HANSA BIOPHARMA

Investor Road Show Presentation Q4 2022

Lund, February 2 2023

Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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HANSA BIOPHARMA

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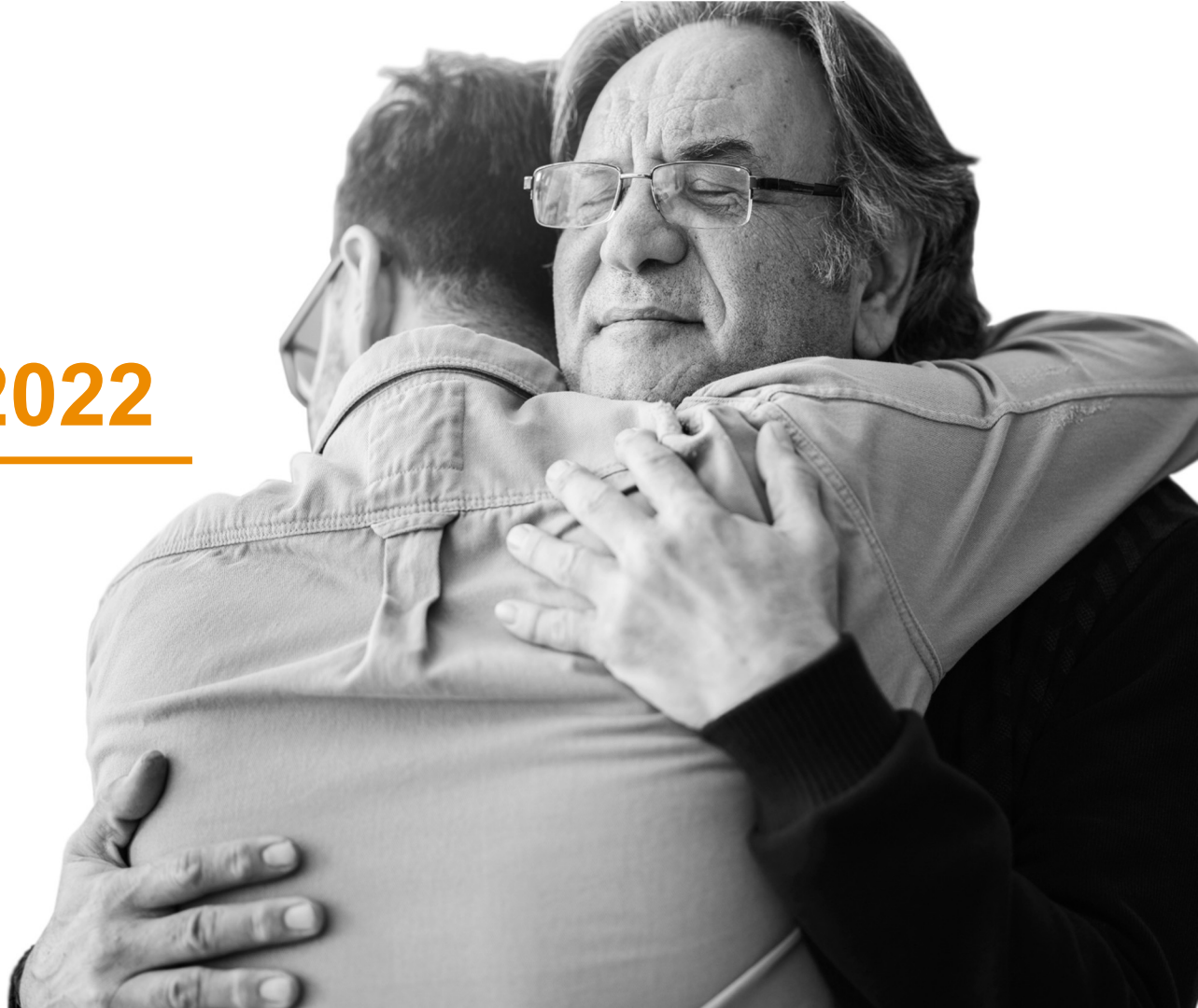
HANSA BIOPHARMA

Business update Q4’2022



HANSA BIOPHARMA

Total 2022 revenue of SEK 155m; Cash runway extended into 2025; Market Access secured in Italy and Czech Republic; Reported positive Phase 2 top-line data in AMR

Highlights for the fourth quarter of 2022

✓ Idefirix launch in Europe is progressing as planned

- Total Q4 revenue of SEK 31m including SEK 20m in product sales and SEK 11m under our agreements with Sarepta and AskBio
- Positive reimbursement decisions received in Italy and Czech Republic; Market access secured in 11 European countries and procedures are ongoing in nine countries including Spain
- U.K. imlifidase guidelines published by British Transplant Society; Guidelines in line with the NICE and SMC recommendations, from patient selection to transplant and post-transplant patient management and protocols
- Distribution agreement signed with iQone Healthcare to cover Switzerland

✓ Clinical and pre-clinical pipeline

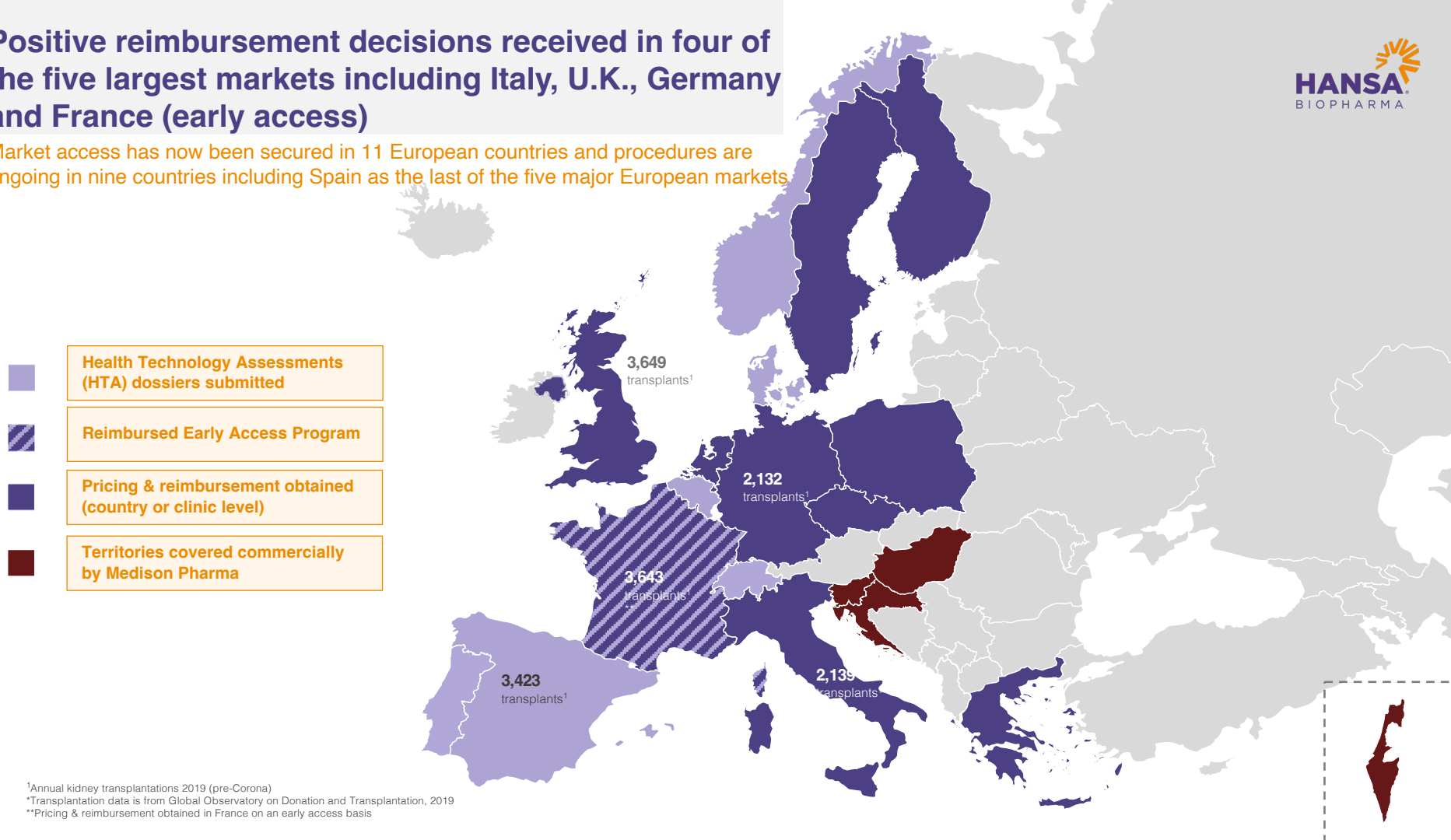
- AMR: Positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation
- Anti-GBM: First sites initiated in the pivotal global phase 3 study
- GBS: 25/30 patients enrolled in the GBS phase 2 study; Completion of enrollment in the GBS trial is anticipated for H1 2023, as previously guided
- U.S. ConfIdeS study: 51/64 patients enrolled; Hansa expect to further increase the enrollment capacity to accelerate the study. Based on this, Hansa aims to completion of enrollment in H1 2023, while completion of randomization is expected in H2 2023. BLA submission is expected in 2024 as previously guided
- NiceR: IND enabling tox studies completed; A Clinical Trial Application was approved to initiate clinical study in the first half of 2023
- Plans to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023

✓ $40 million raised in direct share issue; Cash runway extended into 2025

- Transaction targeting U.S. and other international healthcare specialist investors

Positive reimbursement decisions received in four of the five largest markets including Italy, U.K., Germany and France (early access)

Market access has now been secured in 11 European countries and procedures are ongoing in nine countries including Spain as the last of the five major European markets



[1]Annual kidney transplantations 2019 (pre-Corona)
*Transplantation data is from Global Observatory on Donation and Transplantation, 2019
**Pricing & reimbursement obtained in France on an early access basis

Continuous progress in our ongoing clinical programs

Enrollment status
Feb 1, 2023

Antibody Mediated Rejection Phase 2 study

- 30/30 patients enrolled in the AMR phase 2 study
- Data readout demonstrates a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange (SoC) in the five days following the start of the treatment
- Full data read out expected H2 2023, which will determine the path forward for imlifidase in patients with active AMR

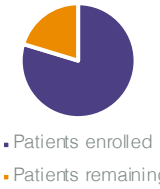
Guillain-Barré Syndrome Phase 2 study

- 25/30 patients enrolled in the GBS program
- 10 centers are active and open for recruitment;
- Aim to complete enrollment of GBS patients H1 2023, as previously guided
- Aim to communicate first high-level data read out in H2 2023

Enrollment status
Feb 1, 2023

Anti-GBM Phase 3 study

- New pivotal Phase 3 study initiated in first sites in the U.S. and U.K end of 2022 as previously guided
- Open-label, randomised controlled study targeting 50 patients to be treated to with imlifidase and SoC or SoC, alone
- Kidney function will be evaluated as the primary endpoint
- First patient expected to be dosed H1 2023



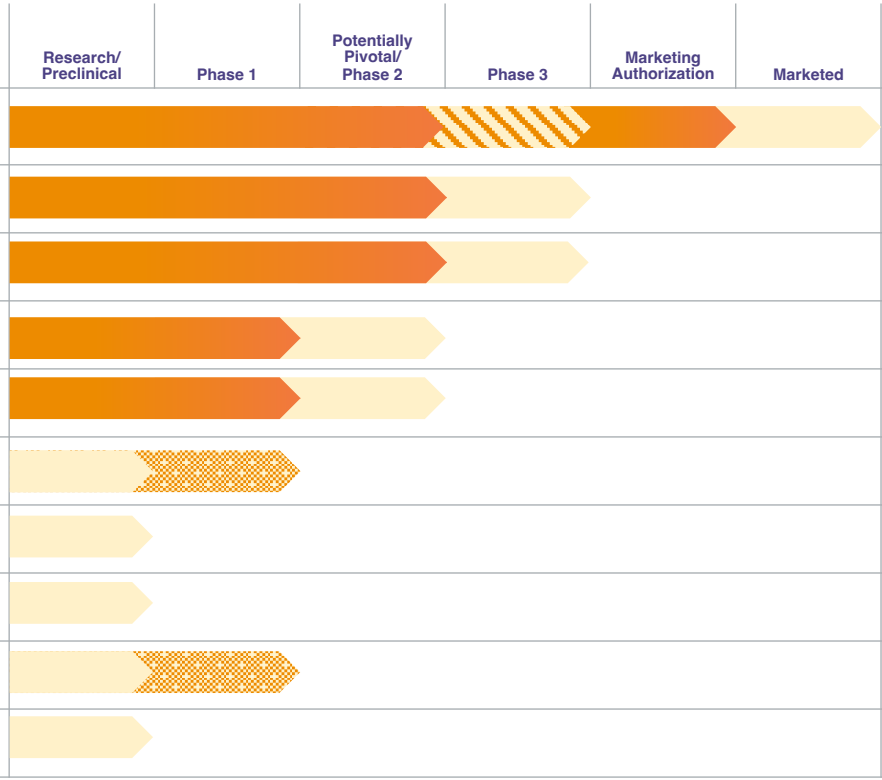
U.S. ConfIdeS Phase 3 study

Randomized, controlled trial in highly sensitized kidney transplant patients

- 51/64 patients enrolled for randomization
- 13 centers active and open for recruitment; continuously adding new clinics, with a goal of at least 20, to further increase enrollment capacity.
- Expect to complete enrollment H1 2023 and complete randomization in H2 2023
- BLA submission is expected in 2024 under the accelerated approval path, as previously guided

Broad clinical pipeline in transplantation and auto-immune diseases

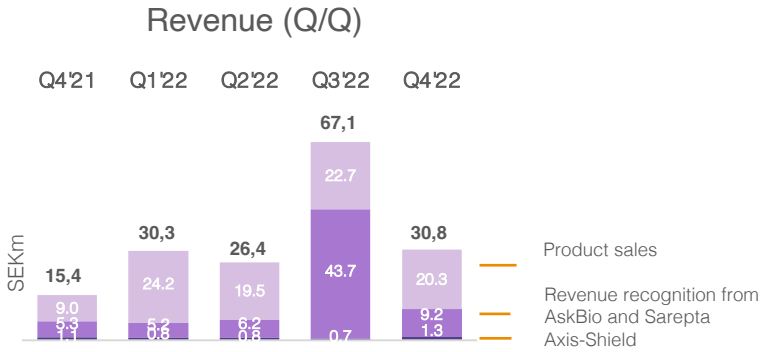
Candidate/ Project	Indication	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]	EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients[1,2]	Completion of enrollment (64 patients) H1 2023
	Anti-GBM antibody disease[3]	First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)	Completion of enrollment (30 patients) H1'23
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Preclinical research
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
EnzE	Cancer immunotherapy	Research

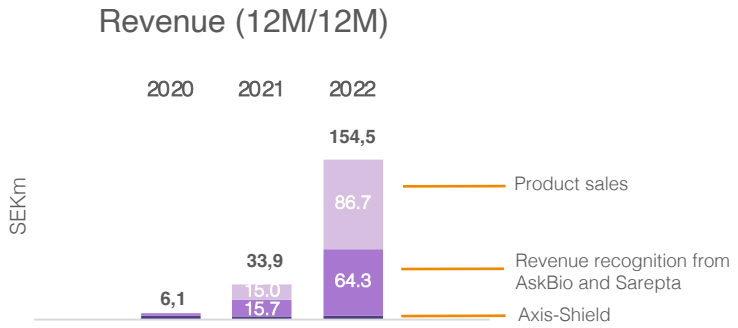


[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7)
[2] Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)
[3] Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping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

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

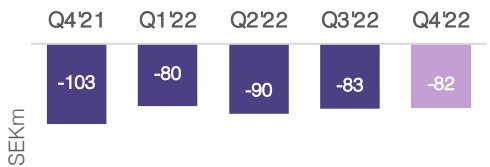
Total 2022 revenue of SEK 155m; Q4 2022 Revenue amounted to SEK 31m including SEK 20m in product sales



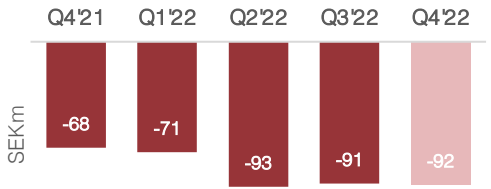


For 2022 SG&A amounted to SEK 336m, while R&D costs amounted to SEK 346m, as Hansa continues to invest in commercial and pipeline activities

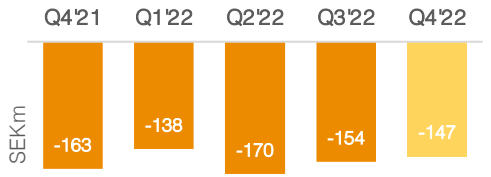
SG&A expenses (Q/Q)



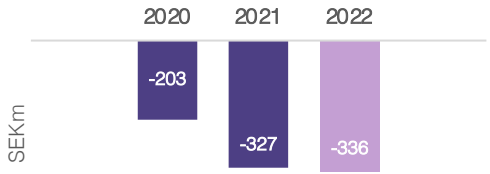
R&D expenses (Q/Q)



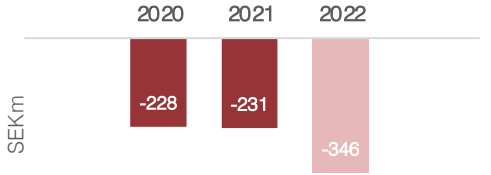
Net loss (Q/Q)



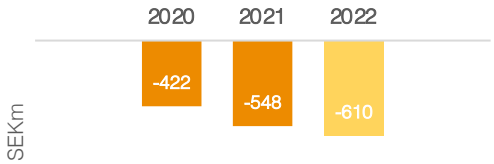
SG&A expenses (12M/12M)



R&D expenses (12M/12M)

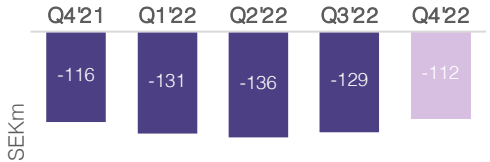


Net loss (12M/12M)

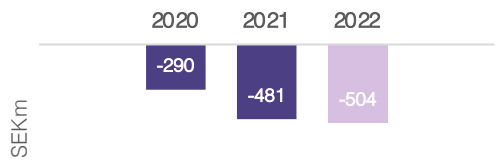


Hansa's cash runway now extends into 2025 as a result of a non-dilutive debt-financing of USD ~70m in July 2022 and an equity financing of USD ~40m in December 2022

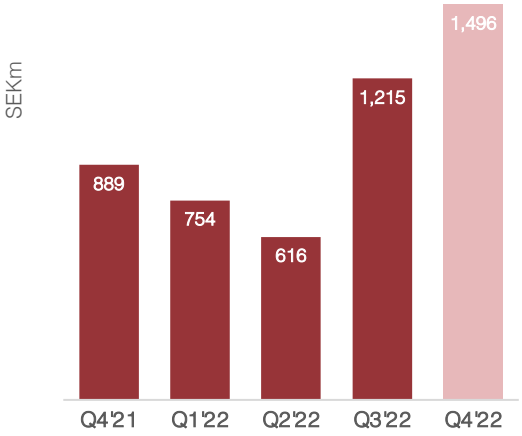
Operating cash flow (Q/Q)



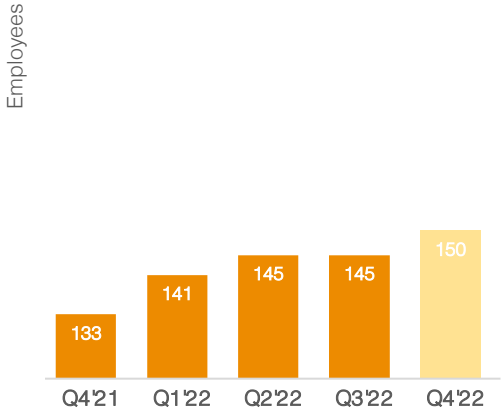
Operating cash flow (12M/12M)



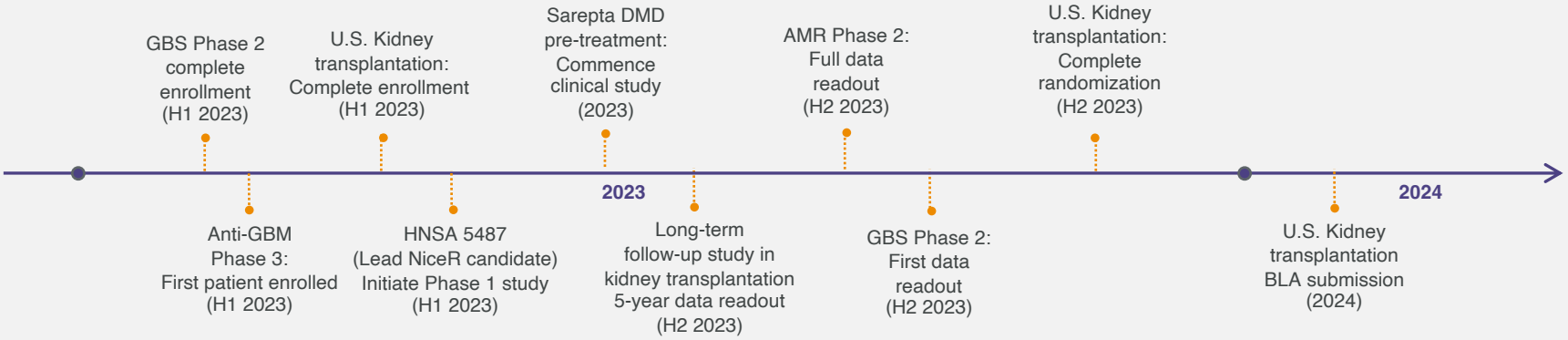
Cash & short-term investments (Q/Q)



