HANSA BIOPHARMA

Investor Presentation

Canaccord NDRS
April 4, 2022

Søren Tulstrup
President & CEO

Forward-looking statements

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HANSA BIOPHARMA

Introduction to Hansa Biopharma

HANSA BIOPHARMA

Hansa Biopharma today

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

A validated technology

VALIDATION ACROSS THREE AREAS

- Approval in kidney transplantations
- Proof of concept in autoimmune diseases
- Partnerships to explore gene therapy

Idefirix® is our first approved drug in Europe*

EUROPE KIDNEY TRANSPLANTS

For highly sensitized patients in Europe

Broad pipeline in transplantation and autoimmunity

PROGRAMS IN CLINICAL DEVELOPMENT

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

Established a high-performance organization

NEW COMPETENCIES ADDED

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

Highly qualified team with 20 years on average in life science

Purpose driven culture

With recent capital injection Hansa is financed into 2023

FINANCIALS

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

Created shareholder value and diversified our ownership base

MARKET CAPITALISATION (USD): ~0.3bn

Listed on Nasdaq Stockholm
18,000 shareholders
Foreign ownership make up ~40% through leading international life science specialist funds

*Idefirix approved in EEA under conditional approval for kidney transplantation

**Actual patient has given consent to provide images

Many milestones achieved during the last 15 months

2021 January

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

March
Hansa Biopharma records first commercial sale of Idefirix®

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

April

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

June
First national market access agreement achieved for Idefirix® in Sweden and Finland (hospital basis)

July

August
Full national reimbursement agreement achieved for Idefirix® in the Netherlands

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

September

October

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

Market access agreement achieved in Greece on a hospital basis

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

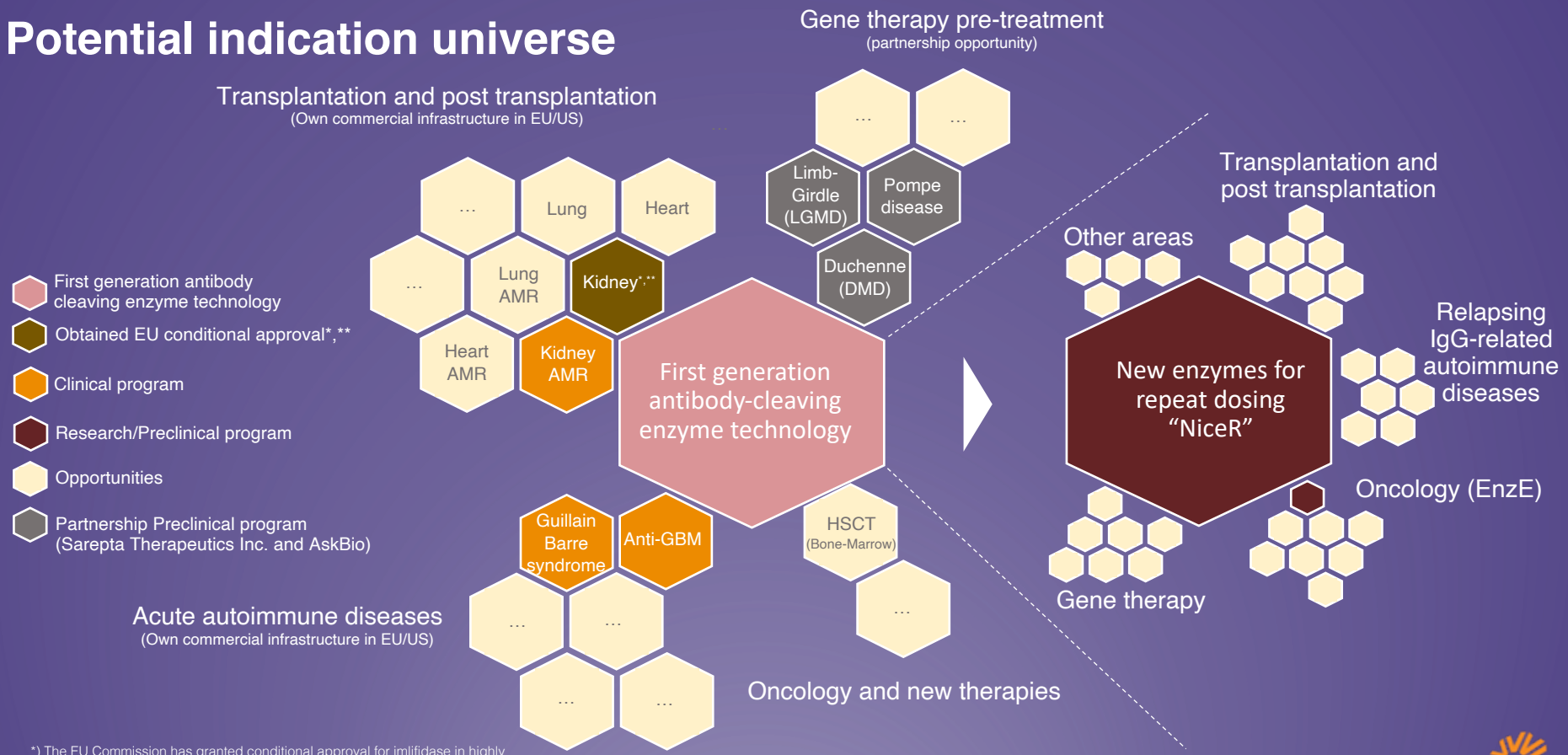
2022 January
Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease

February
Pricing and reimbursement for Idefirix® obtained in France on an early access basis

March
Pricing and reimbursement achieved for Idefirix® in Germany

Results of the Phase 2 study of imlifidase in patients with anti-GBM) disease published in Journal of the American Society of Nephrology

Potential indication universe



*) The EU Commission has granted conditional approval for imlifidase in highly sensitized kidney transplant patients.
**) In the US a new study has commenced targeting a BLA filing by H1 2024

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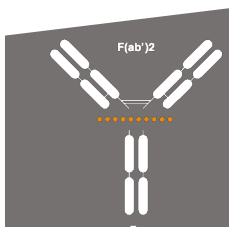
Our Business model

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

Growth engine

Leveraging our proprietary antibody cleaving enzyme technology



Value chain

We are controlling the full value chain

- Drug discovery
- Drug development
- Supply Operations
- Distribution

Commercialization

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

Evolution into a fully integrated biopharmaceutical company

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Broad clinical pipeline in transplantation and auto-immune diseases

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

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

Completed
Ongoing
Planned
Conditional approval based on Phase 2 data

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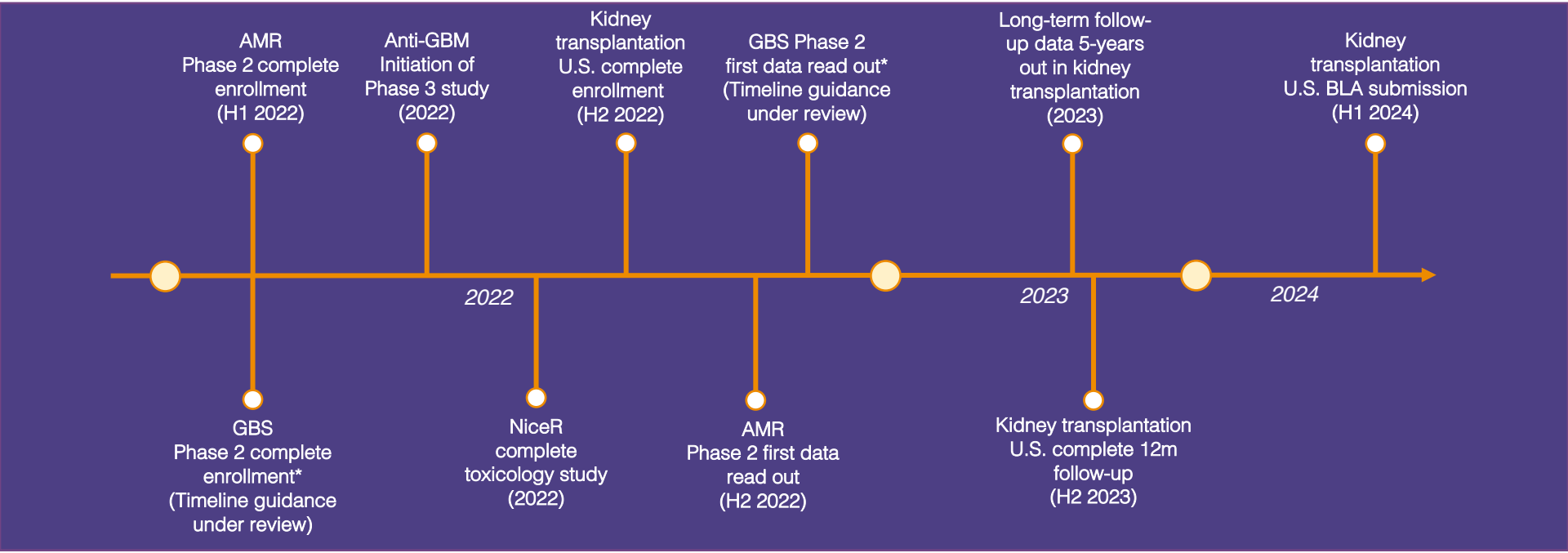
Upcoming milestones

