plasma exchange). Recruitment from 11 sites in the U.S., EU and Australia.

DOSES/FOLLOW UP TIME

1 dose of imlifidase (0.25 mg/kg) or 5-10 sessions of plasma exchange

MAIN OBJECTTIVES

- Imlifidase ability to reduce the amount of DSA in comparison with plasma exchange in patients who have an active AMR post transplantation
- Ensure safety for patients

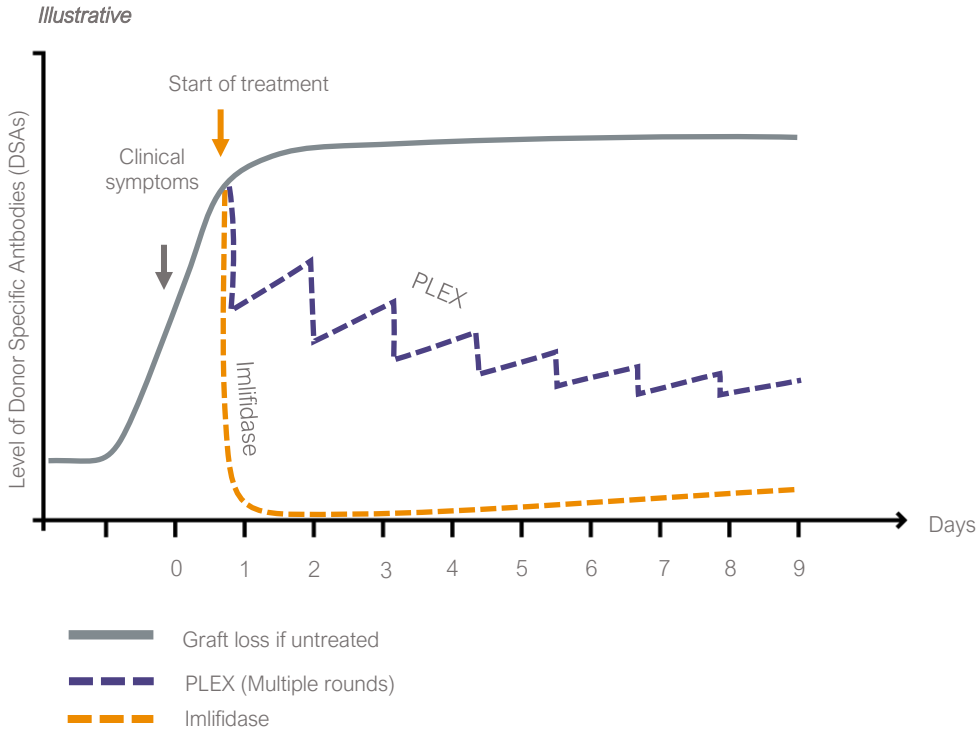
STUDY DESIGN

- Randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

STATUS

Ongoing recruitment

Potential of using imlifidase vs. PLEX in AMR



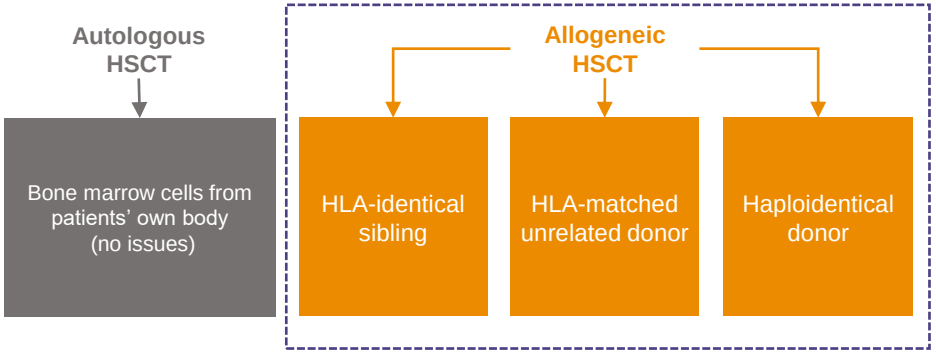
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge; Imlifidase may have the potential to inactivate DSAs prior to transplantation

Transplantations are often acutely needed, which reduces the time available to find an adequately matched donor