Number of employees (Q/Q)



Near term milestones



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

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

150 employees Dec 31. 2022 (~3x in 3 years)

Highly qualified team with 20 years on average in life science

Purpose driven culture

With current cash position Hansa is financed into 2025

FINANCIALS

SEK ~1.5bn in Cash and short term investments (USD ~143m) December 2022

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~350 Feb 1, 2023

Listed on Nasdaq Stockholm
19,000 shareholders
Foreign ownership make up ~47% 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 and conditions 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

IPO
October 2007
39 SEKm
valuation

Pre-clinical proof-of-concept established

Imlifidase GMP process development and toxicology studies initiated

2. Clinical development

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

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

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

Market access secured in nine countries

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

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

1. Turning foe into friend

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

First-in-man study

First Ph. II study of imlifidase in kidney transplantation

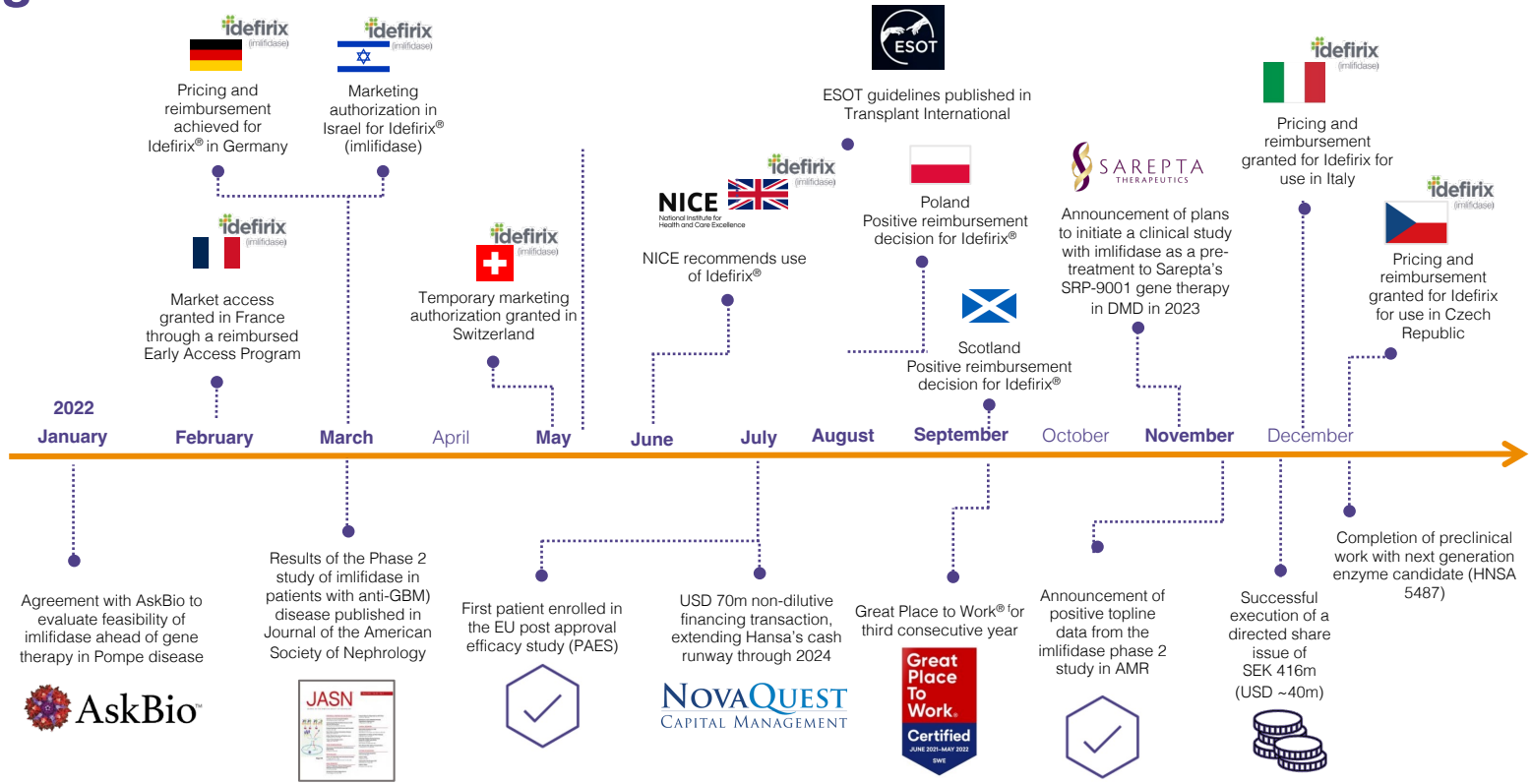
Starts trading on NASDAQ Stockholm main board

3. Commercialization

In august **2020**, Hansa received conditional approval for Idefirix (imlifidase) in kidney transplantation. Additionally, Hansa entered into the gene therapy field through a commercial partnership with Sarepta Therapeutics. Thus far, Hansa achieved market access in the first 7 European markets incl. UK, Germany and France (early access). Market Acces procedures are ongoing in 11 additional countries

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

Many milestones achieved during 2022



Imlifidase

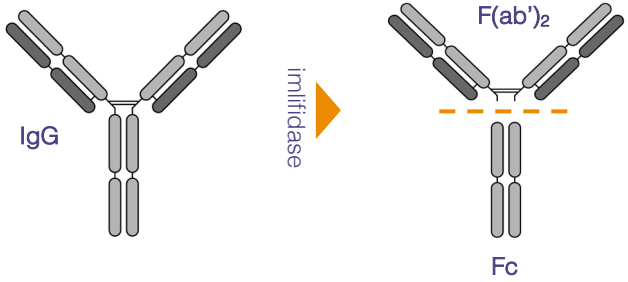
a novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

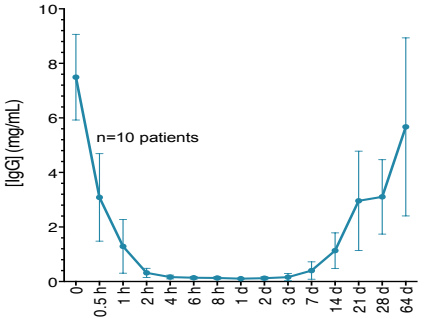
A unique IgG antibody-cleaving enzyme

- 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



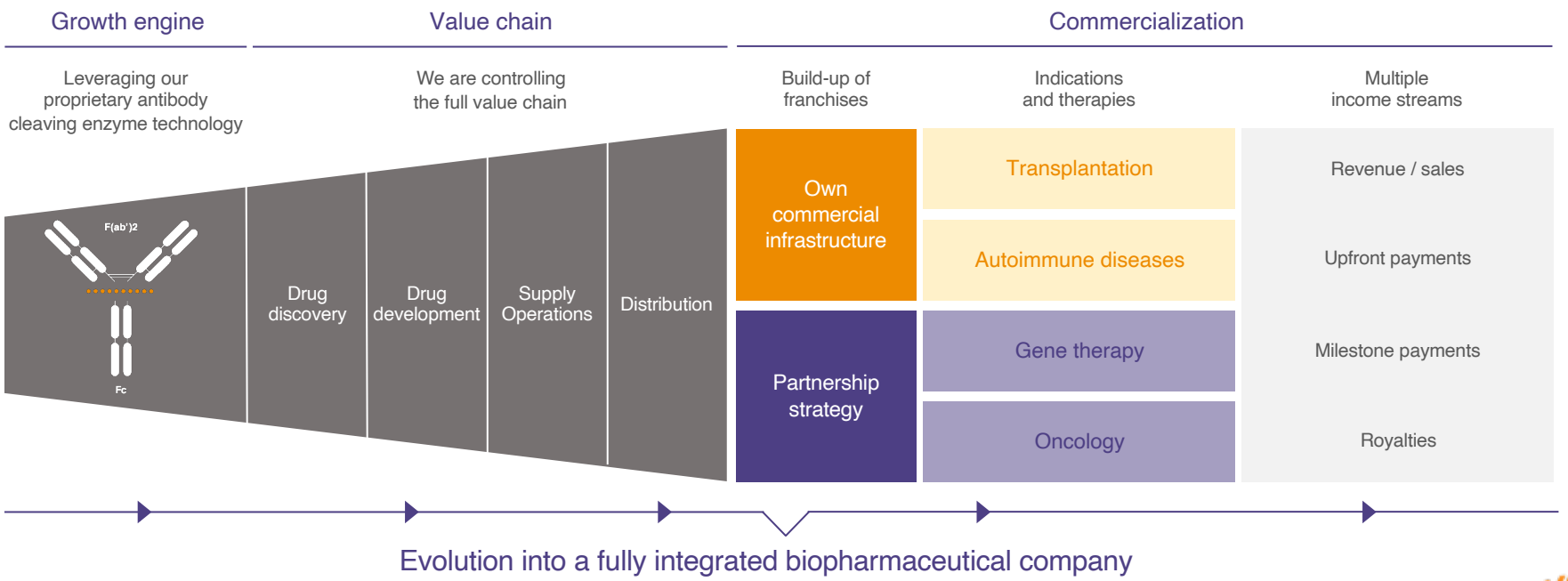
Inactivates IgG in 2-6 hours

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

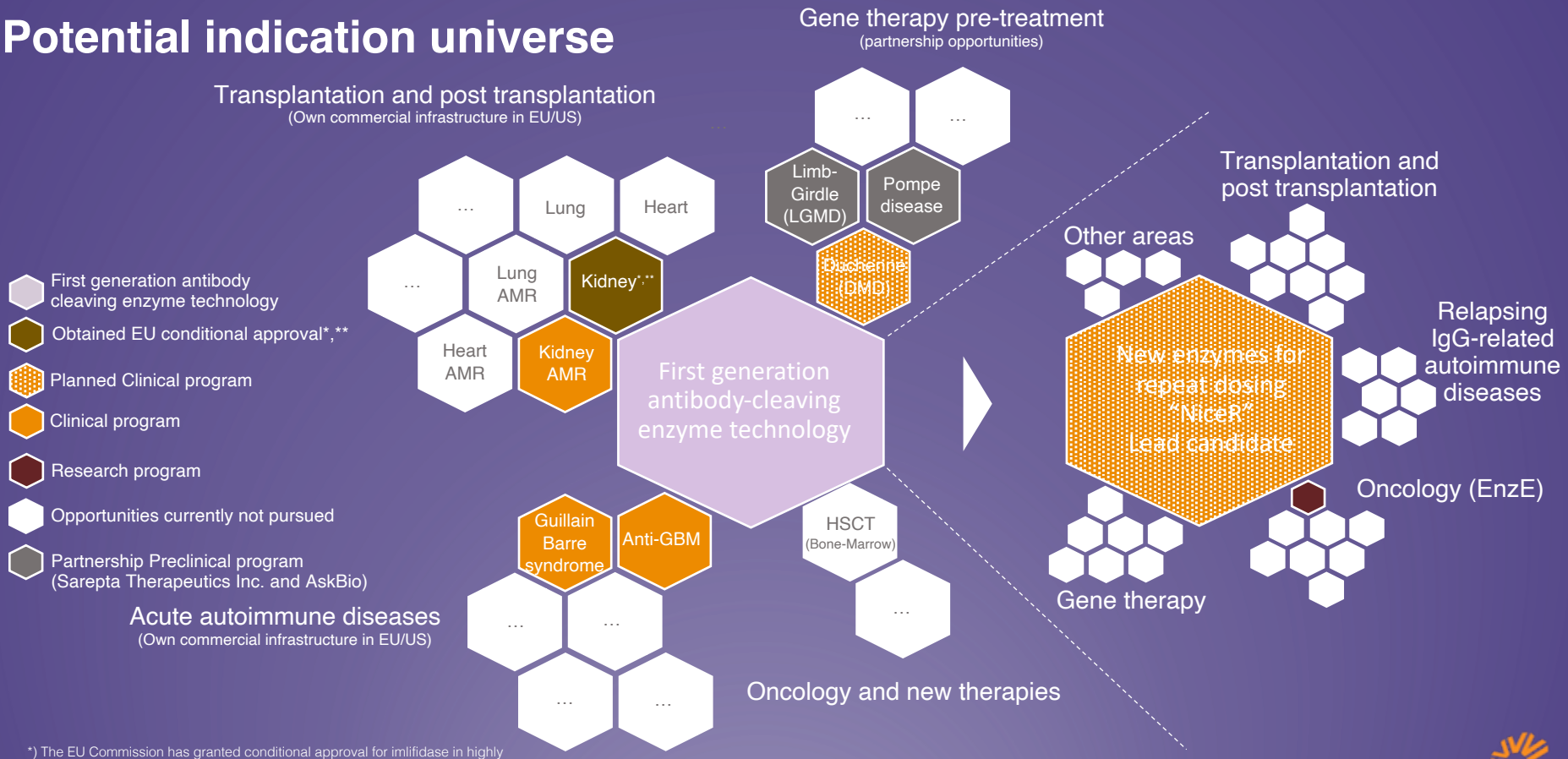


Our Business model

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 in 2024

Our strategic priorities

Our mission is to become a global leader in rare diseases

1. **Successfully commercialize Idefirix® in kidney transplantation in Europe, the U.S. and selected international markets**
2. **Advance our ongoing clinical programs in AMR and rare autoimmune diseases to regulatory approval**
3. **Develop imlifidase as pre-treatment to gene therapy, starting with our collaborations with Sarepta and AskBio**
4. **Develop our next generation IgG-cleaving enzymes to allow for recurring treatment**
5. **Successfully develop and market our products by pursuing a hybrid partnering model**

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
- Market Access secured in 11 countries, including four of the five big European markets
- Expanding commercial teams and adding territory management
- Securing supply chain management
- Progressing pipeline and advancing our technology footprint

* Idefirix approved in EEA under conditional approval for kidney transplantation

Our culture is driven by people passionate about making changes

Purpose driven culture

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

Diverse and international

~45%

Internationals across ~30 nationalities

~55/45

Male/female gender split in the leadership team

Skilled and experienced team

>50%

With relevant PhD in R&D

~20 years*

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

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

Motivated workforce

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

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

Experienced Board and Executive Committee

Extensive experience from the global healthcare industry

Executive Committee

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
Shareholding: 26,541

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

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

Donato Spota

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

Achim Kaufhold

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

Henk D. van Troostwijk

SVP & CCO (2016)
+20 years in the Healthcare sector
Ex-GM at Raptor Pharmaceuticals
Ex-BU Director at Genzyme Europe
Shareholding: 2,564

Anne Säfström Lanner

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

Board of Directors

Peter Nicklin

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

Hilary Malone

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

Anders Gersel Pedersen

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

Eva Nilsagård

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

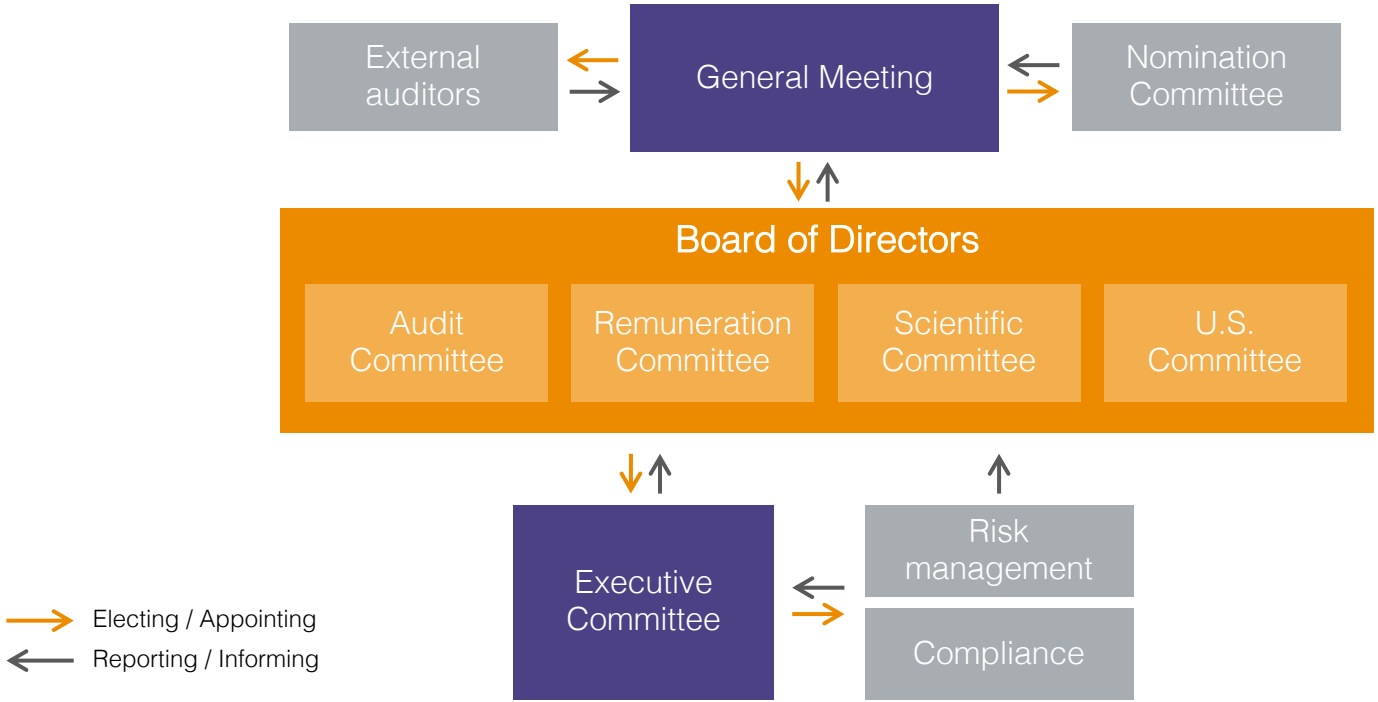
Mats Blom

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

Andreas Eggert

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

Hansa Biopharma's Governance Structure

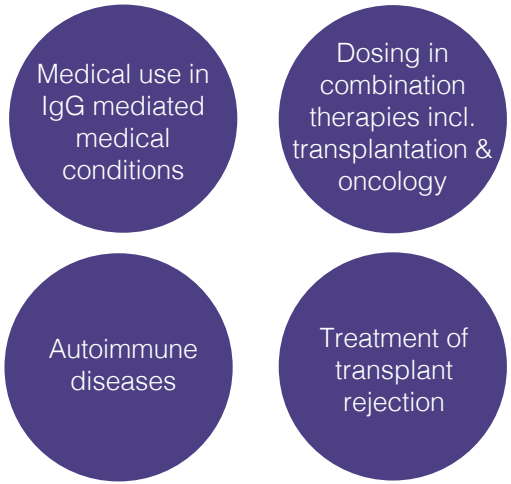


Strong technology protection

through patents and orphan drug designations

Patent coverage out to 2035 in key markets

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



Orphan drug designation (ODD)

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

EMA/EC

Orphan drug designation & marketing authorization

- ODD for the prevention of graft rejection following solid organ transplantation. Conditional marketing authorization for imlifidase was granted in 2020[1].

