



**Investor Road Show
Presentation Q1 2023**

Lund, April 20, 2023

Forward-looking statements

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

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

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Business update Q1'2023



Q1 progress on key deliverables

Our mission is to become a global leader in rare diseases

1 European launch of Idefirix® progresses as planned

- ✓ Repeat business of Idefirix® at first clinics
- ✓ Market Access secured in Spain completing access in the five of the largest European markets
- ✓ Expanded commercialization partnership with Medison Pharma in the Baltics

2 Exciting pipeline advances

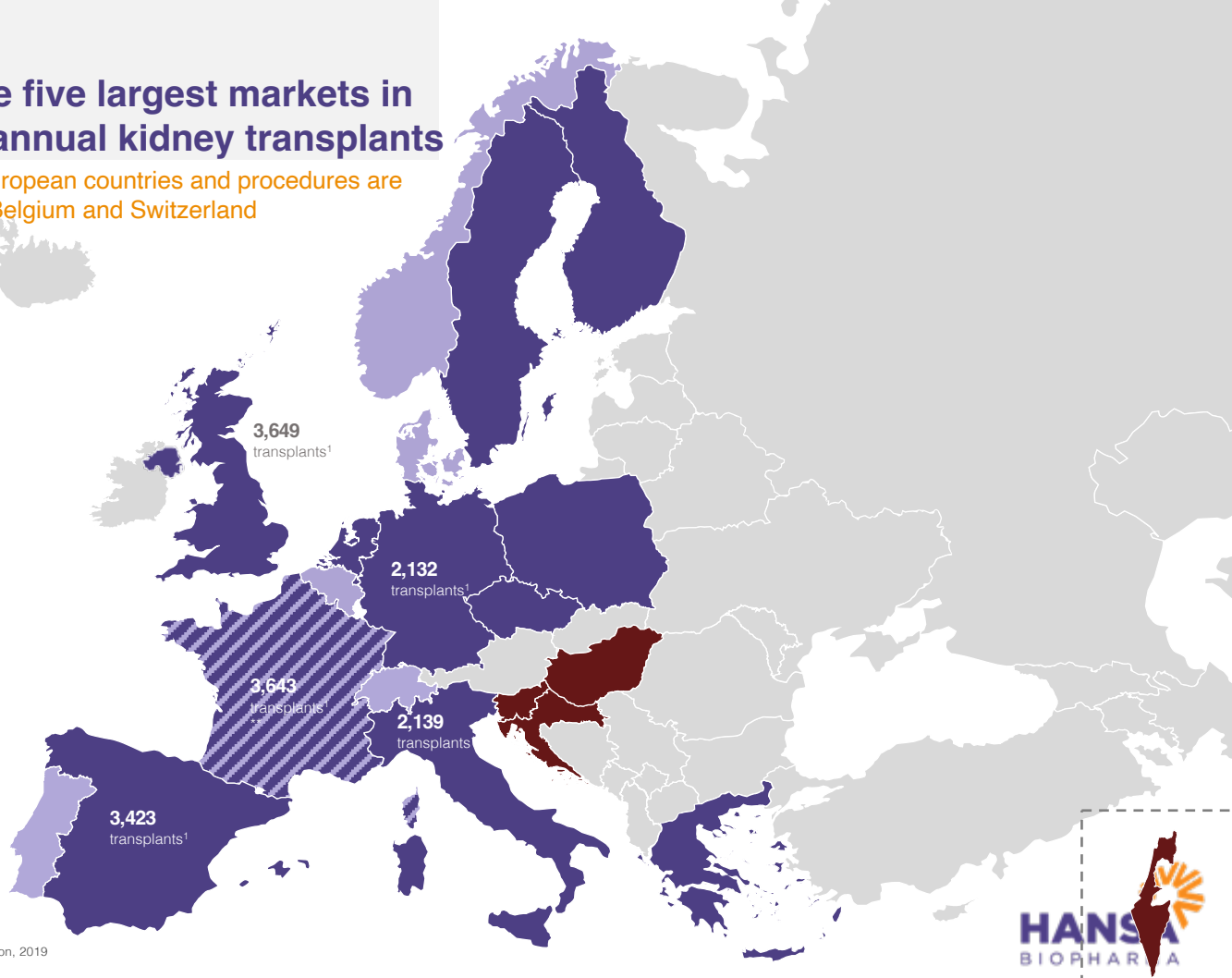
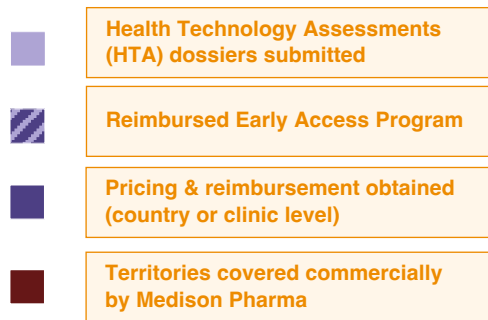
- ✓ Guillain-Barré Syndrome (GBS): Phase 2 study enrolment completion
- ✓ HNSA-5487: Clinical study initiated with our next generation enzyme in healthy volunteers
- ✓ U.S. ConfIdes study: 62/64 patients enrolled; adding more centers in the U.S.

3 Performance continues at pace

- ✓ Total Q1 revenue - SEK 24m incl. SEK 14m in product sales and SEK 9.9m in revenue recognition from partnerships
- ✓ Cash position - SEK 1.287m end of Q1'23; Hansa financed into 2025
- ✓ Matthew Shaulis - appointed new CCO and U.S. President

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

Market access has now been secured in 12 European countries and procedures are ongoing in eight countries including Portugal, Belgium and Switzerland



Exciting pipeline advances potential new medicines in areas of high unmet need

Antibody Mediated Rejection (AMR)

Phase 2

- 30/30 patients enrolled
- Demonstrated a statistically significantly superior capacity to rapidly reduce levels of DSAs compared to PLEX (SoC)
- Full data read out expected H2 2023



Guillain-Barré Syndrome (GBS)

Phase 2

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



Anti-GBM

Phase 3

- Open-label, randomised controlled study
- 50 patients to be treated to with imlifidase and SoC or SoC, alone
- Kidney function evaluated as primary endpoint
- First patient dosed H1 2023



U.S. ConfideS

Phase 3

- 62/64 patients enrolled for randomization
- 13 centers open for recruitment; Hansa expects to add additional centers up to a total of 20
- Hansa will continue enrollment to accelerate randomization
- Enrollment completion expected in H1 2023; Randomization expected to be complete H2 2023

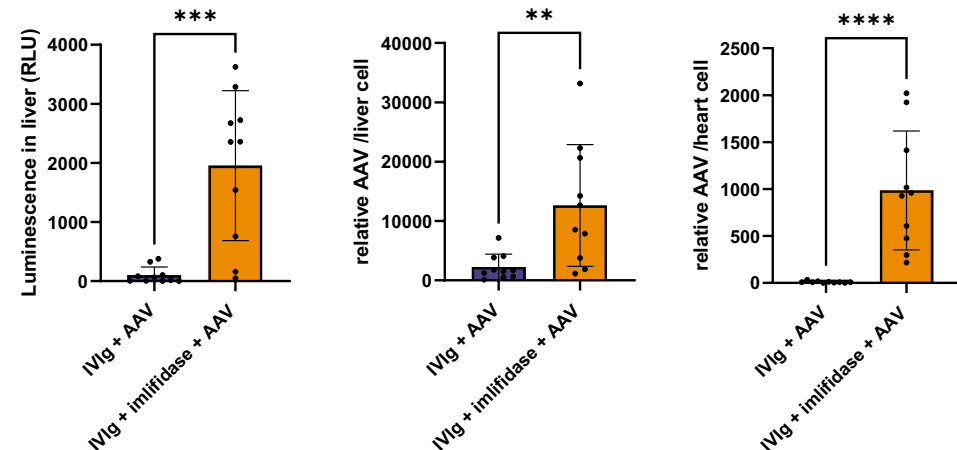


- Patients enrolled
- Patients remaining

Imlifidase facilitates transduction of AAV8 in a mouse model

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

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



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

Imlifidase has previously been highlighted in Nature Medicine¹ with encouraging outcome



Leborgne et al. Nat Med (2020)

¹ Nature Medicine <https://doi.org/10.1038/s41591-020-0911-7>

Broad clinical pipeline in transplantation and autoimmune diseases

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	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)							Next milestone topline data H2 2023/ Comparison to IGOS (2024)
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)							Read out of phase 1 in healthy volunteers
EnzE	Cancer immunotherapy							Research

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)


² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

³ Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

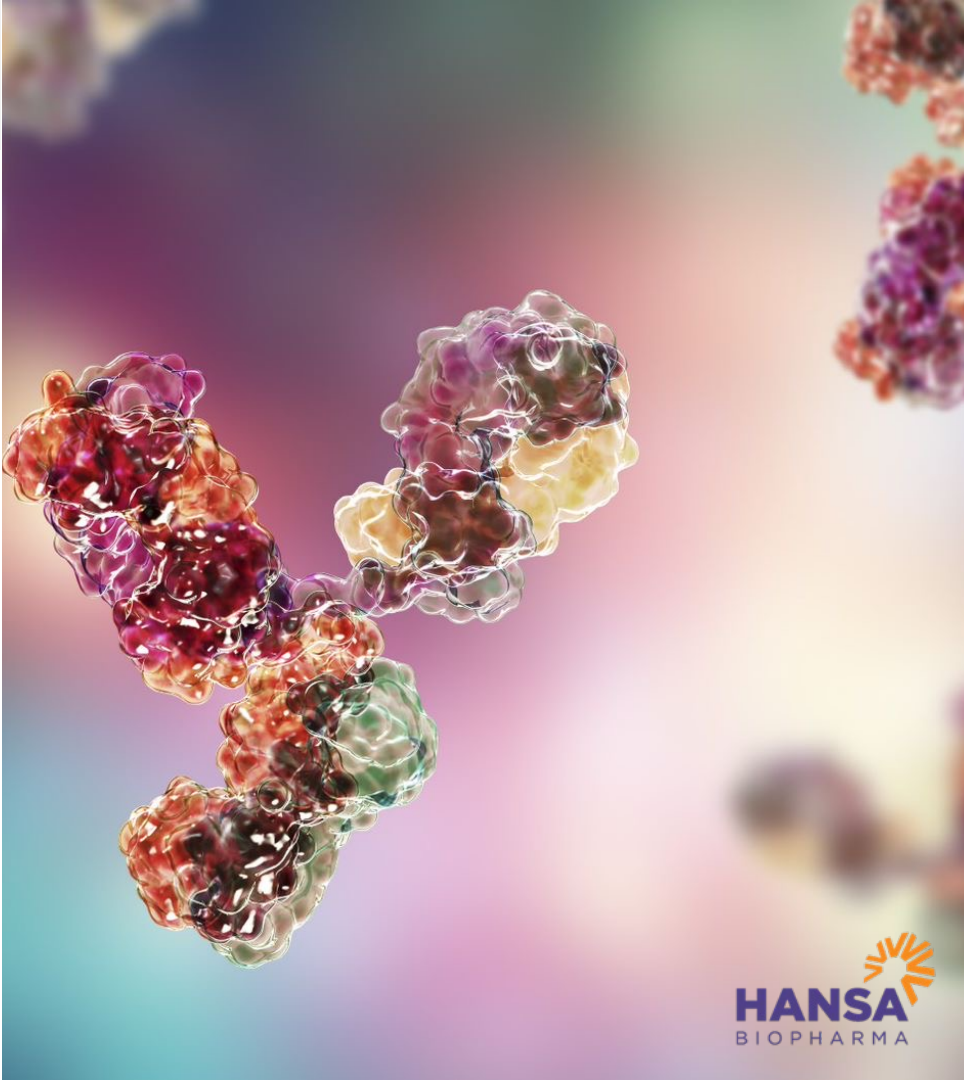
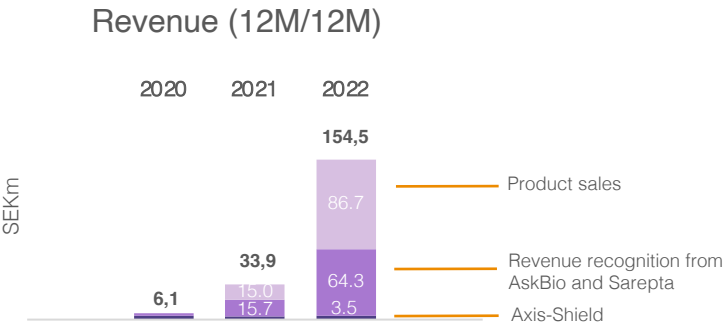
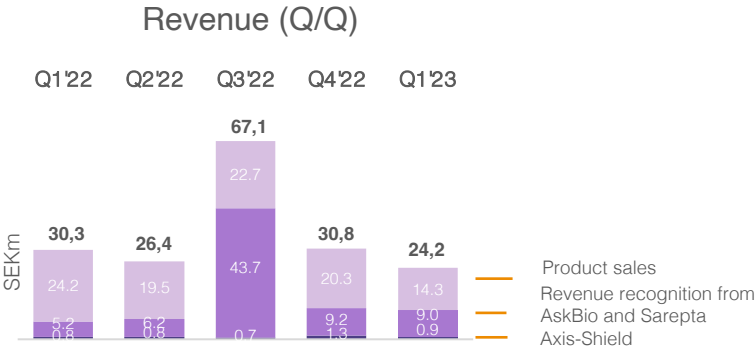
 Completed

 Planned

 Ongoing

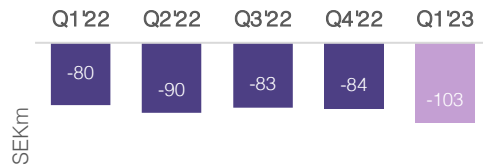
 Post approval study running in parallel with commercial launch

Q1 2023 Revenue amounted to SEK 24m including SEK 14m in product sales

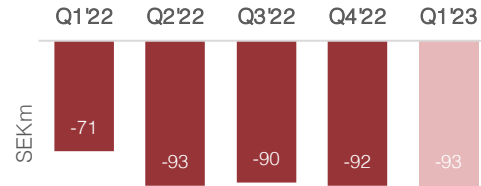


Continued investments in our commercialization and R&D activities

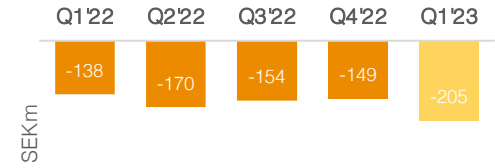
SG&A expenses (Q/Q)



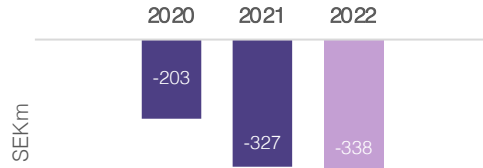
R&D expenses (Q/Q)



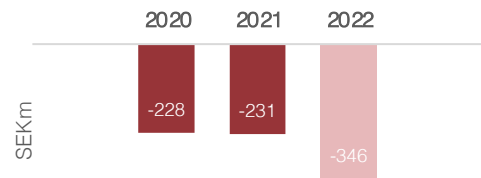
Net loss (Q/Q)



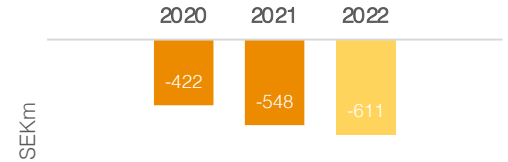
SG&A expenses (12M/12M)



R&D expenses (12M/12M)

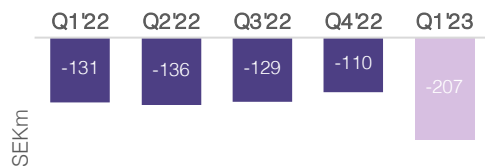


Net loss (12M/12M)

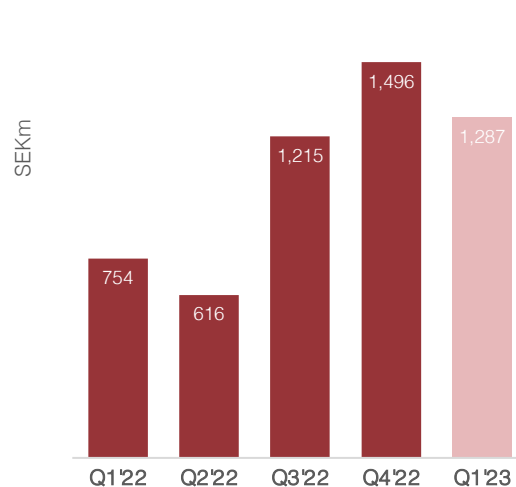


With current cash position and projected burn-rate, Hansa's operations are financed into 2025

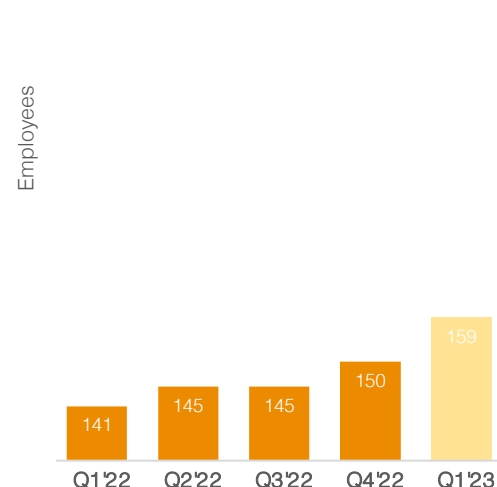
Operating cash flow (Q/Q)



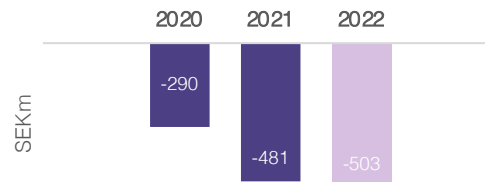
Cash & short-term investments (Q/Q)