Milestones subject to potential COVID-19 impact



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

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

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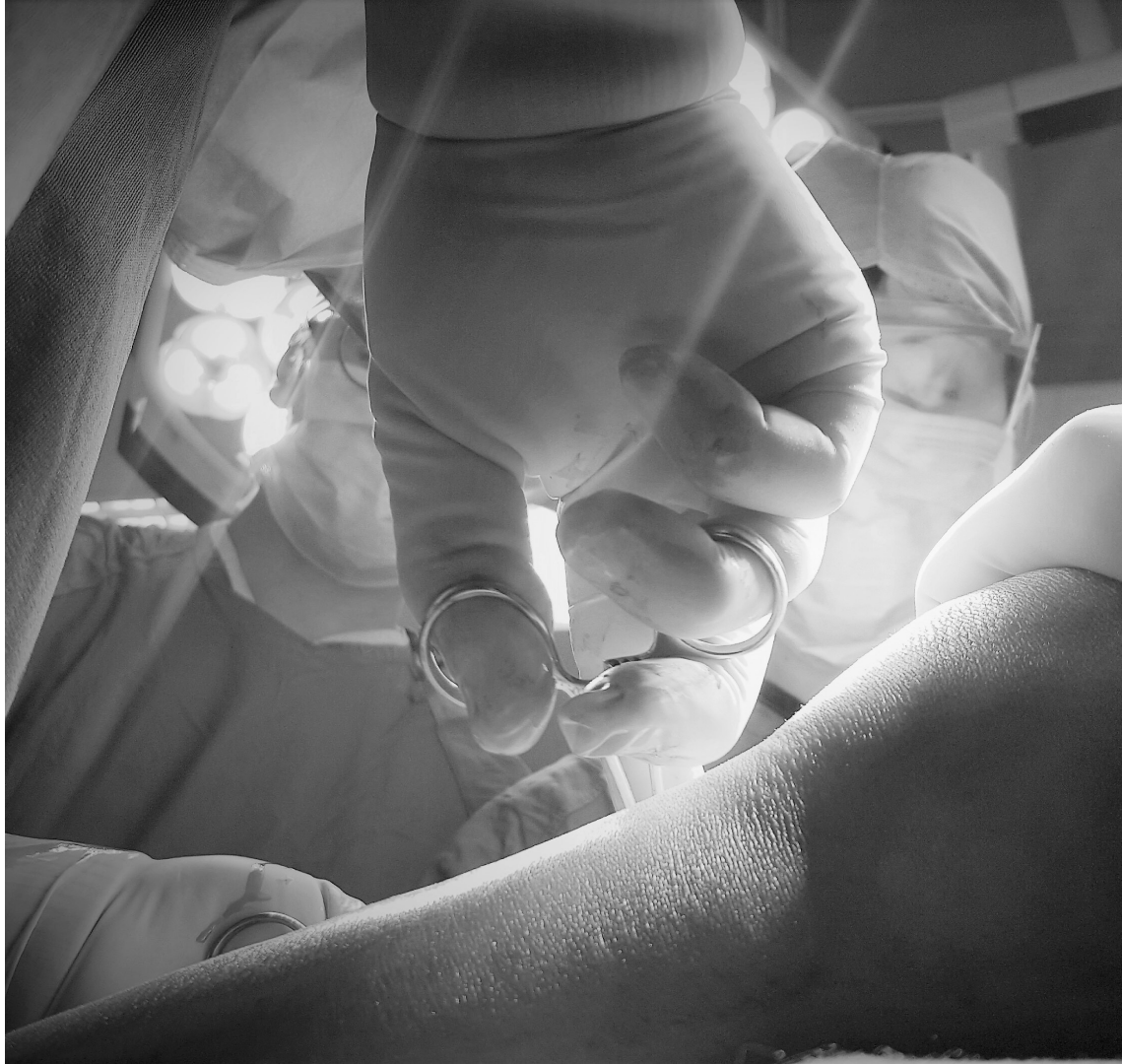
Our strategic priorities

Building tomorrow's Hansa Biopharma

Commercialize Idefirix® in first markets and indication	Advance ongoing clinical programs in transplantation and autoimmune diseases	Expand IgG-cleaving enzyme technology in new indications and disease areas
SUCCESSFULLY LAUNCH IDEFIRIX® IN EUROPE*	ACHIEVE APPROVAL FOR IMLIFIDASE IN FOLLOW-ON INDICATIONS	EXPLORE GENE THERAPY OPPORTUNITY
GEOGRAPHICAL EXPANSION		DEVELOP NEXT-GENERATION IgG-CLEAVING ENZYMES
COMPLETE PHASE 3 STUDY, SECURE FDA APPROVAL AND LAUNCH IDEFIRIX IN THE U.S.	BUILD NEW FRANCHISES TO CAPTURE FULL VALUE OF OUR TECHNOLOGY PLATFORM	DEVELOP EXISTING PARTNERSHIPS WITH SAREPTA AND ARGENX AND CREATE NEW ONES

*Idefirix approved in EEA under conditional approval for kidney transplantation

Our technology platform



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Imlifidase

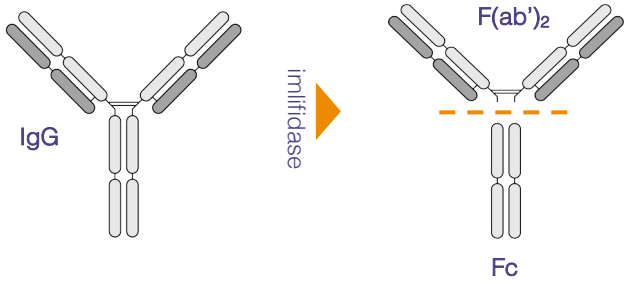
A novel approach to eliminate pathogenic IgG

Origins from a bacteria *Streptococcus pyogenes*

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

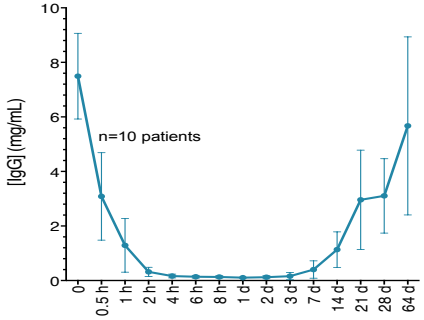
A unique IgG antibody-cleaving enzyme

- 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



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

Targeting rare IgG mediated diseases

Expanding our commercial franchises

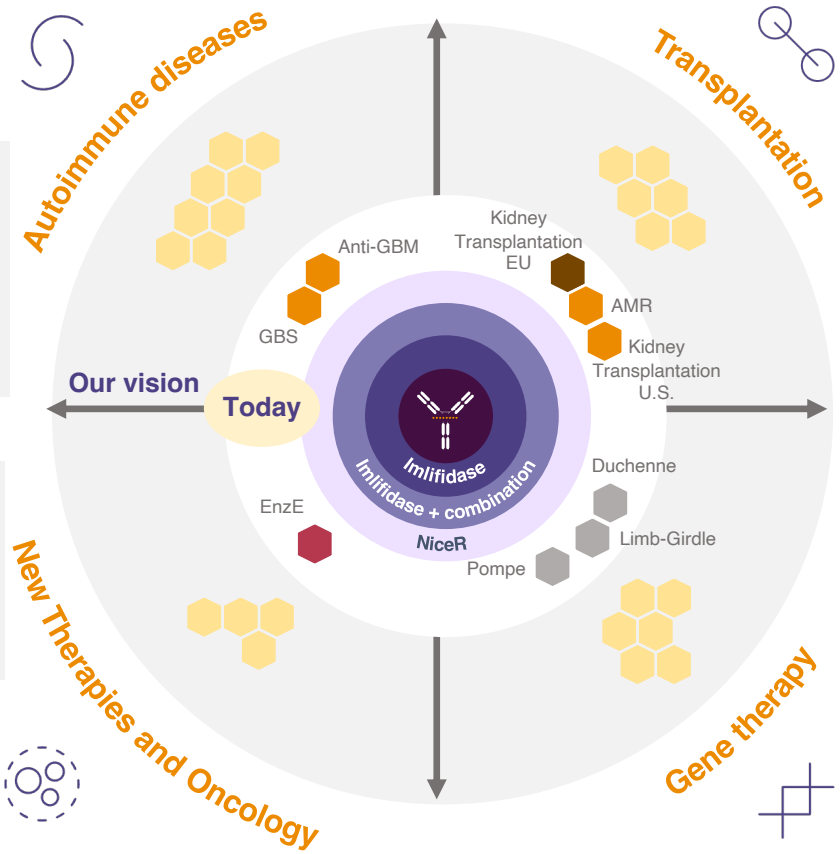
- Regulatory approval (conditional)
- Clinical development
- Partnership (preclinical development)
- Preclinical development