Orphan drug designation

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

FDA

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)

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

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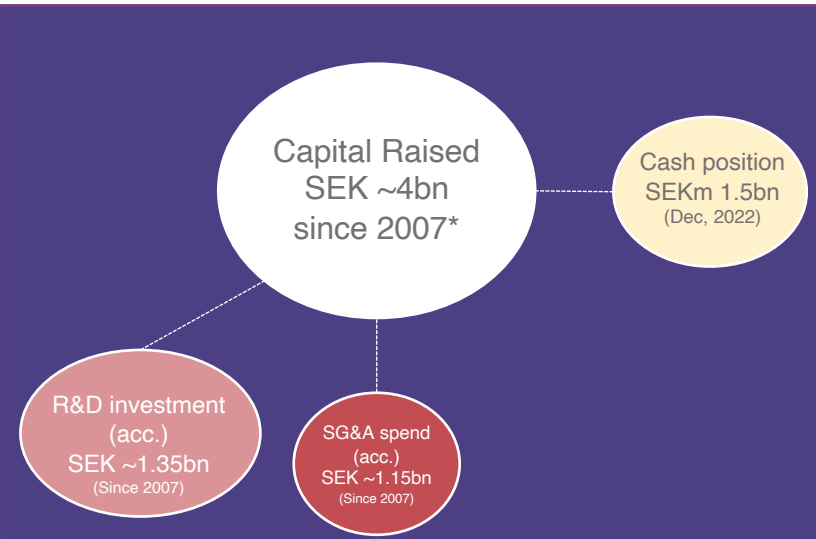
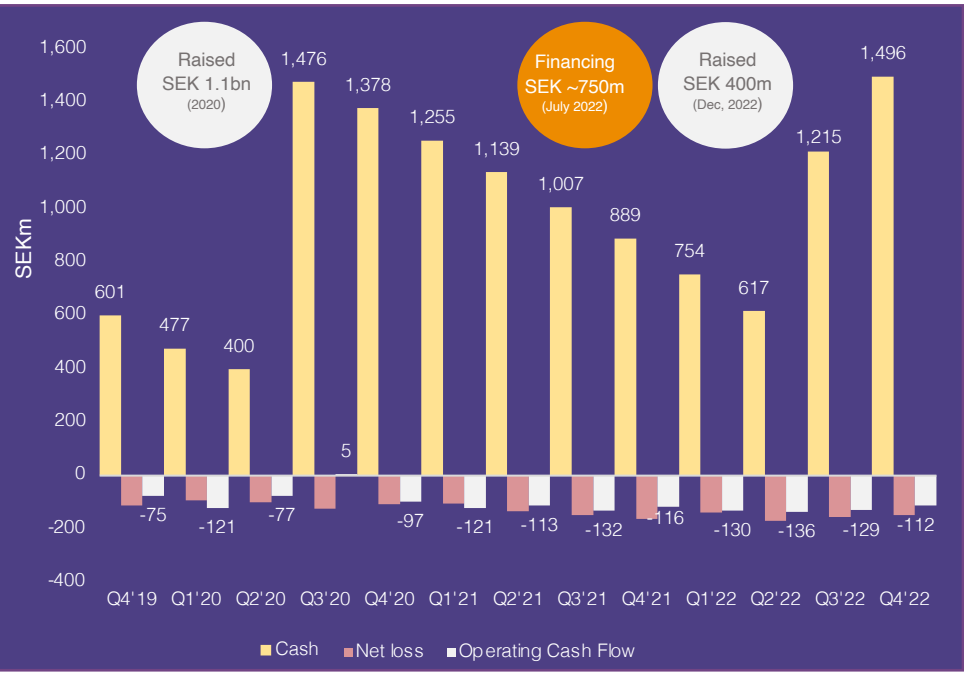
Hansa Biopharma is financed into 2025

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





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

Mid-term financial priorities

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

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

SEK ~1.5bn
(USD ~143m)
in cash and short-term investments post recent financing

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

HANSA BIOPHARMA

An exciting journey ahead!

This is just the beginning!

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

Key milestones to be achieved

- Expand Idefirix® label in transplantation and in other solid organs
- Expand our platform and obtain regulatory approval in indications beyond kidney transplantation
- Advance our next gen enzymes (NiceR) into the clinic
- Expand partnerships in gene therapy and oncology
- Advance imlifidase as pre-treatment into Limb-Girdle, Duchenne and Pompe Disease in gene therapy
- Show PoC in new indications such as oncology
- Advance potential combination treatment into the clinic (e.g., argenx collaboration)

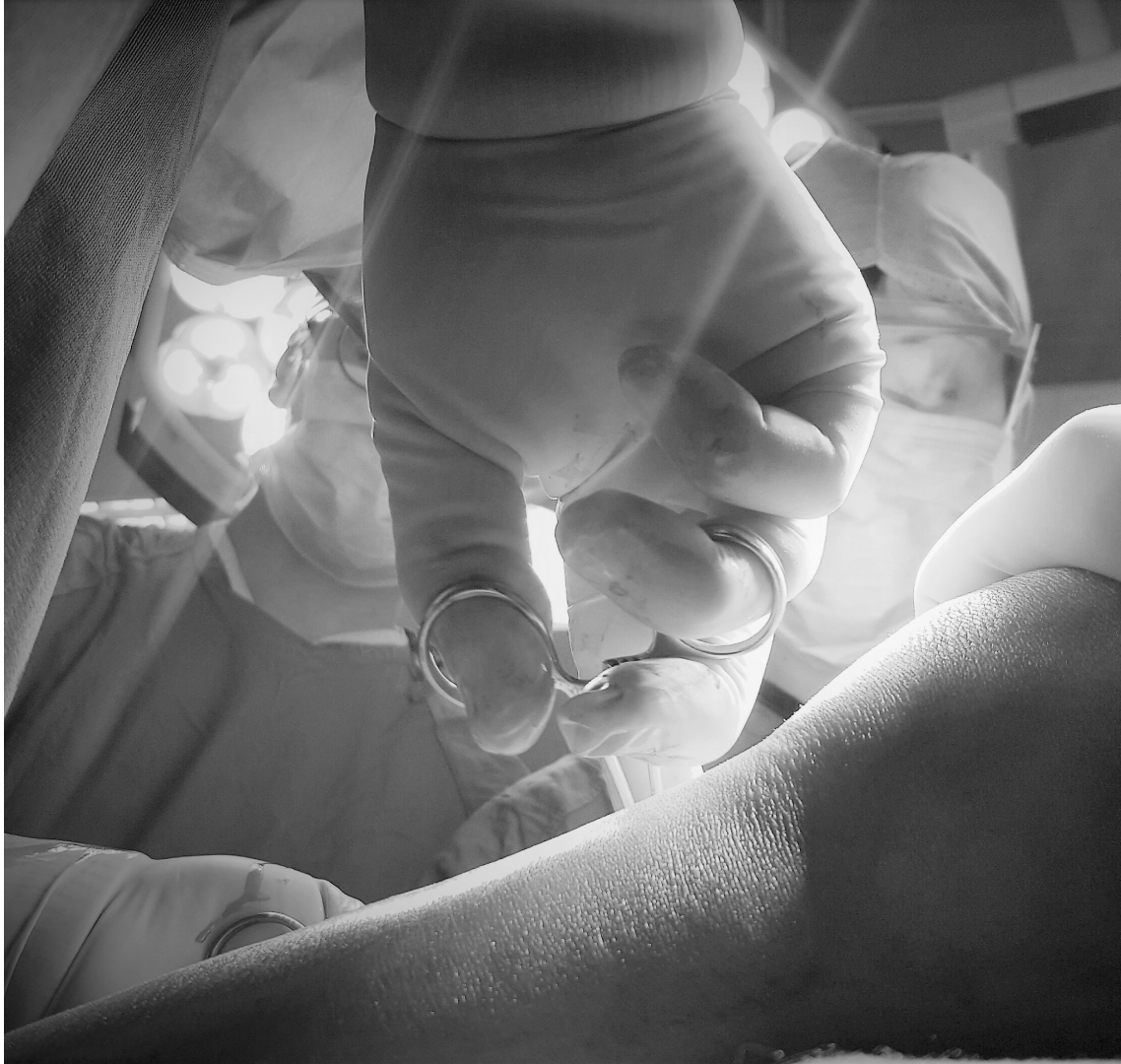
Our future

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



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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

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

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

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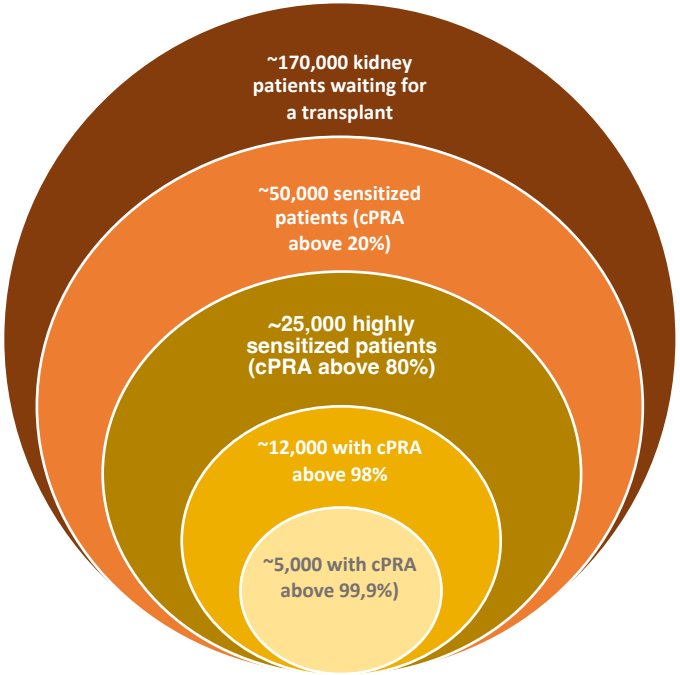
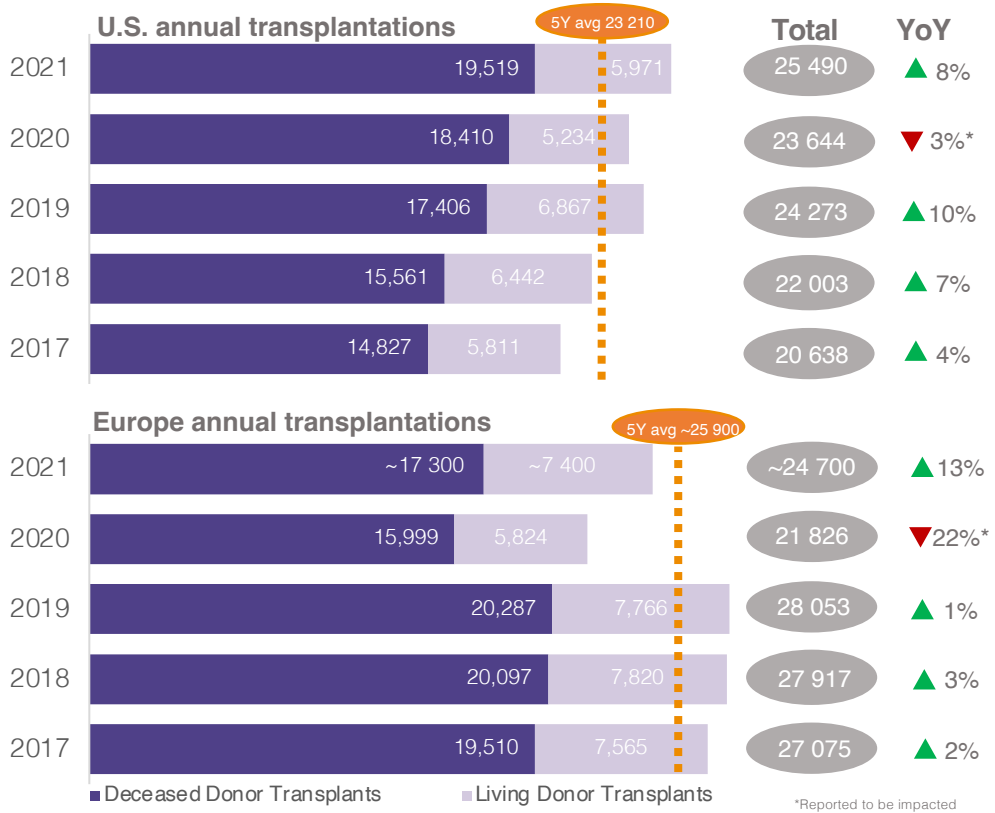
Up to 15% of patients waiting for a new kidney are highly sensitized

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



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

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

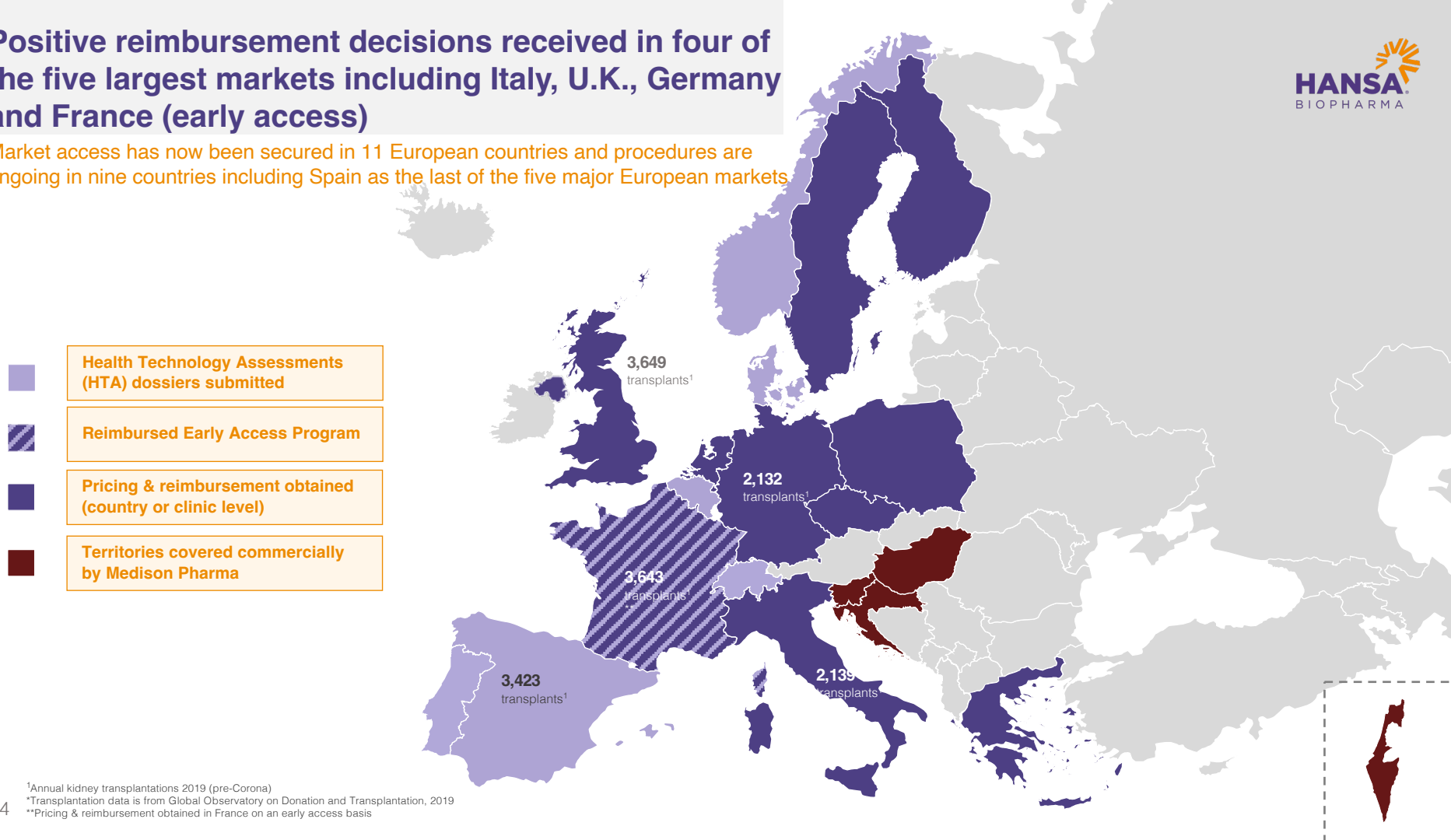


Source: Global Observatory on Donation and Transplantation, http://www.transplant-observatory.org/

*Reported to be impacted by the COVID-19 pandemic

Positive reimbursement decisions received in four of the five largest markets including Italy, U.K., Germany and France (early access)

Market access has now been secured in 11 European countries and procedures are ongoing in nine countries including Spain as the last of the five major European markets

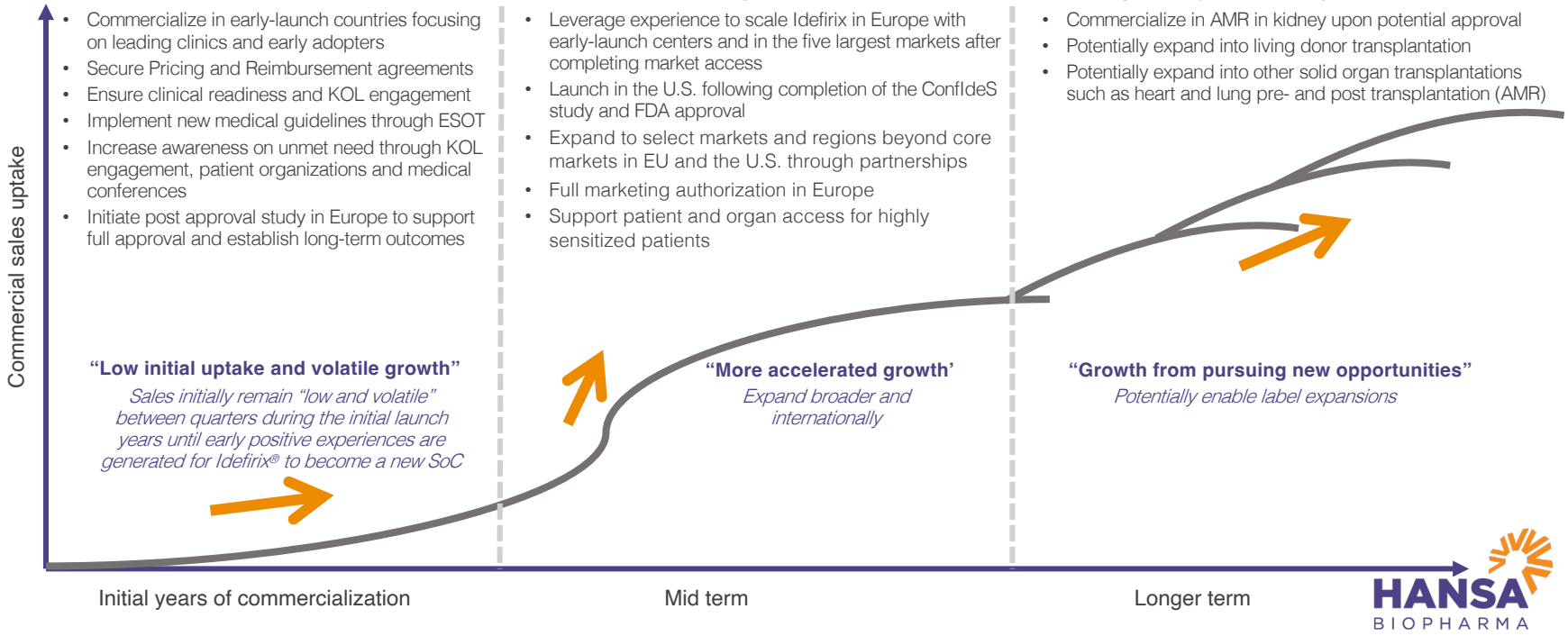


[1]Annual kidney transplantations 2019 (pre-Corona)
*Transplantation data is from Global Observatory on Donation and Transplantation, 2019
**Pricing & reimbursement obtained in France on an early access basis

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

Idefirix® is the first and only approved treatment in Europe for desensitization treatment of highly sensitized kidney transplant patients. The long-term market uptake is highly dependent on successful early experiences in key early adopter centers

Illustrative



1 Build the foundation for Idefirix® in EU to become a new Standard of Care

- Commercialize in early-launch countries focusing on leading clinics and early adopters
- Secure Pricing and Reimbursement agreements
- Ensure clinical readiness and KOL engagement
- Implement new medical guidelines through ESOT
- Increase awareness on unmet need through KOL engagement, patient organizations and medical conferences
- Initiate post approval study in Europe to support full approval and establish long-term outcomes

"Low initial uptake and volatile growth"

Sales initially remain "low and volatile" between quarters during the initial launch years until early positive experiences are generated for Idefirix® to become a new SoC

2 Expanding internationally will lead to more accelerated growth mid term

- Leverage experience to scale Idefirix in Europe with early-launch centers and in the five largest markets after completing market access
- Launch in the U.S. following completion of the ConfIdeS study and FDA approval
- Expand to select markets and regions beyond core markets in EU and the U.S. through partnerships
- Full marketing authorization in Europe
- Support patient and organ access for highly sensitized patients

"More accelerated growth'

Expand broader and internationally

3 Potential label expansion will enable new growth pockets longer term

- Commercialize in AMR in kidney upon potential approval
- Potentially expand into living donor transplantation
- Potentially expand into other solid organ transplantations such as heart and lung pre- and post transplantation (AMR)

"Growth from pursuing new opportunities"