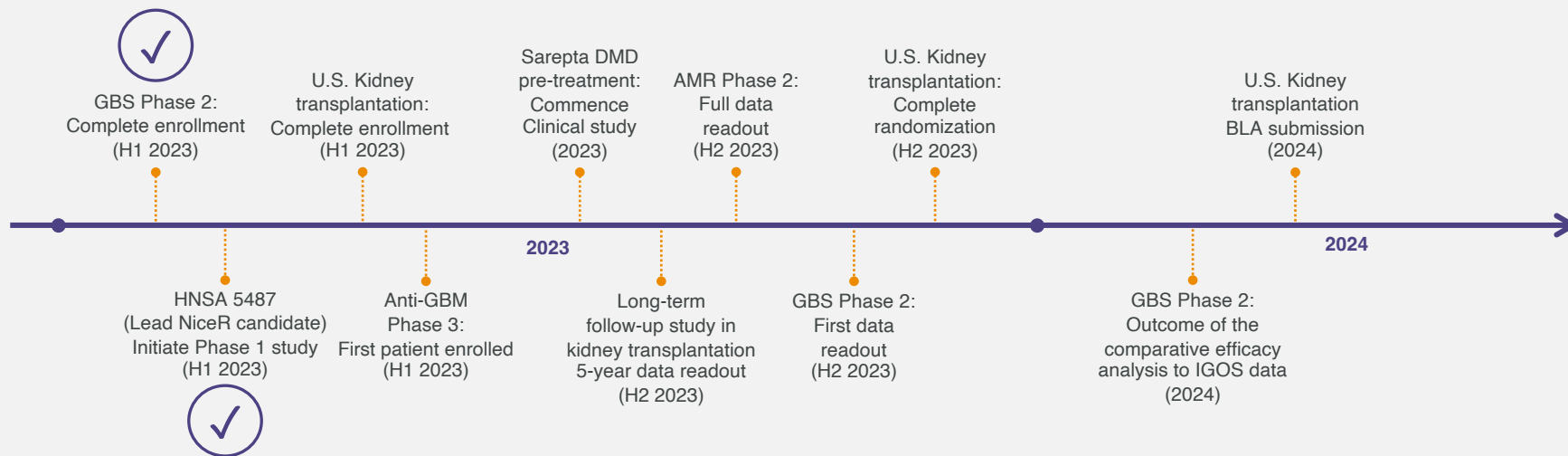
Number of employees (Q/Q)



Operating cash flow (12M/12M)



Key near term milestones



Company overview



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)
HANSA-5487 (second generation)

Established a high-performance organization

NEW COMPETENCIES ADDED

159 employees March 31. 2023
(~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 ~1.3bn in Cash and short term investments (USD ~125m) March 2023

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~270m March 31, 2023

Listed on Nasdaq Stockholm
20,000 shareholders
Foreign ownership make up ~47% through leading international life science specialist funds



Patient*

This is a break-through for the patients who need but can't access kidney transplantation today

*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

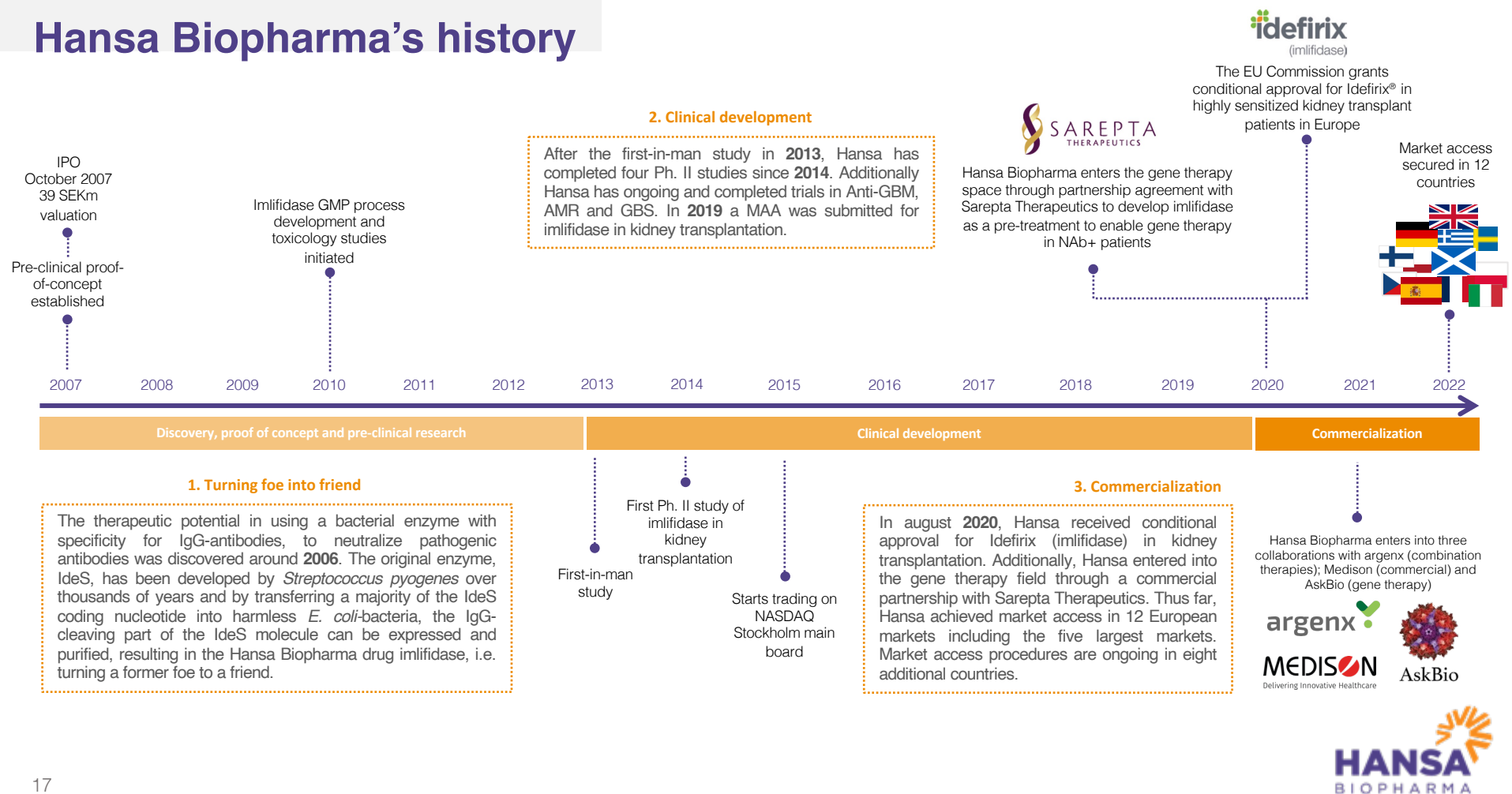
We envision a world where patients with rare immunologic diseases and conditions can lead long and healthy lives



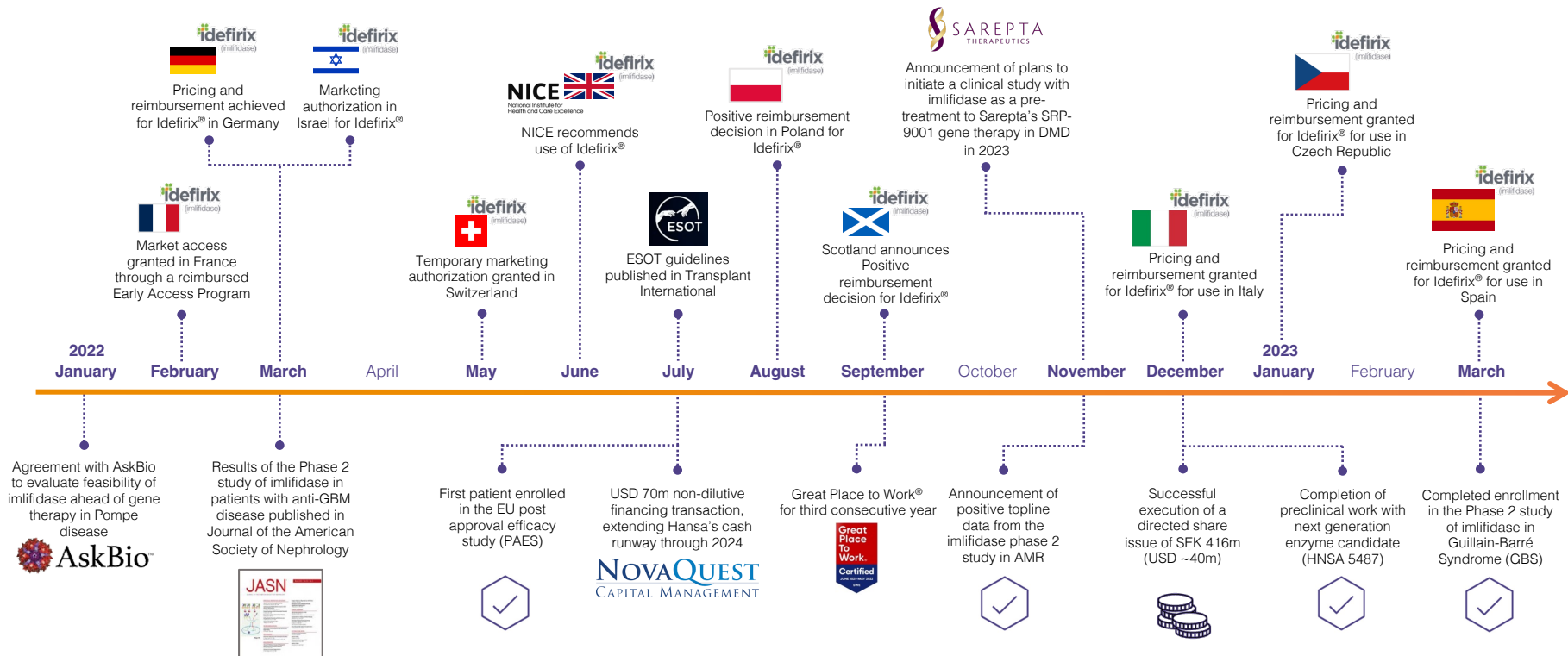
* European Economic Area incl EU plus Iceland, Liechtenstein and Norway

Stock images

Hansa Biopharma's history



Key milestones achieved during the last 15 months



Imlifidase

a novel approach to eliminate pathogenic IgG

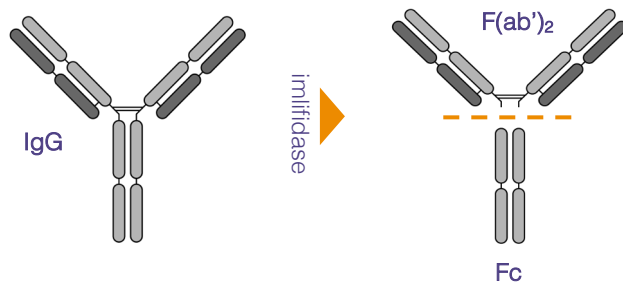
Origins from a bacteria *Streptococcus pyogenes*

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



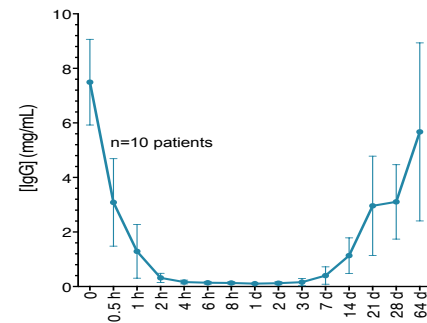
A unique IgG antibody-cleaving enzyme

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



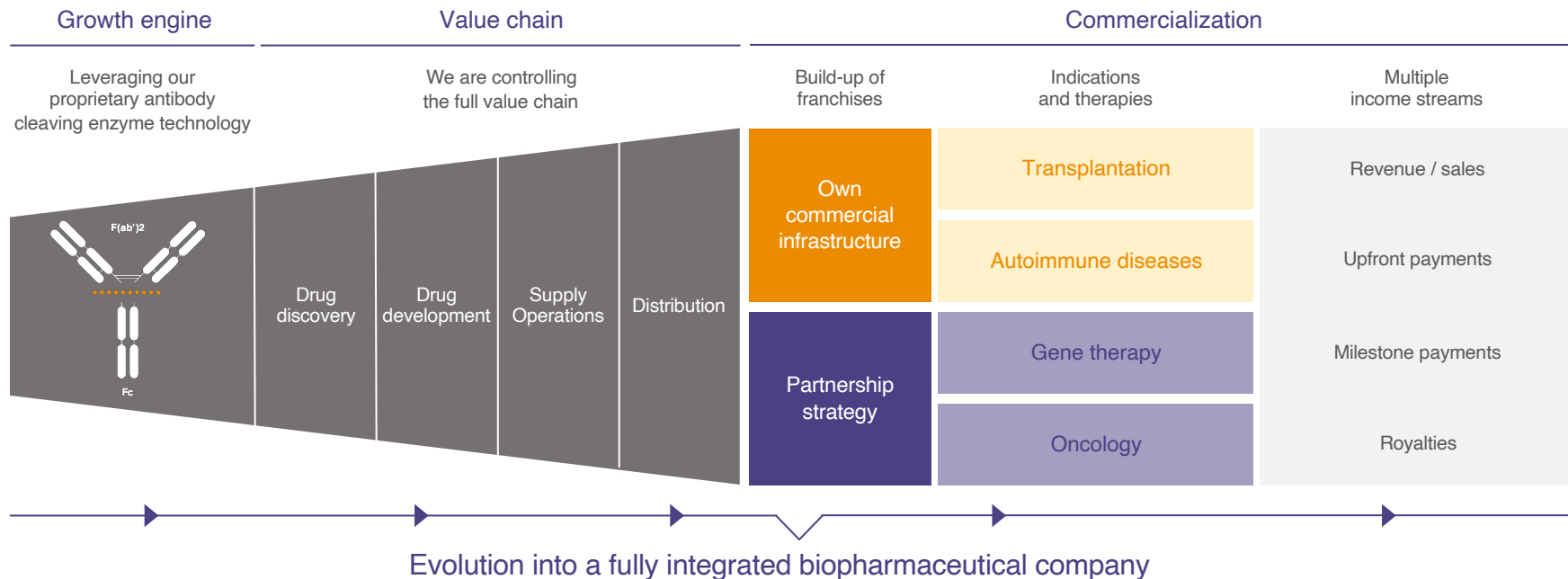
Inactivates IgG in 2-6 hours

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

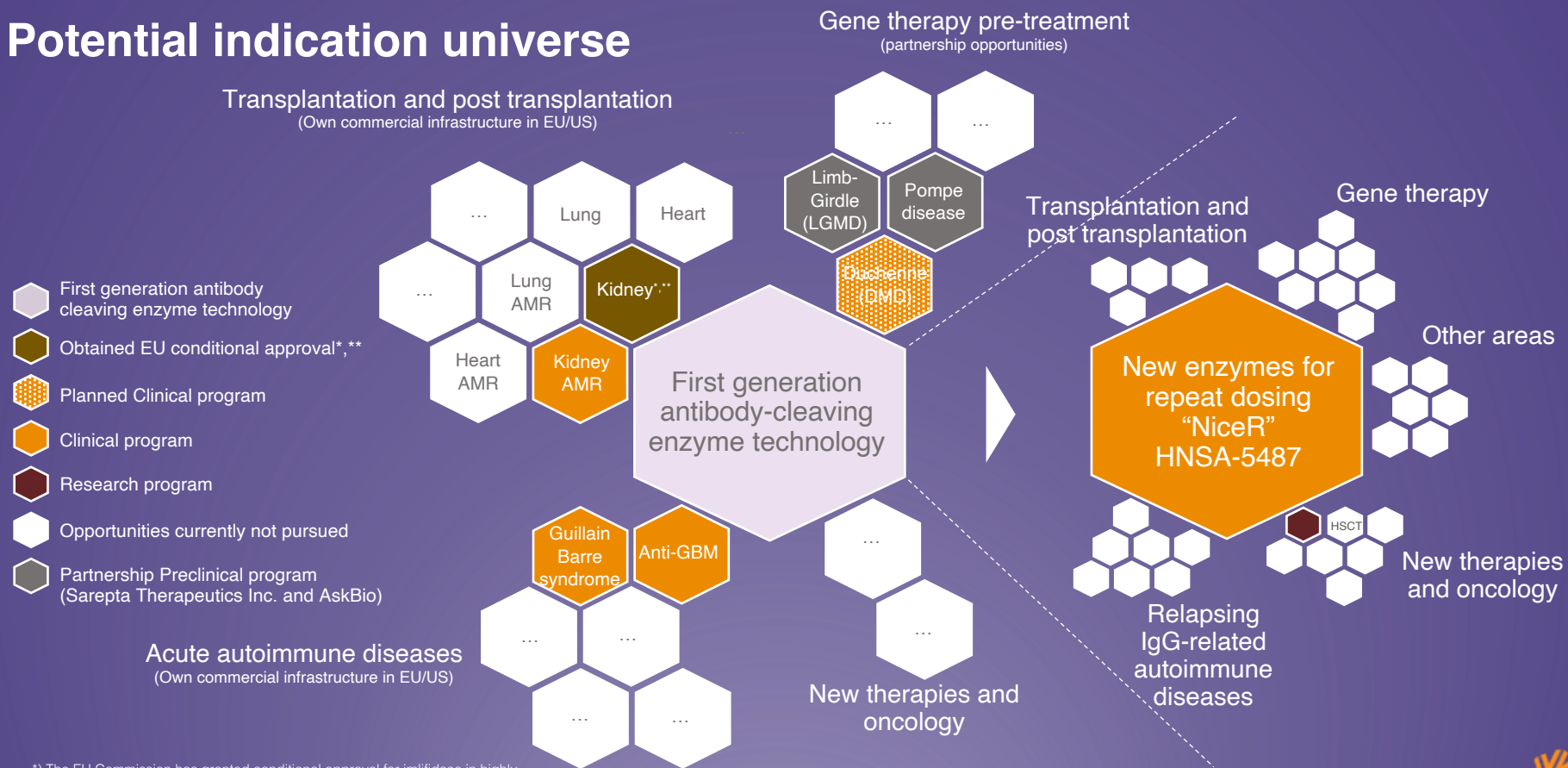


Our Business model

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



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 Commercialize Idefirix® in first indications and markets

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

2 Advance ongoing imlifidase clinical programs in transplantation and autoimmune diseases

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

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

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

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

Becoming a fully integrated commercial stage biopharmaceutical company

while expanding our technology and global footprint

We are
here!