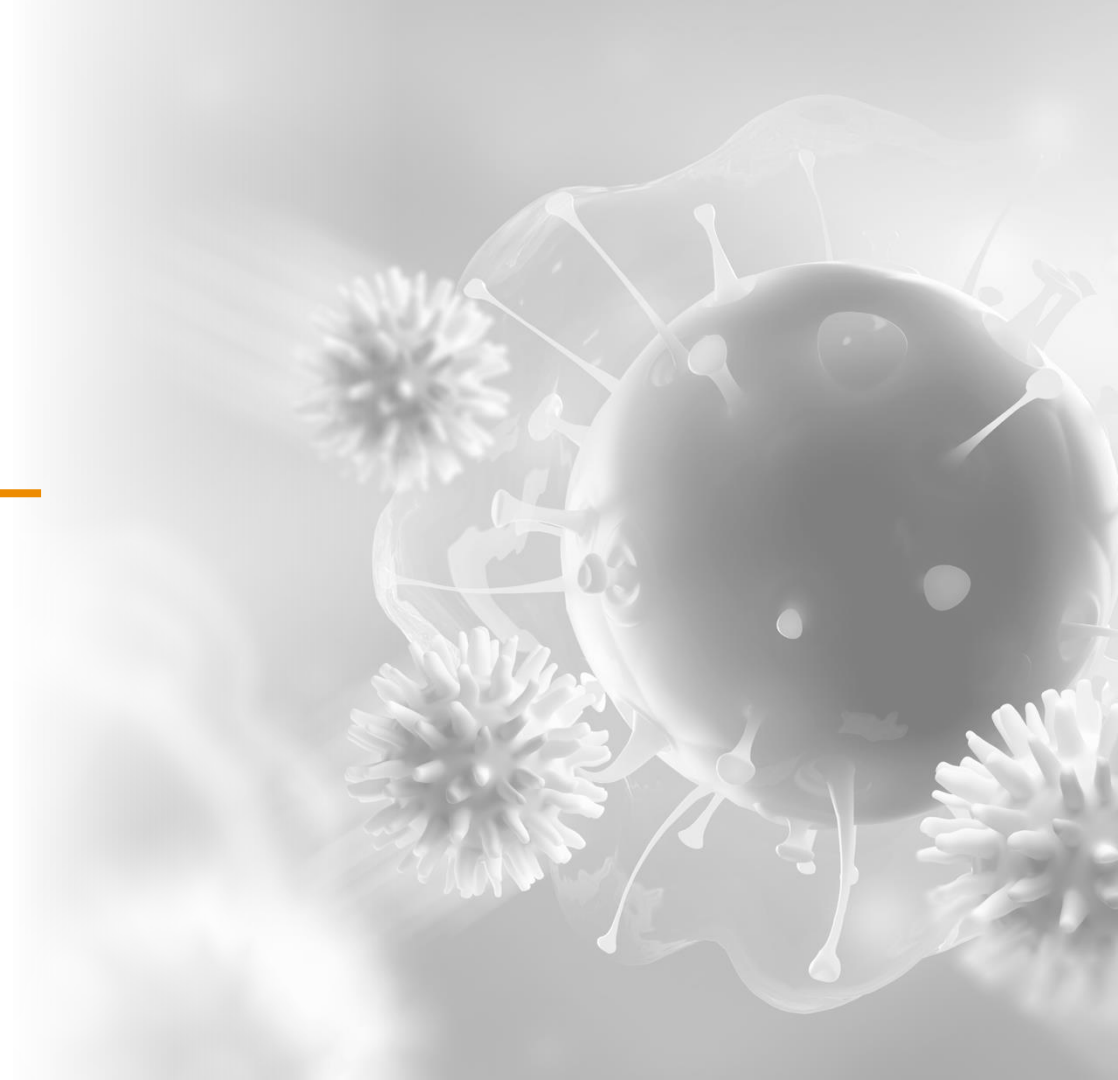
- Haploidentical donors (e.g. parents, children) are often available and transplant outcome is good (e.g. engraftment, graft survival, survival)
- However, presence of donor specific antibodies (DSAs) have a negative impact on transplant outcome[2] (e.g. graft failure and survival) Prevalence of DSAs in allogeneic HSCT is typically between 10-21%[1].
- There are currently no approved drugs to manage patients with high levels of DSAs and current desensitization methods are inadequate, thus preventing patients from having a potentially life-saving HSCT
- Consensus recommendations published[1] by the EBMT[3] on testing, monitoring and treatment of patients with donor specific antibodies recommend to desensitize all patients with DSAs
- Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation

Pre-existing DSAs may result in primary graft failure and poor survival after allogeneic hematopoietic stem cell transplantations

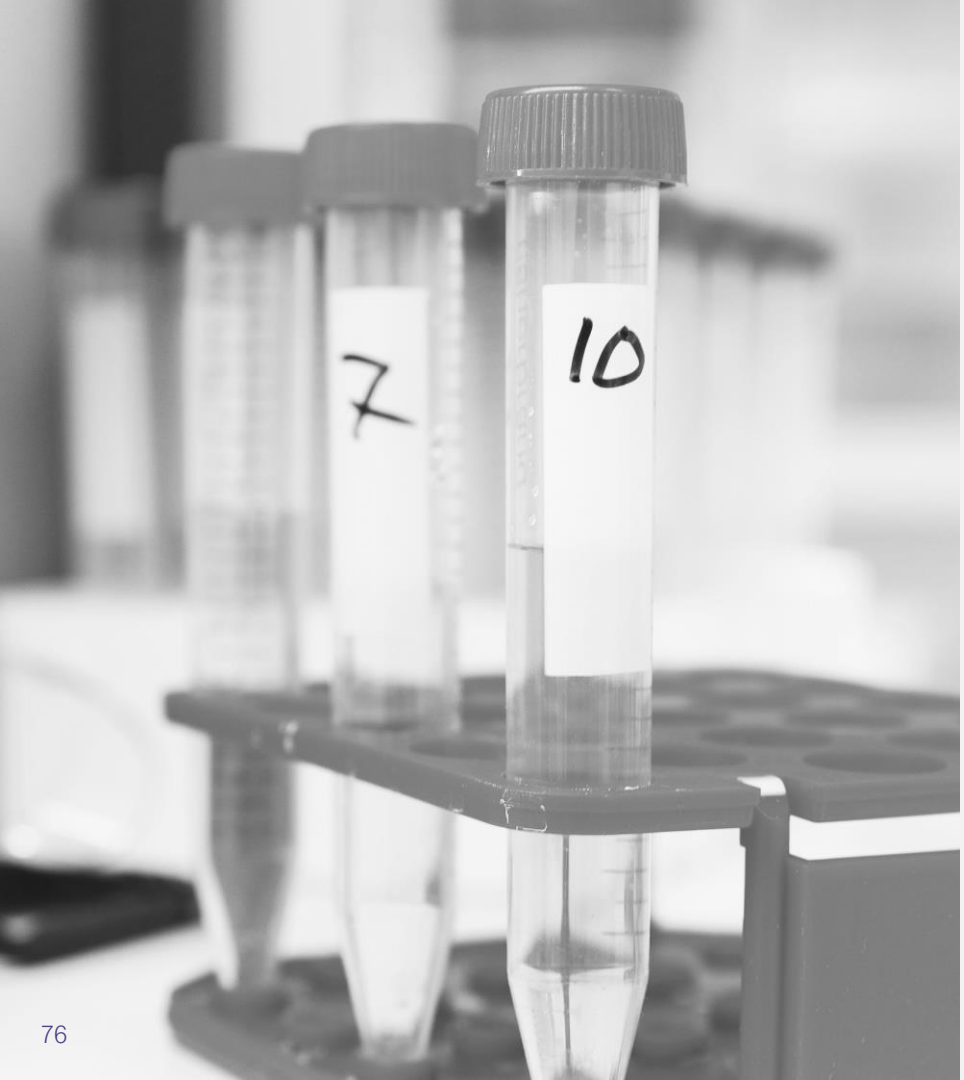


[1] Ciurea et al., Bone Marrow Transplantation, 2018
[2] European Society for Blood and Marrow Transplantation

Pre-clinical programs



HANSA BIOPHARMA



New preclinical collaboration with argenx BV

Collaboration to evaluate the potential combination of companies' IgG-modulating approaches

- A combination of Hansa's IgG antibody-cleaving enzyme, and efgartigimod, argenx's FcRn antagonist could potentially be used in both the acute and chronic setting of autoimmune diseases and transplantation to potentially unlock additional therapeutic value
- Under the agreement, both parties will contribute equally in terms of resource allocation and will share all IP and data developed through the collaboration
- Both parties will maintain exclusive rights to their respective technologies and products.