Potentially enable label expansions

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

Highly sensitized patients are difficult to match with an available kidney

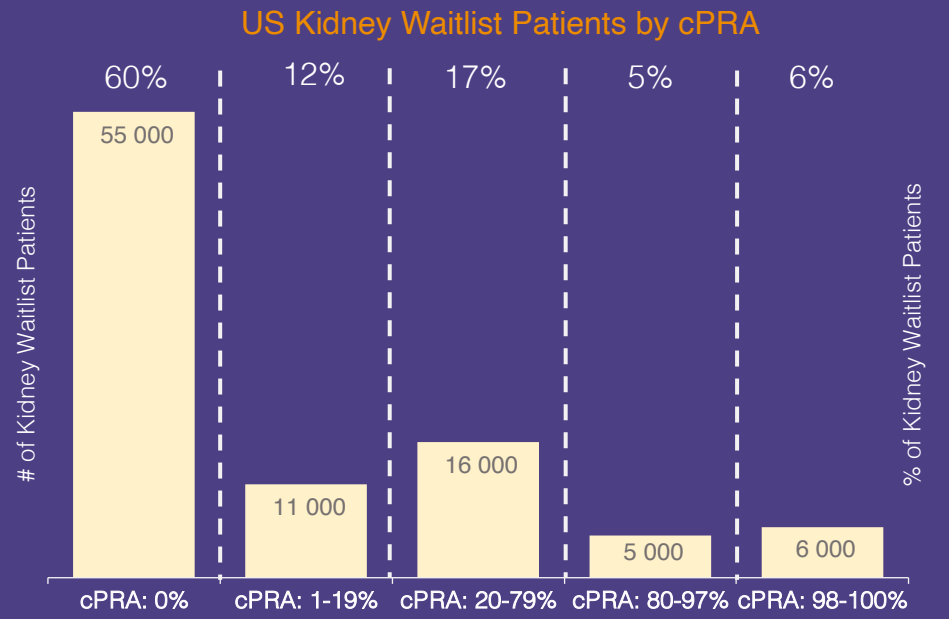
Causes of sensitization include

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

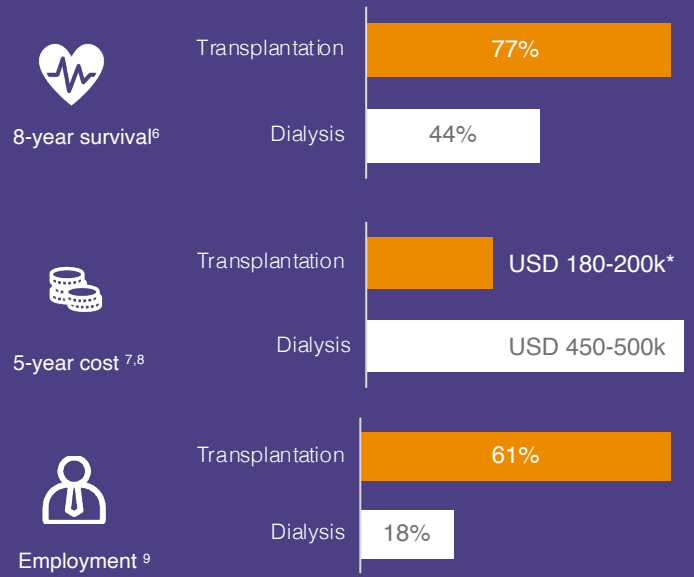
Transplantation leads to better outcomes

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

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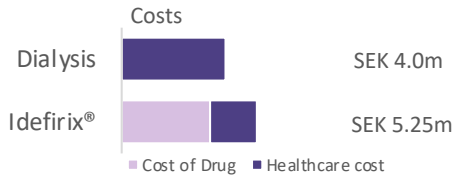
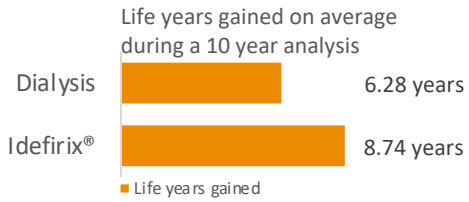
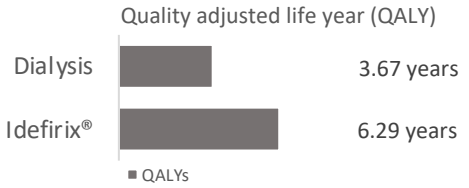
First HTA report (TLV) published in Sweden favourable to the use Idefirix® in highly sensitized patients incompatible to a deceased donor

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

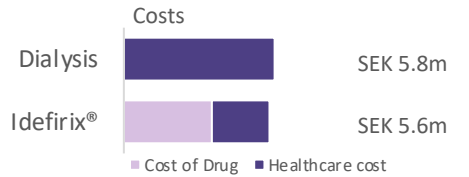


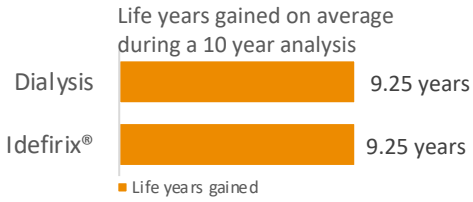


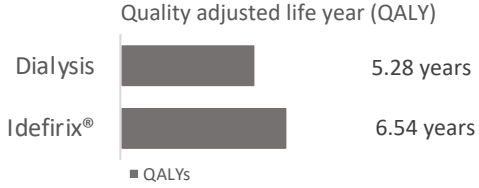


Costs per quality adjusted life year (QALY)
SEK 460k
(EUR 45k)

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

First patient experiences with Idefirix (imlifidase) in highly sensitized kidney transplant patients post approval published

29-year-old woman transplanted with Idefirix at Erasmus Medical Center, Rotterdam

The woman has had kidney disease since childhood and has been dialysis dependent since 2016, after previously having had two transplantations where the organs were rejected.

Due to high levels of antibodies, it was virtually impossible for her to find a match through Eurotransplant but in March 2022, the 29-year-old was transplanted using Idefirix and is since doing well.

"She gained new perspective on a good life through transplantation" says nephrologist Annelies de Weerd

Link article in Amazing Erasmus from July 7, 2022

54-year-old man successfully transplanted at Vall d'Hebron, Barcelona after being on dialysis since 1984

The first patient transplanted in the post-approval study was a 54-year-old man who had been on dialysis since 1984. After two failed transplantation attempts in the 90s, the patient's immune system became sensitized, with very high antibody levels.

In May 2022, the patient received imlifidase treatment followed by a kidney transplant. After three months, he continues to be followed up on and does not require dialysis.

"This drug may open the door to transplantation for a group of highly sensitized individuals with virtually no option for a compatible transplant." says Dr. Francesc Moreso

Link article from Vall d'Hebron news forum August 25, 2022

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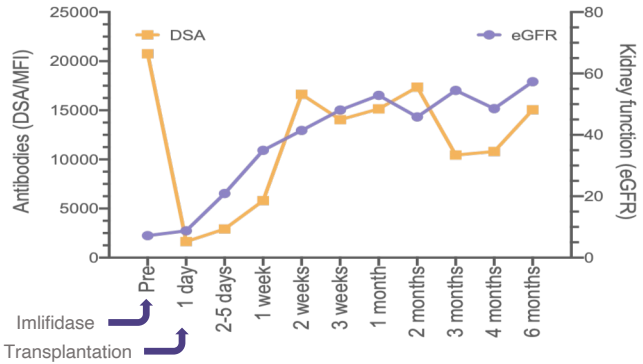
Completed and ongoing studies in kidney transplantation

HANSA BIOPHARMA

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

Pooled analysis from four Phase 2 trials

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



Study design of our four Phase 2 trials

Study 02 Phase 2

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

Study 03 Phase 2

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

Study 04 Phase 2

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

Study 06 Phase 2

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

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

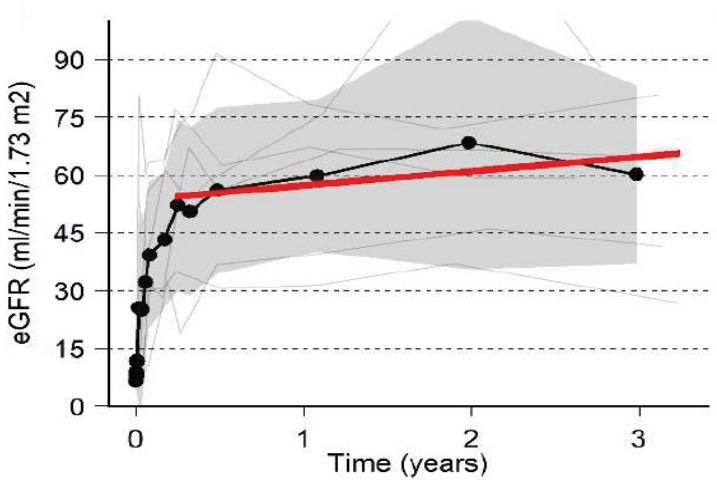
Data accepted for publication in the American Journal of Transplantation[1] Link AJT article

30 patients participating in follow-up study at year three

AMR frequency in line with other desensitization protocols

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

Improved kidney function for patients with cPRA ≥ 99.9%



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

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

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

HANSA BIOPHARMA

U.S. ConfIdeS study: Randomized controlled study in 64 highly sensitized patients with highest unmet medical need; BLA submission expected 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
- 51 patients enrolled across thirteen sites February 1, 2023

1:1 Randomization

- When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase or to a control arm, where patients either remain waitlisted for a match or receive experimental desensitization treatment*

Primary endpoint

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

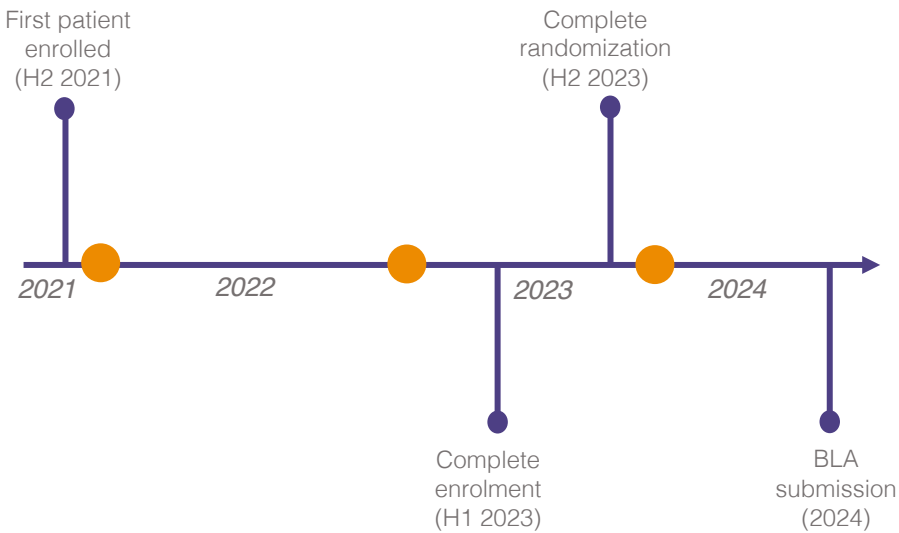
Secondary endpoint

- Patient survival at 12 months

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

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

Timeline



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

U.S. kidney transplantation landscape

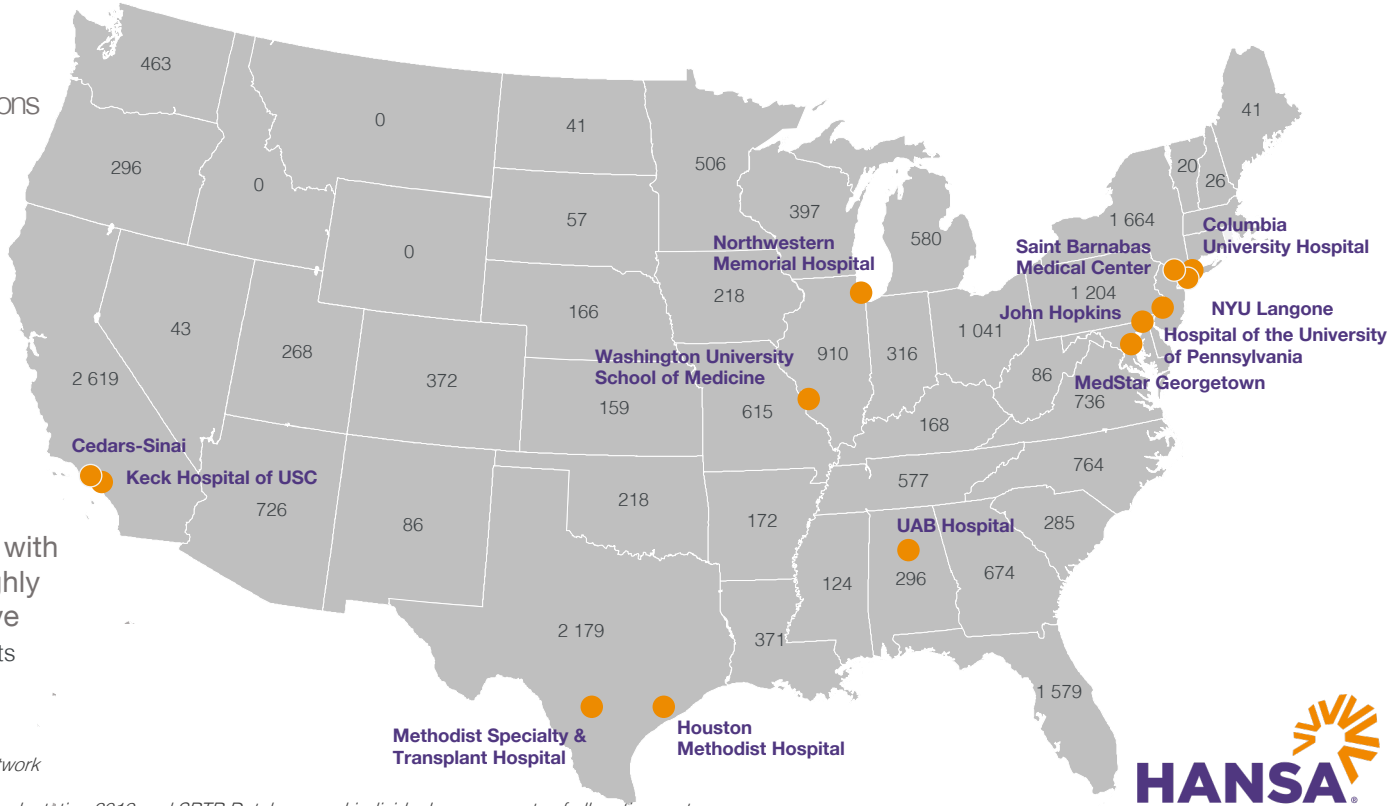
Our ConfIdeS study is currently enrolling patients across ten leading transplantation centers across seven states covering ~10% of annual kidney transplants in the U.S.; Aim to have up to 20 centers recruiting patients

>23,000[1] annual kidney transplantations

~71%[1] deceased donor

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

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



13 leading transplantation centers with experience in desensitization and highly sensitized patients are currently active

>2,500[1] combined annual kidney transplants

>300[1] highly sensitized (>80% cPRA)

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

HANSA BIOPHARMA

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

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

An open-label Phase 3 study in 50 patients

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

Study to assess imlifidase in combination to optimize patient outcome

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

Trial design (ClinicalTrials.gov ID: NCT05049850)

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

Open label, single arm study

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

Primary endpoint

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

Secondary endpoint

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

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

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

Study 01
Phase 1

CLINICALTRIALS.GOV ID

NCT01802697 (2013/2014)

SUBJECTS

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

DOSES/FOLLOW UP TIME

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

MAIN OBJECTTIVES

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

STUDY DESIGN

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

STATUS

Completed

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

The 01 study results

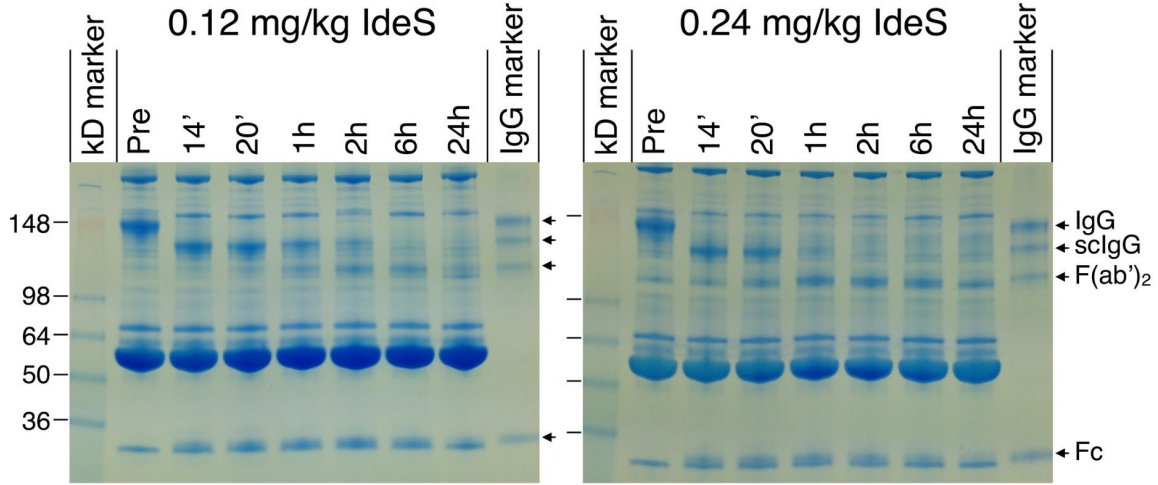
Data showed complete removal of IgG and a good tolerability profile

Efficacy

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

Safety

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



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

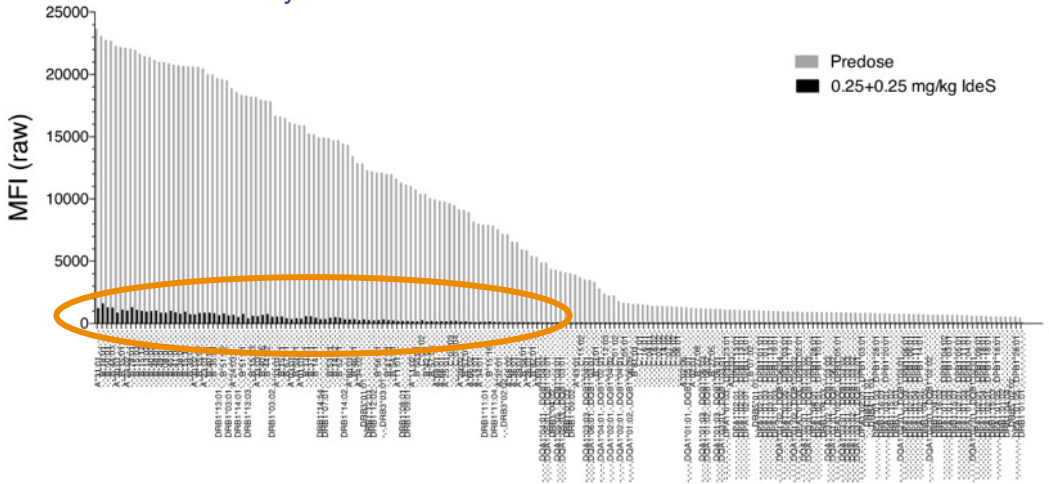
Study 02
Phase 2

The 02 study results

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

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

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



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

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

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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

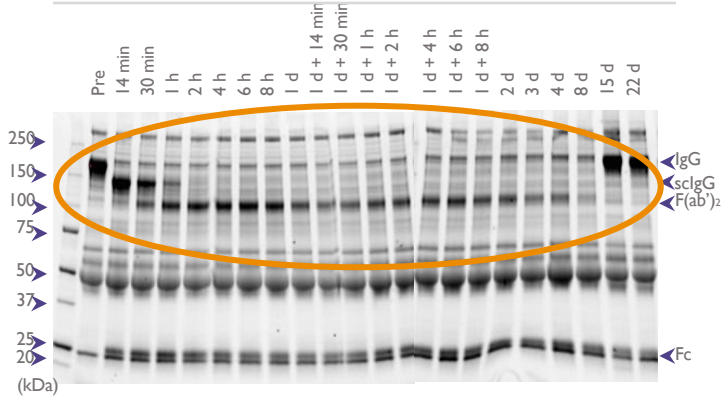
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

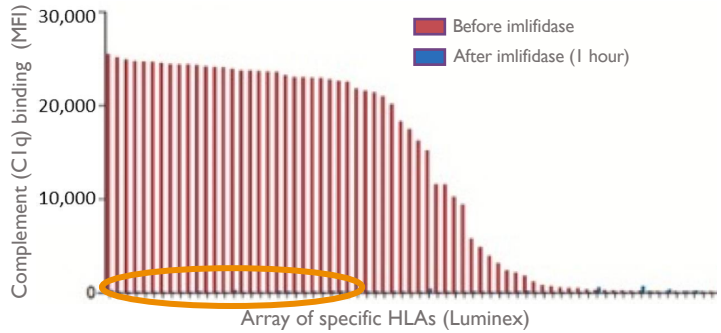
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment



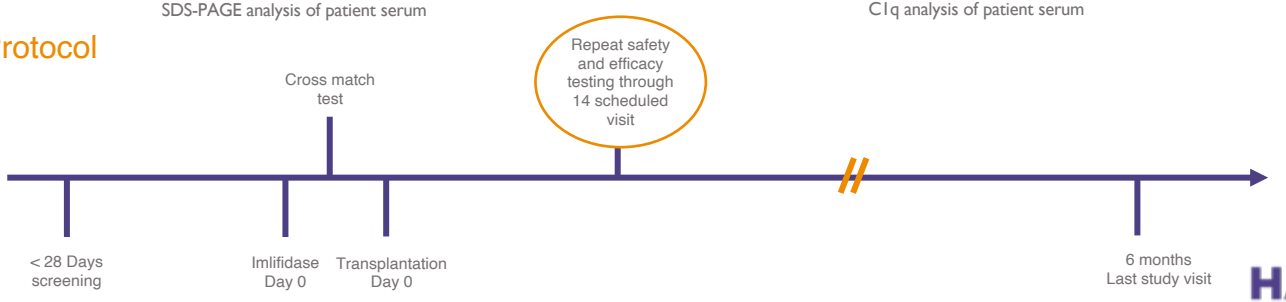
SDS-PAGE analysis of patient serum

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.