Pre-clinical

Early-stage clinic

Late-stage clinic

Commercial stage

1

Creating a scientific platform

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

2

Preparing the company for commercial success

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

3

Building and capturing value in new indications and markets

- First drug approval in kidney transplantation in EU*
- Commercialization
- Market Access secured in 12 countries, including the five largest European markets
- Expanding commercial teams and adding territory management
- Securing supply chain management
- Progressing pipeline and advancing our technology footprint

Our culture is driven by people passionate about making changes



Purpose driven culture

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



Diverse and international

~45%
Internationals across
~30 nationalities

~55/45
Male/female gender split in
the leadership team



Skilled and experienced team

>50%
With relevant PhD in R&D

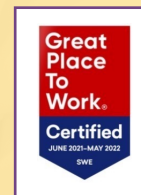
~20 years*
of life science experience
on average from
Big Pharma, Biotech
and Academia

*covers Management, R&D, and Commercial functions



Motivated workforce

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



Experienced Board and Executive Committee

Extensive experience from the global healthcare industry

Executive Committee



Søren Tøulstrup

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: 6,763



Achim Kaufhold

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



Matthew Shaulis

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



Anne Säfström Lanner

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



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. Adolife, Bulab, Itras, Abbrane
Ex-CFO of Vitrolite and Plasta
Chairman of Hansa Biopharma's Audit Committee
Shareholding: 3,000



Mats Blom

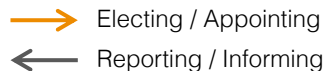
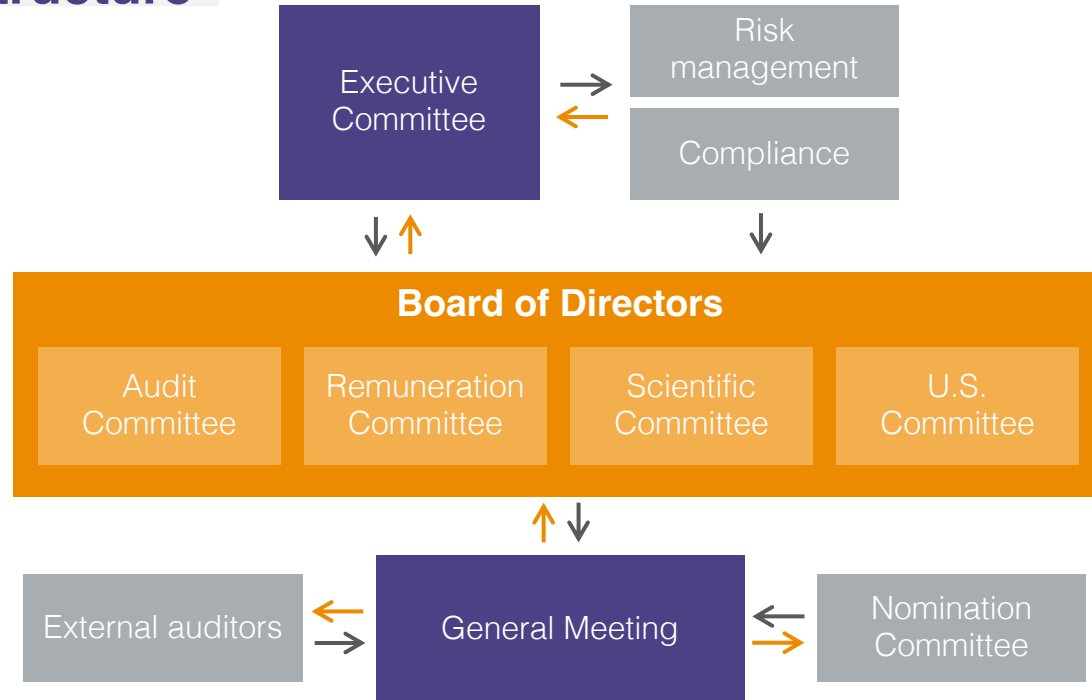
Board Member (2019)
CFO of NorthSea Therapeutics
Ex-CFO Zealand Pharma
Member of Hansa Biopharma's Audit Committee
Shareholding: 1,000



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 Remuneration 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:

Medical use in
IgG mediated
medical
conditions

Dosing in
combination
therapies incl.
transplantation &
oncology

Autoimmune
diseases

Treatment of
transplant
rejection

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 2020¹.

Orphan drug designation

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

FDA

Orphan drug designations

- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)

- Imlifidase for the treatment of Guillain-Barré Syndrome (2018)

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

Hansa Biopharma is financed into 2025

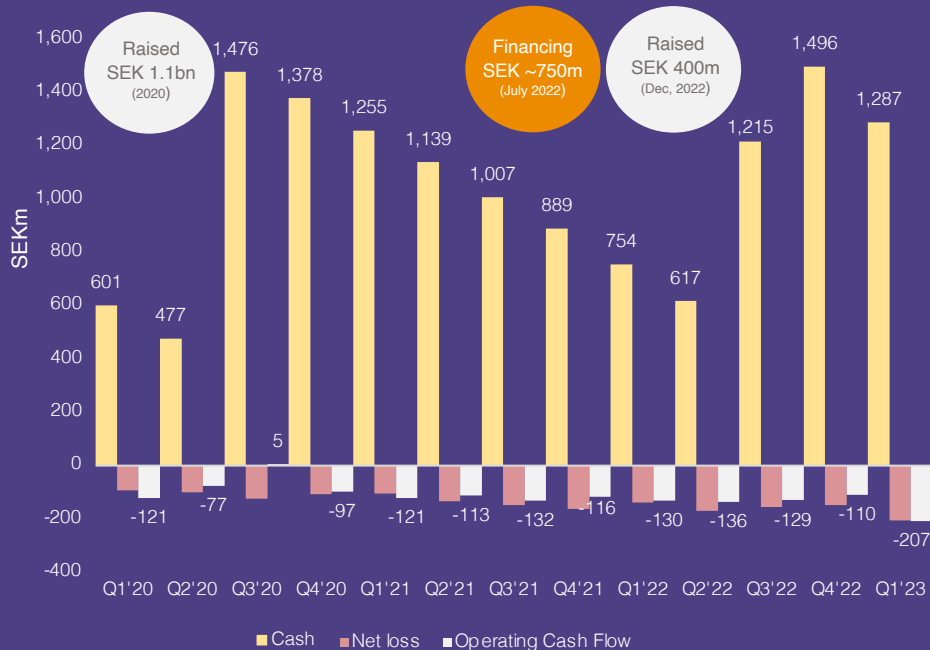
Financing to support the continued development of Hansa's antibody-cleaving enzyme technology platform and commercial preparations toward regulatory approval in the U.S.

Capital Raised
SEK ~4bn
since 2007*

Cash position
SEK ~1.3bn
(March, 2023)

R&D investment
(acc.)
SEK ~1.4bn
(Since 2007)

SG&A spend
(acc.)
SEK ~1.3bn
(Since 2007)



*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 ~1.3bn

(USD ~125m)

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 enrolment in our ConfIdeS study as well as advance in our long-term follow-up study to the five-year data readout in 2023

Strengthen ongoing product development activities and expand the Company's R&D pipeline, including AMR, GBS and anti-GBM

Advance our next generation enzymes for repeat dosing ("NiceR", HNSA-5487) into clinical development as well as our initiatives in our other indications such as gene therapy and oncology

Fund working capital and general corporate purposes

An exciting journey ahead!

✓ This is just the beginning!

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

Key milestones to be achieved

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

Idefirix approved in EU under conditional approval for kidney transplantation

Our future

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



Stock images

Imlifidase in kidney transplantation



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

Idefirix® is indicated for

desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

The use of Idefirix® should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients

Potential patients

idefirix®
imlifidase

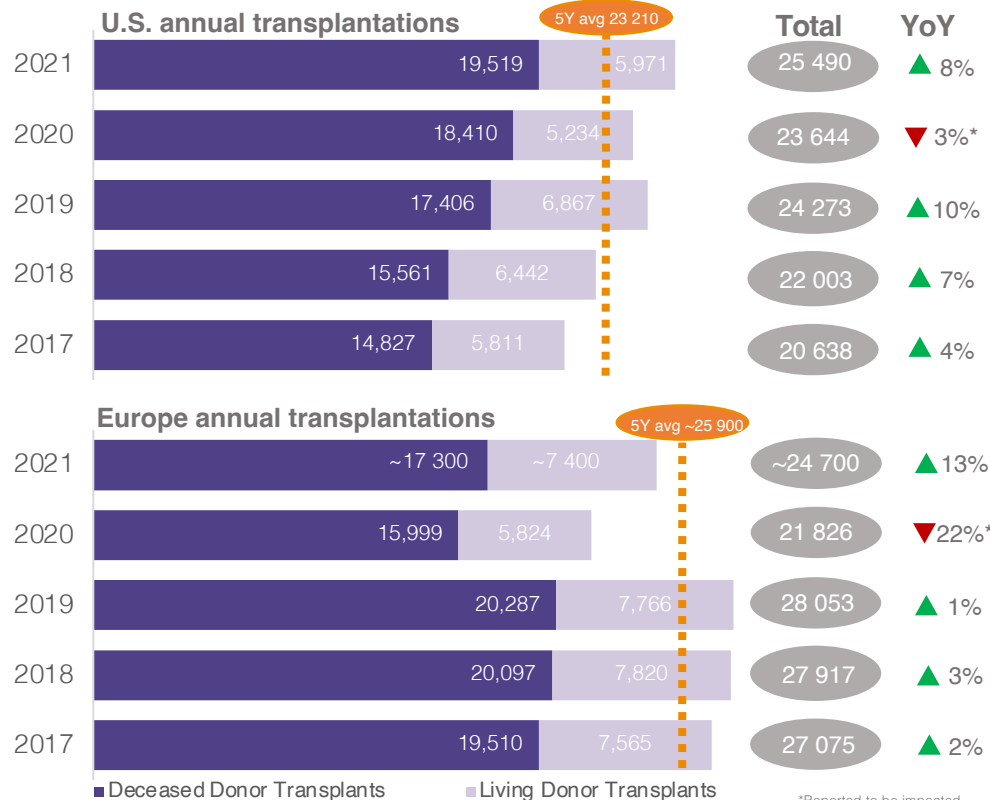
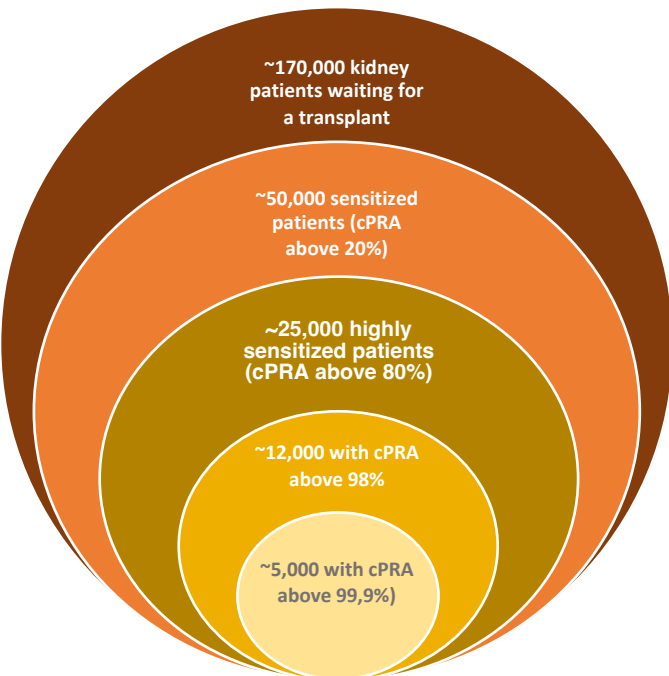
HANSA
BIOPHARMA

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

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

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

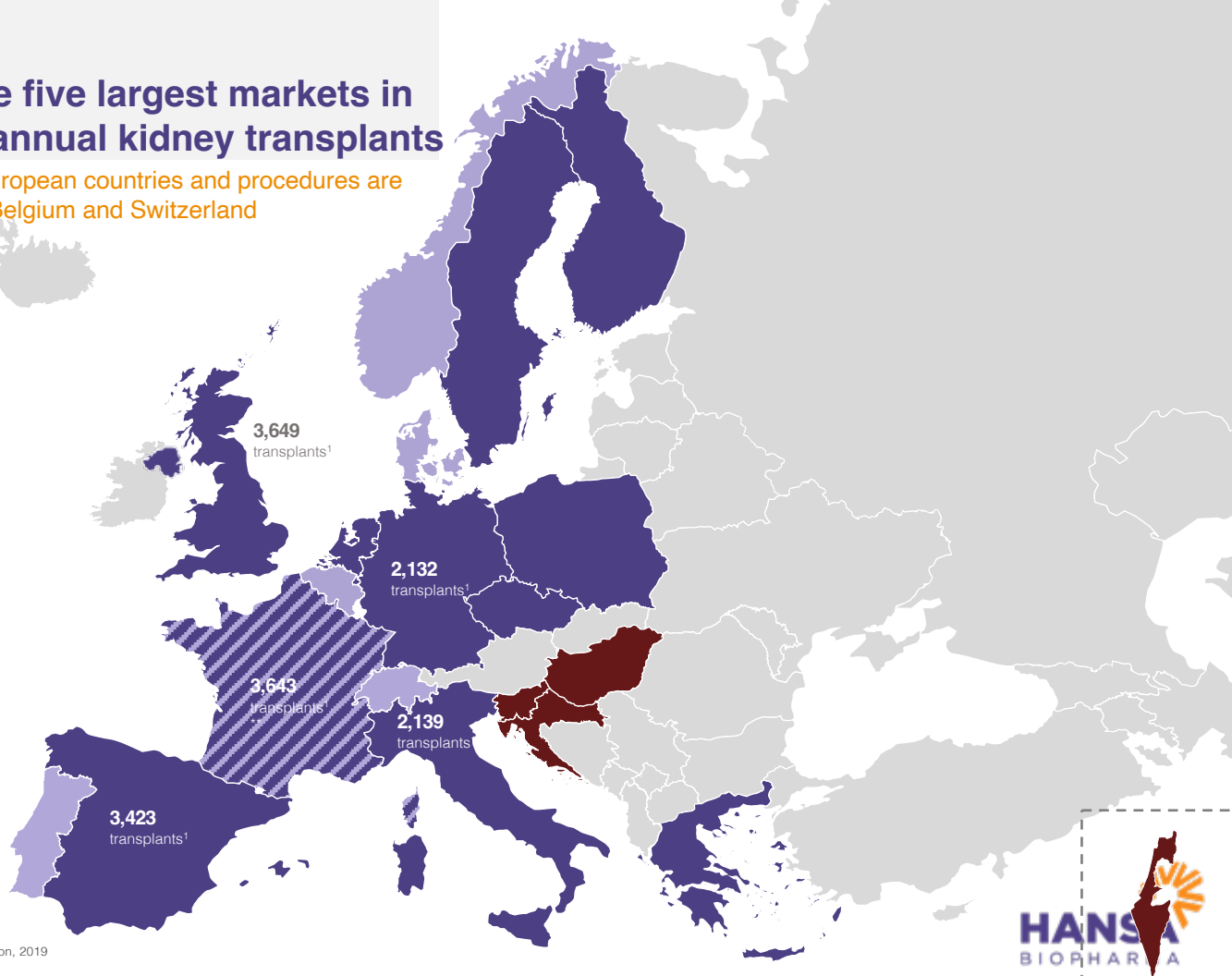
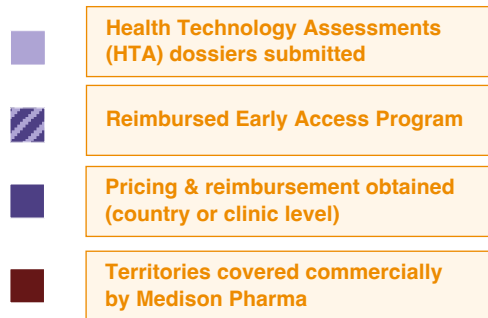
Breakdown of the kidney transplant waitlist in U.S. and EU



*Reported to be impacted by the COVID-19 pandemic

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

Market access has now been secured in 12 European countries and procedures are ongoing in eight countries including Portugal, Belgium and Switzerland



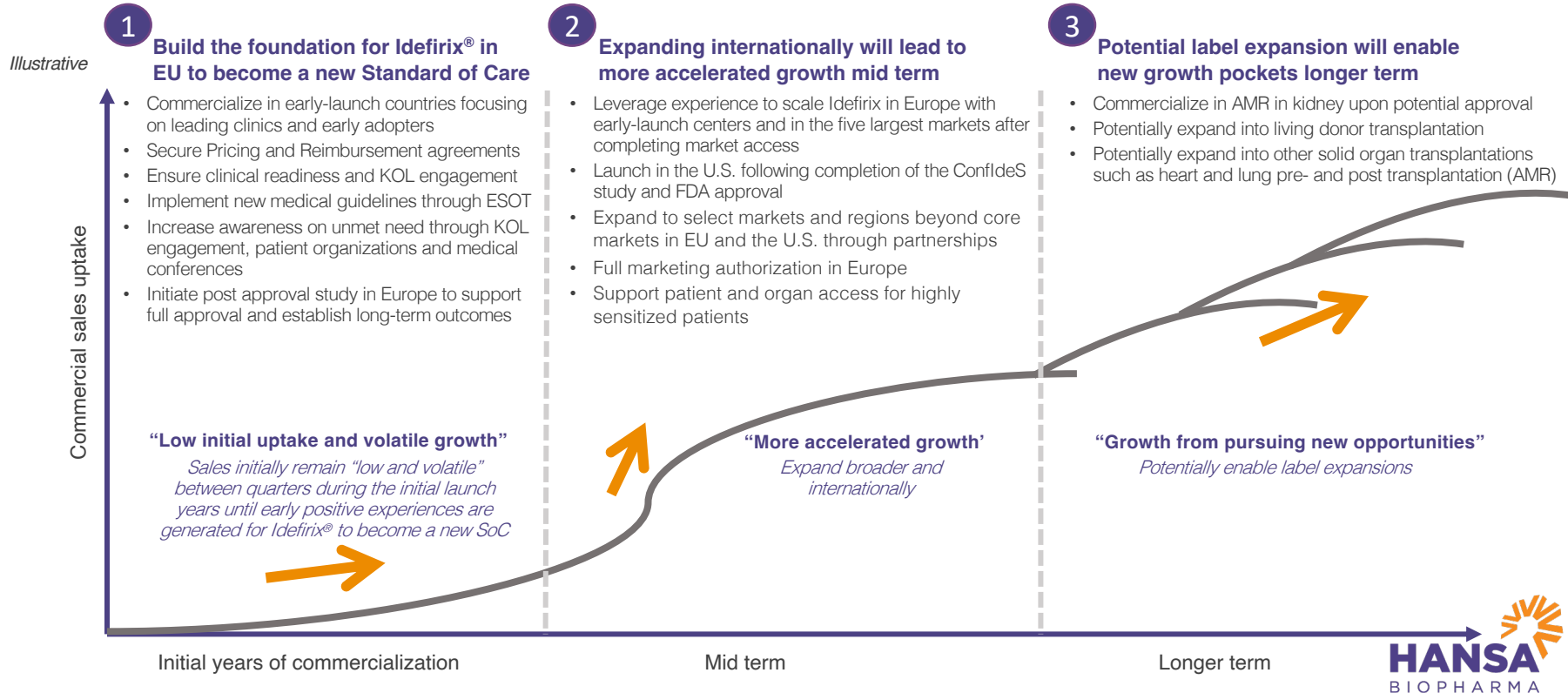
¹Annual kidney transplantations 2019 (pre-Corona)

^{*}Transplantation data is from Global Observatory on Donation and Transplantation, 2019