HANSA BIOPHARMA

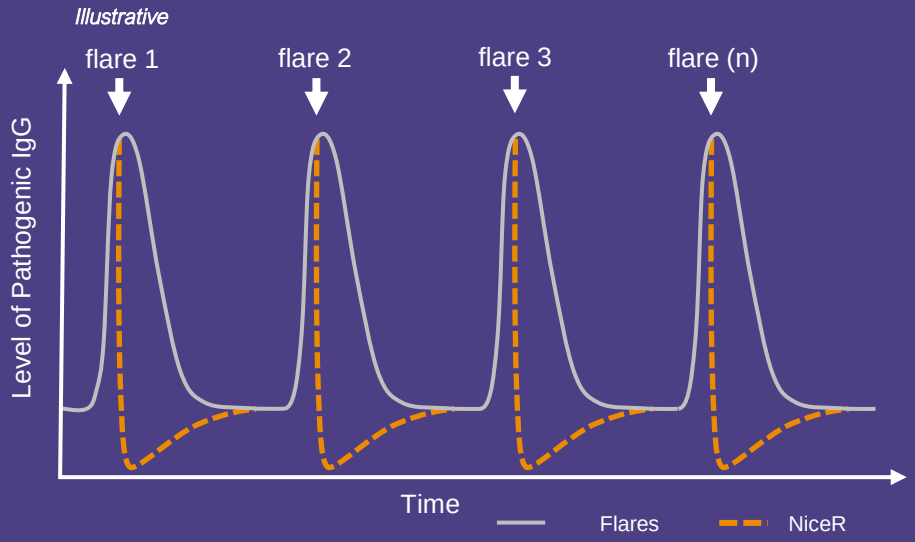
“NiceR” for repeat dosing

a new set of enzymes for repeat dosing for potential inactivation of flares in relapsing diseases

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 and oncology
- The first selected promising new drug candidate from the NiceR program is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with lowered immunogenicity
- IND-enabling tox studies initiated in H1’21. Completion of GLP tox studies in 2022

NiceR can potentially inactivate flares



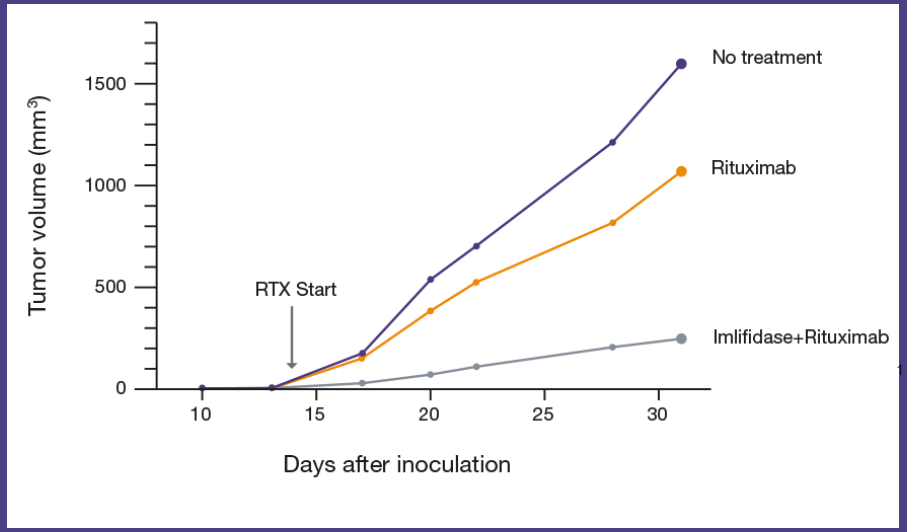
Our antibody cleaving enzymes

may potentially improve the therapeutic effect of immunotherapy in oncology (EnzE)

Proof of concept demonstrated in vivo for mice

- Enzyme based antibody enhancement through pre-treatment
- The abundance of normal IgG in blood interferes with therapeutic monoclonal antibodies
- Pre-treatment with imlifidase / NiceR has potential to significantly potentiate antibody-based cancer therapies
- Suppressive effect of IVIg on effector cell function abrogated by imlifidase
- Imlifidase can significantly improve the therapeutic effect of rituximab