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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

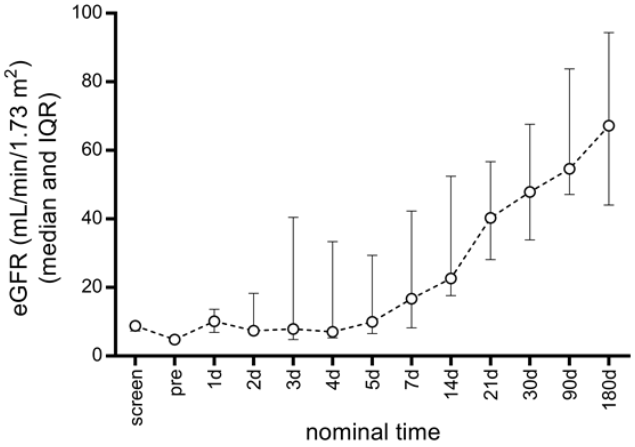
STUDY DESIGN

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

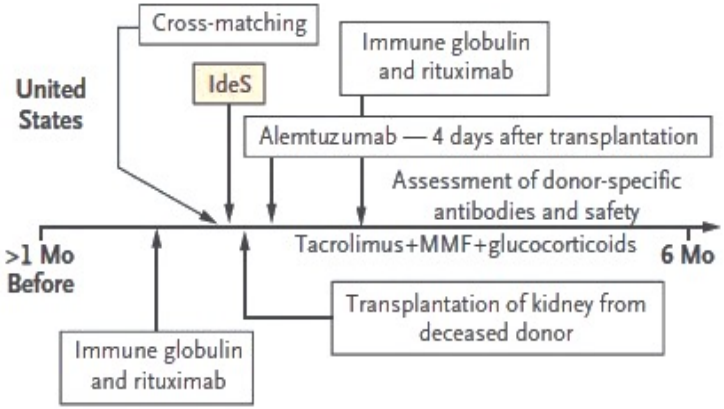
STATUS

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.

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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

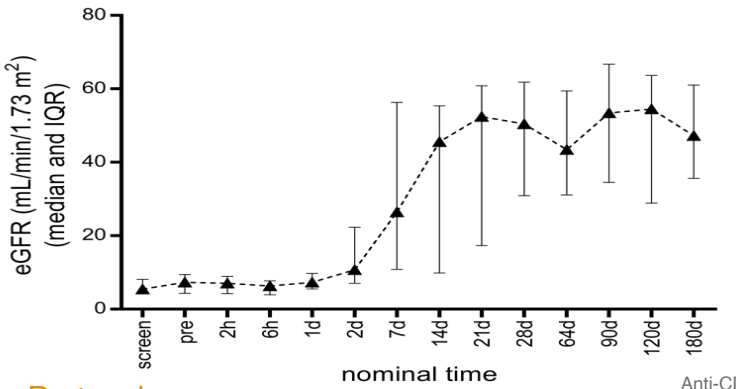
STUDY DESGIN

- 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

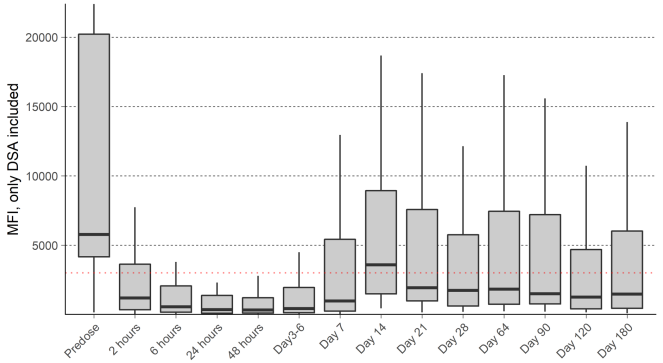
STATUS

Completed

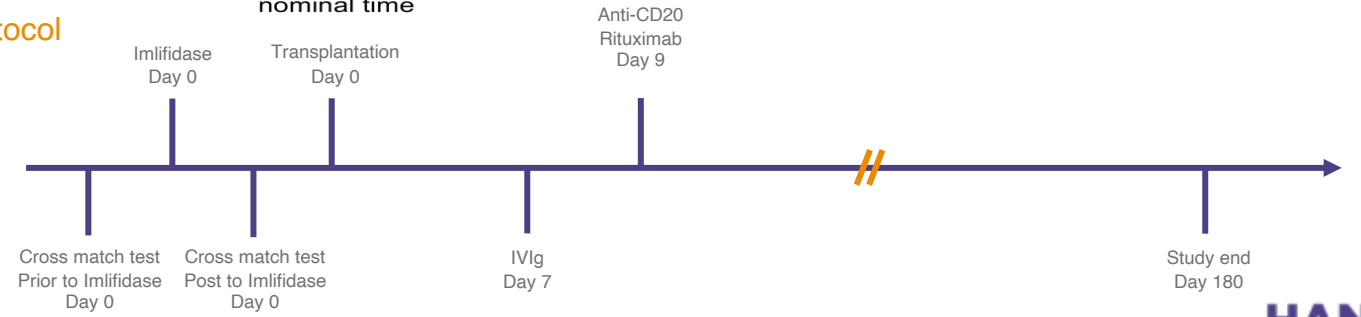
Graft function (eGFR) post imlifidase



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.

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

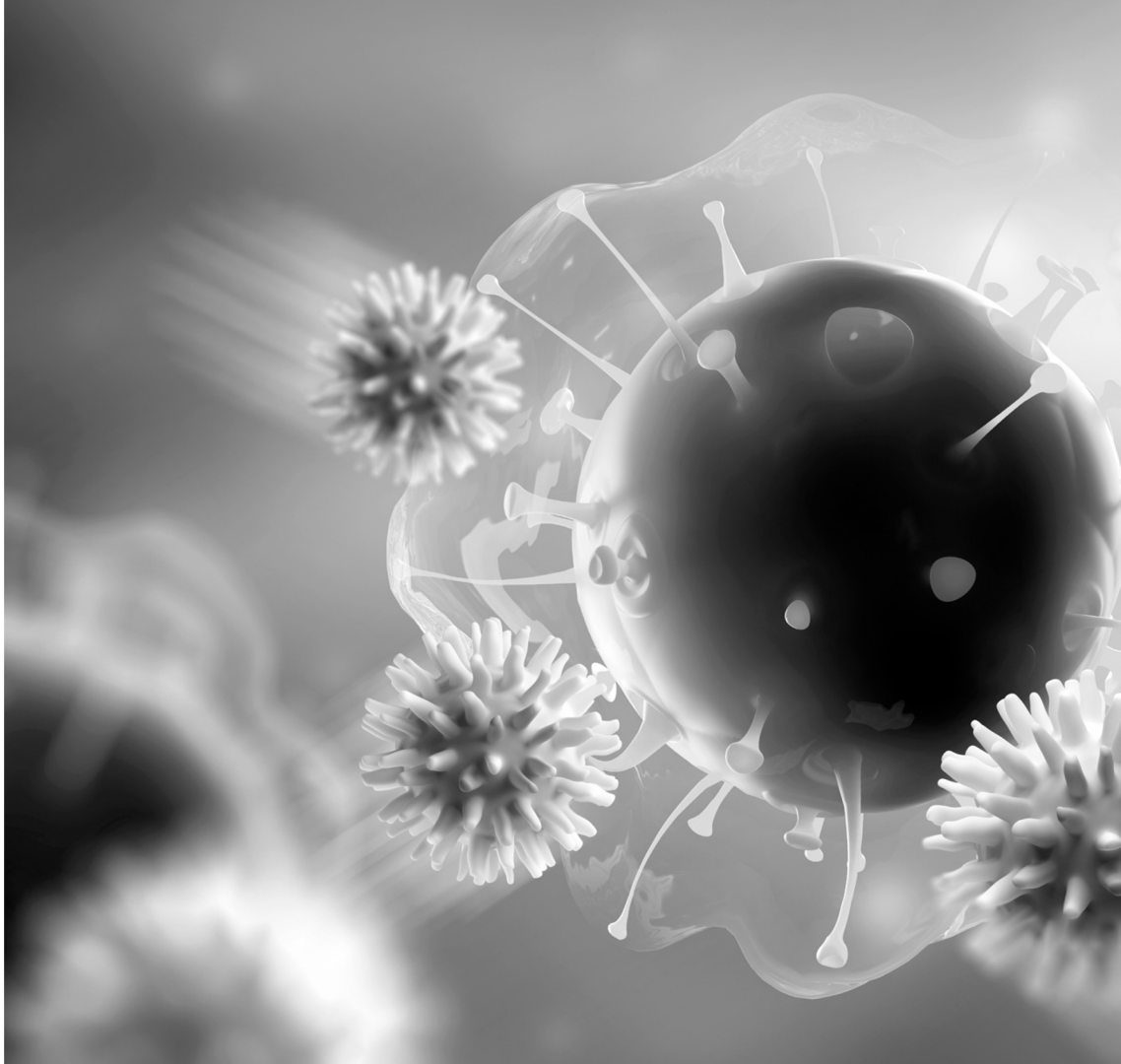
Professor Christophe Legendre

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



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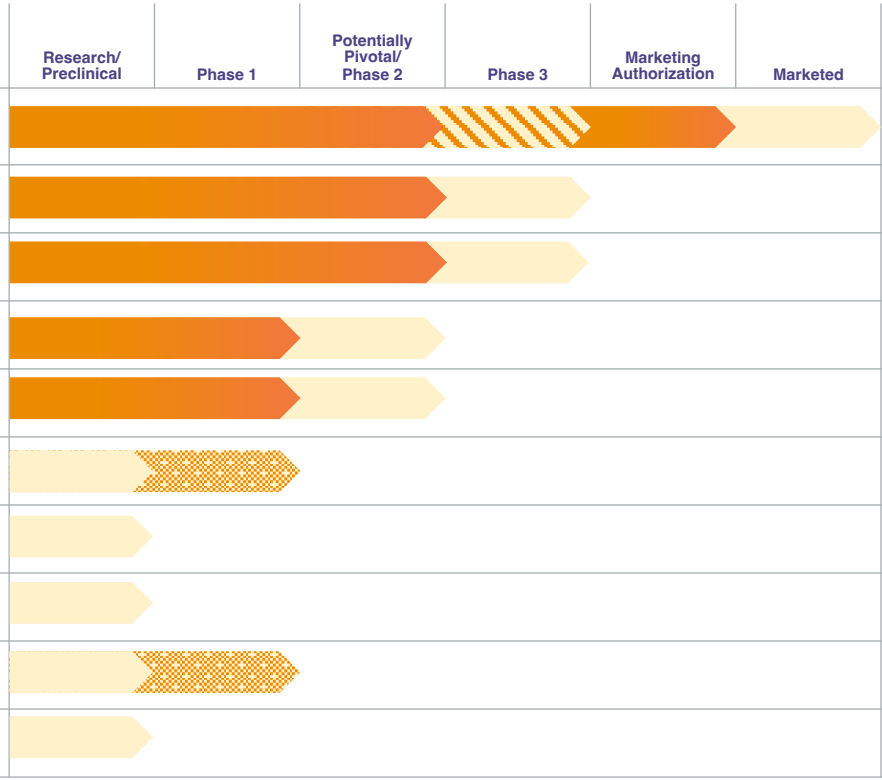
Broad clinical pipeline in transplantation and auto-immune diseases

Candidate/ Project	Indication	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients[1,2]	EU: Additional agreements around reimbursement / Post approval study to be completed by 2025
	US: Kidney transplantation in highly sensitized patients[1,2]	Completion of enrollment (64 patients) H1 2023
	Anti-GBM antibody disease[3]	First patient enrolled (50 patients)
	Antibody mediated kidney transplant rejection (AMR)	Full data read-out H2 2023
	Guillain-Barré syndrome (GBS)	Completion of enrollment (30 patients) H1'23
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)	Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)	Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)	Preclinical research
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Initiate Phase I study of HNSA-5487 (Lead NiceR candidate) H1 2023
EnzE	Cancer immunotherapy	Research



[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

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

Continuous progress in our ongoing clinical programs

Enrollment status
Feb 1, 2023

Antibody Mediated Rejection Phase 2 study

- 30/30 patients enrolled in the AMR phase 2 study
- Data readout demonstrates a statistically significantly superior capacity of imlifidase to rapidly reduce levels of DSAs compared to plasma exchange (SoC) in the five days following the start of the treatment
- Full data read out expected H2 2023, which will determine the path forward for imlifidase in patients with active AMR

- Patients enrolled
- Patients remaining

Guillain-Barré Syndrome Phase 2 study

- 25/30 patients enrolled in the GBS program
- 10 centers are active and open for recruitment;
- Aim to complete enrollment of GBS patients H1 2023, as previously guided
- Aim to communicate first high-level data read out in H2 2023

Enrollment status
Feb 1, 2023

- Patients enrolled
- Patients remaining

Anti-GBM Phase 3 study

- New pivotal Phase 3 study initiated in first sites in the U.S. and U.K end of 2022 as previously guided
- Open-label, randomised controlled study targeting 50 patients to be treated to with imlifidase and SoC or SoC, alone
- Kidney function will be evaluated as the primary endpoint
- First patient expected to be dosed H1 2023

- Patients enrolled
- Patients remaining

U.S. ConfIdeS Phase 3 study

Randomized, controlled trial in highly sensitized kidney transplant patients

- 51/64 patients enrolled for randomization
- 13 centers active and open for recruitment; continuously adding new clinics, with a goal of at least 20, to further increase enrollment capacity.
- Expect to complete enrollment H1 2023 and complete randomization in H2 2023
- BLA submission is expected in 2024 under the accelerated approval path, as previously guided

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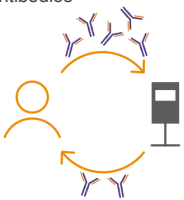
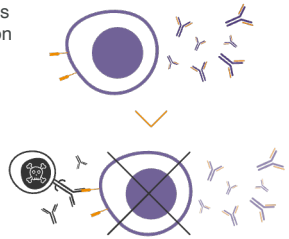
Development of IgG-modulating technologies

Mechanisms can be both complementary and competing

PLEX, plasmapheresis, immunoadsorption
Mechanically removes antibodies from circulation



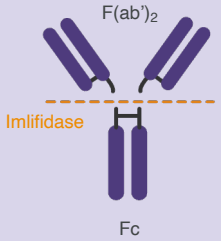
B-cell depleting mAbs
Lowering antibody levels through B-cell elimination



Imlifidase – IgG-cleaving enzyme

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

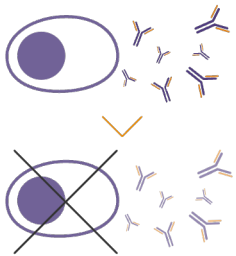
Unique mechanism-of-action is the basis for competitive advantage vs other IgG-modulating therapies



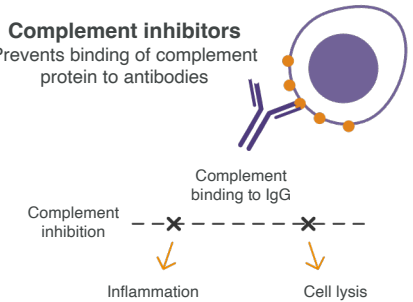
1950s | 1980s | 1990s | 2000s | 2010s | 2020s

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

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



Complement inhibitors
Prevents binding of complement protein to antibodies



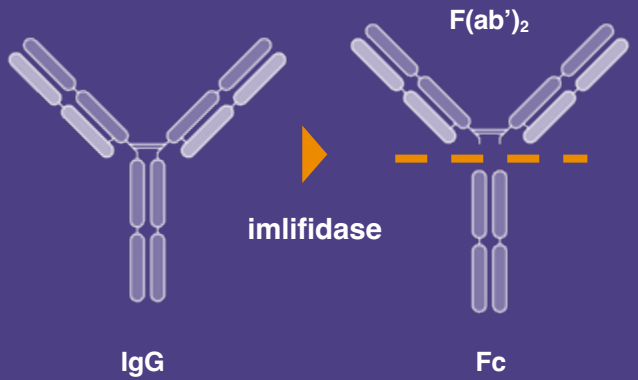
FcRn-inhibitors
Lowering IgG through blocking of antibody recycling

Imlifidase mode of action

Novel approach to effectively eliminate pathogenic IgG

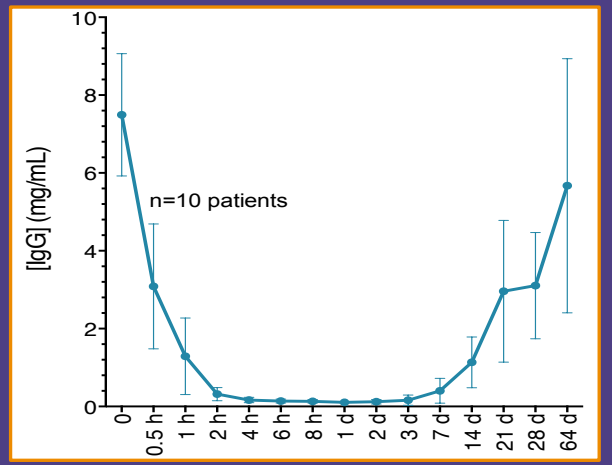
Proven mechanism of action

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



Inactivation of IgG in human serum

- Rapid onset of action that takes down IgG below detectable level in 2-6 hours post 15 min infusion
- IgG antibody-free window for approximately one week



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

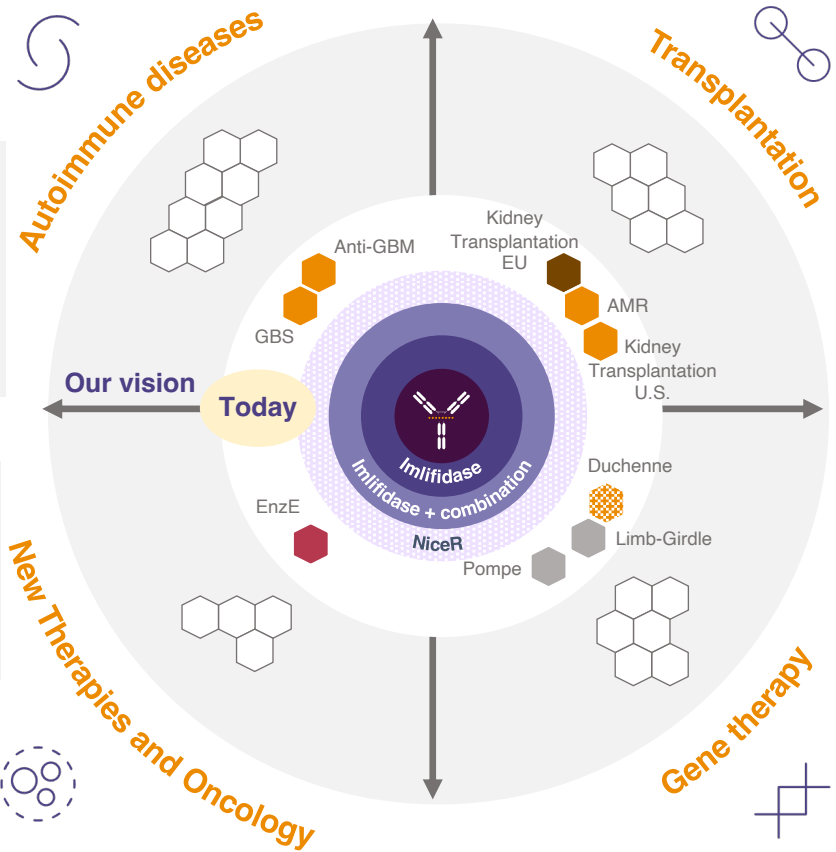
Targeting rare IgG mediated diseases

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
- Planned clinical trial
- Partnership (preclinical development)
- Preclinical development
- Potential indications (currently not pursued)

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

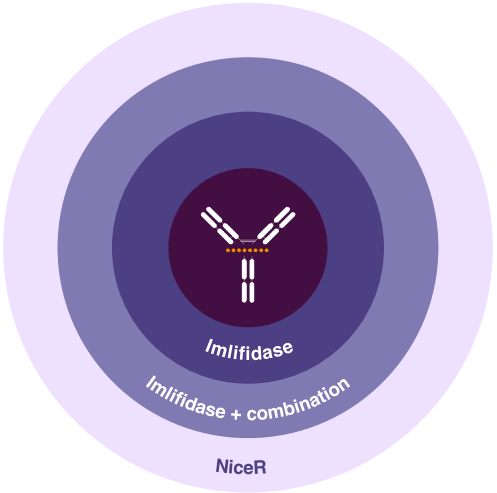
- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta and AskBio
- Wide indication landscape beyond