^{**}Pricing & reimbursement obtained in France on an early access basis

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

Idefix[®] 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



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



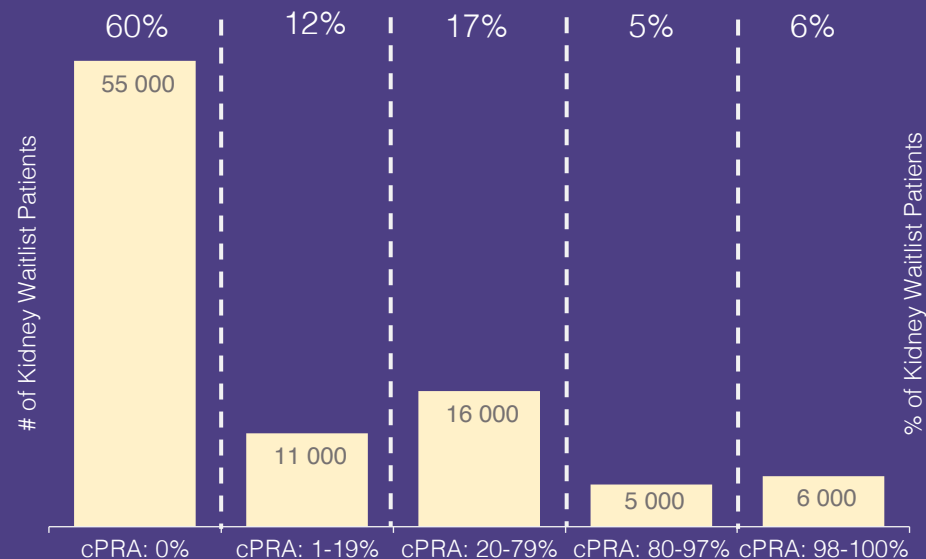
Blood transfusion



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

US Kidney Waitlist Patients by cPRA



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 diseases¹. In the long term, patients may also eventually lose access to dialysis as a result of failed ports, bad veins, and other factors²
- 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 transplanted³
- 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 list⁶

Better outcomes for transplantation patients



8-year survival⁶

Transplantation

77%

Dialysis

44%



5-year cost^{7,8}

Transplantation

USD 180-200k*

Dialysis

USD 450-500k



Employment⁹

Transplantation

61%

Dialysis

18%

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

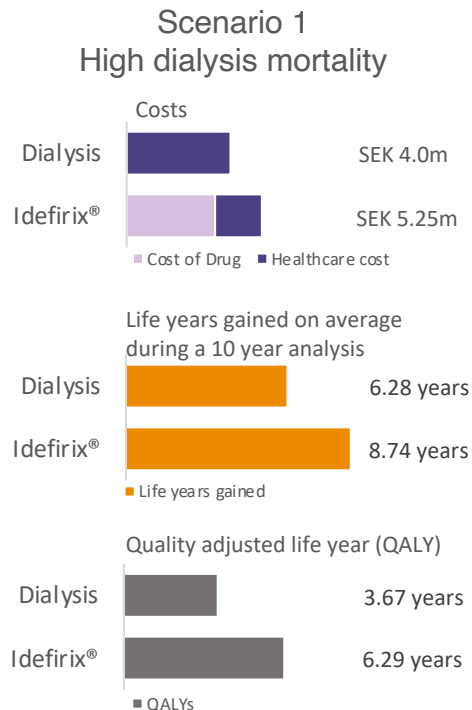
⁹ Jarl et al. Transplantation, 2018, 102:1375-1381

*Cost of kidney transplantation and 5 years of immuno-suppression treatment^{6,7}

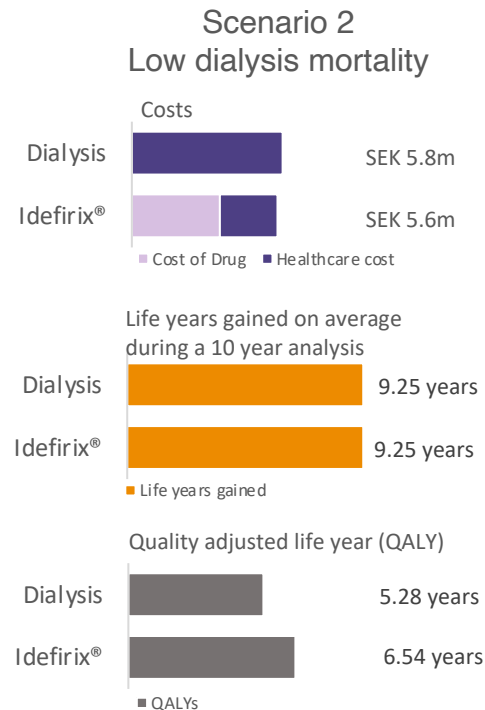
First HTA report (TLV) published in Sweden favourable to the use Idefirix® in highly sensitized patients incompatible to a deceased donor

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



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



Scenario 2 supports Idefirix®
as a cost saving drug

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

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](#)

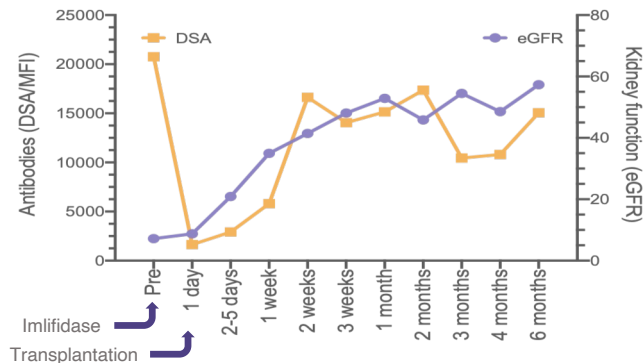
Completed and ongoing studies in kidney transplantation









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

Pooled analysis from four Phase 2 trials

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



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

Study 02 Phase 2	Subjects	8 patients 
	Design	Single-center, single-arm, open-label
	Main objective	Efficacy defined as Imlifidase dosing scheme resulting in HLA antibody levels acceptable for transplantation, within 24 hours
Study 03 Phase 2	Subjects	10 patients 
	Design	Single-center, single-arm, open-label, no prior desensitization
	Main objective	Safety in the transplantation setting and efficacy defined as HLA antibody levels acceptable for transplantation
Study 04 Phase 2	Subjects	17 patients 
	Design	Investigator initiated, single-center, single-arm, open-label. All patients had prior desensitization with IVIG and/or PLEX
	Main objective	Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patient
Study 06 Phase 2	Subjects	18 patients   
	Design	Multicenter, multinational, single-arm, open-label
	Main objective	Efficacy in creating a negative crossmatch test

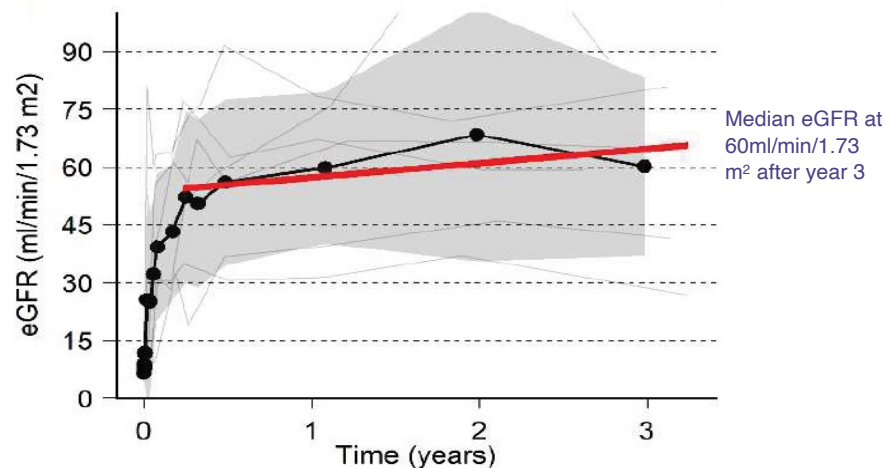
3-year follow up demonstrate graft survival of 84% after imlifidase treatment and transplantation

Data accepted for publication in the American Journal of Transplantation¹ [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 m² (61 mL/min/m² for those without AMR)
- For a subgroup of patients (n=13) with cPRA of $\geq 99.9\%$ graft survival was 92% and improved kidney function for patients with a mean eGFR at 60 mL/min/1.73 m² 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 patients²
- 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 $\geq 99.9\%$



¹ American Journal of Transplantation - Outcomes at 3 years post-transplant in imlifidase-desensitized kidney transplant patients (AJT16754)

Link to AJT article <https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16754>

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

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

U.S. trial design

64 highly sensitized kidney patients with the highest unmet medical need

- Patients with a cPRA score of $\geq 99.9\%$ will be enrolled
- First patients enrolled at Columbia University, NYC
- 62 of 64 targeted patients enrolled across thirteen sites as of April 20, 2023
- 1:1 Randomization
- When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase or to a control arm, where patients either remain waitlisted for a match or receive experimental desensitization treatment*

Primary endpoint

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

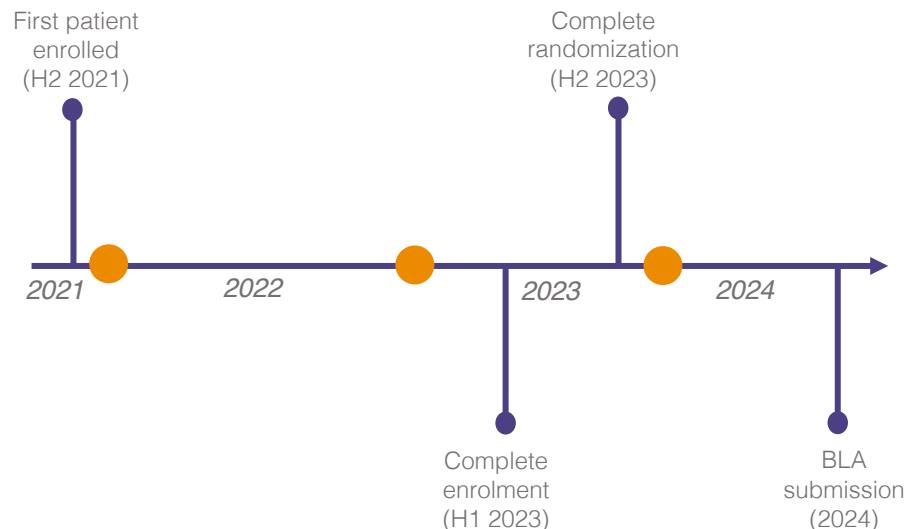
Secondary endpoint

- Patient survival at 12 months

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

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

Timeline



*Experimental desensitization treatment can include any combination of plasma exchange (PLEX), intravenous IVIg, anti-CD20 antibody, and eculizumab. Link to the full protocol at [ClinicalTrials.gov](https://clinicaltrials.gov)

U.S. kidney transplantation landscape

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

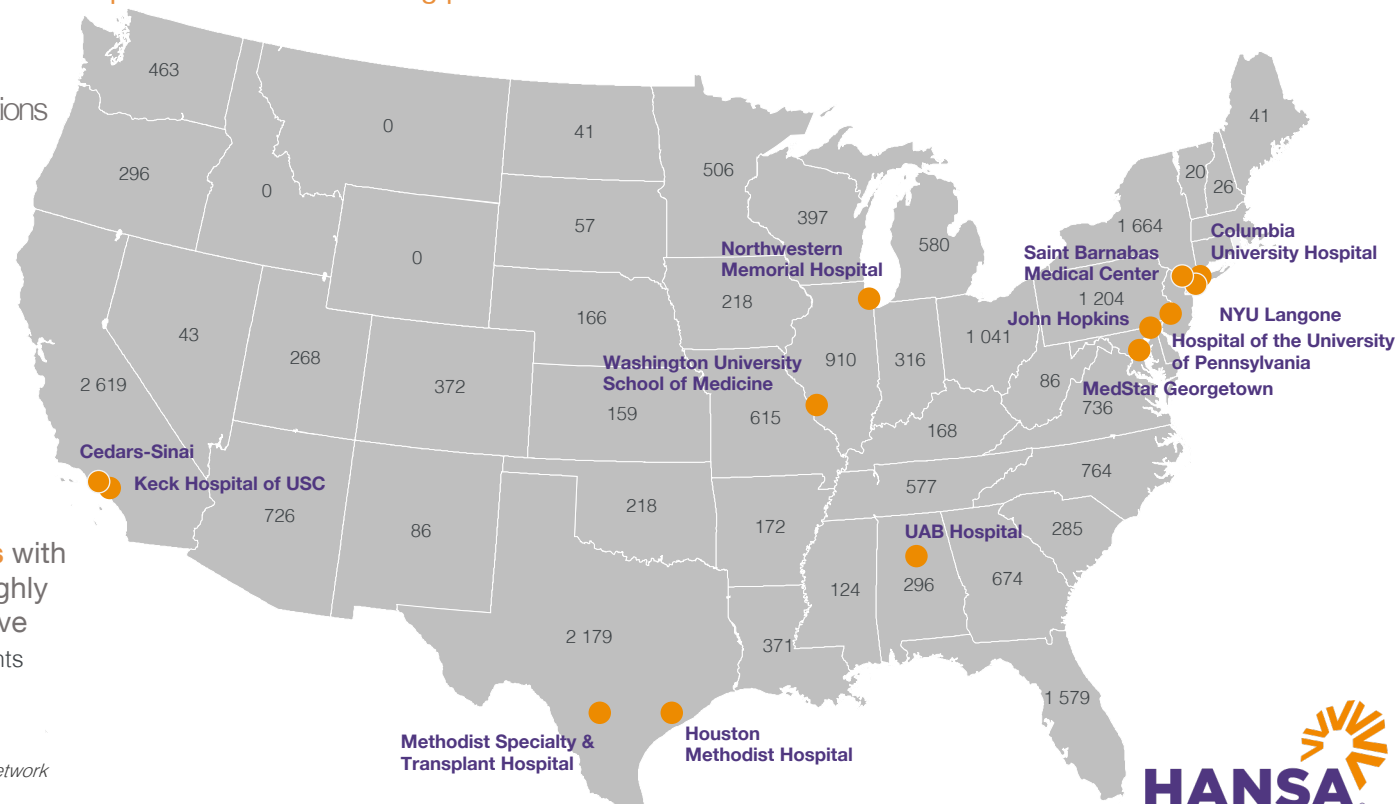
~**25,000**¹ annual kidney transplantations

~**71%**¹ deceased donor

~**90,000**² waiting for a kidney transplant

10-15%³ of waitlisted patients are highly sensitized

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)



¹2019 data from Organ Procurement & Transplantation Network

²United Network for Organ Sharing

³EDQM. (2020). International figures on donation and Transplantation 2019 and SRTR Database and individual assessments of allocation systems

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

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

An open-label Phase 3 study in 50 patients

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



Study to assess imlifidase in combination to optimize patient outcome

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

Trial design (ClinicalTrials.gov ID: NCT05049850)

The study is designed to assess if imlifidase in combination with bortezomib¹, belatacept², rituximab³ and IVIg⁴ 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 [ClinicalTrials.gov](https://clinicaltrials.gov)



Study 01 Phase 1

The 01 study results

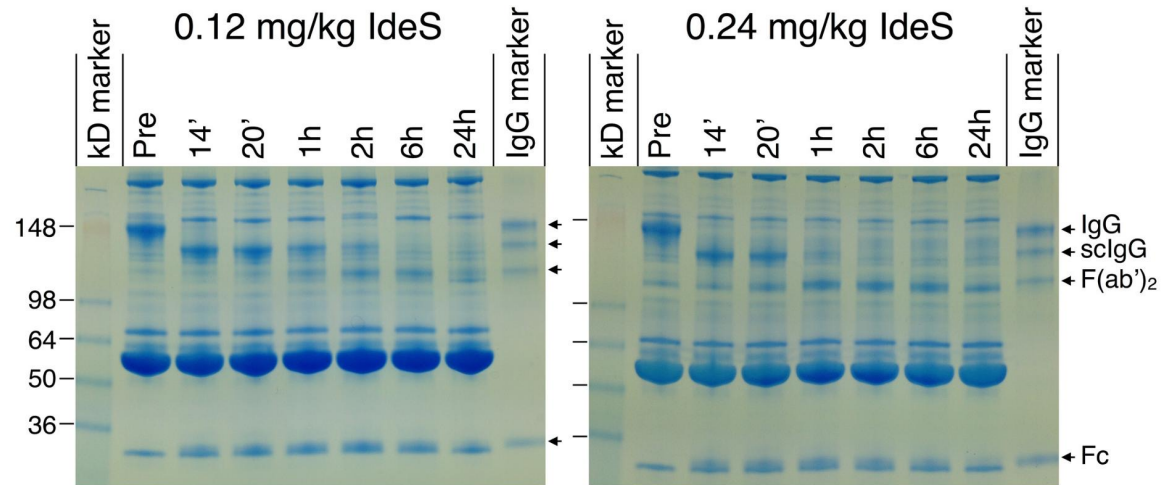
Data showed complete removal of IgG and a good tolerability profile

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



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 OBJECTIVES

- 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

Study 02 Phase 2

CLINICALTRIALS.GOV ID

NCT02224820

SUBJECTS

8 Patients with chronic kidney disease
(Sweden)

DOSES/FOLLOW UP TIME

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

MAIN OBJECTIVES

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

STUDY DESIGN

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

STATUS

Completed

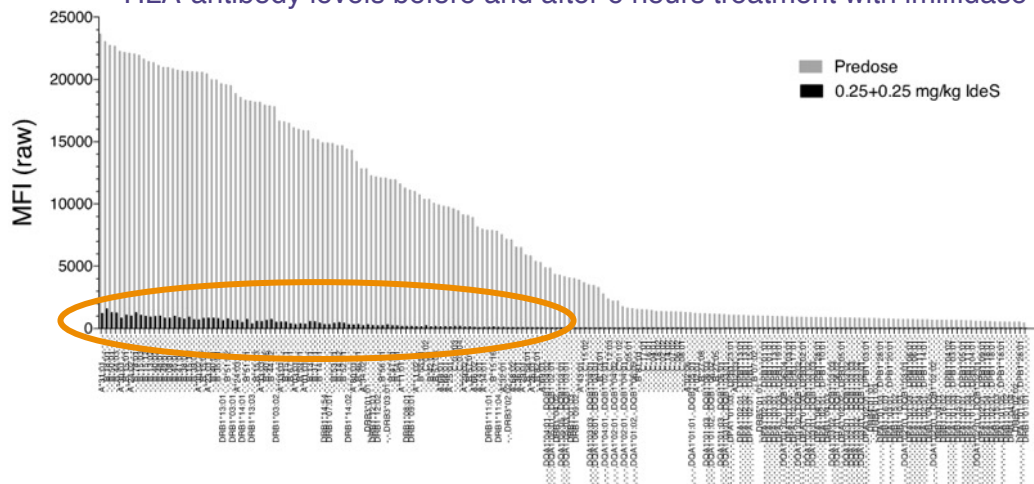
- Primary efficacy endpoint reached
- Safe and well tolerated