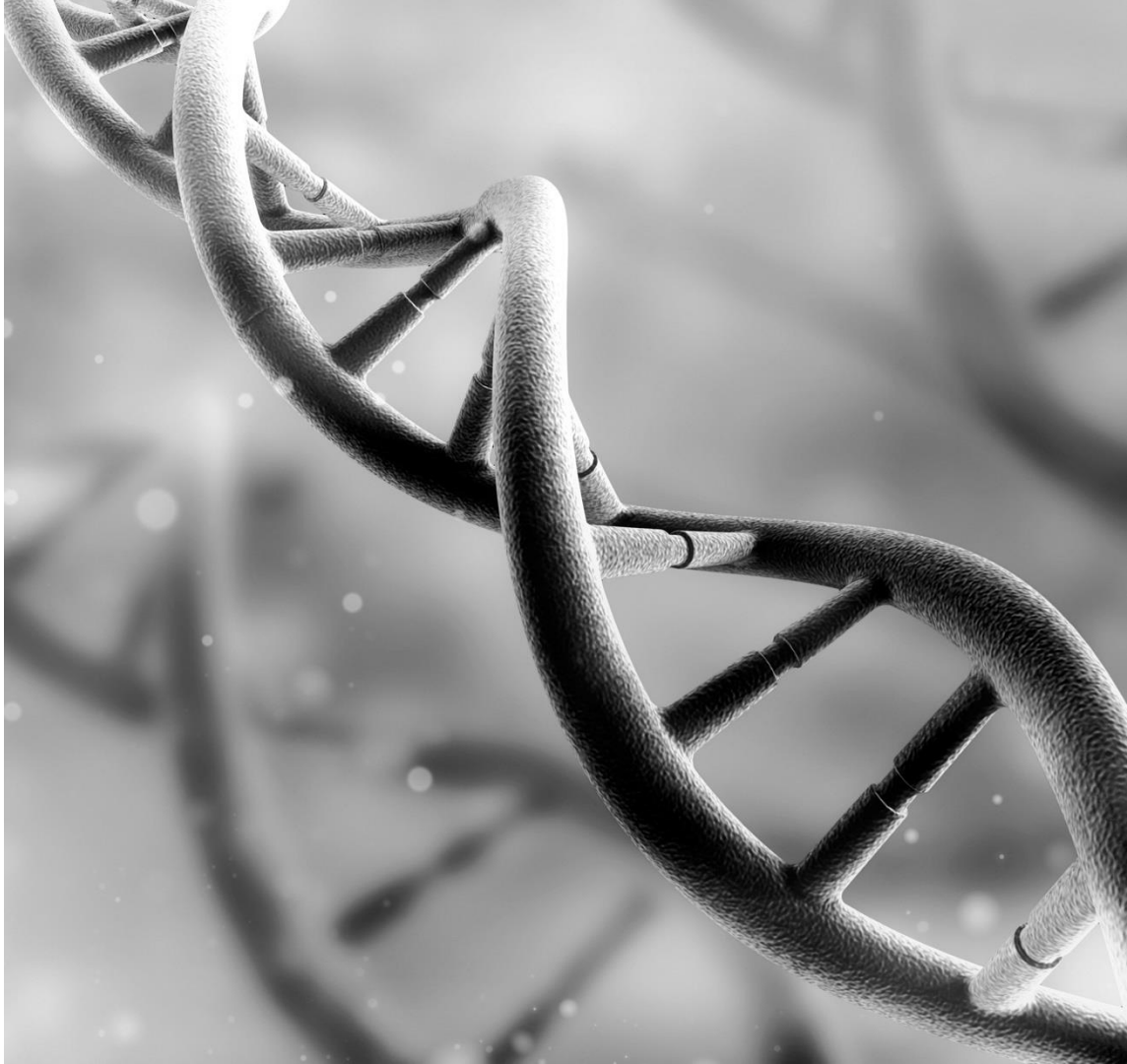
Mice with human IgG (~9mg/mL)