The technology platform is the primary basis for achieving our vision

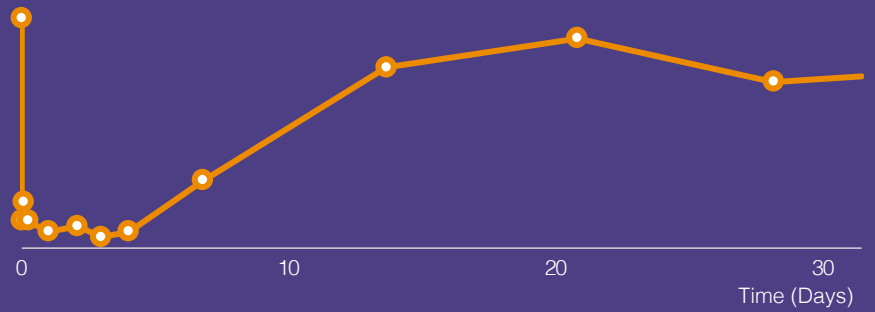
Targeting rare IgG mediated diseases and conditions

Key opportunities:

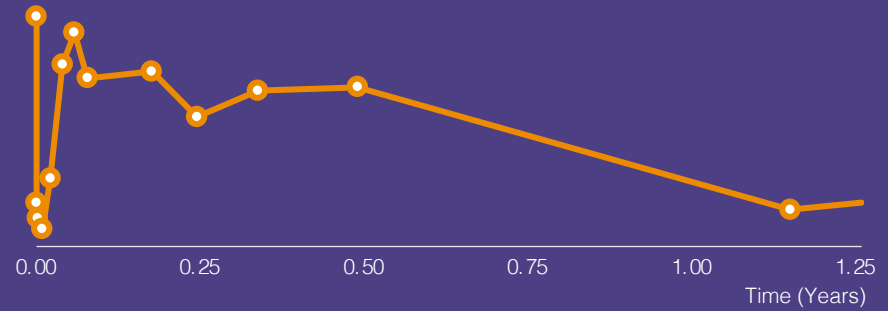
- Expanding into **new indications**
- Reduce immune response to IgG-cleaving enzyme, i.e. allow **repeated treatment**
- **Combination therapy**, i.e. induction and maintenance therapy



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



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



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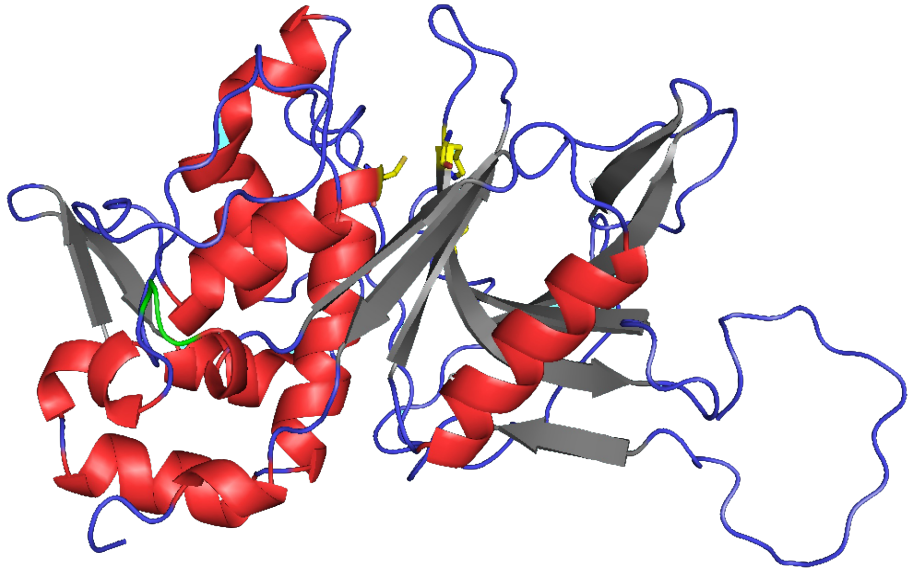
Our IgG antibody-cleaving enzyme, imlifidase

Origins from Streptococcus pyogenes

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

Imlifidase consists of 311 amino acids



Imlifidase is a lyophilized product formulation

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

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

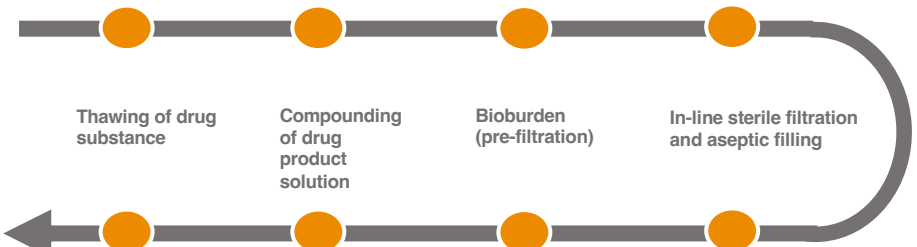
Protein purification
- Cell Disruption
- Protein Release

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



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

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

Clinical development programs

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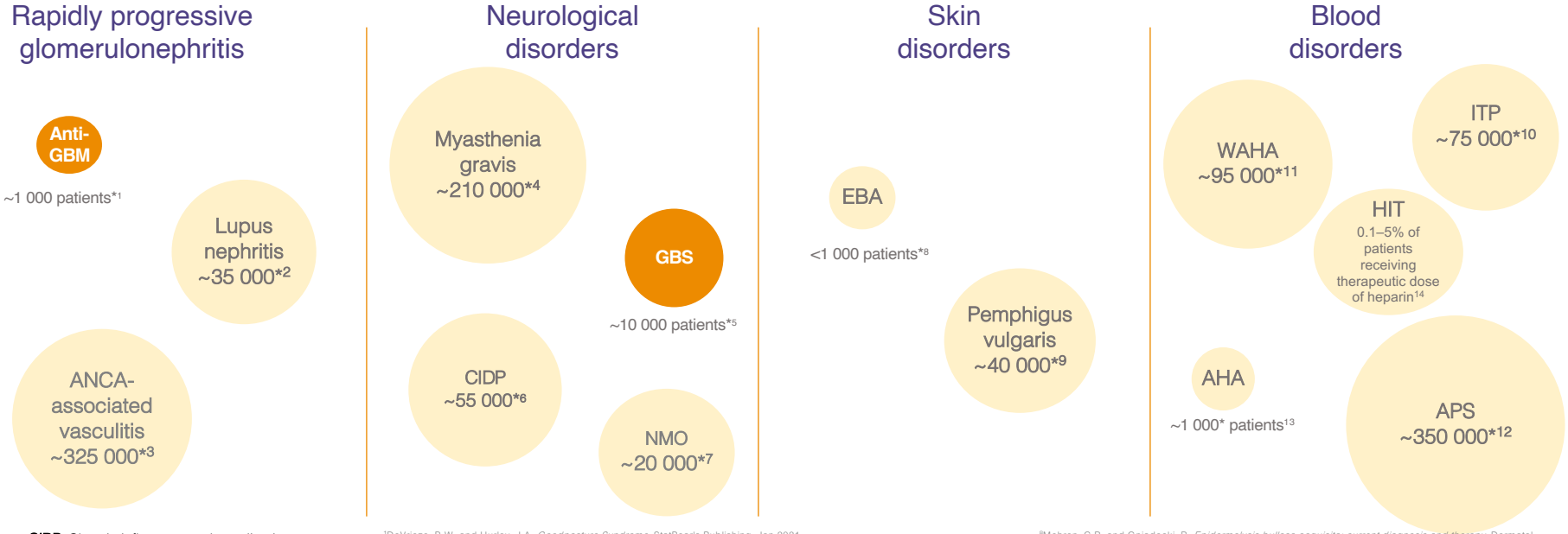
Hansa's antibody cleaving enzyme technology

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

Clinical programs

Potential autoimmune indications (currently not pursued)

*Total disease populations in EU & US, based on prevalence and population data



CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita
ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome
AHA: acquired hemophilia A
HIT: Heparin-induced thrombocytopenia

[1]DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021. https://www.ncbi.nlm.nih.gov/books/NBK459291/ [accessed 2021-03-29]
[2]Patel, M et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK*. Arthritis & Rheumatism, 2006.
[3]Berti A, Cornec D, Crowson CS, Specks U, Matteson EL. *The Epidemiology of ANCA Associated Vasculitis in the U.S.: A 20 Year Population Based Study*. Arthritis Rheumatol. 2017;69.
[4]*Myasthenia Gravis*. National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/myasthenia-gravis/ [accessed 2021-03-29]
[5]*Guillain-Barré syndrome*. Orpha.net, https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=2103 [accessed 2021-03-29]
[6]*Chronic Inflammatory Demyelinating Polyneuropathy: Considerations for Diagnosis, Management, and Population Health*. The American Journal of Managed Care, https://www.ajmc.com/view/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health [accessed 2021-03-29]
[7]Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica*. International Journal of MS Care, 2013 Fall: 113-118
[8]Mehren, C.R. and Gniadecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05
[9]Wertenteil, S. et al. Prevalence *Estimates for Pemphigus in the United States*. JAMA Dermatol, May 2019: 627-629.
[10]*Immune Thrombocytopenia*. National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/immune-thrombocytopenia/ [accessed 2021-03-29]
[11]*Warm Autoimmune Hemolytic Anemia*. National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/ [accessed 2021-03-29]
[12]Litvinova, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.
[13]NORD, Acquired Hemophilia [accessed 2022-10-17], available at https://rarediseases.org/rare-diseases/acquired-hemophilia/
[14]Hogan M, Berger JS. Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

Anti-GBM, a rare acute autoimmune disease

New pivotal phase 3 study commenced end of December 2022 twith first patient expected to be dosed H1 2023

Anti-GBM “Goodpasture’s disease”

- 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
- Positive read-out from phase 2 study with 2/3 of anti-GBM patients achieving dialysis independence six months after treatment
- New pivotal open-label, randomized controlled study targeting 50 patients to be treated to with imlifidase and SoC or SoC, alone
- Kidney function will be evaluated after six months as the primary end point, while anti-GBM antibody levels, pulmonary symptoms, safety, PK/PD and health related QoL measures, among others, will be assessed as secondary endpoints.
- 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 3

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

NCT05679401 (Since 2023)

SUBJECTS

50 patients targeted. Patients will be monitored for six months
Recruitment at 30-40 clinics

DOSES/FOLLOW UP TIME

Dosage 0.25mg/kg 180 days follow up

MAIN OBJECTTIVES

- Renal function as evaluated by estimated glomerular filtration rate (eGFR) at 6 months

STUDY DESIGN

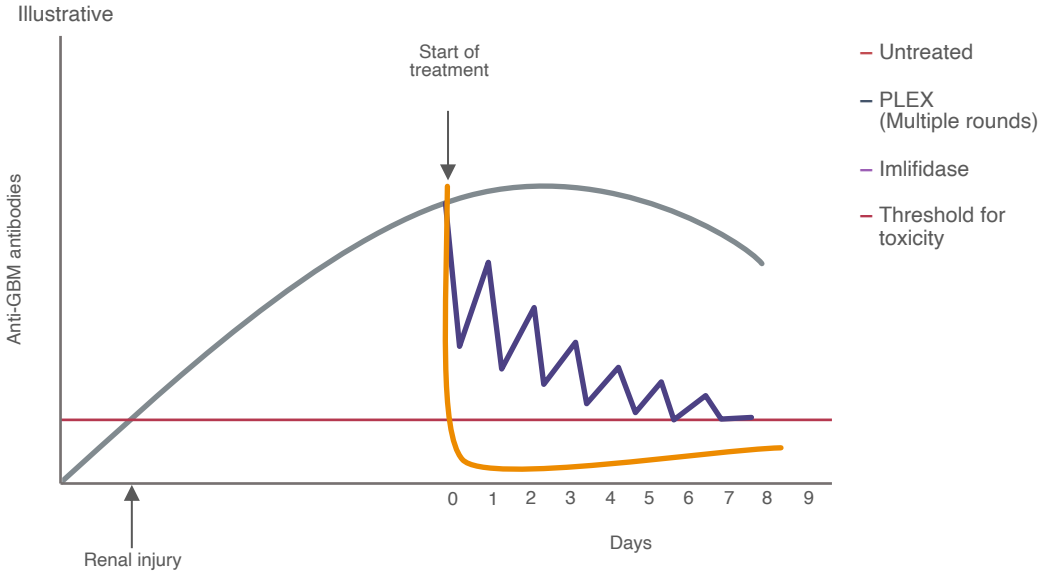
- Open-label, controlled, randomised, multi-centre Phase 3 trial evaluating renal function in patients with severe anti-GBM disease imlifidase + SoC vs SoC

STATUS

First patient enrolled expected H1 2023

Potential of using imlifidase plus SoC vs. SoC in anti-GBM

Standard of Care (SoC) consists of PLEX, CYC, and glucocorticoids



Results from Phase 2 study of imlifidase in anti-GBM disease published in Journal of American Society of Nephrology (JASN)[1]

U.S. FDA has accepted Hansa's Investigational New Drug (IND) application to proceed with a global Phase 3 study expected to commence in 2022

JASN recognises the potential in deactivation of autoantibodies in autoimmune diseases

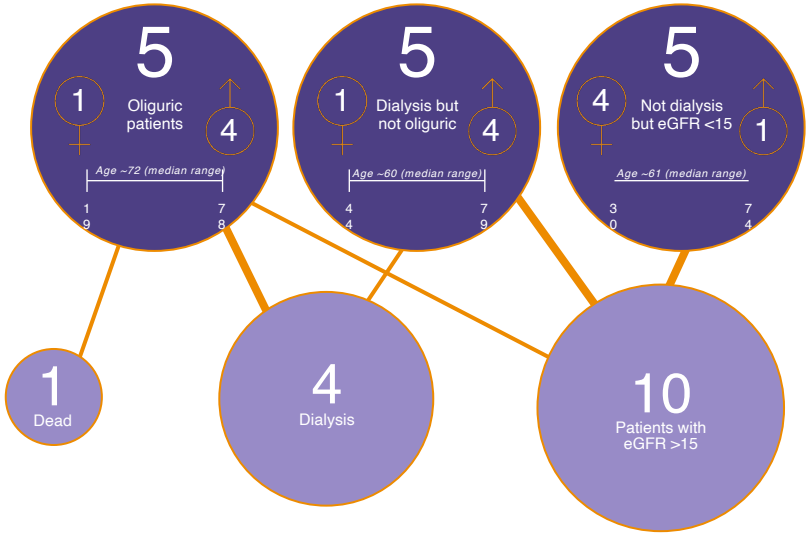

CLINICAL RESEARCH www.jasn.org

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

ABSTRACT

69

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



Segelmark et al. JASN (2022)

New Anti-GBM Phase 3 study of imlifidase in 50 patients

- Global protocol in place and approved by FDA. Selection of investigators and site set up is now ongoing
- New Phase 3 trial will be an open-label, controlled, randomized, multi-centre trial comparing imlifidase and SoC with SoC alone
- EMA submission preparation in progress
- Plans to expand the trial to include Japan

[1] Journal of the American Society of Nephrology https://pubmed.ncbi.nlm.nih.gov/35260419/

[2] McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. Kidney Int 92: 693–702, 2017

HANSA BIOPHARMA

Phase 2 study to evaluate safety, tolerability and efficacy of imlifidase

in patients with Guillain-Barré syndrome (GBS)

Design of the GBS trial

- Open-label, single-arm trial in combination with SoC treatment given within 10 days of onset of GBS
- Infusion of 0.25mg/kg imlifidase at Day 1, followed by IVIg (400 mg/kg) at Days 3-7, and follow-up of PK/PD for 14 days, safety and efficacy parameters at 6 months and 12 months
- 30 patients targeted and matched to controls based on geographical location, age, presence of diarrhea, severity of condition
- Outcome compared to matched controls (up to 4 controls per patients) from the IGOS[1] database

[1] IGOS: International GBS Outcome Study

Main objective

- To evaluate safety, tolerability, PK/PD, and efficacy of imlifidase in GBS patients in combination with SoC intravenous immunoglobulin

Idefirix/imlifidase is approved in EU under conditional approval in kidney transplantation

Status

- 25/30 patients enrolled February 1, 2023. Completion of enrollment expected H1 2023
- 10/10 sites are recruiting patients
- Recruitment will be done across France, UK and The Netherlands
- Enrollment is expected to be completed in H1 2023 (temporary halted during 2019 due to Covid-19)
- First data readout H2 2023

In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

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 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)
- 25/30 patients enrolled end of January 2023. Ongoing recruitment of patients at 10 centers across France, UK and the Netherlands.
- Initiatives implemented to support the completion of enrollment incl. simplification of the protocol and increased capacity; Up to six new sites to be added in the coming months
- Completion of enrollment expected in H1 2023 with a first data read-out in H2 2023
- 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

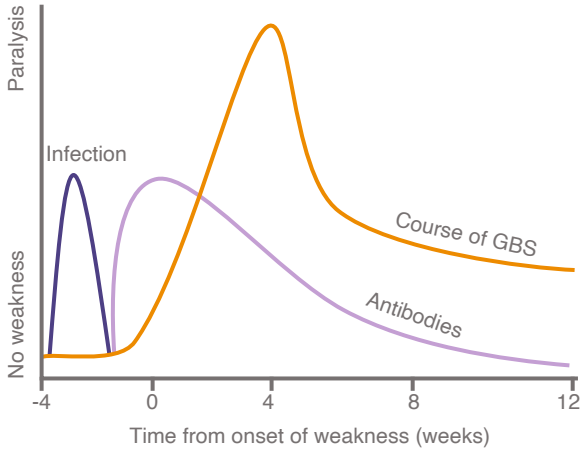
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing recruitment

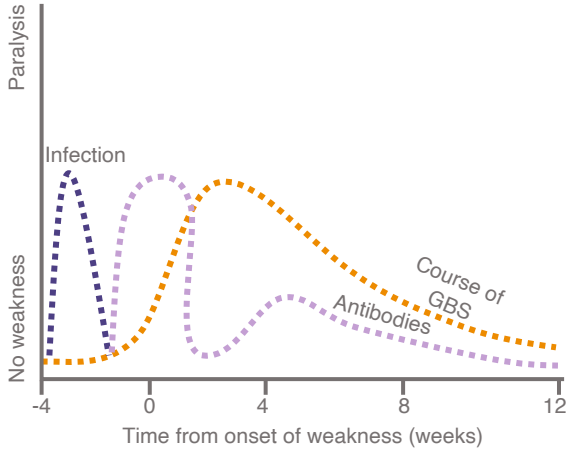
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



HANSA BIOPHARMA

Enrollment in Phase 2 program in Antibody Mediated Rejection (AMR) post kidney transplantation completed

Long term graft survival is challenged by AMR episodes post transplantation

Indication

- Acute antibody mediated rejection episodes post transplantation occurs in 5-7% of kidney transplants[1] annually and is a significant challenge to long term graft survival
- Today's standard of care include plasma exchange, steroids and IVIg.
- There is no approved treatment for AMR

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

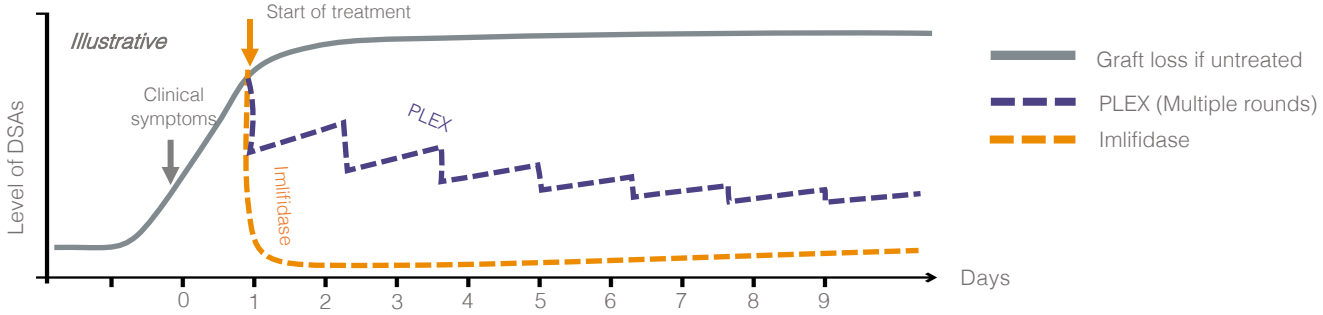
Phase 2 Study

- 30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled and randomized 2:1 to imlifidase vs. SoC
- The AMR phase 2 program is a randomized, open-label, multi-center and controlled study
- 20 individuals have been randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 individuals in the active control arm received 5-10 sessions of plasma exchange (PLEX)
- Efficacy and safety is monitored over a six-month period post treatment.

Path forward

- **H1'22:** Completion of enrollment
- **H2'22:** Positive topline data from the phase 2 study in AMR with imlifidase
- **H2'23:** Full data read out expected to be announced or published in peer reviewed journal
- **Decision on a regulatory path forward**

Potential of using imlifidase vs. PLEX in AMR



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 5-7% 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 and chronic acute AMR in kidney transplant patients
- The topline data associated with the primary endpoint demonstrated that imlifidase has significantly superior efficacy compared to plasma exchange in reducing DSAs during the five days following the start of treatment
- Full data expected to be published in H2 2023

[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

AMR Phase 2 study

The topline data associated with the primary endpoint shows that imlifidase has significantly superior efficacy compared to plasma exchange in reducing DSAs during the five days following the start of treatment

AMR is one of the most challenging adverse events after kidney transplantation and it constitutes a main cause for graft dysfunction and loss, with acute AMR episodes occurring in 5-7% of kidney transplants.