The 02 study results

Data showed that 1-2 doses of imlifidase at 0.25 mg/kg BW resulted in HLA antibody levels acceptable for transplantation¹

- ✓ 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)

Study 03 Phase 2

The 03 study proved safety and efficacy

HLA antibodies at acceptable levels; enabling transplantation in all patients

CLINICALTRIALS.GOV ID

NCT02475551

SUBJECTS

10 Patients (Sweden)

DOSES/FOLLOW UP TIME

0.25 and 0.50 mg/kg during 180 days

MAIN OBJECTIVES

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

STUDY DESIGN

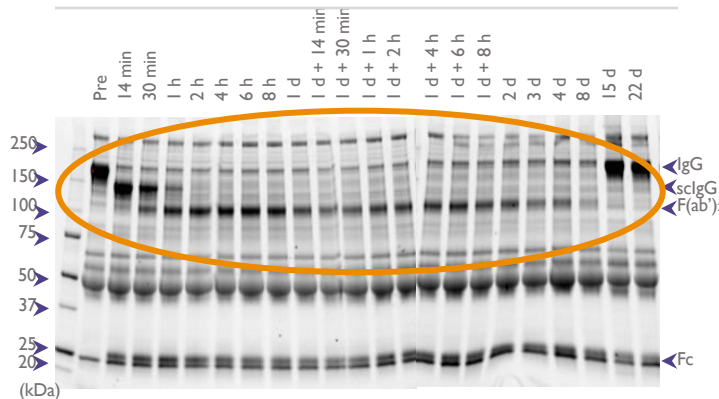
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

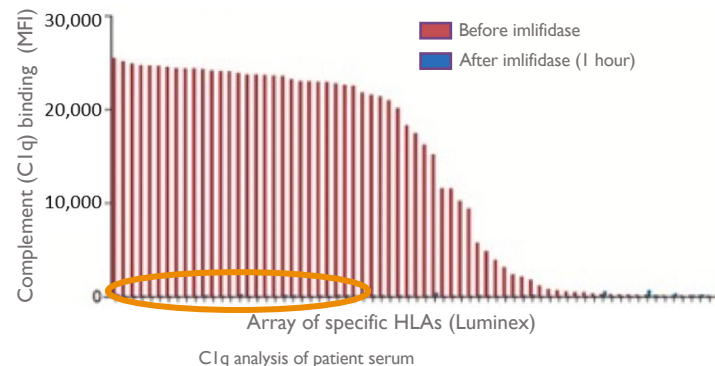
- Proved safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment

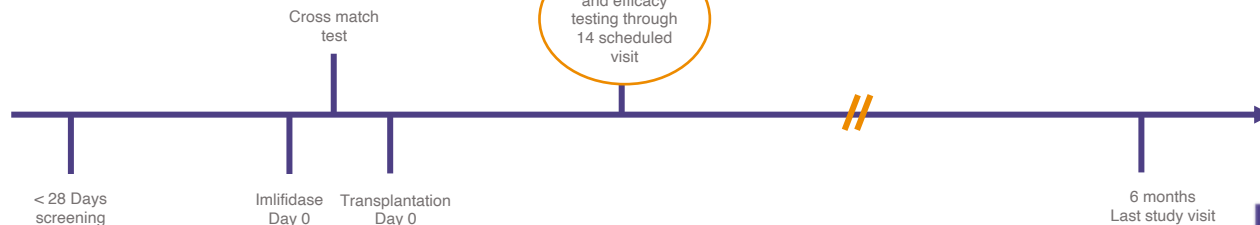


SDS-PAGE analysis of patient serum

Analysis of complement binding HLA antibodies before and after imlifidase



Protocol

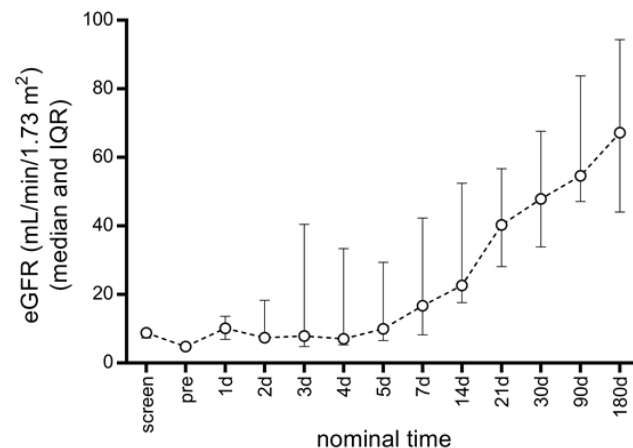


Study 04 Phase 2

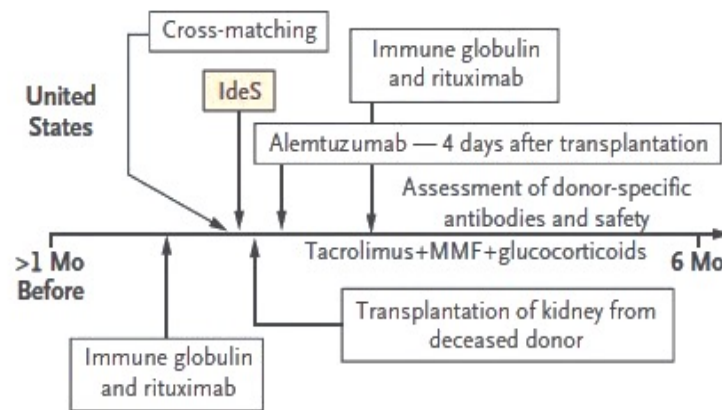
The 04 study results

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

Graft function (eGFR) post six months



Cedar's desensitization protocol in combination with imlifidase



CLINICALTRIALS.GOV ID

NCT024226684

SUBJECTS

17 Patients (US)

DOSES/FOLLOW UP TIME

0.24 mg/kg 180 days

MAIN OBJECTIVES

- 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

Study 06 Phase 2

CLINICALTRIALS.GOV ID

NCT02790437

SUBJECTS

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

DOSES/FOLLOW UP TIME

0.25 mg/kg 180 days

MAIN OBJECTIVES

- Efficacy in creating a negative crossmatch test

STUDY DESIGN

- 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

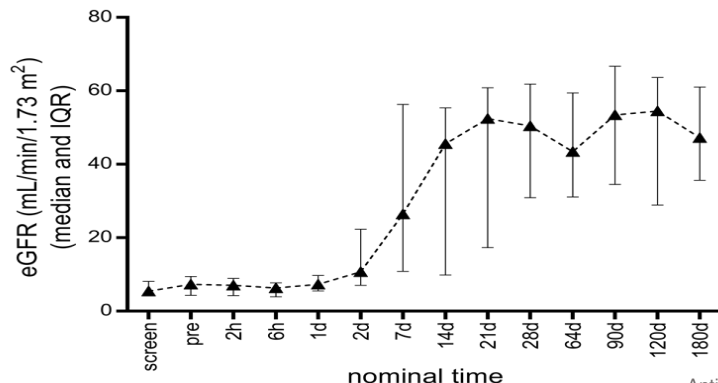
STATUS

Completed

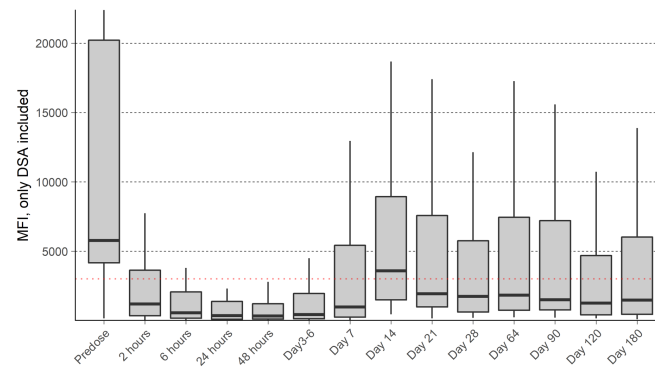
The 06 study results

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

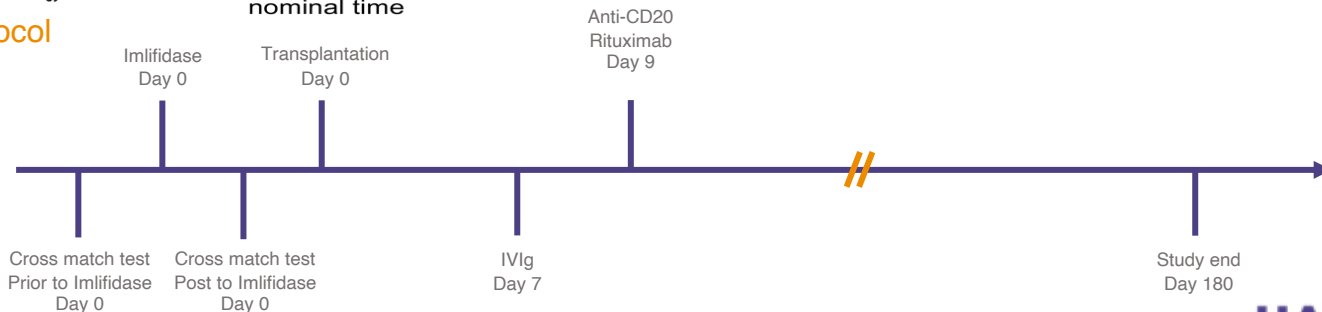
Graft function (eGFR) post imlifidase



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 	<ul style="list-style-type: none"> Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase 	Complete PLOS ONE (2015) ¹
Study 02 Phase 2	8 subjects 	<ul style="list-style-type: none"> Single-center, single-arm, open-label 	<ul style="list-style-type: none"> Dosing resulting in HLA-antibody reduction (MFI<1100) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Single-center, single-arm, open-label No prior desensitization 	<ul style="list-style-type: none"> Safety: AEs, clinical laboratory tests, vital signs, ECGs 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Investigator initiated study, Single-center, single-arm, open-label All patients had prior desensitization with IVIG and/or plasmapheresis 	<ul style="list-style-type: none"> Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients Assessment of safety Assessment of efficacy/kidney function 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation 	<ul style="list-style-type: none"> Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration 	<ul style="list-style-type: none"> Patient survival, kidney function, comorbidity, treatments and QoL Safety DSA Immunogenicity 	Ongoing

¹ Winstedt et al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)

² Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762

³ Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Kidney 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

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.

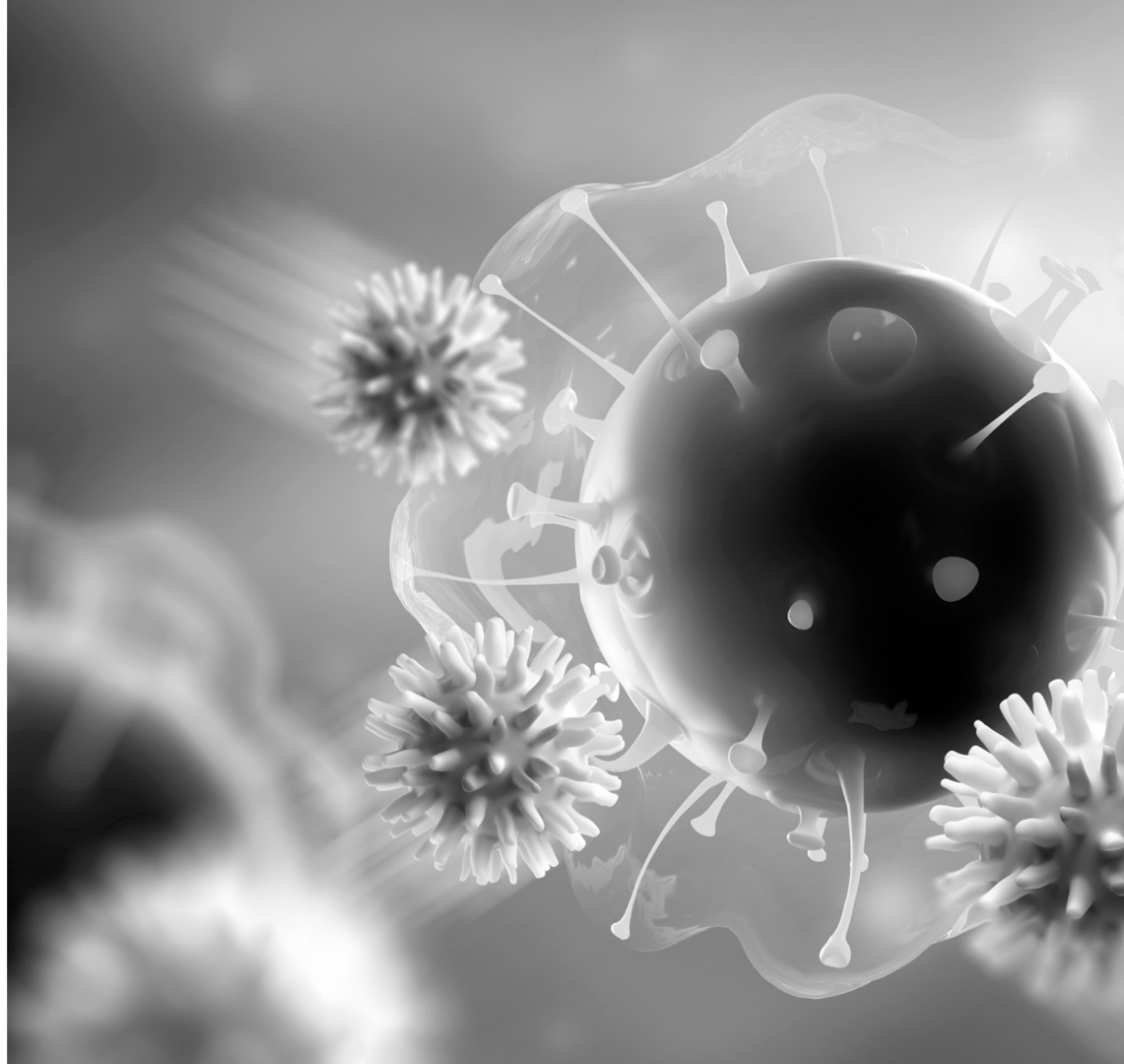


Professor Kathryn Wood

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



Broad clinical pipeline in transplantation and autoimmune diseases

Candidate/ Project	Indication	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Marketing Authorization	Marketed	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)							Next milestone topline data H2 2023/ Comparison to IGOS (2024)
	Pre-treatment ahead of gene therapy in Duchenne (Partnered with Sarepta)							Initiate clinical study of imlifidase as pre-treatment in DMD 2023
	Pre-treatment ahead of gene therapy in Limb-Girdle (Partnered with Sarepta)							Preclinical research
	Pre-treatment ahead of gene therapy in Pompe disease (Partnered with AskBio)							Preclinical research
HNSA-5487	Lead molecule from second-generation IgG antibody cleaving enzymes (NiceR)							Read out of phase 1 in healthy volunteers
EnzE	Cancer immunotherapy							Research

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)


² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

³ Investigator-initiated study by Mårten Segelmark, Professor at the universities in Linköping and Lund