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

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

IgG-cleaving enzymes to enable or even potentiate cancer therapy

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



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

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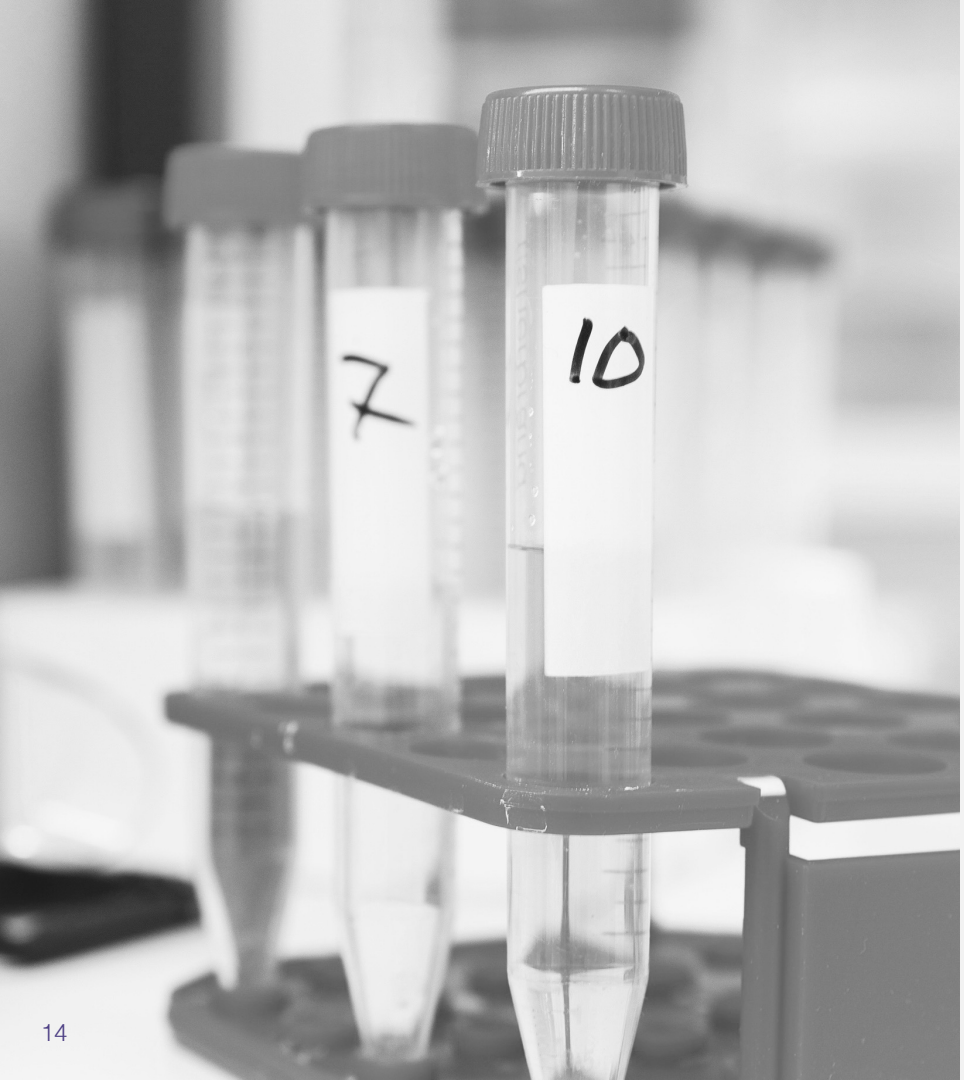

New preclinical collaboration with argenx BV

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

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

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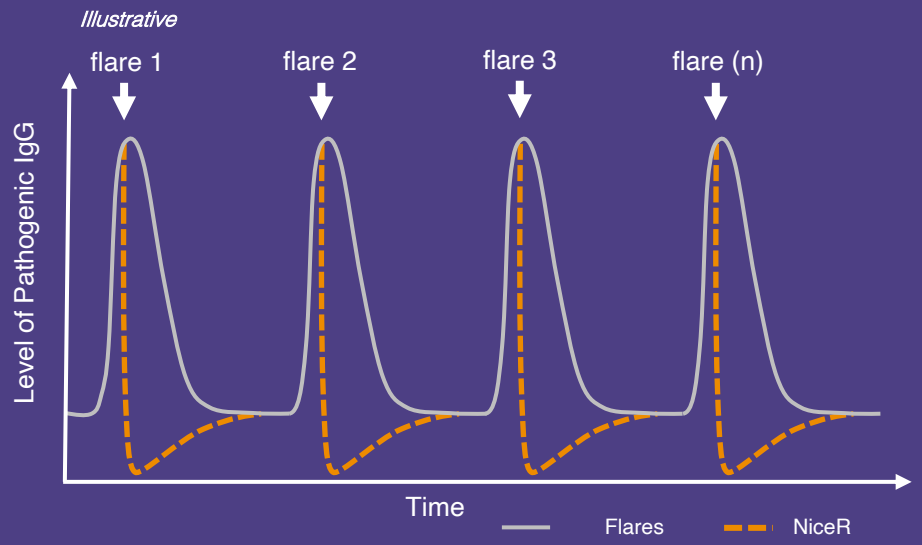
“NiceR” for repeat dosing

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

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

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

NiceR can potentially inactivate flares



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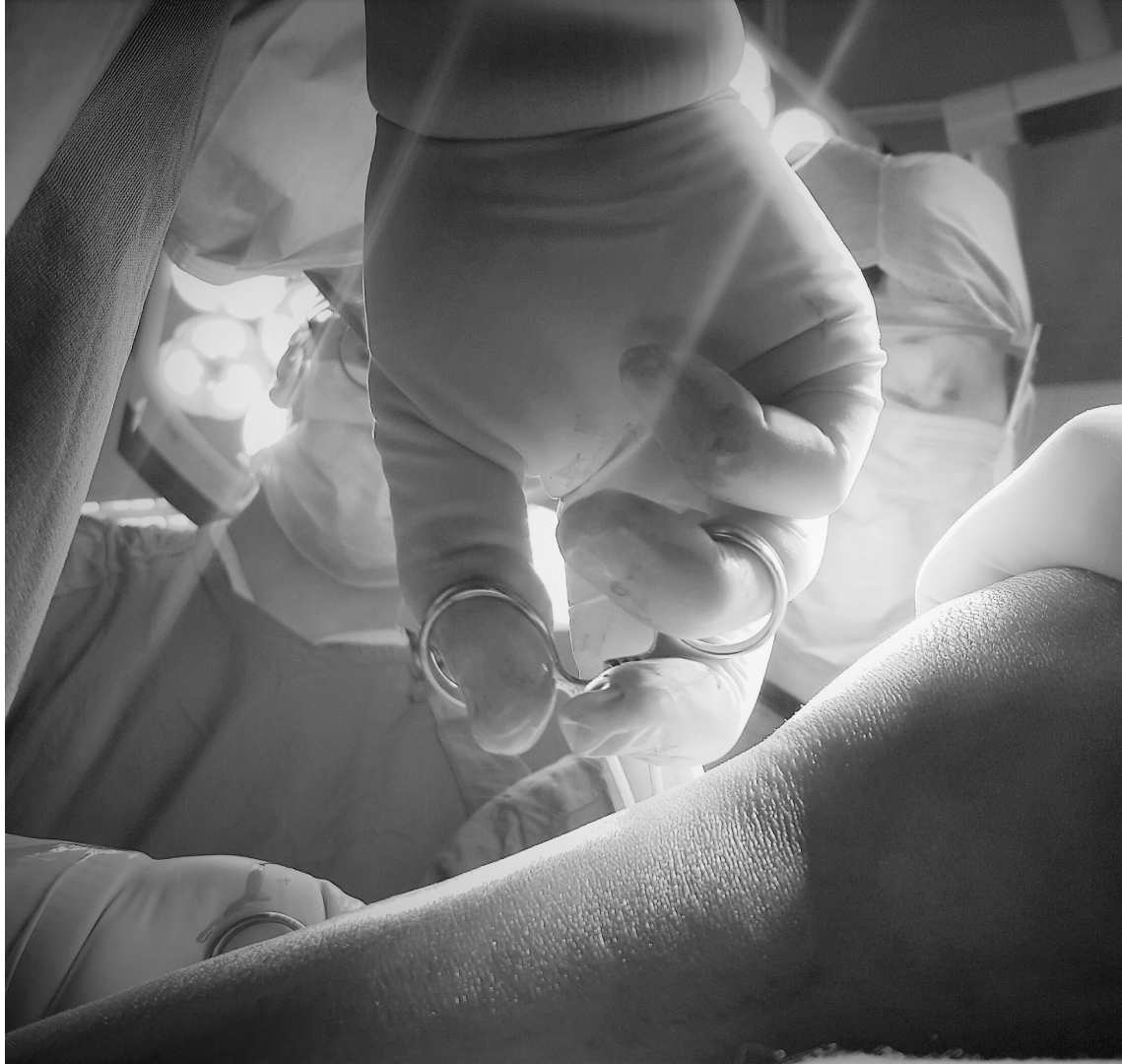
Imlifidase in kidney transplantation