[1] Järnum et al. Mol Cancer Ther 2017;16:1887-1897

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

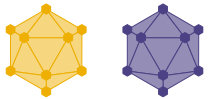
Tropism and target tissue

AAV subtypes targets different tissues

AAV 1, 2 & 5

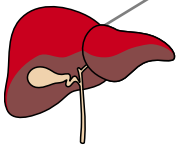
Eye (local target)
~1x10^{11} vg

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

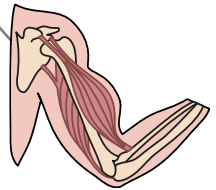


AAV 4 & 8

AAV 3, 7 & 8

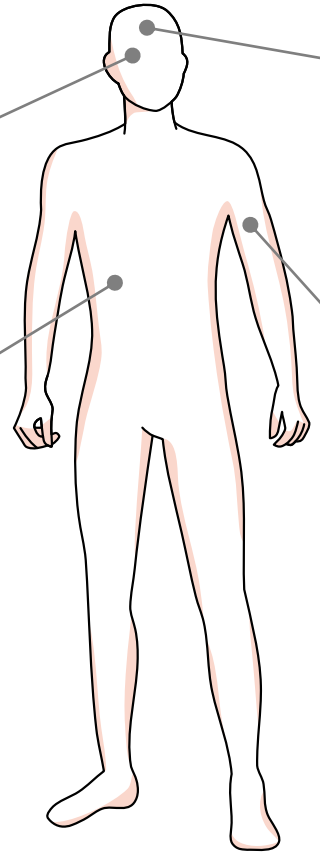


Liver (systemic)
~1x10^{14} vg



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

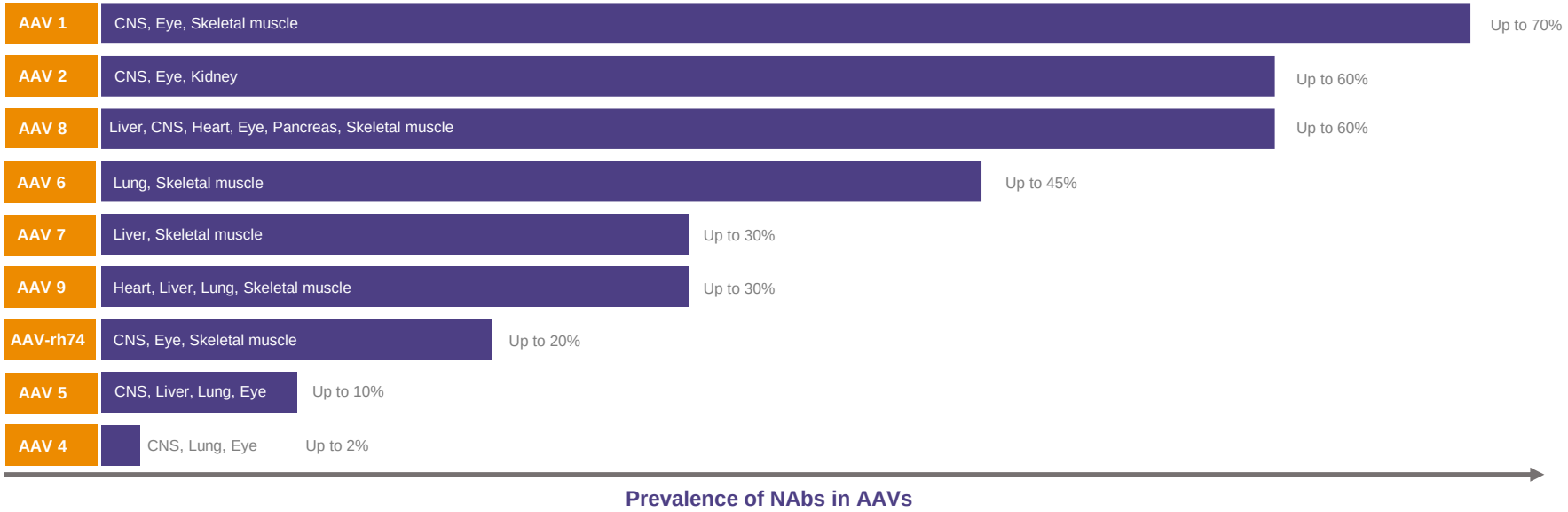
AAV 6, 7, rh74



Target tissues
Dose of gene therapy (vg)

Neutralizing antibodies are a barrier that precludes gene therapies

from working in a large group of patients. The prevalence of NAbs varies significantly across the different vectors



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)

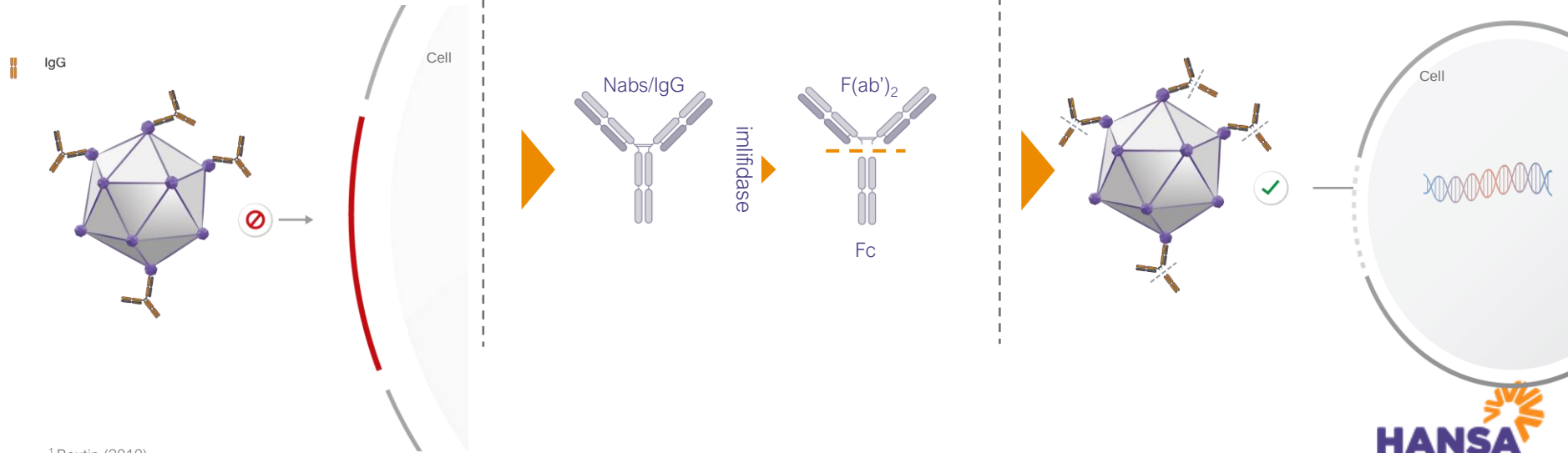
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

Between approximately 5% and 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

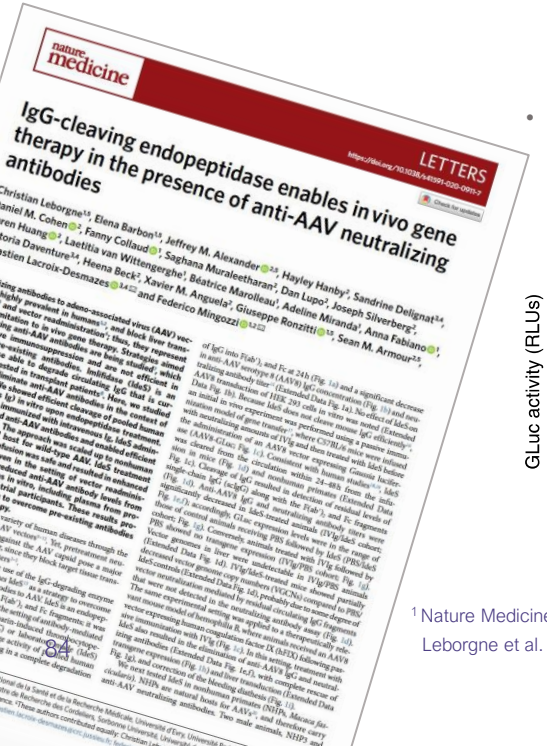
3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



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

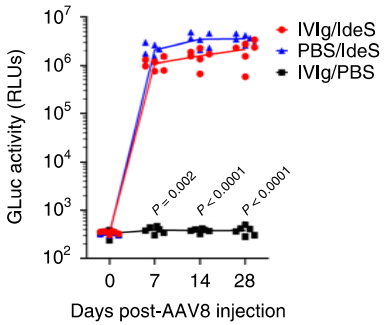
Imlifidase (IdeS) was highlighted in Nature Medicine[1]

with encouraging outcome demonstrating imlifidase as a potential solution to overcome pre-existing antibodies to AAV-based gene therapy