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

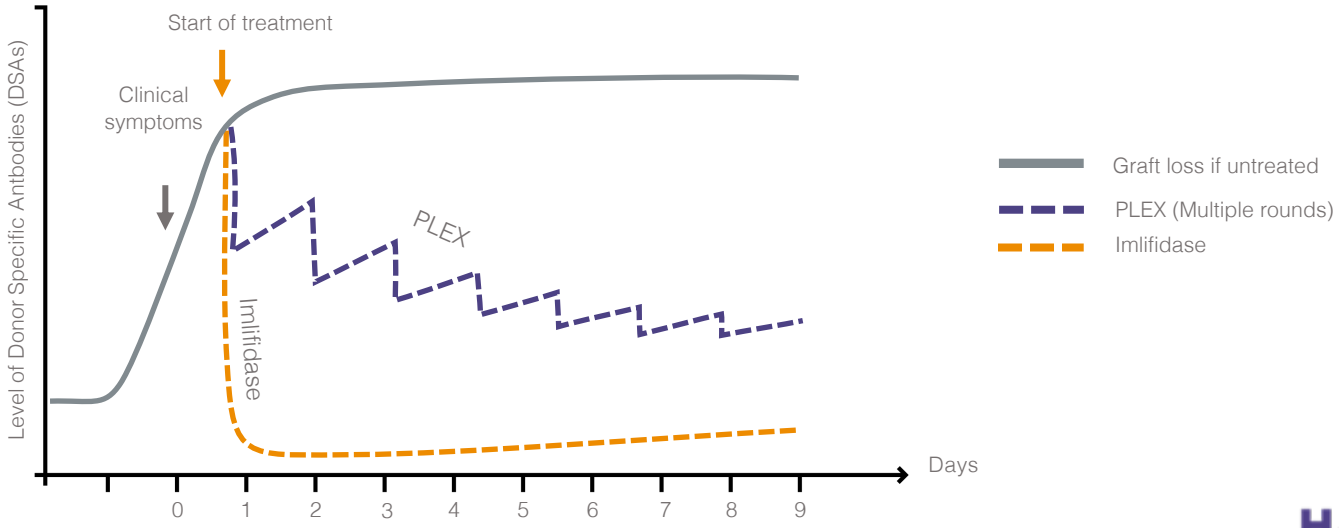
- Randomized, open-label multi-center active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

STATUS

Topline data presented November 2022

Potential of using imlifidase vs. PLEX in AMR

Illustrative



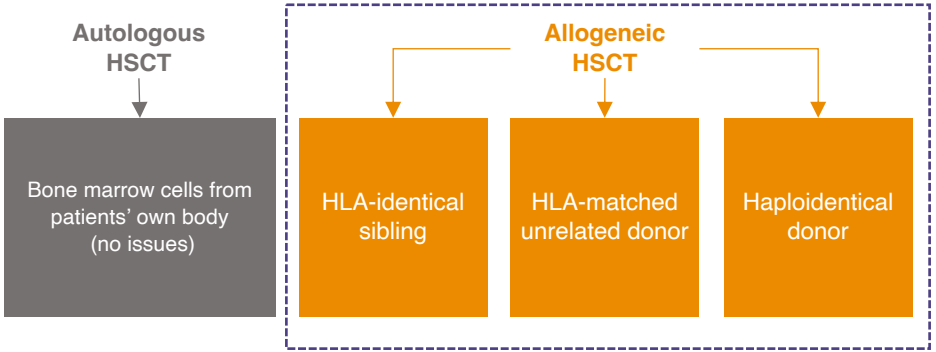
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

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

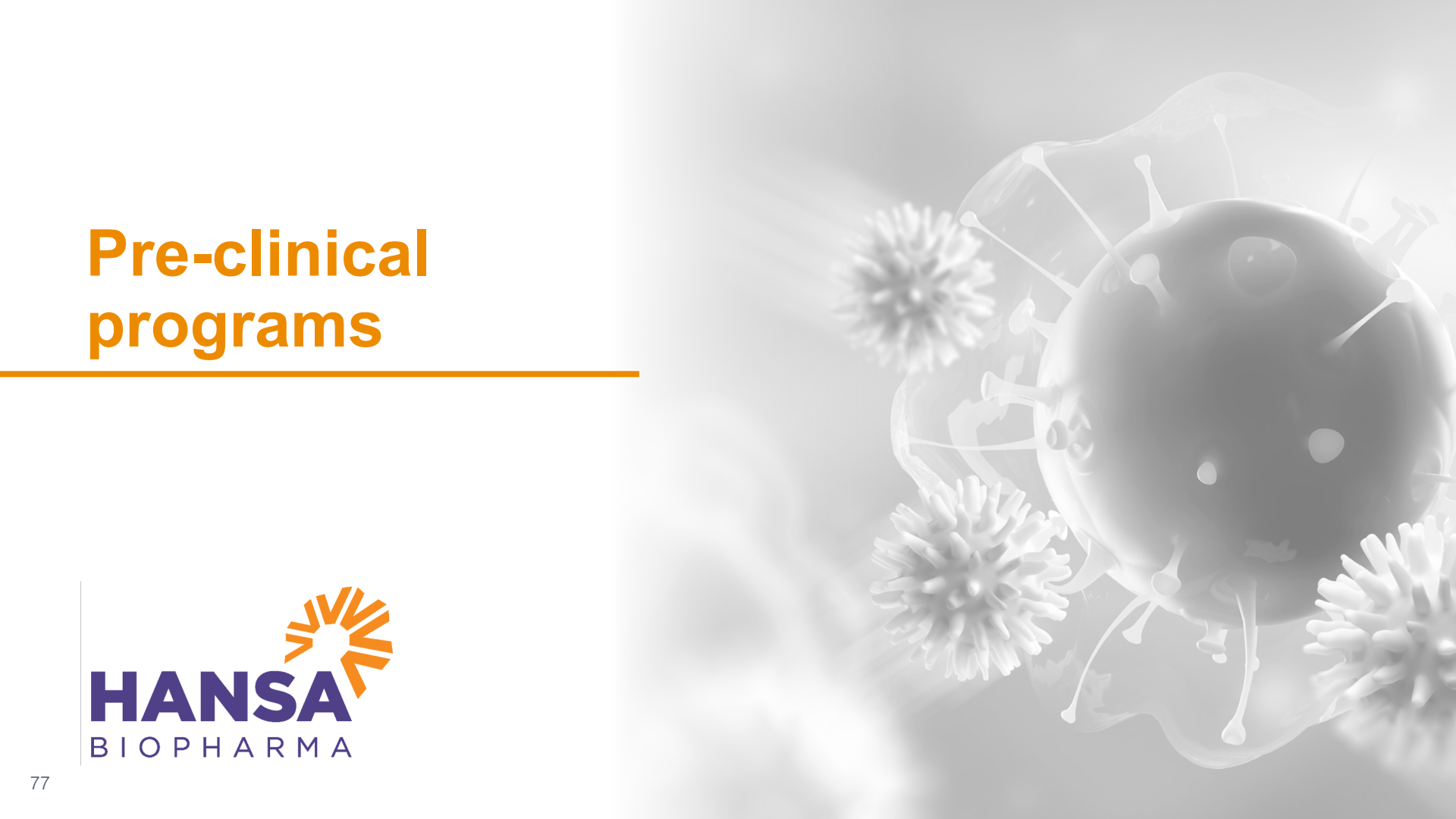
- Haploidentical donors (e.g. parents, children) are often available and transplant outcome is good (e.g. engraftment, graft survival, survival)
- However, presence of donor specific antibodies (DSAs) have a negative impact on transplant outcome[2] (e.g. graft failure and survival) Prevalence of DSAs 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



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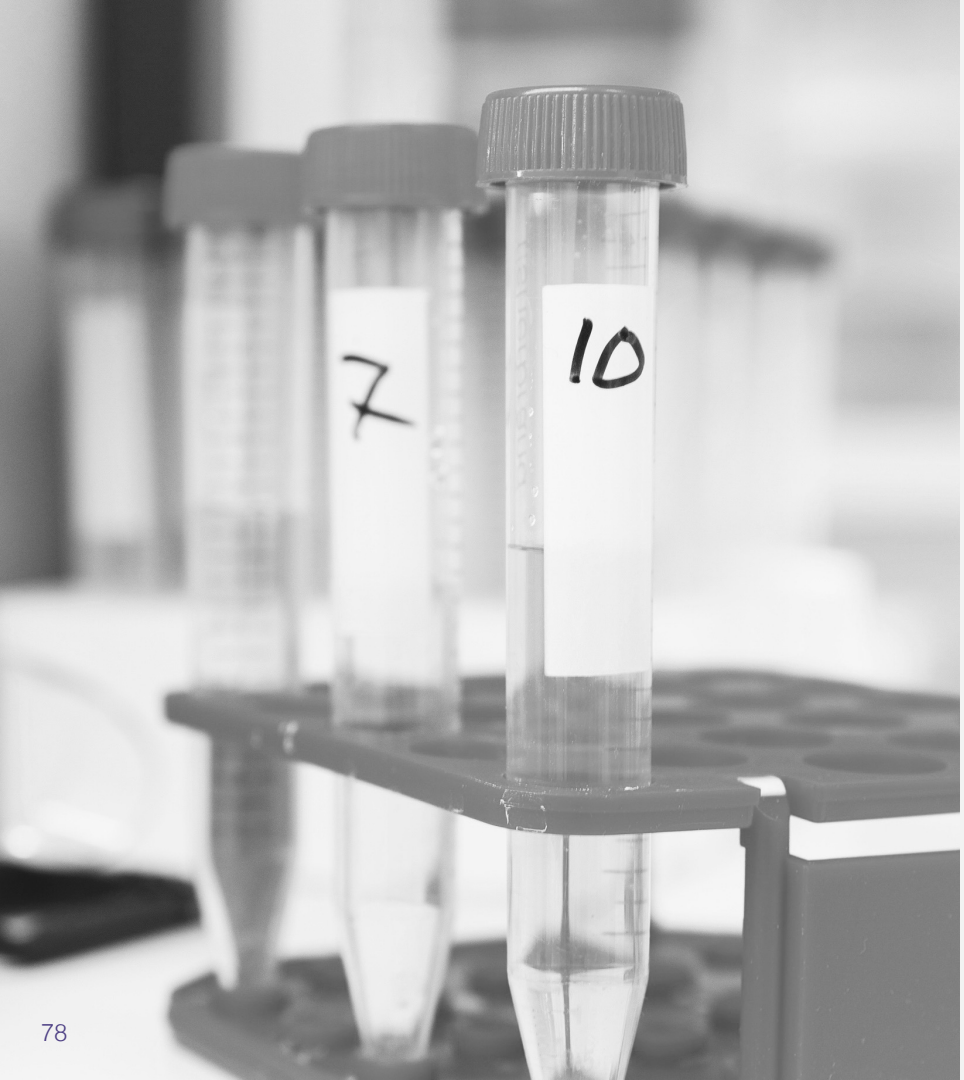


Preclinical collaboration with argenx BV

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

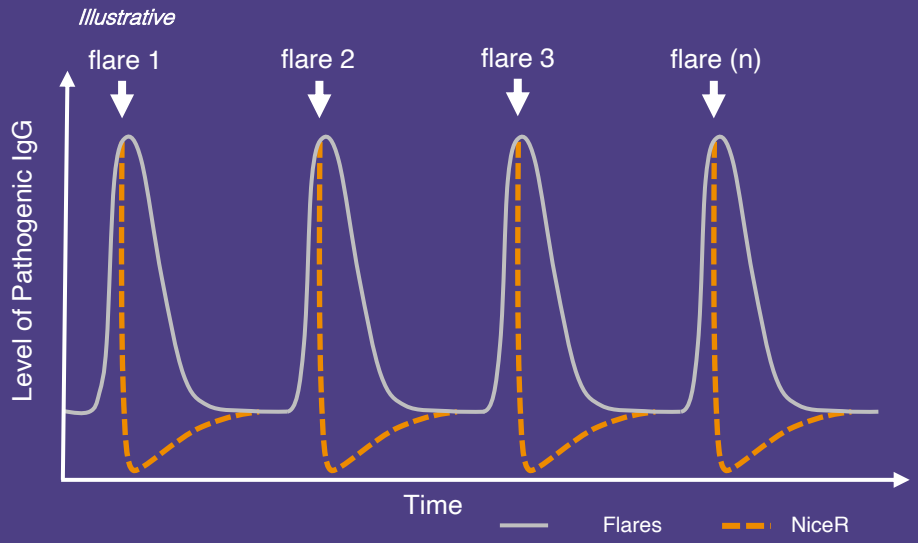
“NiceR” program
- our second generation enzymes for repeat dosing

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 toxicology studies was completed end of 2022 for the NiceR lead candidate HNSA 5487.
- A CTA approval has since been obtained and we expect to start a clinical trial in the first half 2023.

NiceR can potentially inactivate flares



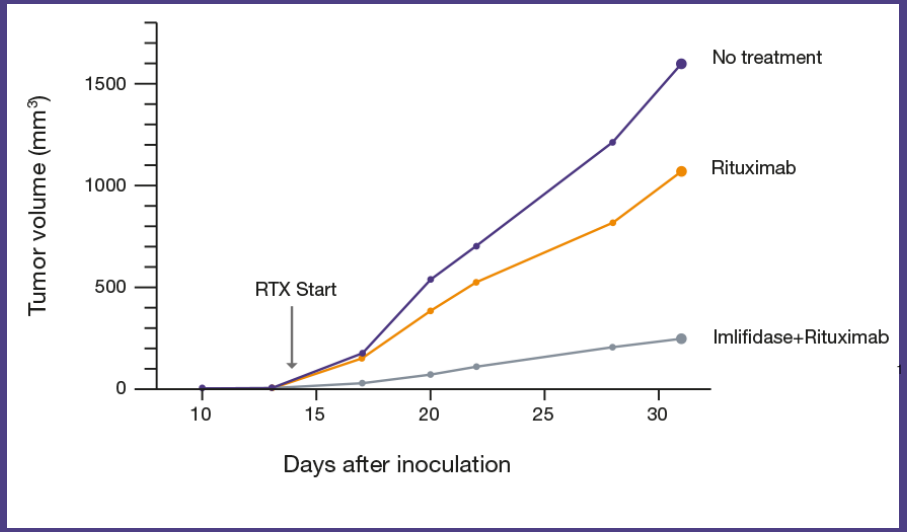
Our antibody cleaving enzymes

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

Proof of concept demonstrated in vivo for mice

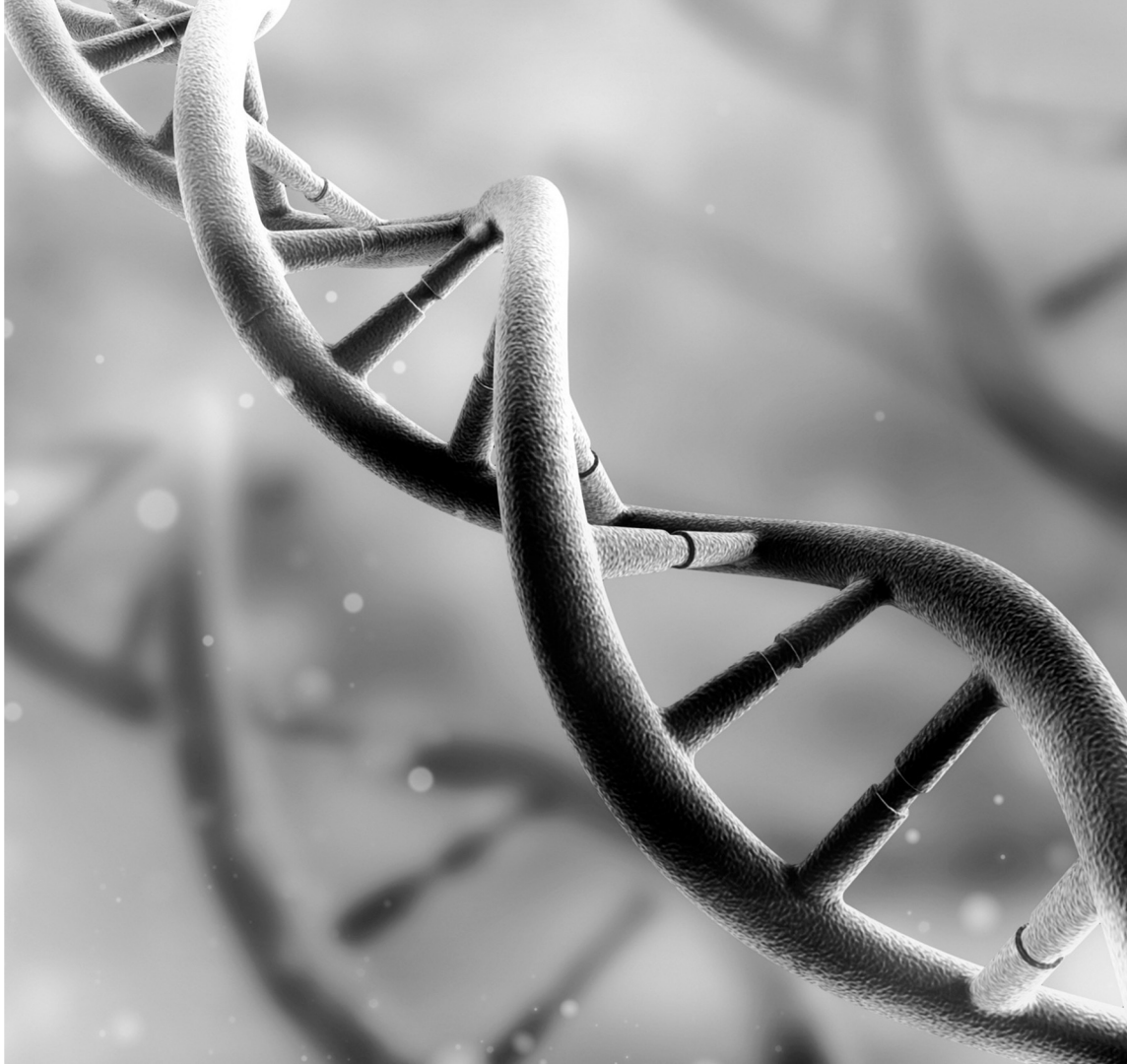
- Enzyme based antibody enhancement through pre-treatment
- The abundance of normal IgG in blood interferes with therapeutic monoclonal antibodies
- Pre-treatment with imlifidase / NiceR has potential to significantly potentiate antibody-based cancer therapies
- Suppressive effect of IVIg on effector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



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Exploring opportunities in gene therapy