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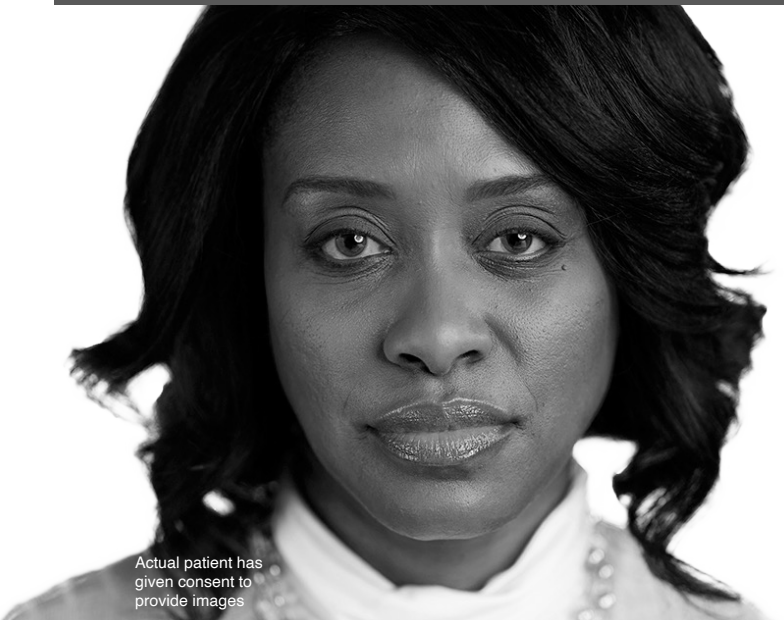
Idefirix® (imlifidase) has received conditional approval in the European Union

Low complexity transplants ⟷ Higher complexity transplants

~70% of patients[1,2]	15-20% of patients[1,2]	10-15% of patients[1,2]	
Non or less sensitized (cPRA < 20%)	Moderately sensitized (20% < cPRA < 80%)	Highly sensitized (cPRA > 80%)	
		Highly sensitized patients that are likely to be transplanted with a compatible donor	Highly sensitized patients unlikely to be transplanted under available KAS, including prioritization programs



Actual patient has given consent to provide images

Idefirix® is indicated for

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

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

Potential patients

idefirix® imlifidase

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

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

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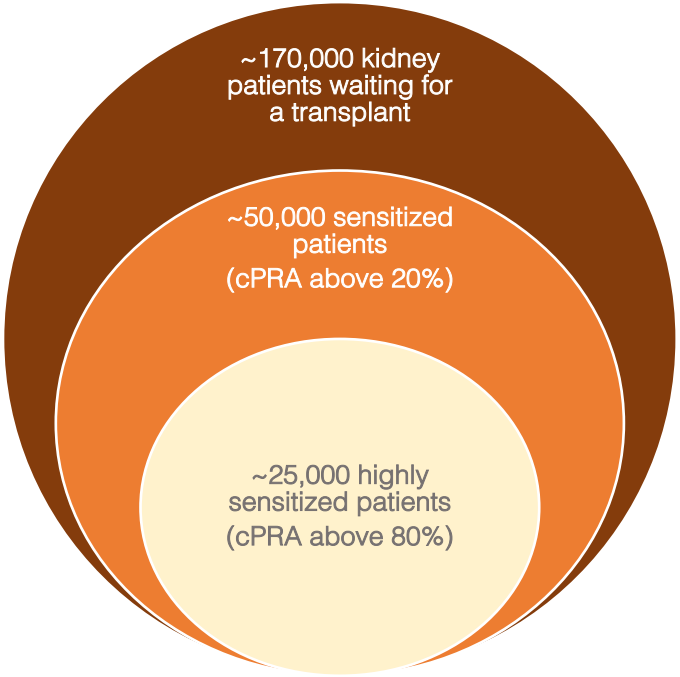
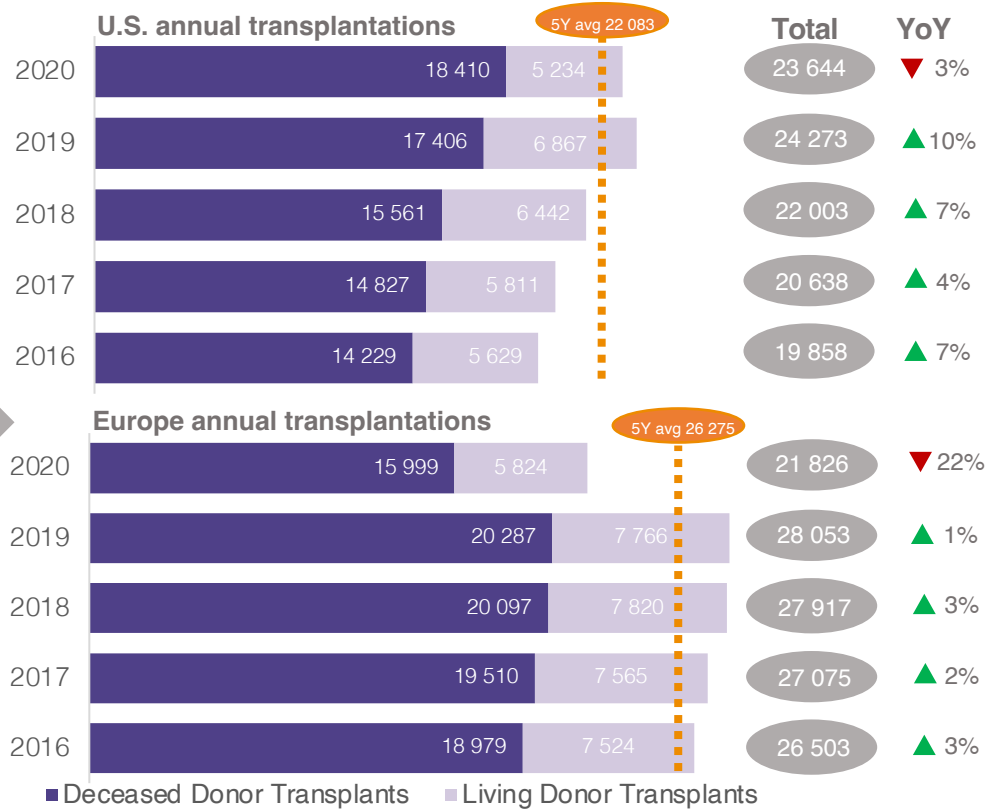
Up to 15% of patients waiting for a new kidney are highly sensitized

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



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

European transplantation rates were negatively affected by COVID-19



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

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

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

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

Illustrative

Commercial sales uptake

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

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

"Low initial uptake and volatile growth'

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

2 Expanding internationally will lead to more exponential growth mid term

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

"More exponential growth'

Expand broader and internationally

3 Potential label expansion will enable new growth pockets longer term

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

"Growth from pursuing new opportunities"

Potentially enable label expansions

Initial years of commercialization | Mid term | Longer term

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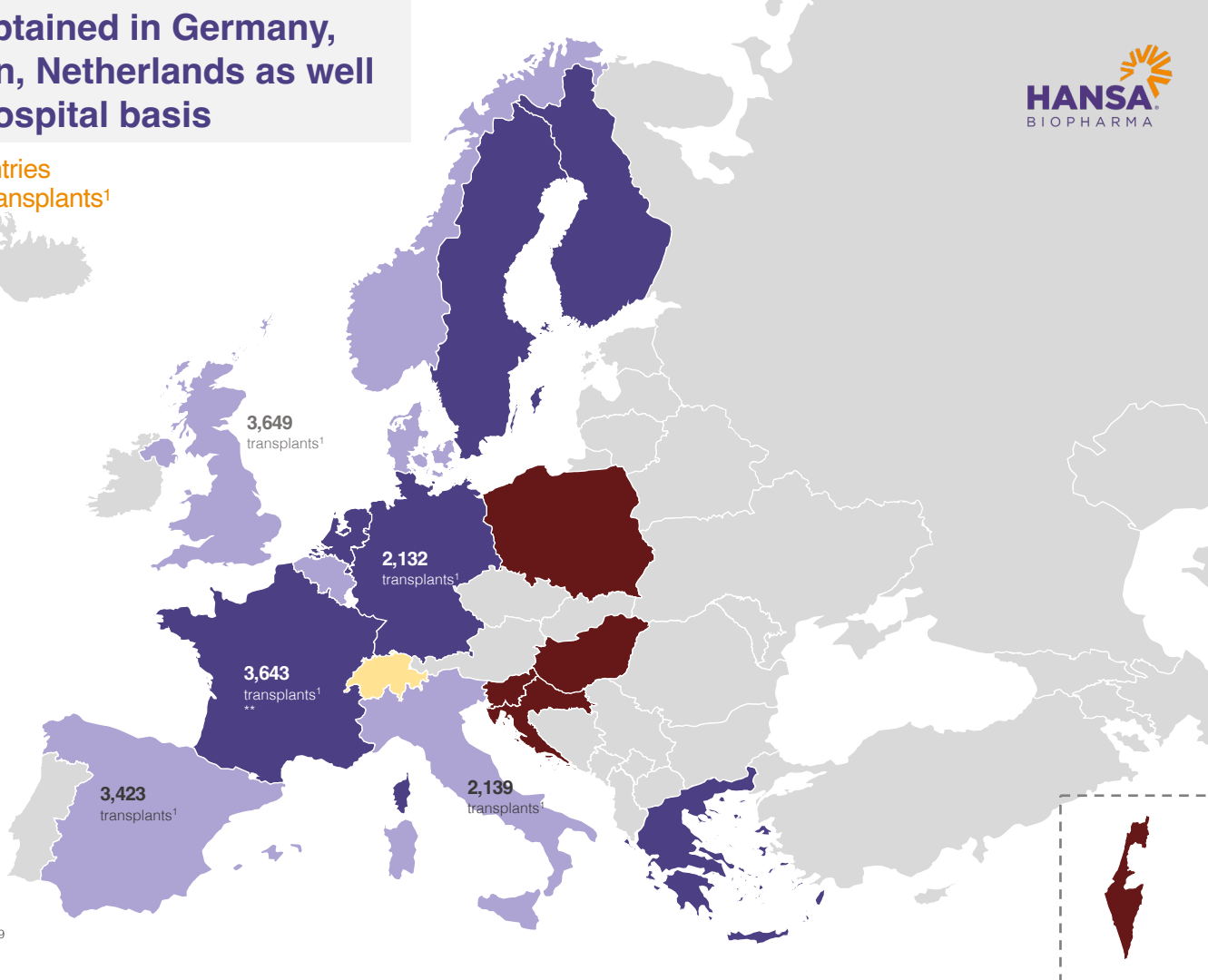
Pricing and reimbursement obtained in Germany, France (early access), Sweden, Netherlands as well as Finland and Greece on a hospital basis