 Completed

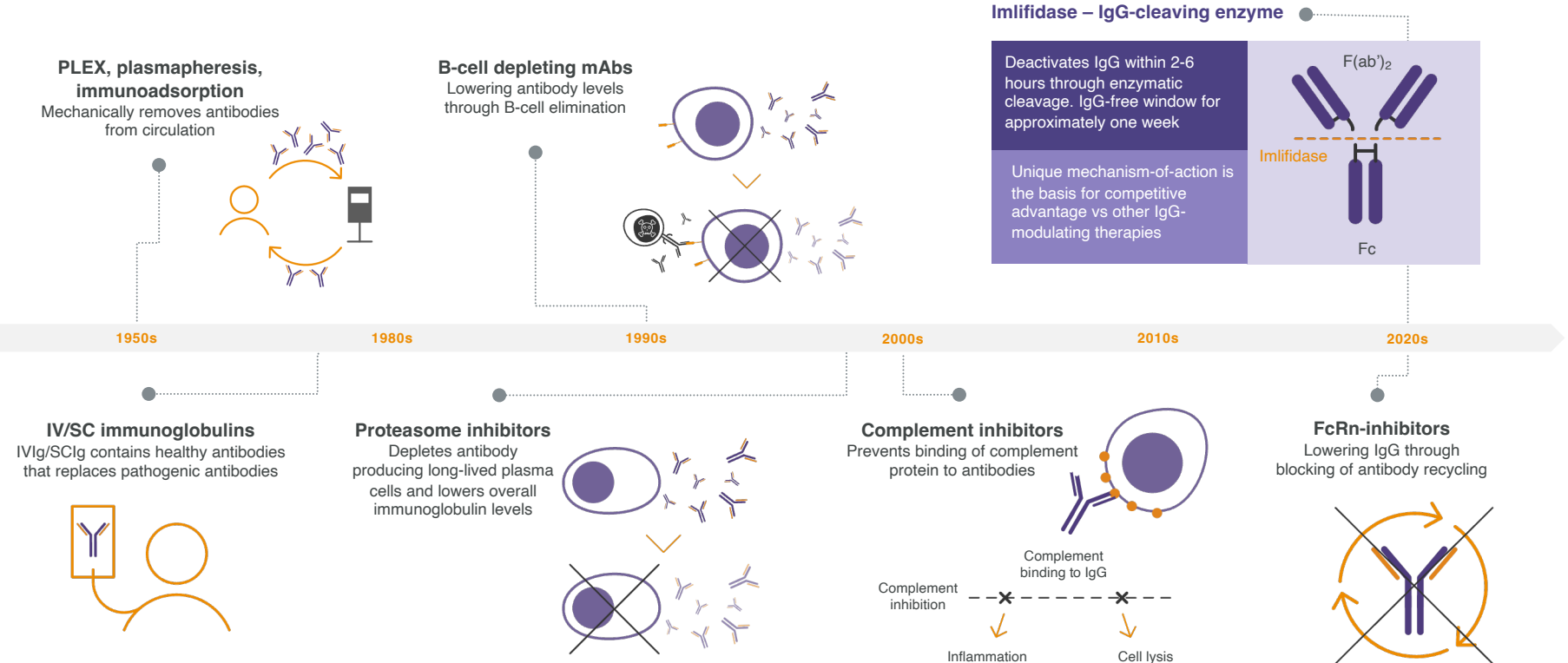
 Planned

 Ongoing

 Post approval study running in parallel with commercial launch

Development of IgG-modulating technologies

Mechanisms can be both complementary and competing

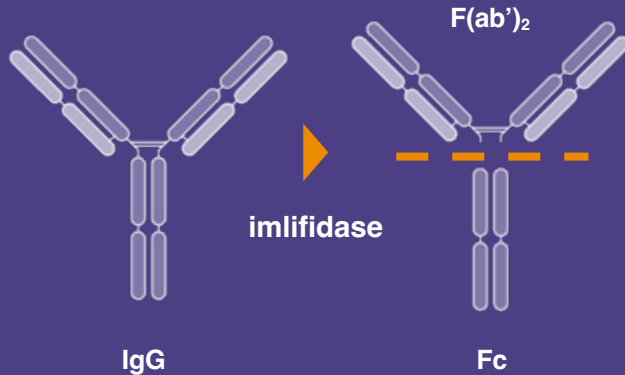


Imlifidase mode of action

Novel approach to effectively eliminate pathogenic IgG

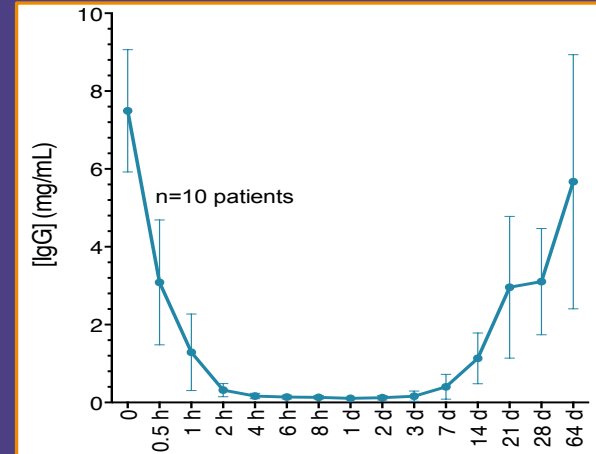
Proven mechanism of action

- 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

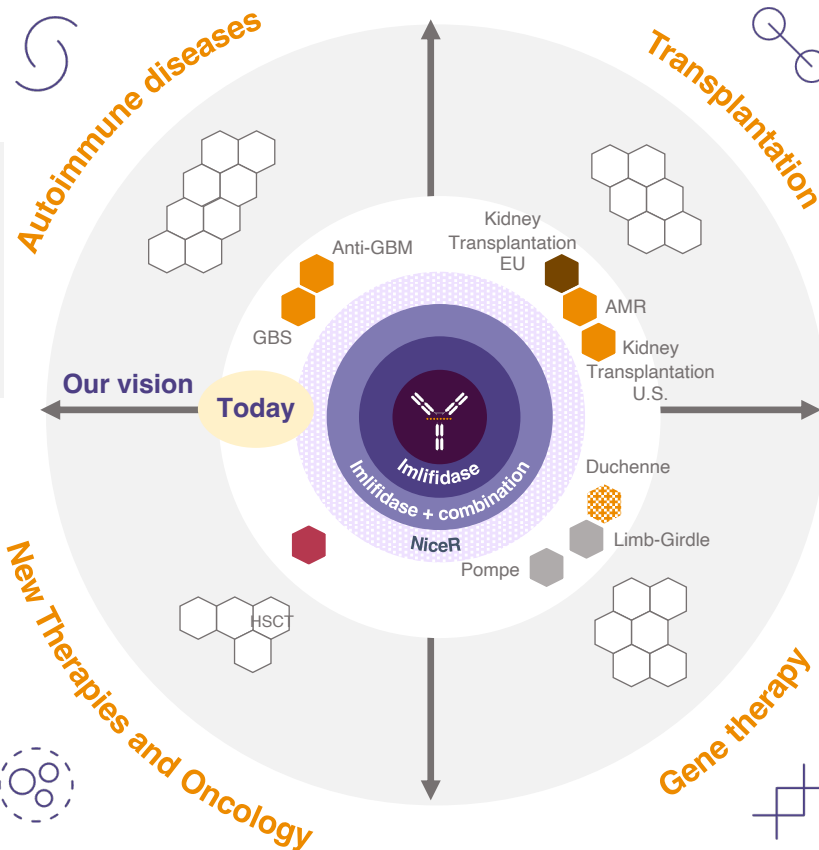
Targeting rare IgG mediated diseases

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

- Allogeneic 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

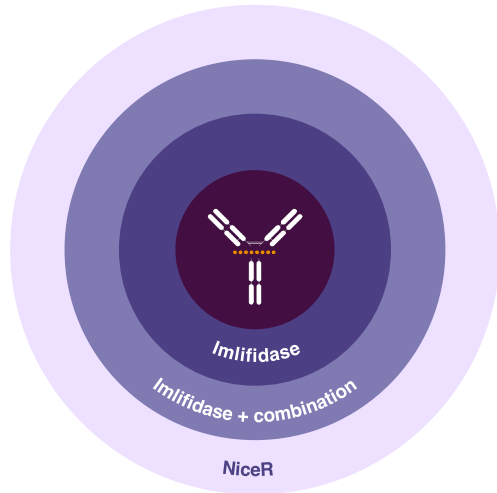
- Encouraging preclinical data published in Nature
- Validation through collaborations with Sarepta and AskBio
- Wide indication landscape beyond

The technology platform is the primary basis for achieving our vision

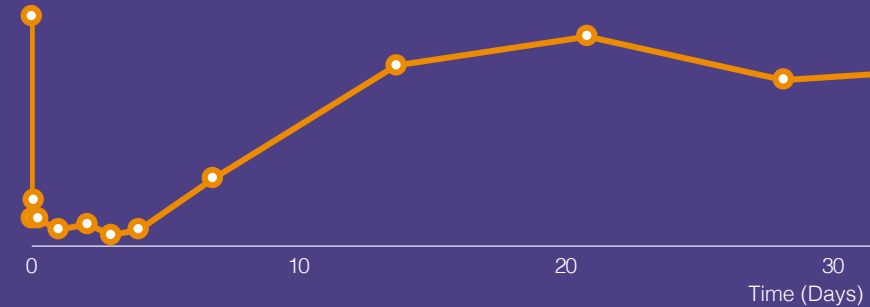
Targeting rare IgG mediated diseases and conditions

Key opportunities:

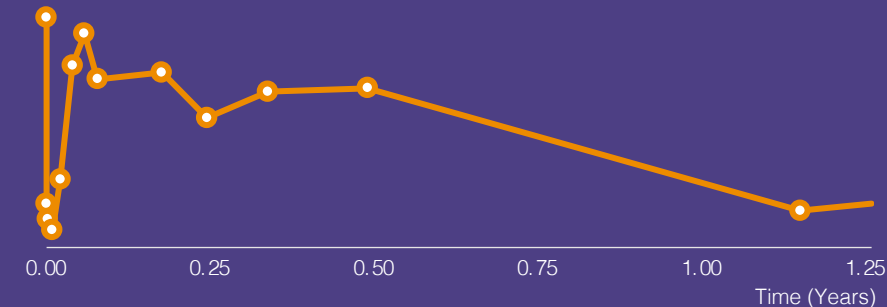
- Expanding into **new indications**
- Reduce immune response to IgG-cleaving enzyme, i.e. allow **repeated treatment**
- **Combination therapy**, i.e. induction and maintenance therapy



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



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

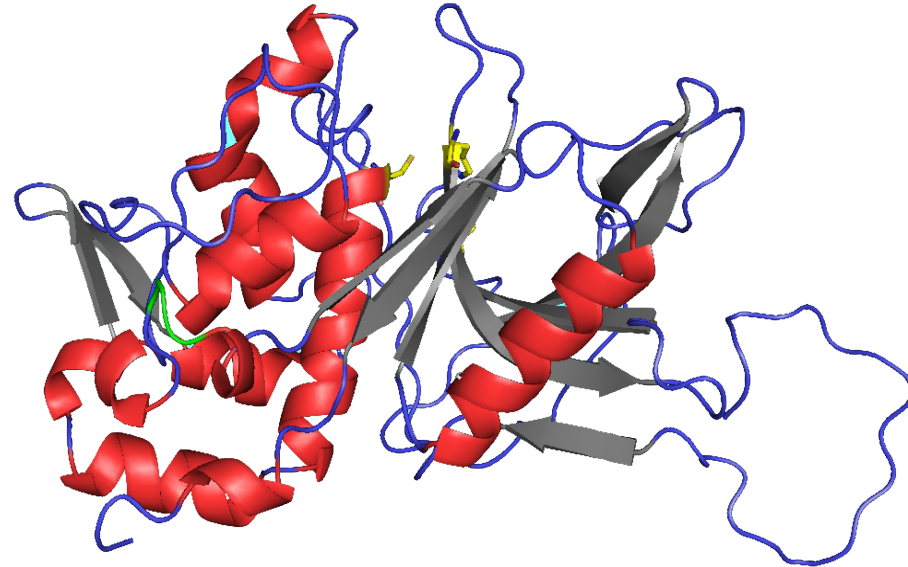


Our IgG antibody-cleaving enzyme, imlifidase

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 2-8° 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 2-8°C 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)

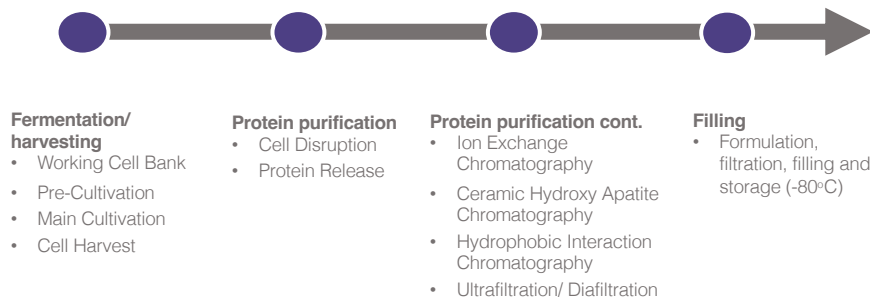


Manufacturing process

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

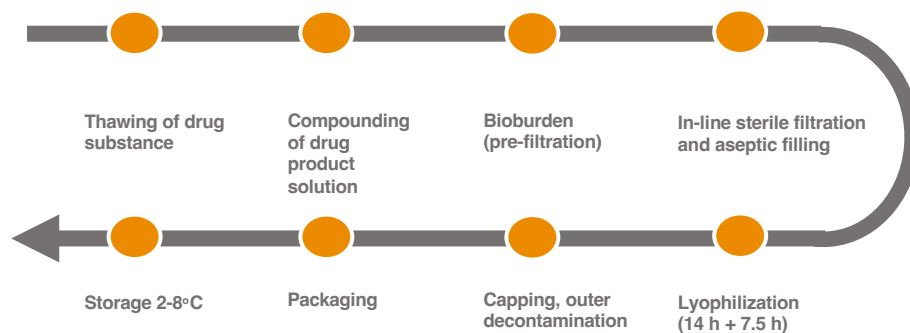
Drug substance production process (API)

Northway Biotech



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



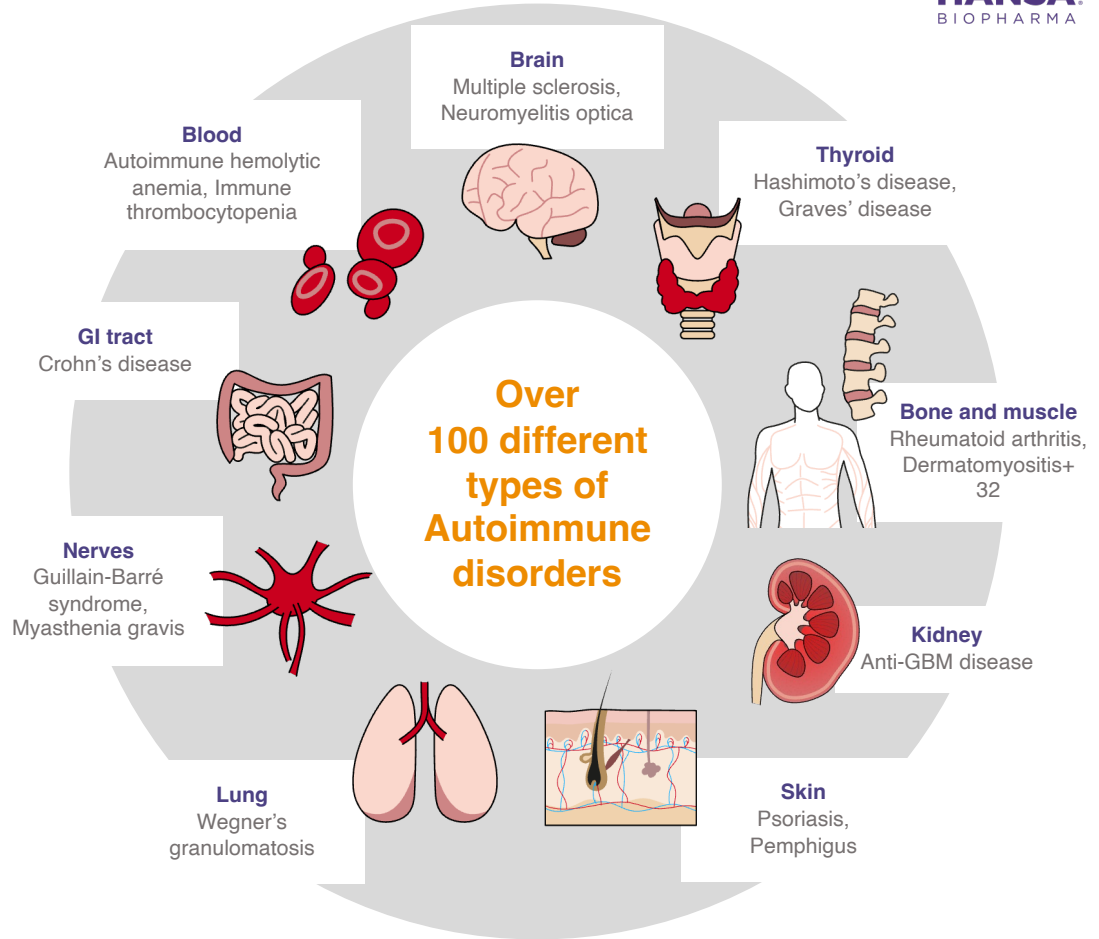
Autoimmune attacks

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

Autoimmune disease remains a big challenge and requires immediate treatment

What is an autoimmune disease?

- Immune-mediated destruction of autologous cells and/or tissues
- Interplay between predisposing genes and triggering environmental factors (e.g. bacteria or virus), leading to loss of self-tolerance
- 3-5%¹ of populations affected; more common in women (75%)²



¹ Wang et al., J. Intern. Med., 2015

² Desai et al., Front. Endocrinol., 2019

Hansa's antibody cleaving enzyme technology

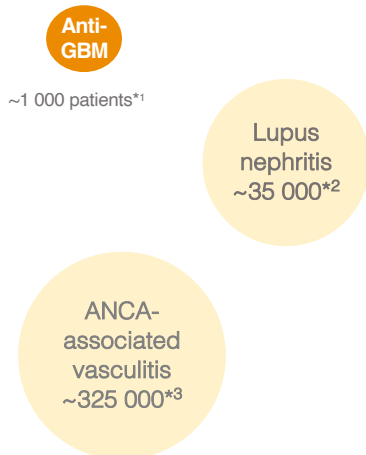
may have relevance in several autoimmune diseases where IgG plays an important role in the pathogenesis

- Clinical programs
- Potential autoimmune indications (currently not pursued)



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

Rapidly progressive glomerulonephritis



CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy

NMO: Neuromyelitis optica

EBA: Epidermolysis bullosa acquisita

ITP: Immune thrombocytopenia

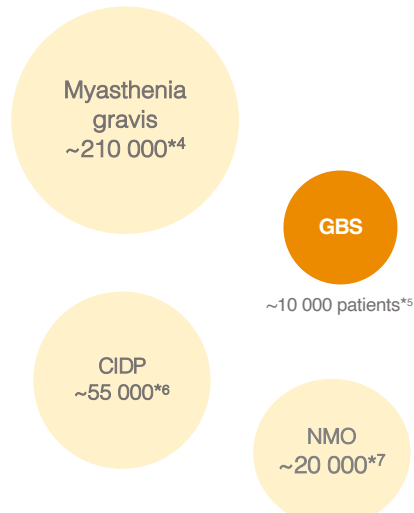
WAHA: Warm antibody hemolytic anemia

APS: Antiphospholipid syndrome

AHA: acquired hemophilia A

HIT: Heparin-induced thrombocytopenia

Neurological disorders



¹DeVrieze, B.W. and Hurley, J.A. *Goodpasture Syndrome*. StatPearls Publishing, Jan 2021.

²<https://www.ncbi.nlm.nih.gov/books/NBK459291/> [accessed 2021-03-29]

³Patel, M. et al. *The Prevalence and Incidence of Biopsy-Proven Lupus Nephritis in the UK*. Arthritis & Rheumatism, 2006.

⁴Berti 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.

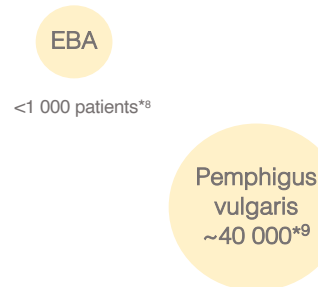
⁵Myasthenia Gravis. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/myasthenia-gravis/> [accessed 2021-03-29]

⁶Guillain-Barré syndrome. Orpha.net. https://www.orpha.net/consor/cgi-bin/OC_Eyn.php?lng=GB&Expert=2103 [accessed 2021-03-29]

⁷Chronic 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]

⁸Marrie, R.A. *The Incidence and Prevalence of Neuromyelitis Optica*. International Journal of MS Care, 2013 Fall: 113-118

Skin disorders



⁸Mehren, C.R. and Gnidecki, R. *Epidermolysis bullosa acquisita: current diagnosis and therapy*. Dermatol Reports, 2011-10-05

⁹Vertentell, S. et al. *Prevalence Estimates for Pemphigus in the United States*. JAMA Dermatol, May 2019: 627-629.

¹⁰Immune Thrombocytopenia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/immune-thrombocytopenia/> [accessed 2021-03-29]

¹¹Warm Autoimmune Hemolytic Anemia. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/> [accessed 2021-03-29]

¹²Altino, E. et al. *Prevalence and Significance of Non-conventional Antiphospholipid Antibodies in Patients With Clinical APS Criteria*. Frontiers in Immunology, 2018-12-14.

¹³NORD. *Acquired Hemophilia* [accessed 2022-10-17], available at <https://rarediseases.org/rare-diseases/acquired-hemophilia/>

¹⁴Hogan M, Berger JS. *Heparin-induced thrombocytopenia (HIT): Review of incidence, diagnosis, and management*. Vascular Medicine. 2020;25(2):160-173. doi:10.1177/1358863X19898253

Blood disorders



Anti-GBM, a rare acute autoimmune disease

Incidences

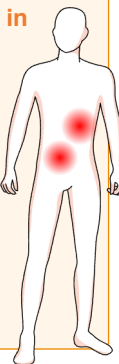
1.6

in a million affected annually^{1,2}

Inflammation in the glomeruli

Early symptoms are unspecific...