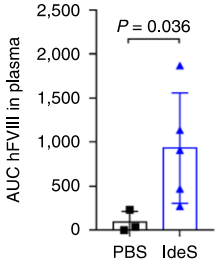
Imlifidase tested in a mouse model

- Imlifidase decreased anti-AAV antibodies and enabled efficient gene transfer



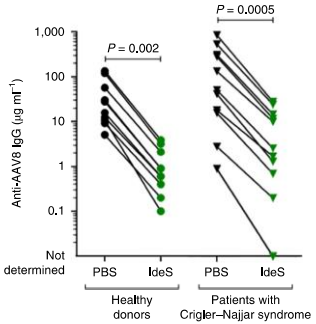
Imlifidase tested in NHP ahead of AAV vector infusion

- Pre-treatment with imlifidase in anti-AAV positive nonhuman primates (NHP) ahead of AAV vector infusion was safe and resulted in enhanced liver transduction and hFVIII plasma levels



Imlifidase tested in human plasma samples (GT patients)

- Imlifidase reduced anti-AAV antibody levels from human plasma samples in vitro, incl. plasma from prospective gene therapy trial participants



[1] Nature Medicine https://doi.org/10.1038/s41591-020-0911-7
Leborgne et al. Nat Med (2020)

HANSA BIOPHARMA

Global and exclusive agreement with Sarepta Therapeutics

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

HANSA BIOPHARMA

HANSA BIOPHARMA

SAREPTA THERAPEUTICS

Indication exclusivity:

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

Hansa's key resources

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

+

Sarepta's key resources

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

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

Antibody cleaving enzyme technology	Preclinical Development	Clinical Development	Regulatory Approvals	Commercialization
HANSA BIOPHARMA	SAREPTA THERAPEUTICS / HANSA BIOPHARMA	SAREPTA THERAPEUTICS / HANSA BIOPHARMA	SAREPTA THERAPEUTICS / HANSA BIOPHARMA	SAREPTA THERAPEUTICS / HANSA BIOPHARMA

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

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

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

HANSA BIOPHARMA

Hansa's key resources and deliverables

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

+

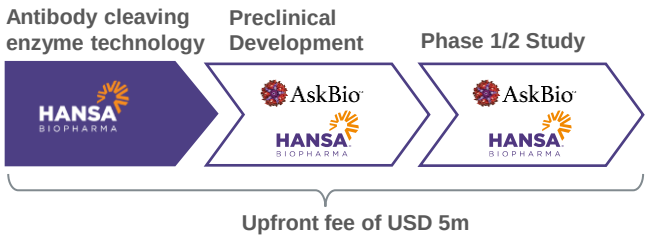
AskBio™

Fully owned subsidiary of Bayer AG

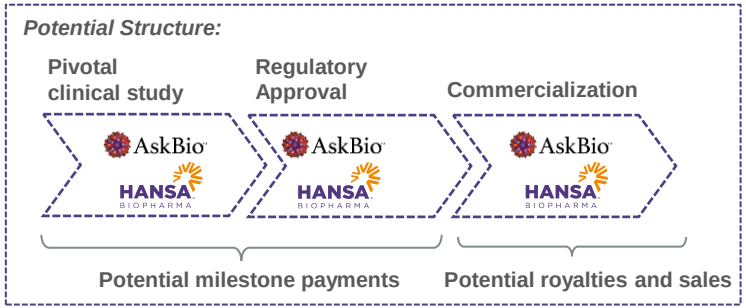
AskBio's key resources and deliverables

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

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



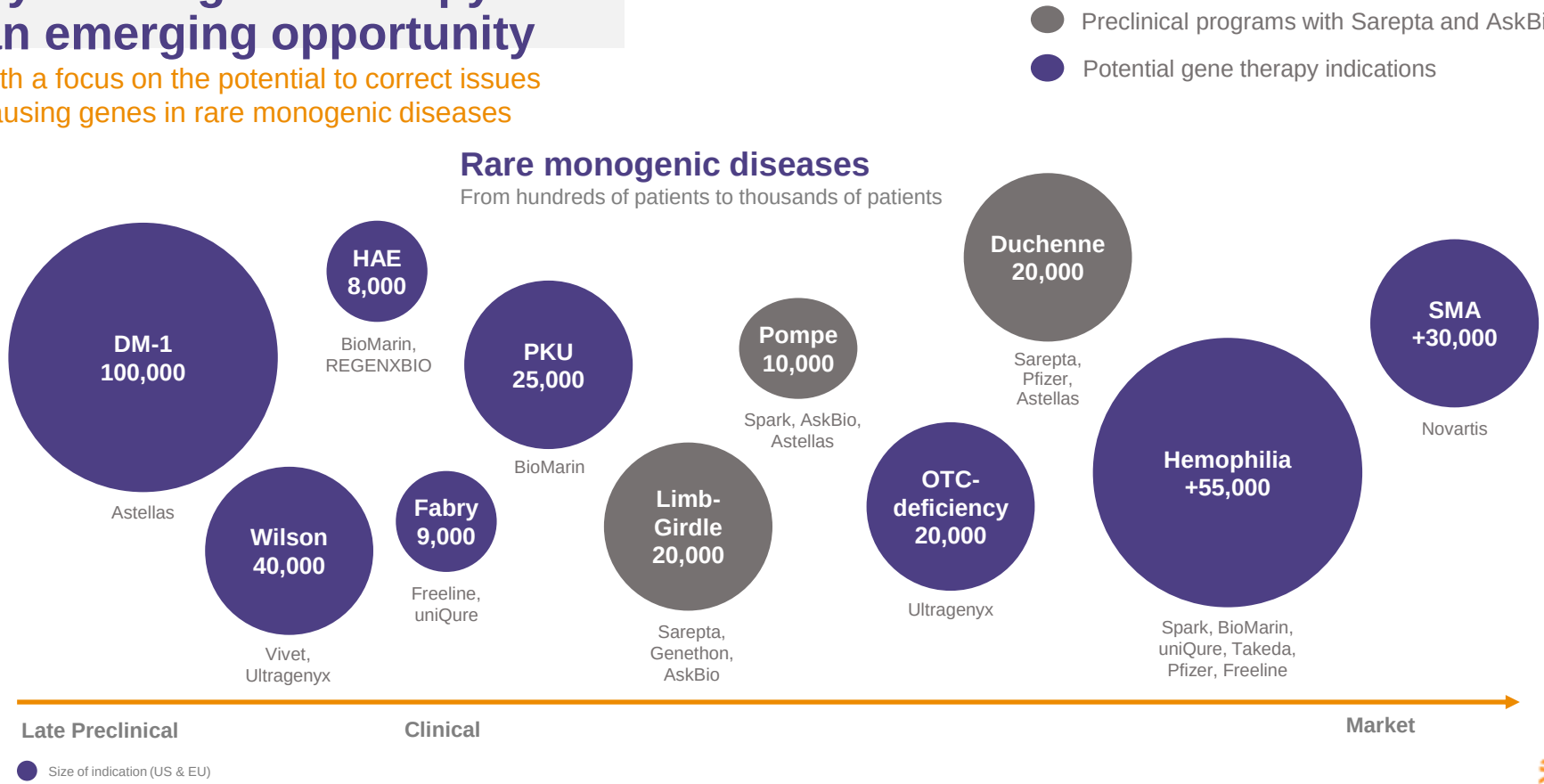
Exclusive option for AskBio to negotiate a potential full development and commercialization agreement