Market access processes ongoing in 10 countries
EU4+UK represent ~15,000 annual kidney transplants[1]

- Health Technology Assessments (HTA) dossiers submitted
- Marketing Authorization Application submitted
- Pricing & reimbursement obtained (country or clinic level)
- Territories covered commercially by Medison Pharma



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

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

U.S. trial design

64 highly sensitized kidney patients with the highest unmet medical need

- Patients with a cPRA score of ≥99.9% will be enrolled
- First patients enrolled at Columbia University, NYC

1:1 Randomization

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

Primary endpoint

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

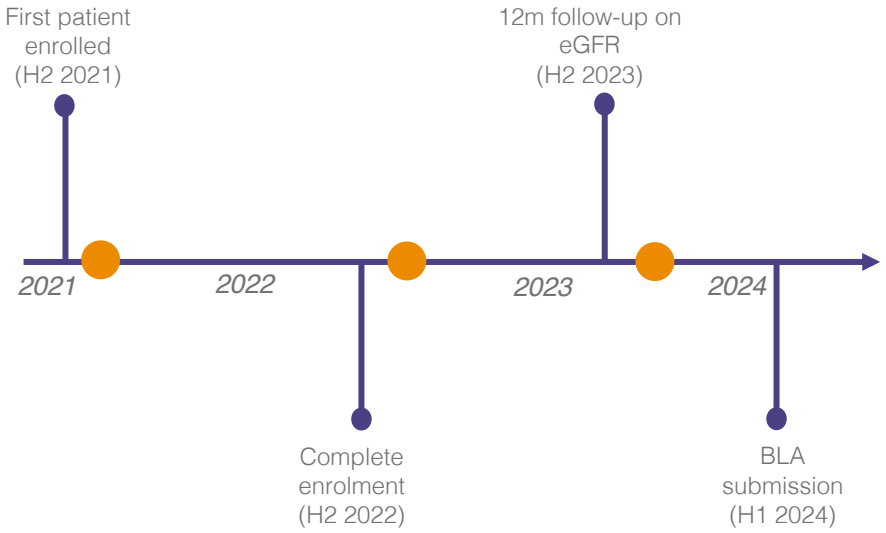
Secondary endpoint

- Patient survival at 12 months

12-15 leading transplantation centers in the U.S. will be engaged in the study

- Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, NYC is appointed to be the principal investigator
- Five clinics are open for recruitment as of February 2, 2022

Timeline



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

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

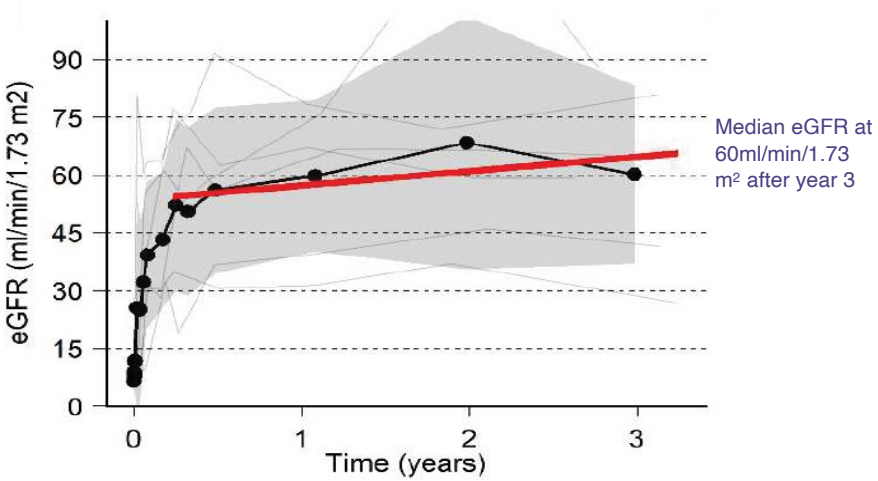
Data accepted for publication in the American Journal of Transplantation[1] Link AJT article

30 patients participating in follow-up study at year three

AMR frequency in line with other desensitization protocols

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

Improved kidney function for patients with cPRA ≥ 99.9%



[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)

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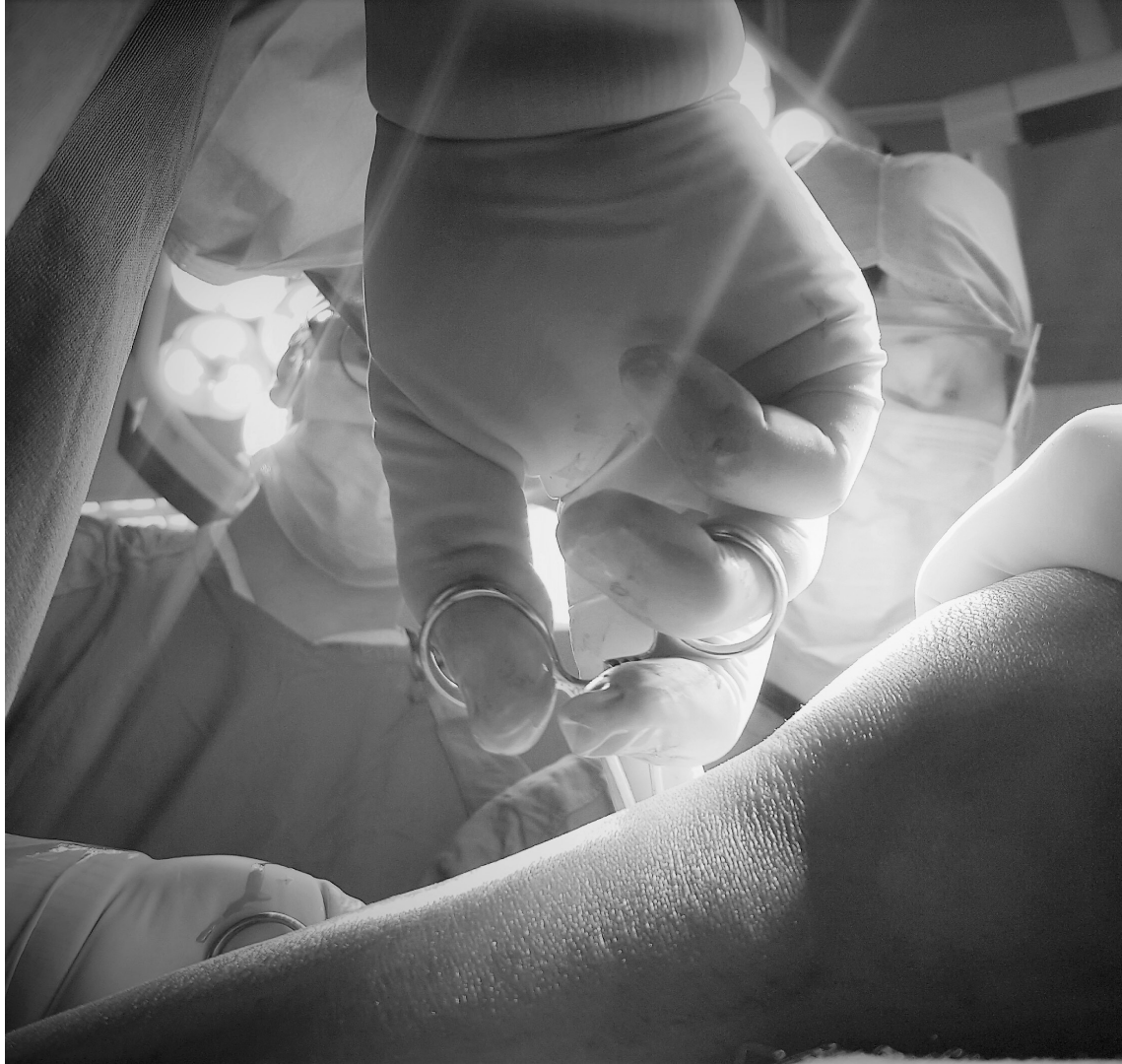
Additional imlifidase indications



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Hansa's antibody cleaving enzyme technology

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

Clinical programs

Potential autoimmune indications

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

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Rapidly progressive glomerulonephritis

Anti-GBM

~1 000 patients*[1]

Lupus nephritis ~35 000*[2]

ANCA-associated vasculitis ~90 000*[3]

Neurological disorders

Myasthenia gravis ~210 000*[4]

GBS

~10 000 patients*[5]

CIDP ~55 000*[6]