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



Today's Standard of Care

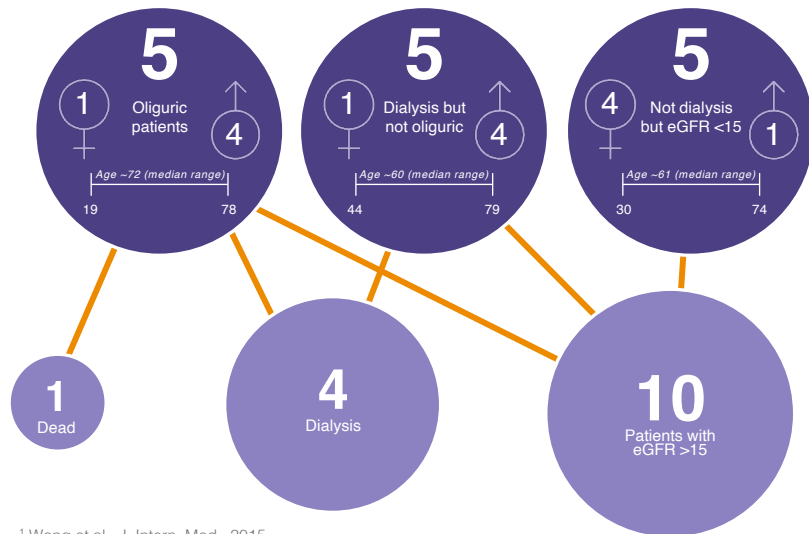
- Plasma Exchange
- Cyclophosphamide (CYC)
- Glucocorticoids

Data published in JASN



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

- 10 out of 15 patients were dialysis independent after six months vs. the historical cohort⁴, where only 18% had functioning kidney



¹ Wang et al., J. Intern. Med., 2015

² Desai et al., Front. Endocrinol., 2019

³ Uthlin et al. JASN (2022)

⁴ McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. Kidney Int 92: 693-702, 2017

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

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

Incidences

1-2

in 100,000 annually
or ~10,000 in 7MM

Indication

Rapidly and progressively
weakens extremities
(e.g., paralyzing arms, legs)

Triggered frequently by viral
infections (such as
Influenza, Zika virus, EBV,
CMV and COVID-19)

Diagnosis and management
complicated due to
heterogeneity

Today's Standard of Care

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

High unmet need

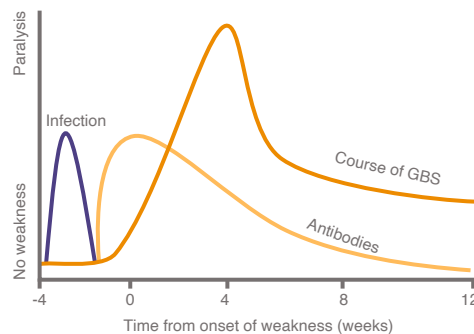
1/3 of hospitalized GBS
patients require mechanical
ventilation

Remaining long lasting
symptoms in ca 40% of
patients incl. fatigue, pain,
psychological distress and
muscle weakness

Mortality 3-7%

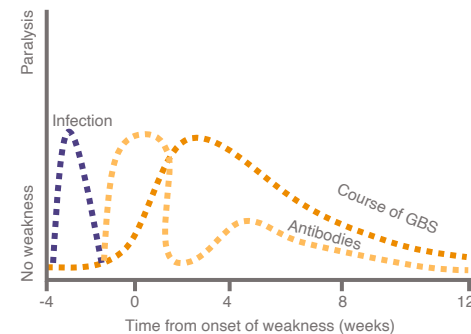
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase


Illustrative



STUDY DESIGN

- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS
- Data will be compared with a control group from the International Guillain-Barré Syndrome Outcome Study (IGOS)

SUBJECTS

- 30 patients targeted at ten clinics 
- Completion of enrollment (H1'23) announced March 31, 2023
- Topline data H2'23
- Comparative efficacy analysis to IGOS data in 2024

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

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 OBJECTIVES

- safety and effectiveness of imlifidase in patients diagnosed with GBS

STUDY DESIGN

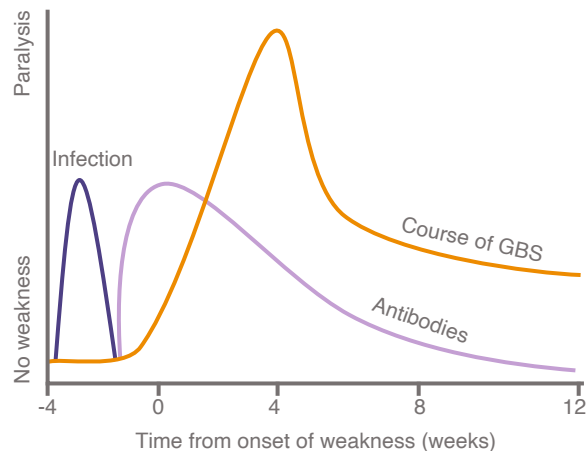
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing recruitment

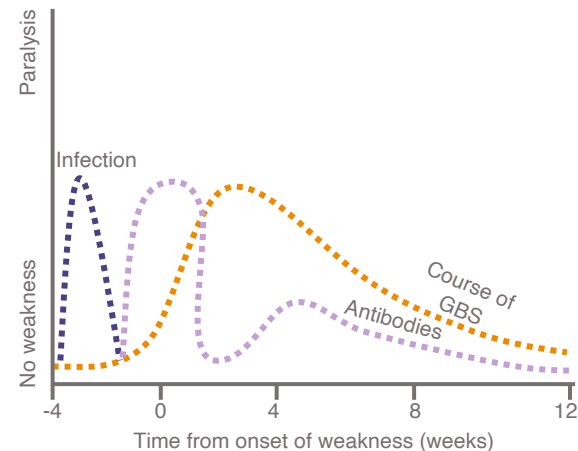
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



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 transplants¹ 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.

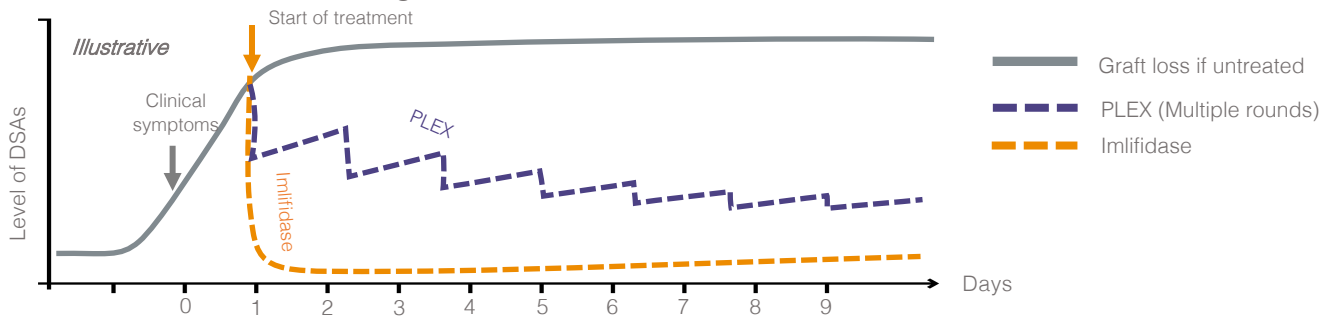
Phase 2 Study

- 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



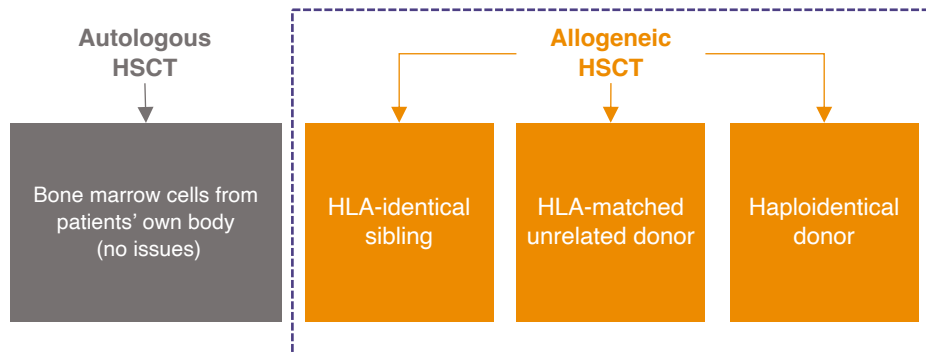
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

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

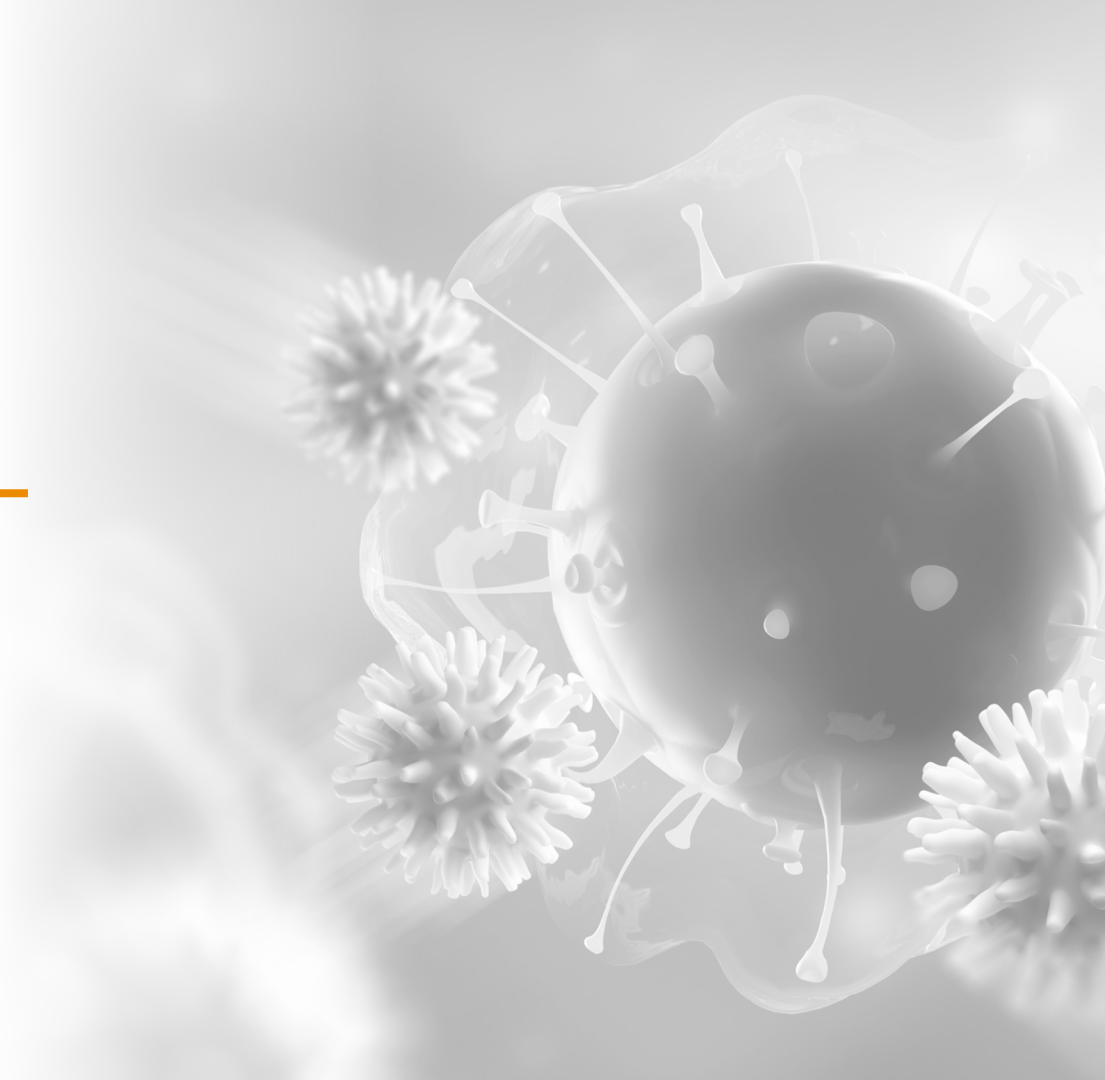
Transplantations are often acutely needed, which reduces the time available to find an adequately matched donor

- 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 outcome² (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 published¹ by the EBMT³ 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



Pre-clinical programs



HNSA-5487, lead molecule from our “NiceR” program

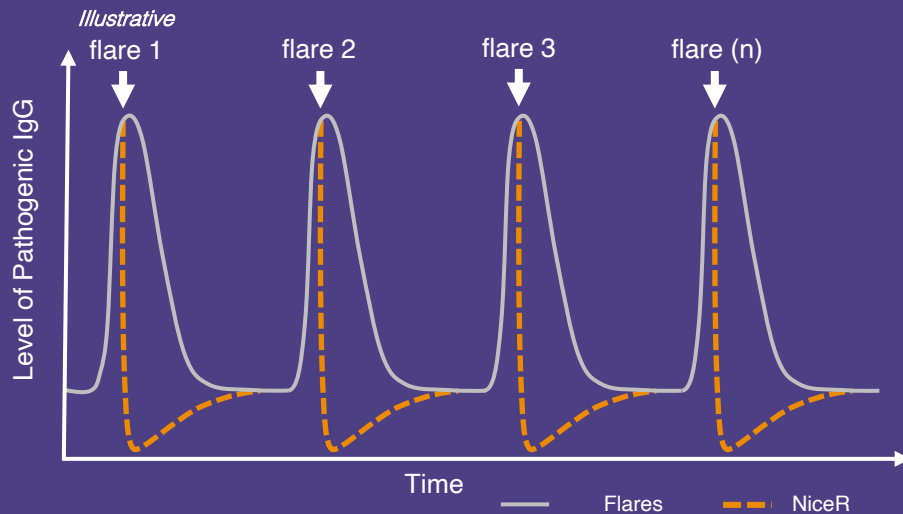
- our next generation enzymes

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

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

- Potential application for a broad array of indications, including reoccurring AMR, relapsing autoimmune diseases, gene therapy and oncology
- HNSA-5487, part of the Company's NiceR program, has been selected as the lead IgG-eliminating enzyme
- HNSA-5487 is an IgG-cleaving enzyme (cysteine peptidase) with characteristics based on a homolog to imlifidase, but with lowered immunogenicity
- During Q1 2023 Hansa has initiated a new clinical phase 1 trial for HNSA-5487 with dosing of the first healthy volunteers.

Our next generation enzymes can potentially inactivate flares



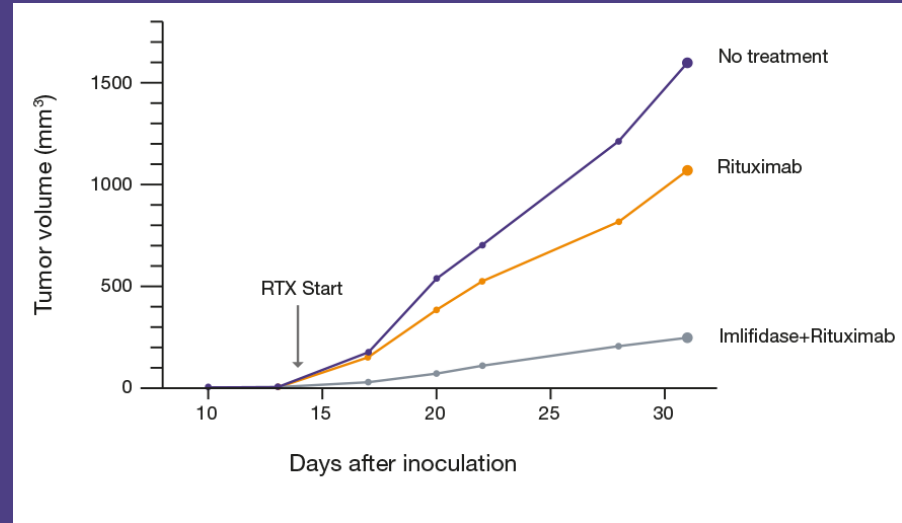
Our antibody cleaving enzymes

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



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

Tropism and target tissue

AAV subtypes targets different tissues



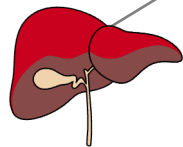
AAV 1, 2 & 5



Eye (local target)
 $\sim 1 \times 10^{11}$ vg



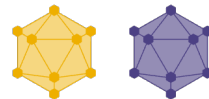
AAV 3, 7 & 8



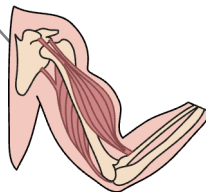
Liver (systemic)
 $\sim 1 \times 10^{14}$ vg



Brain (local target)
 $\sim 1 \times 10^{12}$ vg



AAV 4 & 8



Muscle (systemic)
 $\sim 1 \times 10^{15}$ vg



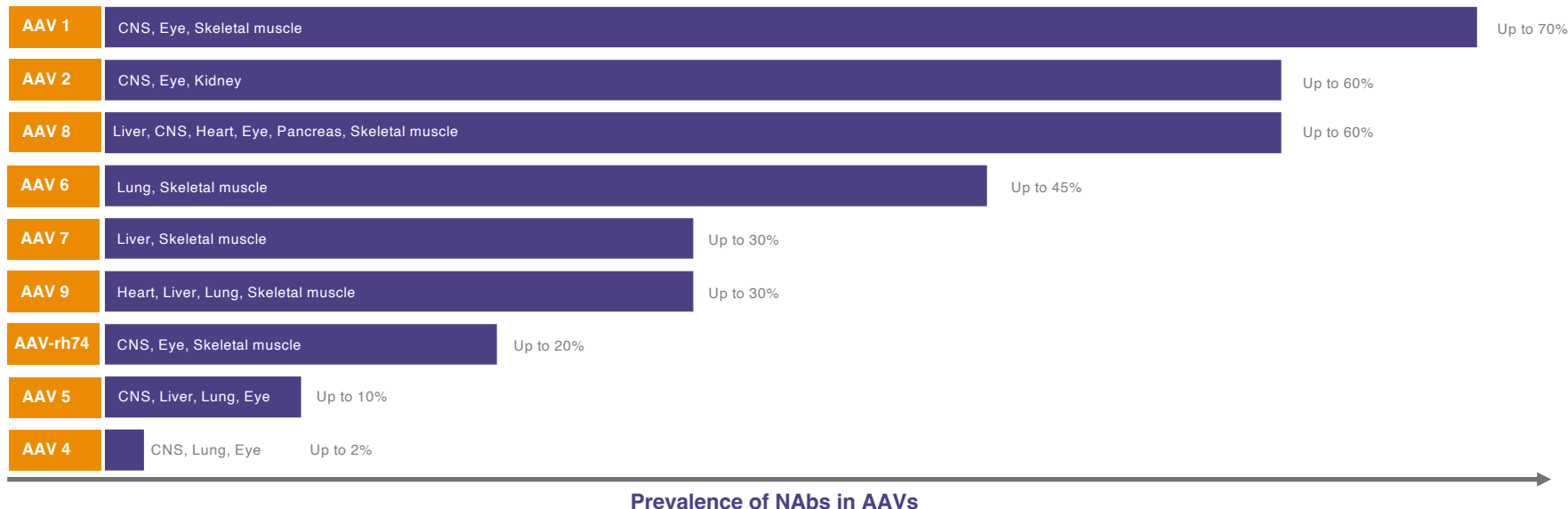
AAV 6, 7, rh74

Target tissues

Dose of gene therapy (vg)