HANSA BIOPHARMA

Systemic gene therapy is an emerging opportunity

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



Duchenne Muscular Dystrophy (DMD) SRP-9001

About Duchenne Muscular Dystrophy (DMD)[1]

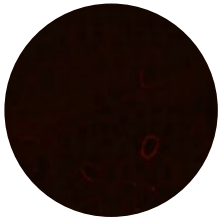
- Rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3 to 5, and most patients use a wheelchair by the time they are 11
- Cardiac and respiratory muscle deterioration becomes life-threatening
- 1/3,500 to 5,000 male births (worldwide)
- Approximately 15% of patients have pre-existing IgG antibodies to rh74

SRP-9001 micro-dystrophin gene therapy for treatment of DMD

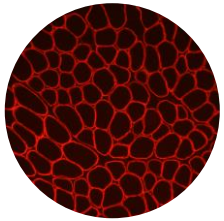
- AAVrh74 vector with micro-dystrophin transgene
- Broad patient experience (77 Duchenne trial participants dosed)
- 4 ongoing clinical trials – including recently initiated pivotal study
- Robust micro-dystrophin protein expression with commercially representative process material
- Functional benefits sustained up to 3 years after administration
- Observed safety profile is consistent

For further information regarding Sarepta's gene therapy programs, please refer to www.sarepta.com

Pre-treatment



Post-treatment



Source:
[1] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad71
[2] National Institutes of Health. Genetics Home Reference. Duchenne and Becker muscular dystrophy. https://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular-dystrophy. Accessed Jan 2020.
[3] Sarepta Therapeutics https://investorrelations.sarepta.com/static-files/e9393c38-646f-45ee-9f56-955f3fbfad7

HANSA BIOPHARMA

Limb-Girdle muscular dystrophy (LGMD) SRP-9003

About limb-girdle muscular dystrophy

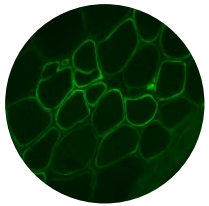
Limb-girdle muscular dystrophy is a group of diseases that cause weakness and wasting of
the muscles

- Caused by defects in genes encoding for proteins residing within the sarcolemma, cytosol or nucleus of the muscle cell
- LGMD subtypes are often grouped according to which protein is affected
- Approximate global prevalence of 1.63 per 100,000 individuals; over 30 subtypes exist
- Approximately 15% of patients have pre-existing IgG antibodies to rh74

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

- AAVrh74 vector with transgene β-sarcoglycan
- Open label study ongoing (N=6)
- Interim analysis disclosed in May 2021[2]:
  - Two dosing cohorts
    - Cohort 1 (n=3) - 1.85 × 10^{13} vg/kg; 2-year follow-up
    - Cohort 2 (n=3) - 7.41 × 10^{13} vg/kg; 1-year follow-up
  - No new safety signals, and treatment-related AEs occurred early and were transient and manageable
  - Robust, dose-dependent SGCB protein expression in all patients at Day 60, resulting in reconstitution of the sarcoglycan complex; SGCB expression sustained up to 2 years in cohort 1
  - Demonstrated functional improvements, including both NSAD and timed function tests, compared to baseline that were sustained for 2 years in cohort 1 and 1 year in cohort 2

β-sarcoglycan



For further information regarding Sarepta's gene therapy programs, please refer to www.sarepta.com

*Doses are based on titer method using supercoiled plasmid standard

Source:
1) National Institutes of Health. Genetics Home Reference. Duchenne and Becker muscular dystrophy. https://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular-dystrophy. Accessed Jan 2020.
2) Rodino-Klapac et al. Presented at the annual meeting of the American Society of Cell and Gene Therapy May 11-14, 2021

HANSA BIOPHARMA

ESG Overview

HANSA BIOPHARMA

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

HANSA BIOPHARMA

Ownership in Hansa Biopharma

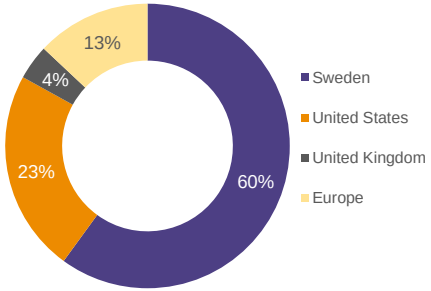
Top 10 ownership as per December 31, 2021

Name	No. of shares	Ownership in pct.
Redmile Group, LLC	5 768 619	13.0
Handelsbanken Asset Management*	2 266 350	5.1
Fjärde AP-Fonden (AP 4)	2 207 397	4.9
Nexttobe AB	2 155 379	4.8
Invesco Advisers, Inc.	1 973 200	4.4
Olausson, Thomas	1 820 500	4.1
Tredje AP-Fonden (AP 3)	1 389 650	3.1
Försäkrings AB Avanza Pension	1 232 081	2.8
Schroder Investment Management, LTD	1 160 900	2.6
The Vanguard Group, Inc.	1 158 200	2.6
Other	23 341 176	52,6
Outstanding A shares in total	**44 473 452**	**100.0**