NMO ~20 000*[7]

Skin disorders

EBA

<1 000 patients*[8]

Pemphigus vulgaris ~40 000*[9]

Blood disorders

ITP ~75 000*[10]

WAHA ~95 000*[11]

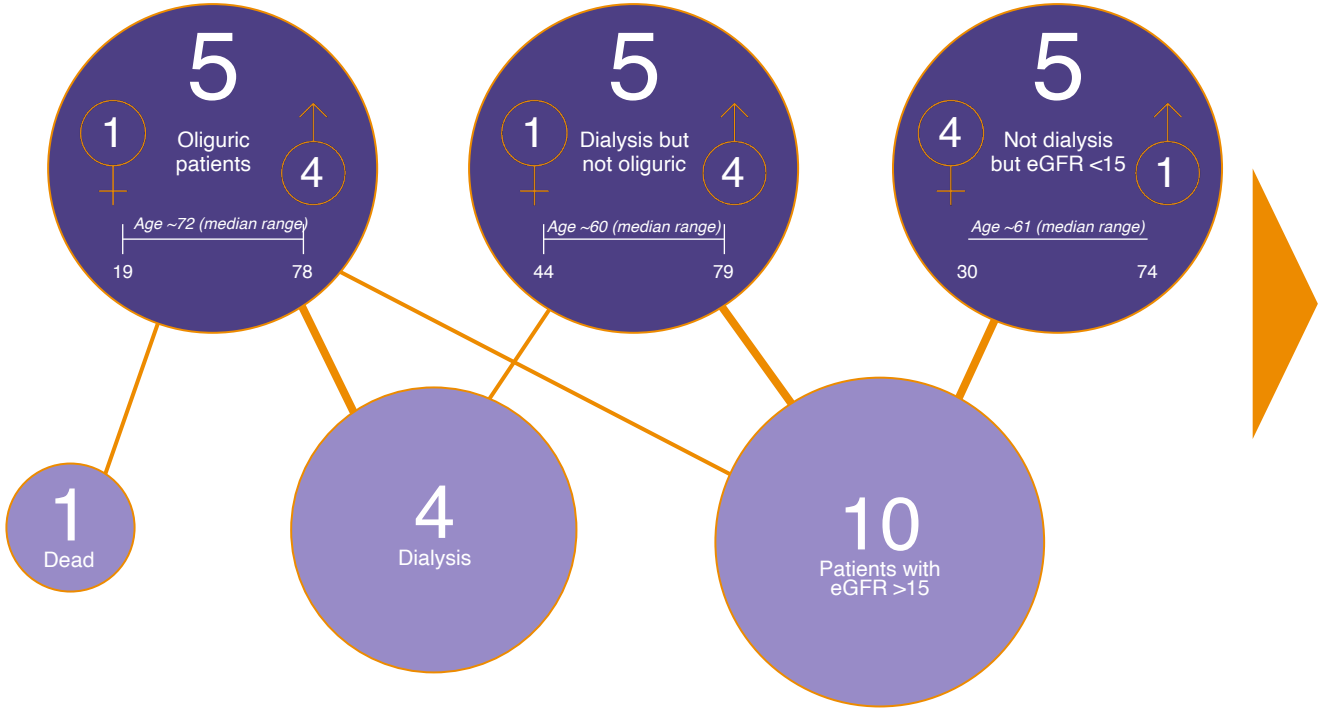
APS ~350 000*[12]

CIDP: Chronic inflammatory demyelinating polyradiculoneuropathy
NMO: Neuromyelitis optica
EBA: Epidermolysis bullosa acquisita
ITP: Immune thrombocytopenia
WAHA: Warm antibody hemolytic anemia
APS: Antiphospholipid syndrome

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

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

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



High-level data read out

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

HANSA BIOPHARMA

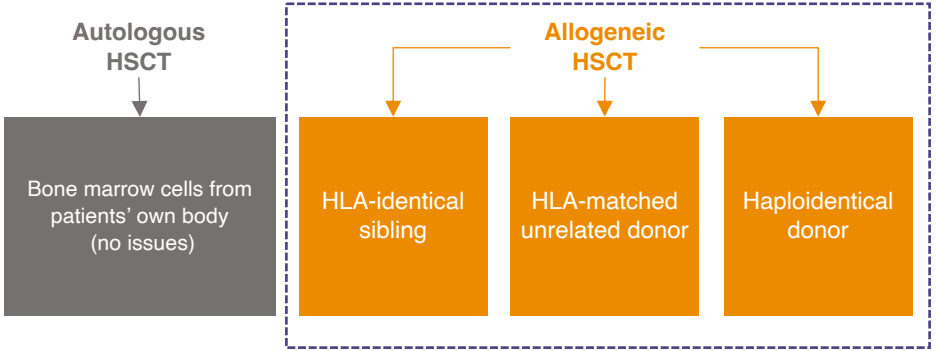
Exploring potential use of imlifidase in allogeneic hematopoietic stem cell transplantation (HSCT)

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

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

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

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



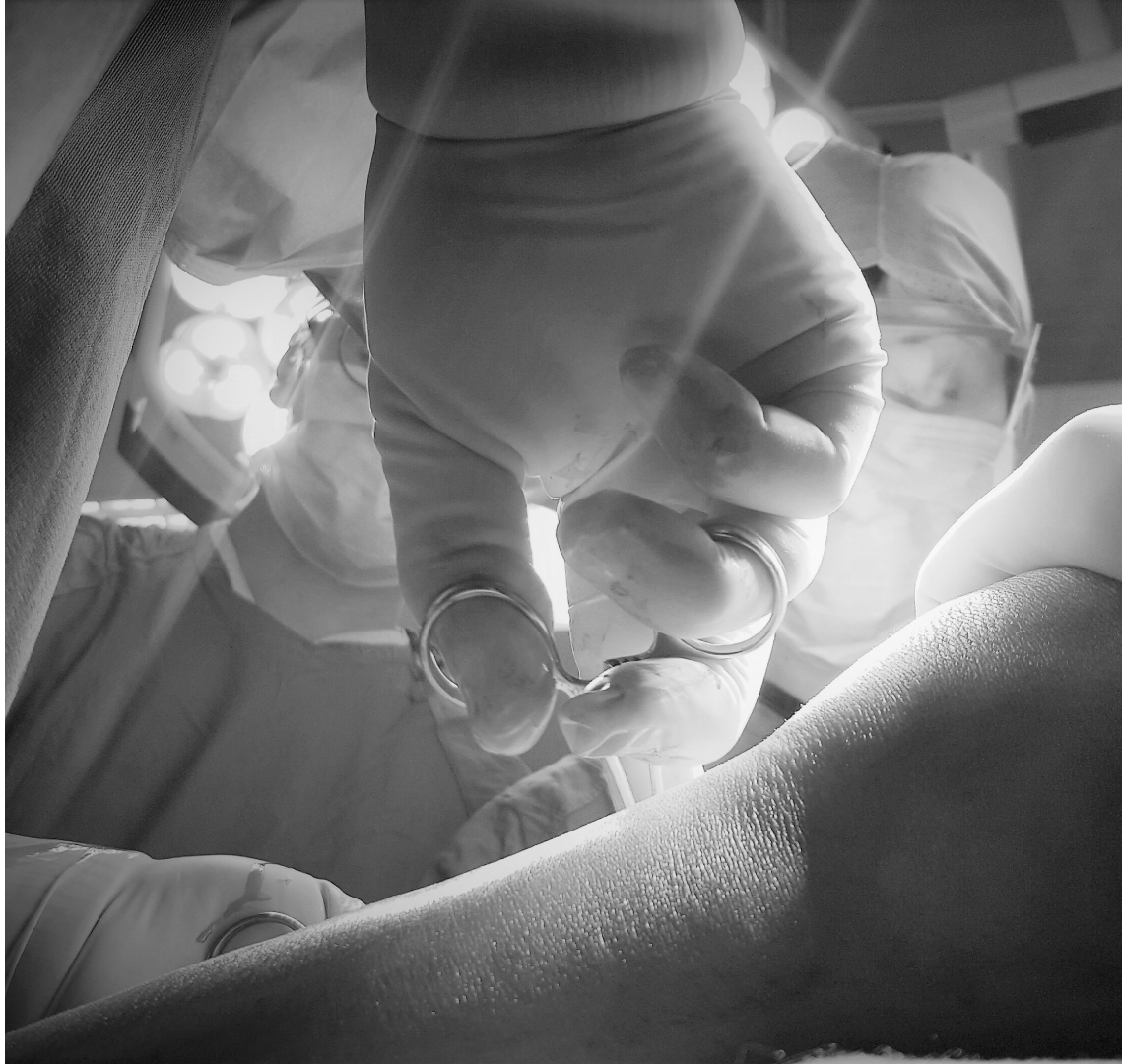
[1] Ciurea et al., Bone Marrow Transplantation, 2018
[2] European Society for Blood and Marrow Transplantation