Neutralizing antibodies are a barrier that precludes gene therapies

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

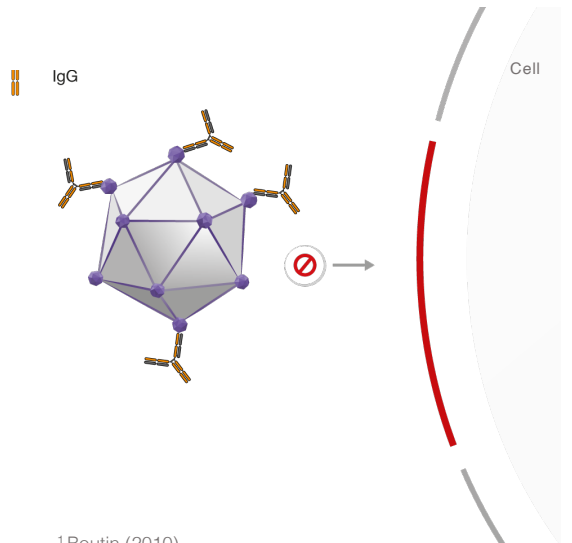


Source: Boutin et al (2010), Griffin et al (2019), Wang et al (2018), Calcedo & Wilson (2013), Falese et al (2017), Haiyan et al (2017), Ellsworth et al (2018), Greig et al (2017)

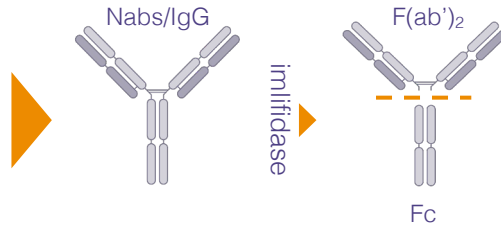
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

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

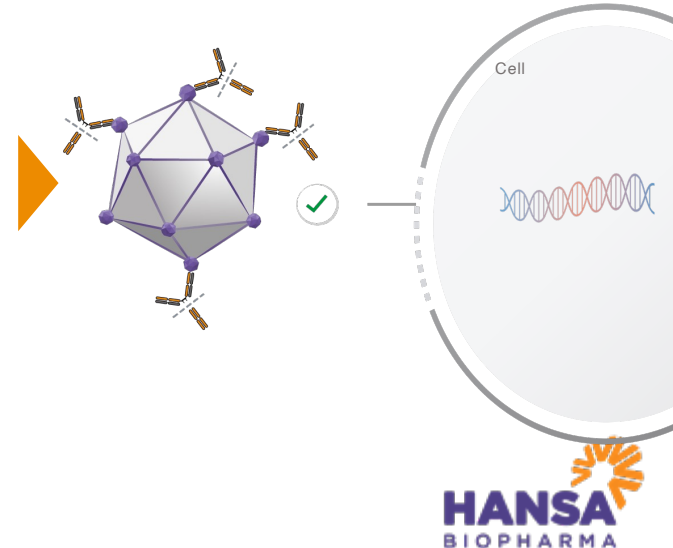
1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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



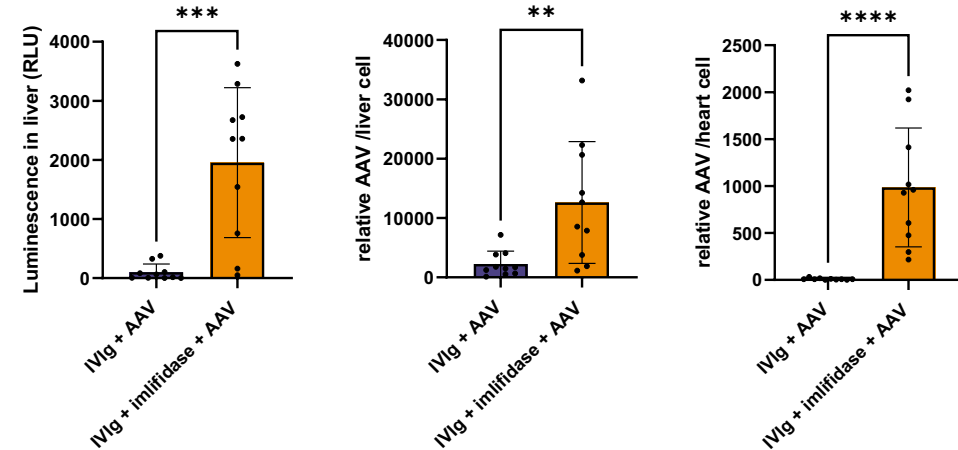
3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



Imlifidase facilitates transduction of AAV8 in a mouse model

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

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



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

Imlifidase has previously been highlighted in Nature Medicine¹ with encouraging outcome



Leborgne et al. Nat Med (2020)

¹ Nature Medicine <https://doi.org/10.1038/s41591-020-0911-7>

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



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

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



Hansa's key resources and deliverables

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



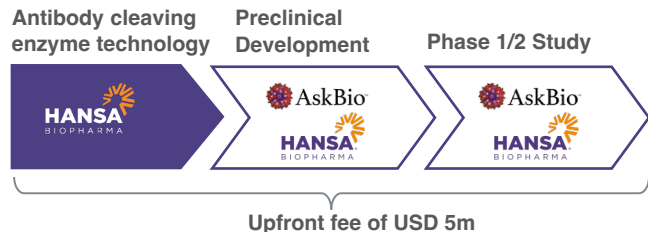
Fully owned subsidiary of Bayer AG

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

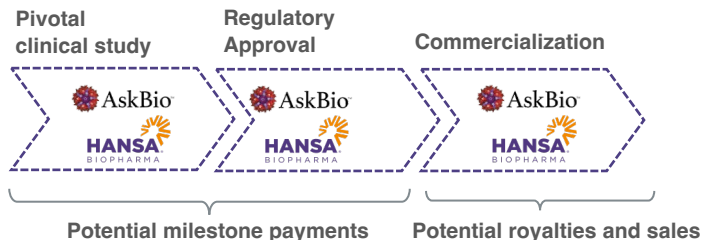


Current agreement scoped around a feasibility program which covers preclinical work and a Phase 1/2 study



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

Potential Structure:



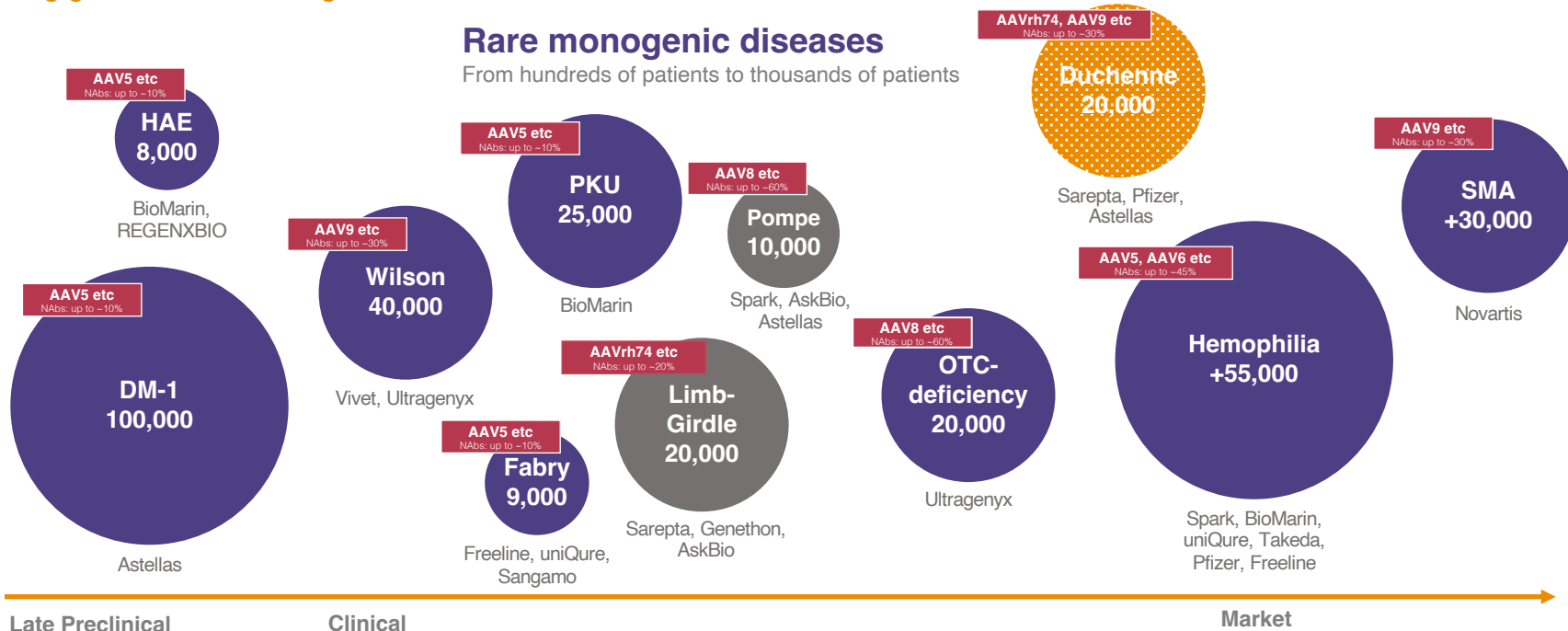
Systemic gene therapy is an emerging opportunity

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

- Preclinical programs with Sarepta and AskBio
- Planned clinical study with Sarepta
- Potential gene therapy indications (currently not pursued)

Rare monogenic diseases

From hundreds of patients to thousands of patients



Late Preclinical

Clinical

Market

● Size of indication (US & EU)

Duchenne Muscular Dystrophy (DMD) SRP-9001

About Duchenne Muscular Dystrophy (DMD)¹

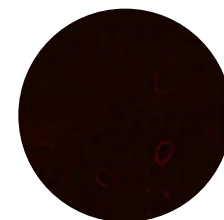
- Rare, fatal neuromuscular genetic disease
- Muscle weakness noticeable by age 3 to 5, and most patients use a wheelchair by the time they are 11
- Cardiac and respiratory muscle deterioration becomes life-threatening
- 1/3,500 to 5,000 male births (worldwide)
- Approximately 14% of patients have pre-existing IgG antibodies to rh74

SRP-9001 gene therapy for treatment of DMD

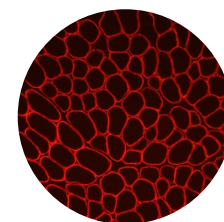
- AAVrh74 vector with micro-dystrophin transgene
- Broad patient experience
- 4 ongoing clinical trials – including fully recruited pivotal study
- Robust micro-dystrophin protein expression with commercially representative process material
- Functional benefits sustained up to 4 years after administration
- 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>

Limb-Girdle muscular dystrophy (LGMD) SRP-9003

About limb-girdle muscular dystrophy

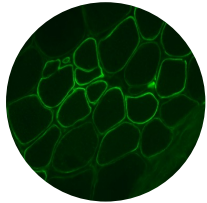
Limb-girdle muscular dystrophy is a group of diseases that cause weakness and wasting of the muscles

- 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 2021²:
 - 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

Pompe Disease (PD) AAV2/8-LSPPhGAA

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 40,000¹ births, or ~200 per year in the US + EU
- Prevalence is estimated to be around 10,000 in the US and Europe combined²
- Approximately 40-60%^{3,4} of patients have pre-existing IgG antibodies to AAV8

AskBio's AAV2/8-LSPPhGAA 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](https://clinicaltrials.gov/ct2/show/study/NCT03533673)

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

Sources:

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

²Calculated 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.

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

⁴Boutin 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/>

ESG Overview



At Hansa Biopharma we are committed to driving our business forward in a sustainable way



Healthy people

Address unmet need and ensure equitable access to care

Develop life-saving treatments for people with rare immunological diseases, ensure sustainable, equitable access to care and put patients at the center of everything we do

Healthy business

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

Commit to operating with the highest integrity and ethical standards complying with laws and regulations and driving personal accountability for employees, partners and vendors

Foster an inclusive culture grounded in individual development, benefits that drive exceptional performance and meaningful work in a healthy, safe environment

Healthy planet

Embrace sustainable decision making and environment stewardship

Utilize approaches that reduce overall environmental impact of our business – creating a default sustainable business – from discovery and clinical trials, to product launches and manufacturing

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.



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.



Capital Markets

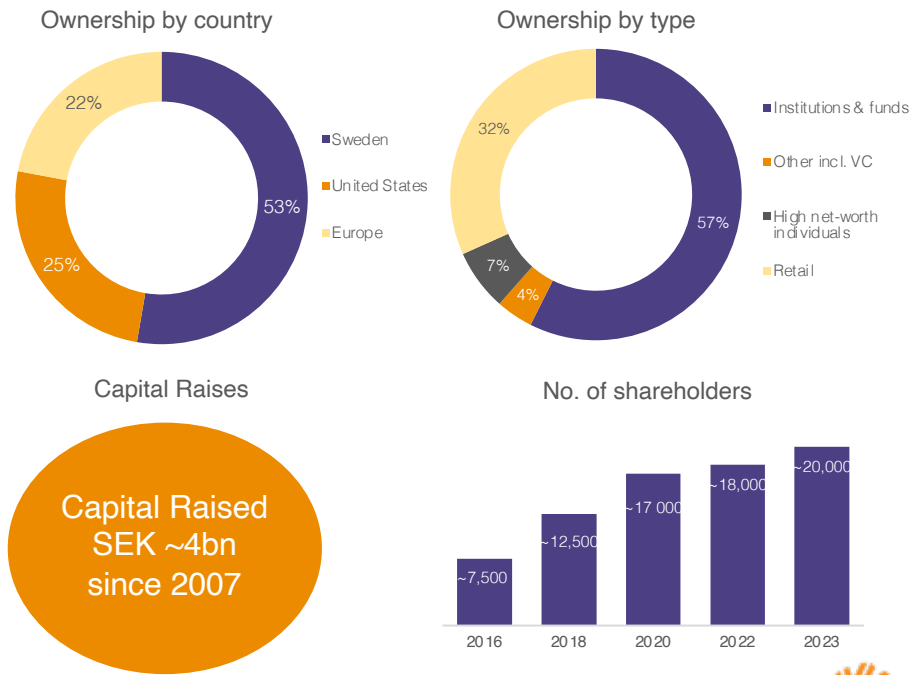


Ownership in Hansa Biopharma

Top 10 ownership as per March 31, 2023

Name	No. of shares	Ownership
Redmile Group, LLC	10 896 553	20.8%
Försäkrings AB Avanza Pension	2 509 535	4.8%
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%
C WorldWide Asset Management	799 749	1.5%
Heights Capital Management, Inc.	667 169	1.3%
VOB & T Trading AB	644 800	1.2%
Other	28 282 202	53.9%
Total	52 443 962	100%

Classification of ownership as per December 31, 2022



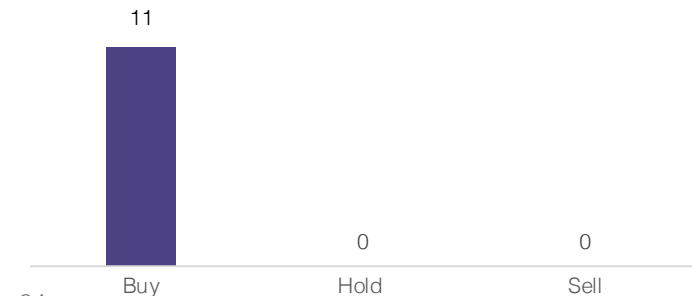
Company collected consensus

Consensus is based on a collection of analyst estimates pre-Q1 2023 report (April 2023)

	Price Target, SEK	WACC	Patient uptake, EU				Revenue, SEKm			
			Q1'23e	FY'23e	FY'24e	FY'25e	Q1'23e	FY'23e	FY'24e	FY'25e
Average	195	12%	6	53	107	202	27	208	389	871
Median	198	12%	6	53	104	197	27	203	363	889
High	244	14%	7	59	127	246	31	235	502	1 105
Low	135	10%	5	50	99	150	23	192	311	692
Number of contributions	6	6	4	6	6	6	5	6	6	6

	EBIT, SEKm				Operating Cash Flow, SEKm				Cash position, SEKm			
	Q1'23e	FY'23e	FY'24e	FY'25e	Q1'23e	FY'23e	FY'24e	FY'25e	Q1'23e	FY'23e	FY'24e	FY'25e
Average	-161	-613	-486	-265	-101	-577	-468	-320	1 341	1 172	1 010	723
Median	-157	-635	-532	-254	-101	-569	-479	-321	1 341	945	954	579
High	-149	-471	-180	-125	-101	-515	-212	-92	1 341	1 887	2 094	1 834
Low	-175	-683	-658	-450	-101	-650	-618	-484	1 341	846	263	-3
Number of contributions	5	6	6	6	1	6	6	6	1	6	6	6

Analyst recommendations



Bank/Research Institution	Analyst	Location	E-mail
SEB	Christopher Uhde, PhD	Stockholm	christopher.uhde@seb.se
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Redeye	Johan Unnerus	Stockholm	johan.unnerus@redeye.se
RBC	Zoe Karamanoli	London	zoe.karamanoli@rbccm.com
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H.C. Wainwright	Douglas Tsao	New York	dtsao@hcwresearch.com
Bryan Garnier & Co	Ingrid Gafanhao	Paris	igafanhao@bryangarnier.com

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VP, Corporate Affairs

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Calendar and events

April 20, 2023	Redeye Investor Forum, Gothenburg
April 21 2023	Redeye Lunch presentation, Stockholm
April 25 2023	Kempen Life Sciences Conference 2023, Amsterdam
May 9, 2023	Midcap Canada event (virtual)
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
Sept 14, 2023	Pareto Annual Healthcare Conference, Stockholm
Oct 19, 2023	Interim Report for January-September 2023
Nov 22, 2023	Ökonomisk Ugebrev Life Science event, Copenhagen