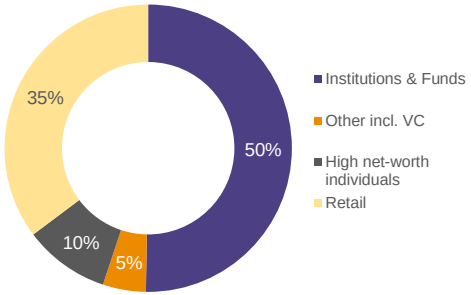
**Handelsbanken Asset Management decreased their ownership to under 5% during January 2022*

Classification of ownership as per Dec 31, 2021

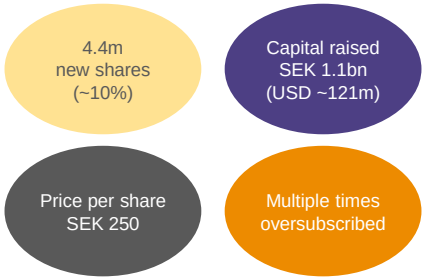
Ownership by country



Ownership by type

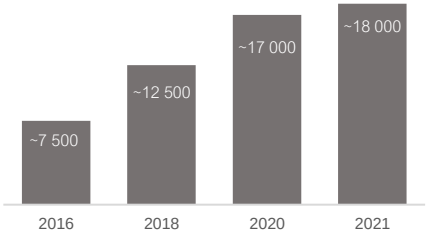


Capital Raise July 2020



High demand from US and European investors incl. Redmile, Consonance, HBM and Fonden TIN Ny Teknik

No. of shareholders



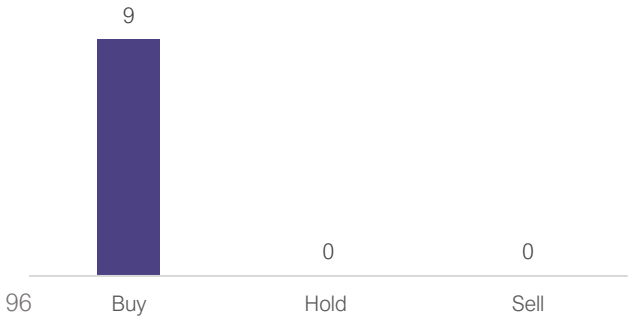
Company collected consensus

Consensus is based on a collection of analyst estimates pre our Q4 2021 report (February 3, 2022)

			Patient uptake, EU			Revenue, SEKm		
	Price Target, SEK	WACC	FY'22e	FY'23e	FY'24e	FY'22e	FY'23e	FY'24e
Average	276	10,3%	28	66	162	98	176	396
Median	290	10,0%	22	60	111	83	189	394
High	385	12,5%	78	173	497	191	348	661
Low	150	8,0%	3	11	24	29	48	133
Number of contributions	9	9	9	9	8	9	9	8

	EBIT, SEKm			Operating Cash Flow, SEKm			Cash position, SEKm		
	FY'22e	FY'23e	FY'24e	FY'22e	FY'23e	FY'24e	FY'22e	FY'23e	FY'24e
Average	-564	-576	-465	-563	-550	-481	577	260	-136
Median	-580	-578	-562	-576	-573	-500	313	200	42
High	-440	-450	516	-439	-241	428	1 788	1 531	881
Low	-685	-700	-990	-671	-725	-1 027	92	-481	-966
Number of contributions	9	9	8	9	9	7	9	8	5

Analyst recommendations



Bank/Research Institution	Analyst	Location	E-mail
SEB	Christopher Uhde, PhD	Stockholm	christopher.uhde@seb.se
ABG Sundal Collier	Adam Karlsson	Stockholm	adam.karlsson@abgsc.se
Carnegie	Erik Hultgård	Stockholm	erik.hultgard@carnegie.com
Redeye	Johan Unnerus	Stockholm	johan.unnerus@redeye.se
RBC	Zoe Karamanoli	London	zoe.karamanoli@rbccm.com
Kempen	Ingrid Gafanhao	Amsterdam	ingrid.gafanhao@kempen.com
Intron Health Research	Naresh Chouhan	London	naresh@intronhealthresearch.com
Ökonomiskt Ugebrev	Lars Hatholt	Copenhagen	hatholt@outlook.com
Danske Bank	Caroline Banér	Stockholm	caroline.baner@danskebank.se
Erik Penser Bank	Ludvig Svensson	Stockholm	ludvig.svensson@penser.se
H.C. Wainwright	Douglas Tsao	New York	dtsao@hcwresearch.com

Corporate Contacts

Investor Relations and Corporate Communications

Visit our web site
www.hansabiopharma.com

Klaus Sindahl

Head of Investor Relations

Mobile: +46 (0) 709-298 269

Email: klaus.sindahl@hansabiopharma.com

Katja Margell

Head of Corporate Communications

Mobile: +46 (0) 768-198 326

Email: katja.margell@hansabiopharma.com

Calendar and events

Feb 3 2022	Year-End report for Jan - Dec 2021
Mar 10 2022	Erik Penser Bolagsdag, Stockholm
Mar 10 2022	Redeye Investor Forum, Gothenburg
Mar 15 2022	Carnegie Healthcare Seminar 2022, Stockholm
Mar 31 2022	Redeye Investor Forum, Malmö
April 7 2022	Annual Report 2021
April 21 2022	Interim Report for January-March 2022
April 21 2022	Kempen Life Sciences Conference 2022, Amsterdam
April 27 2022	Redeye Orphan Drugs 2022, Stockholm
May 2022	RBC Global Healthcare Conference 2022, New York City
May 18 2022	ABG ABGSC Life Science Summit 2022, Stockholm
June 16 2022	Annual General Meeting 2022
July 21 2022	Half year 2022 report
Oct 20 2022	Interim Report for January-September 2022

HANSA BIOPHARMA


HANSA
BIOPHARMA