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

A revolutionary approach

Significant unmet need

Encouraging pre-clinical data

Partnership strategy

Stock images

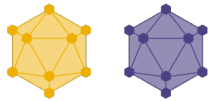
Tropism and target tissue

AAV subtypes targets different tissues

AAV 1, 2 & 5

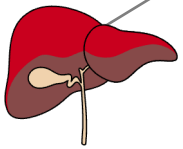
Eye (local target)
~1x10^{11} vg

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

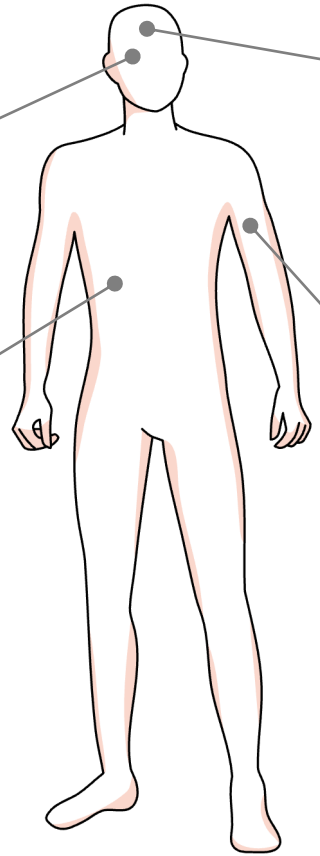


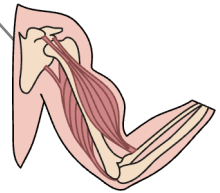
AAV 4 & 8

AAV 3, 7 & 8

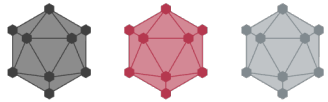


Liver (systemic)
~1x10^{14} vg





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



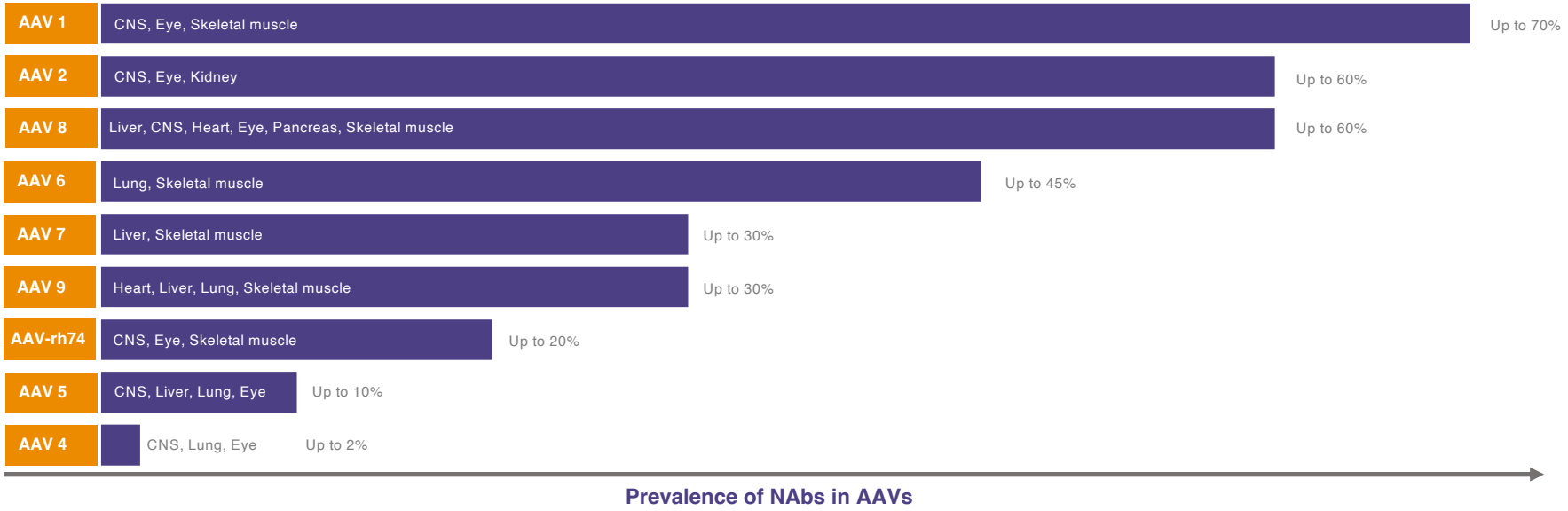
AAV 6, 7, rh74

Target tissues
Dose of gene therapy (vg)

HANSA BIOPHARMA

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)

HANSA BIOPHARMA

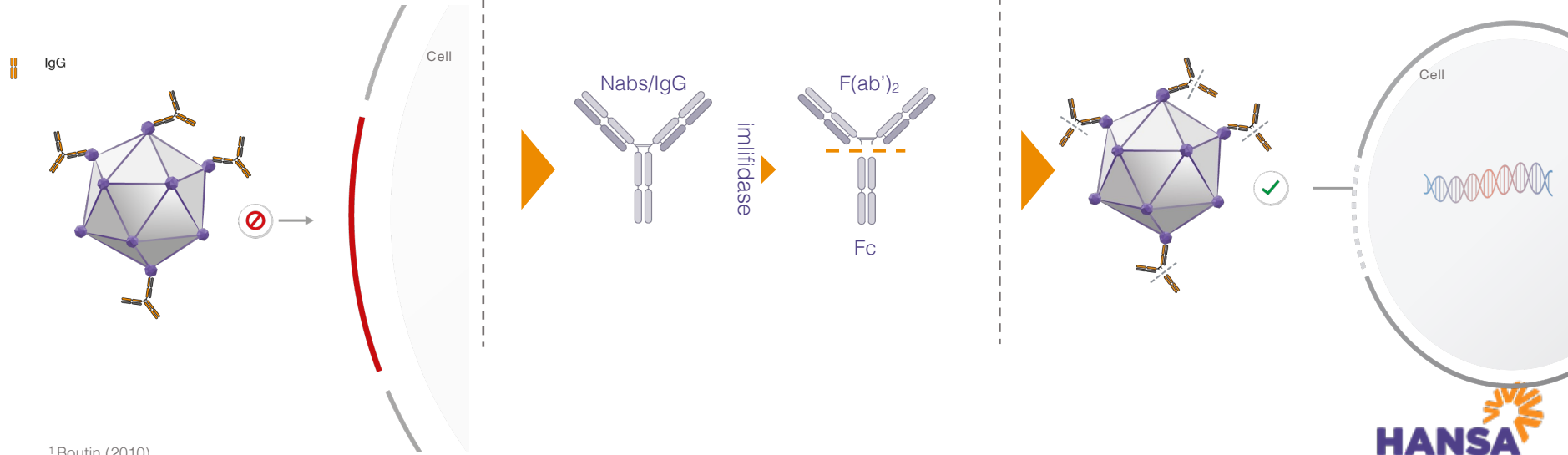
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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)

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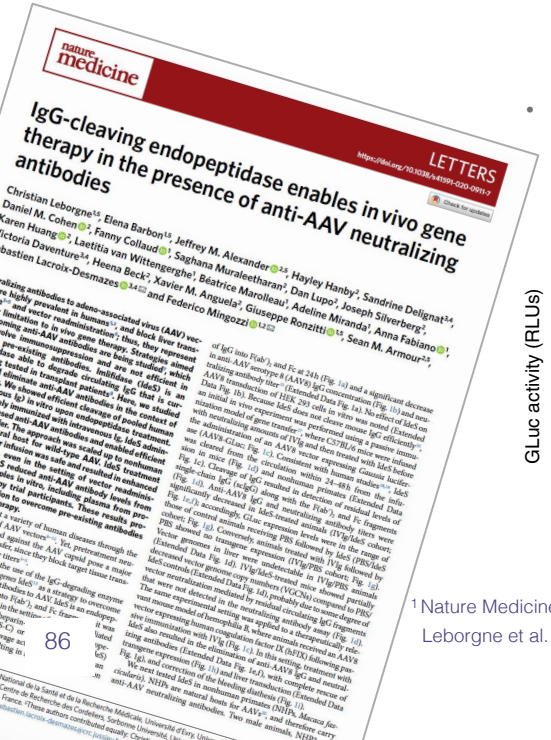
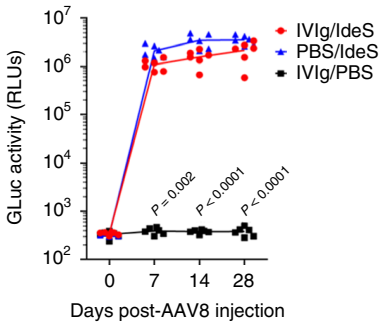
Imlifidase (IdeS) was highlighted in Nature Medicine[1]

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



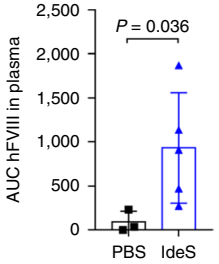
Imlifidase tested in a animal model

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



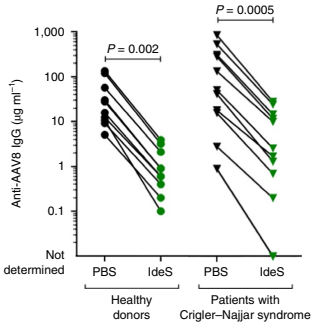
Imlifidase tested in NHP ahead of AAV vector infusion

- 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)

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Global and exclusive agreement with Sarepta Therapeutics

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

Indication exclusivity:

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

Hansa's key resources

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

+

Sarepta's key resources

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

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

Upfront payment
USD 10 million upfront

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

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

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

Update

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

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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

+

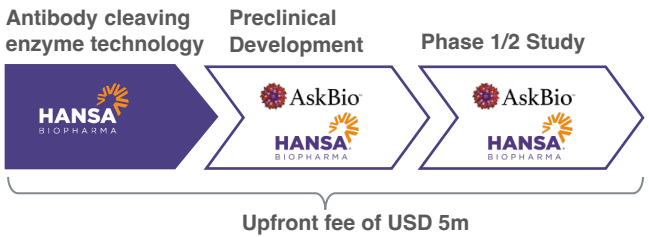
AskBio™

Fully owned subsidiary of Bayer AG

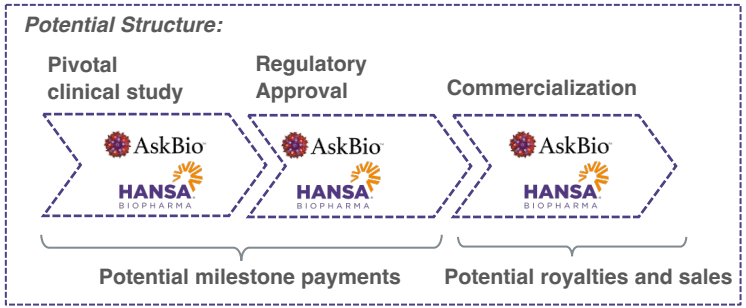
AskBio's key resources and deliverables

- 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



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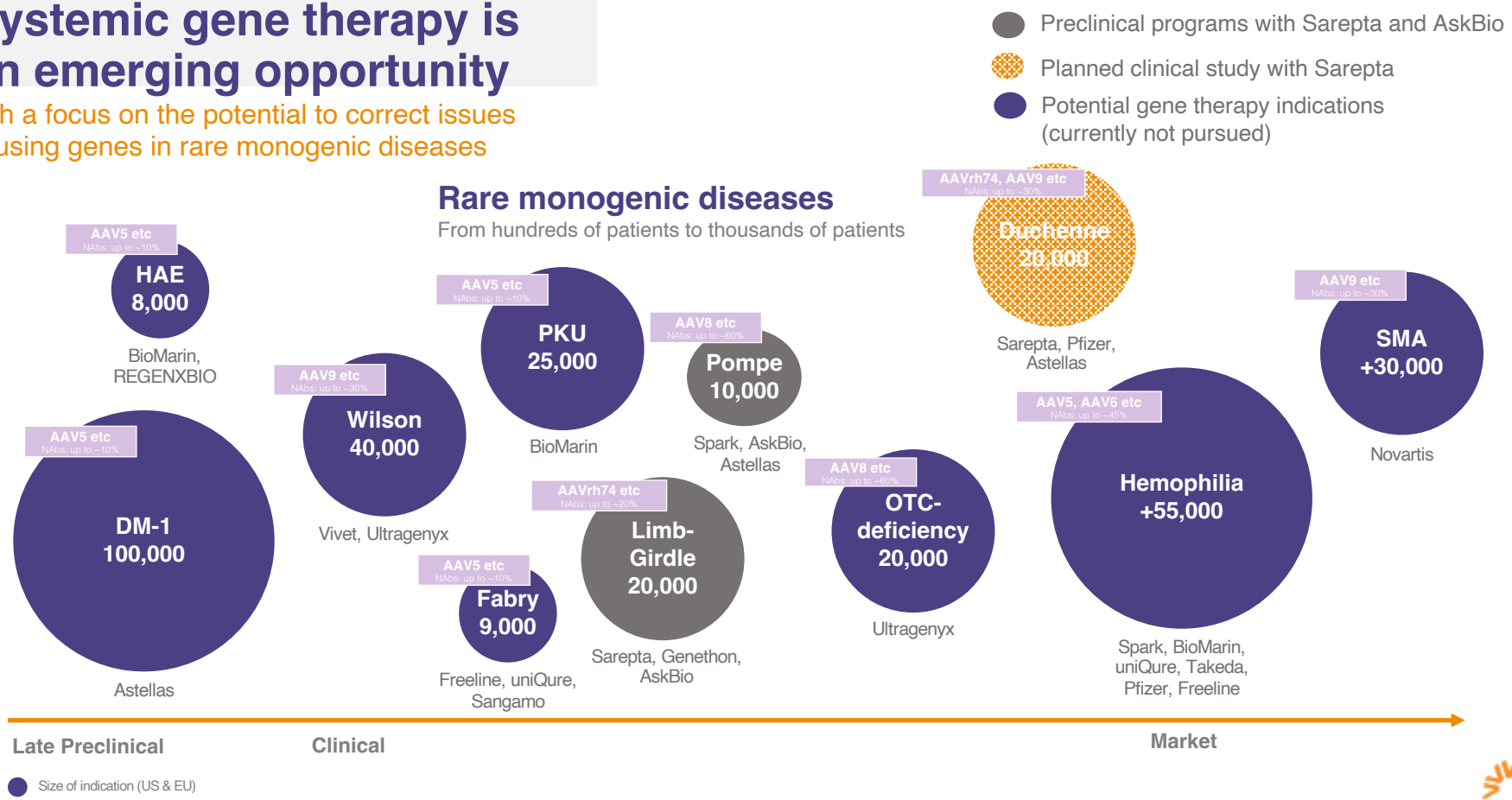
Systemic gene therapy is an emerging opportunity

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]

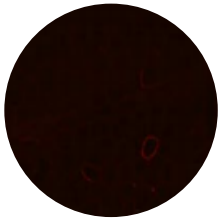
- Rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3 to 5, and most patients use a wheelchair by the time they are 11
- Cardiac and respiratory muscle deterioration becomes life-threatening
- 1/3,500 to 5,000 male births (worldwide)
- Approximately 15% of patients have pre-existing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

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

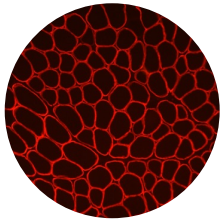
- AAVrh74 vector with micro-dystrophin transgene
- Broad patient experience
- 4 ongoing clinical trials – including recently initiated pivotal study
- Robust micro-dystrophin protein expression with commercially representative process material
- Functional benefits sustained up to 3 years after administration
- Observed safety profile is consistent
- On September 29, 2022, Sarepta announced that it had submitted a Biologics License Application (BLA) to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD.
- On November 2, 2022 Hansa and Sarepta announced plan to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023

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

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Limb-Girdle muscular dystrophy (LGMD) SRP-9003

About limb-girdle muscular dystrophy

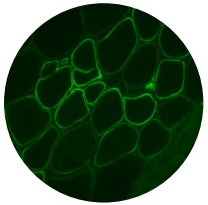
Limb-girdle muscular dystrophy is a group of diseases that cause weakness and wasting of
the muscles

- 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

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Pompe Disease (PD) AAV2/8-LSPhGAA

About Pompe Disease

- Defect in a gene making an enzyme called acid alpha-glucosidase (GAA), which is used to break down glycogen
- Accumulation of glycogen result in severe impact on the normal organ and muscle function
- Current standard of care is enzyme replacement therapy (ERT)
- Approximate incidence is 1 per 40,000[1] births, or ~200 per year in the US + EU
- Prevalence is estimated to be around 10,000 in the US and Europe combined[2]
- Approximately 40-60%[3,4] of patients have pre-existing IgG antibodies to AAV8

AskBio's AAV2/8-LSPhGAA gene therapy

- AAV2 vector genome cross-packaged as AAV8
- Liver-specific promoter to express GAA enzyme
- Open label Phase I/II study ongoing
- Study in 8 Late-Onset Pompe Disease patients
- ClinicalTrials.gov: NCT03533673

For further information regarding AskBio's gene therapy program, please refer to www.askbio.com

Sources:

[1]Pompe Disease. https://rarediseases.org/rare-diseases/pompe-disease/ [accessed 2022-02-08]

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

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

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

HANSA BIOPHARMA

ESG Overview

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

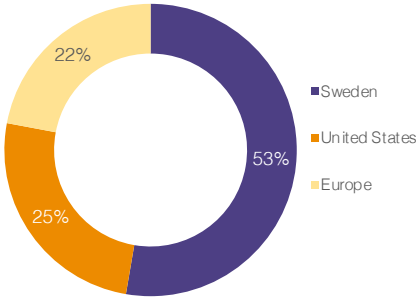
Ownership in Hansa Biopharma

Top 10 ownership as per December 31, 2022

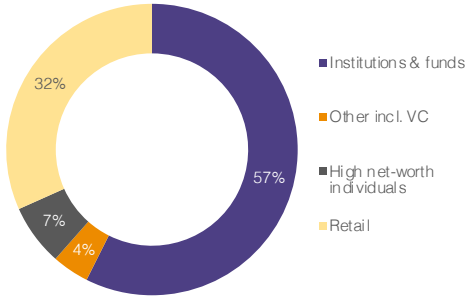
Name	No. of shares	Ownership
Redmile Group, LLC	10 896 553	20.8%
Försäkrings AB Avanza Pension	2 209 783	4.2%
Fjärde AP-Fonden (AP 4)	2 207 397	4.2%
Nexttobe AB	2 155 379	4.1%
Olausson, Thomas	1 917 000	3.7%
Tredje AP-Fonden (AP 3)	1 389 650	2.6%
Braidwell, L.P.	974 528	1.9%
Handelsbanken Asset Management	908 266	1.7%
C WorldWide Asset Management	799 749	1.5%
Heights Capital Management, Inc.	667 169	1.3%
Other	28 318 488	54.0%
Total	**52 443 962**	**100.0%**

Classification of ownership as per Dec 31, 2022

Ownership by country



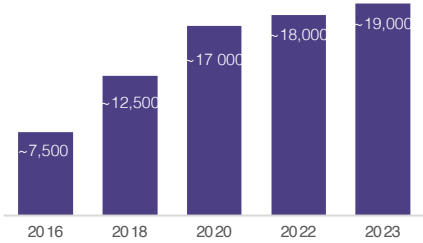
Ownership by type



Capital Raises

Capital Raised
SEK ~4bn
since 2007

No. of shareholders



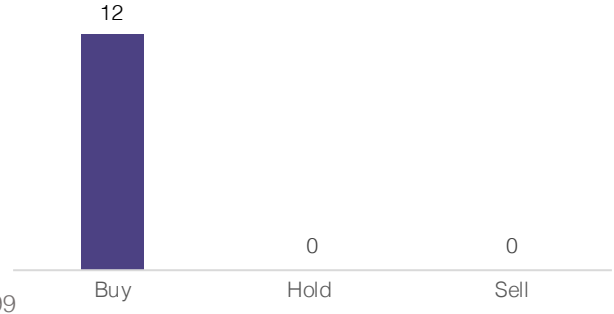
Company collected consensus

Consensus is based on a collection of analyst estimates pre-Q4 2022 report (January 2023)

			Patient uptake, EU				Revenue, SEKm			
	Price Target, SEK	WACC	FY'22e	FY'23e	FY'24e	FY'25e	FY'22e	FY'23e	FY'24e	FY'25e
Average	199	11,2%	27	53	101	180	147	210	399	844
Median	200	11,5%	26	52	101	188	153	206	367	862
High	265	15,0%	30	64	136	242	159	247	570	1 219
Low	121	7,6%	25	46	72	106	131	181	298	552
Number of contributions	12	12	7	7	7	7	7	7	7	7

	EBIT, SEKm				Operating Cash Flow, SEKm				Cash position, SEKm			
	FY'22e	FY'23e	FY'24e	FY'25e	FY'22e	FY'23e	FY'24e	FY'25e	FY'22e	FY'23e	FY'24e	FY'25e
Average	-609	-642	-547	-374	-588	-655	-508	-393	1 455	1 050	784	569
Median	-610	-666	-490	-435	-586	-643	-492	-487	1 442	951	754	719
High	-585	-500	-259	-14	-512	-491	-301	23	1 551	1 569	1 536	1 040
Low	-641	-737	-848	-747	-641	-950	-647	-536	1 400	757	193	-249
Number of contributions	7	7	7	7	7	7	7	7	7	7	7	6

Analyst recommendations



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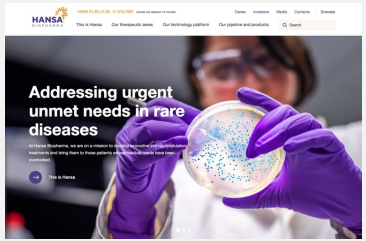

Visit our new web site
www.hansabiopharma.com

Calendar and events

Feb 9, 2023	Mid-cap event, Frankfurt
Feb 23, 2023	Erik Penser Healthcare seminar, Stockholm
Mar 7, 2023	Redeye Healthcare seminar: Commercialization, Stockholm
Mar 8, 2023	Cowen Healthcare Conference, Boston
Mar 9-10, 2023	H.C. Wainwright non-deal road show, Connecticut/NYC
Mar 16, 2023	Carnegie Nordic Healthcare Seminar 2023, Stockholm
Mar 30, 2023	**2022 Annual Report**
April 4, 2023	Guggenheim Healthcare Talks Rare Disease Days, virtual
April 20, 2023	**Interim Report for January-March 2023**
April 20, 2023	Redeye Investor Forum, Gothenburg
April 21 2023	Redeye Lunch presentation, Stockholm
April 25 2023	Kempen Life Sciences Conference 2023, Amsterdam
May 11, 2023	Erik Penser Company Day, Malmö
May 11, 2023	Redeye Investor forum, Malmö
May 25, 2023	Erik Penser Company Day, Stockholm
June 14, 2023	**Annual General Meeting**
July 20, 2023	**Half-year Report for January-June 2023**
Aug 24, 2023	Erik Penser Company Day, Stockholm
Sept 7 2023	CITI Annual BioPharma Conference, Boston
Sept 11, 2023	MorganStanley Global Healthcare Conference, NYC
Oct 19, 2023	**Interim Report for January-September 2023**
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen


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