HANSA BIOPHARMA

Gene Therapy

Christian Kjellman
CSO/COO

HANSA BIOPHARMA



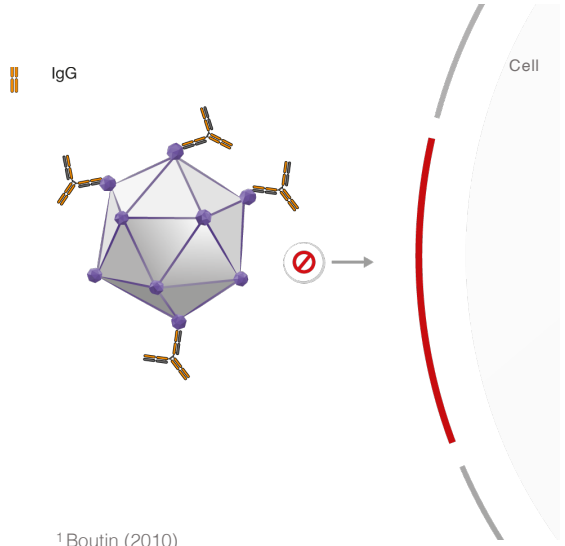
Neutralizing antibodies (Nabs) are immunological barriers in gene therapy; imlifidase may potentially eliminate Nabs

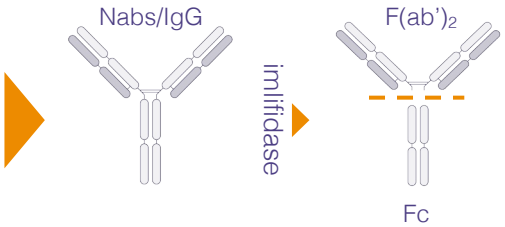
Between approximately 5% and 70%[1,2] of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

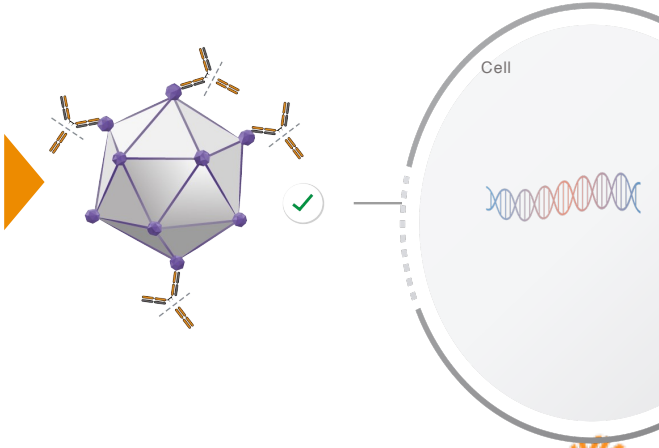
1. Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern

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

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







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

HANSA BIOPHARMA

Systemic gene therapy is an emerging opportunity

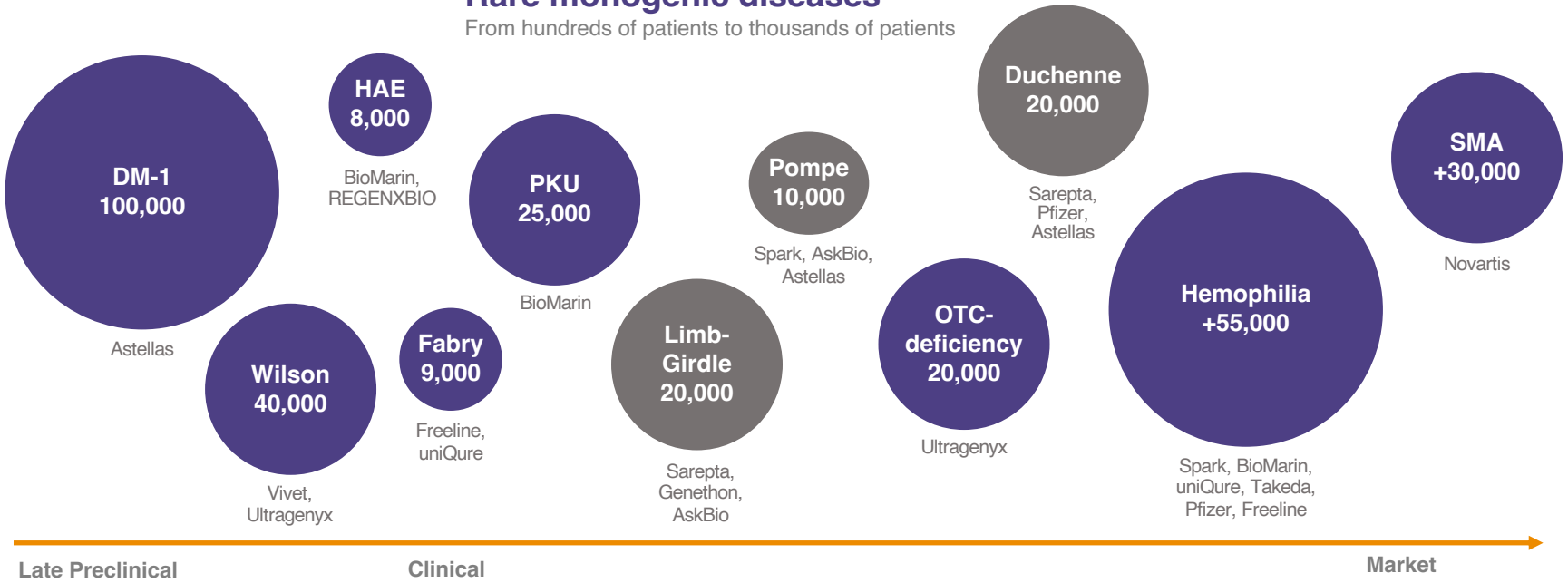
with a focus on the potential to correct issues causing genes in rare monogenic diseases

Preclinical programs with Sarepta and AskBio

Potential gene therapy indications

Rare monogenic diseases

From hundreds of patients to thousands of patients



Size of indication (US & EU)

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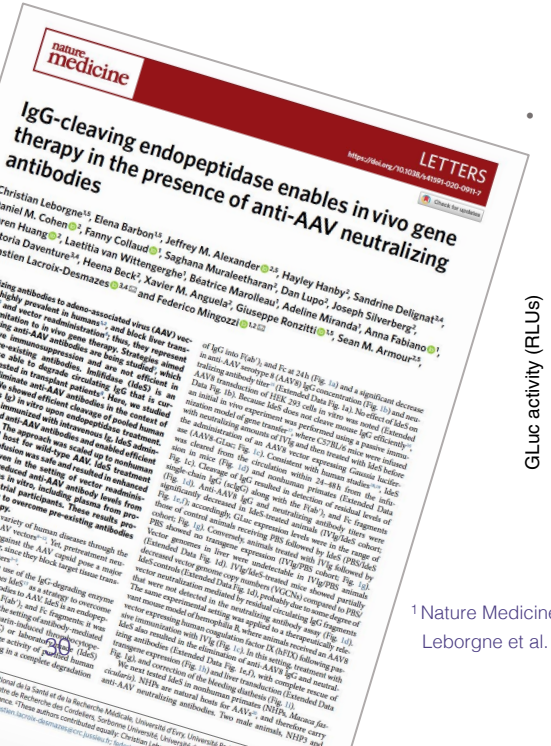
Imlifidase (IdeS) was highlighted in Nature Medicine[1]

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


nature medicine

LETTERS

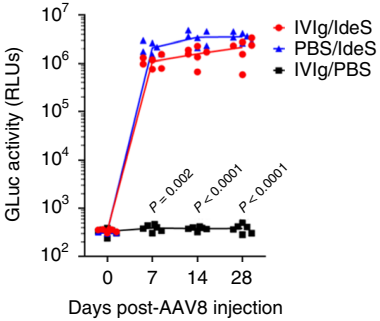
https://doi.org/10.1038/s41591-020-0911-7

IgG-cleaving endopeptidase enables in vivo gene therapy in the presence of anti-AAV neutralizing antibodies

Christian Leborgne[1,5], Elena Barbon[1,5], Jeffrey M. Alexander[2,5], Hayley Hanby[2], Sandrine Delignat[3,4], Daniel M. Cohen[3], Fanny Collaud[1], Saghana Muraleetharan[2], Dan Lupo[2], Joseph Silverberg[2], Koren Huang[2], Laetitia van Wittenberghe[1], Béatrice Marolleau[1], Adeline Miranda[1], Anna Fabiano[1], Victoria Daventure[3,4], Heena Beck[2], Xavier M. Anguela[2], Giuseppe Ronzitti[1,5], Sean M. Armour[2,5], Sebastien Lacroix-Desmazes[3,4] and Federico Mingozzi[1,2]

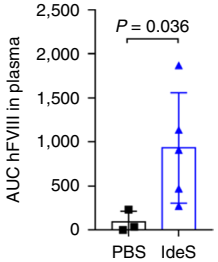
Imlifidase tested in a mouse model

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



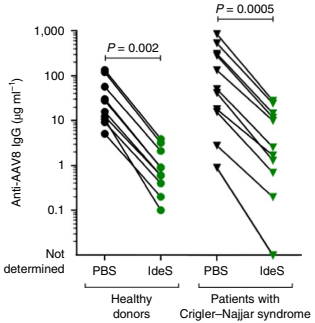
Imlifidase tested in NHP ahead of AAV vector infusion

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



Imlifidase tested in human plasma samples (GT patients)

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



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

HANSA BIOPHARMA

Global and exclusive agreement with Sarepta Therapeutics

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

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SAREPTA THERAPEUTICS

Indication exclusivity:

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

Hansa's key resources

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

+

Sarepta's key resources

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

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

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

Upfront payment
USD 10 million upfront

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

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

HANSA BIOPHARMA

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

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

HANSA BIOPHARMA

Hansa's key resources and deliverables

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

+

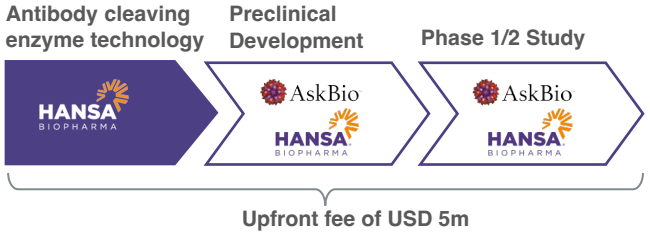
AskBio™

Fully owned subsidiary of Bayer AG

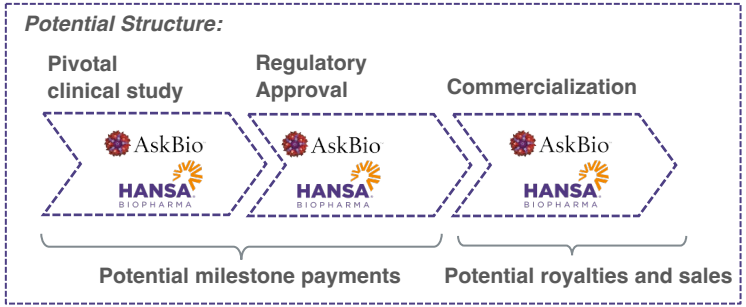
AskBio's key resources and deliverables

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

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



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



HANSA BIOPHARMA

Our mid-term financial priorities

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

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

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

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

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

- Full commercial launch of Idefirix® in Europe and other markets*
- Complete Phase 3 trial for imlifidase in kidney transplantation and secure U.S. approval
- Obtain regulatory approval in anti-GBM, GBS and AMR
- Advance clinical studies with imlifidase in gene therapies for LGMD and DMD with Sarepta
- Demonstrate PoC in our next gen. enzymes (NiceR)
- Expand partnerships in gene therapy and oncology
- Show PoC in new indications such as oncology
- Advance combination treatment into the clinic with argenx to potentially enable new therapeutics in transplantation and autoimmune diseases

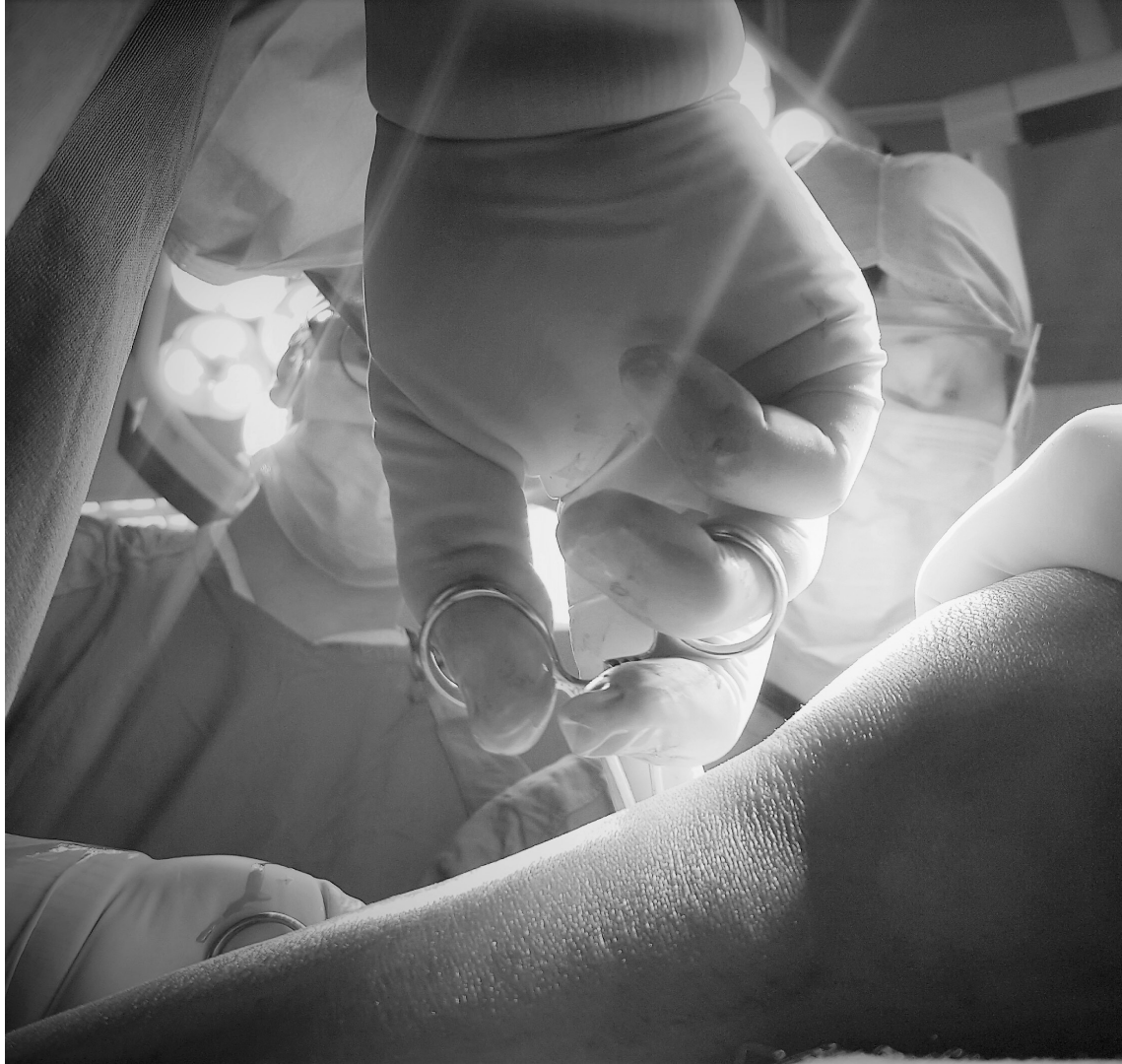
* Idefirix approved in EEA under conditional approval for treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor

Our future

Hansa Biopharma aims to become 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

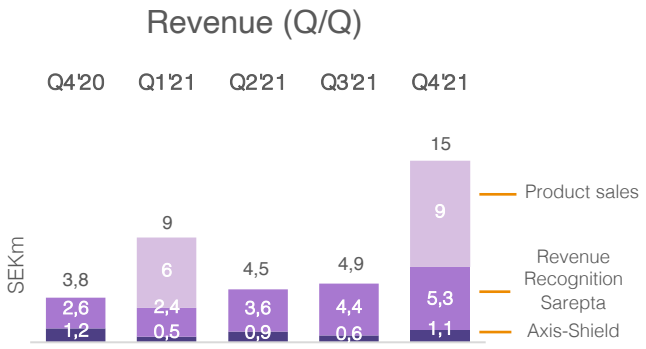
HANSA
BIOPHARMA

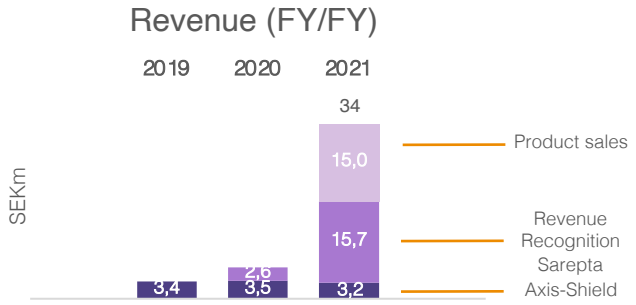
Additional slides



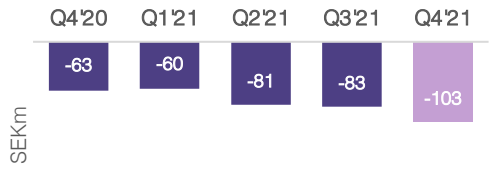
HANSA BIOPHARMA

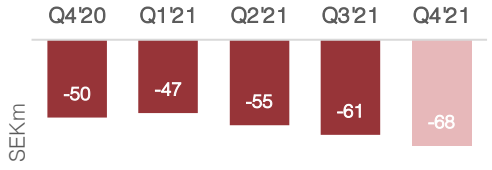
Revenue amounted to SEK 15m for Q4'21 and SEK 34m for FY'21

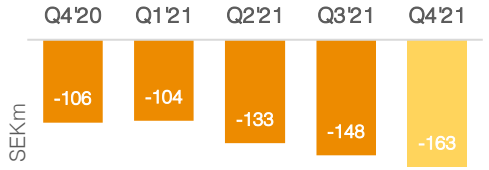


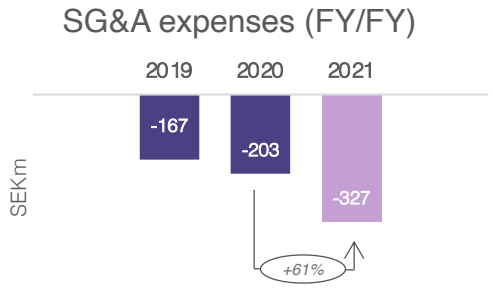


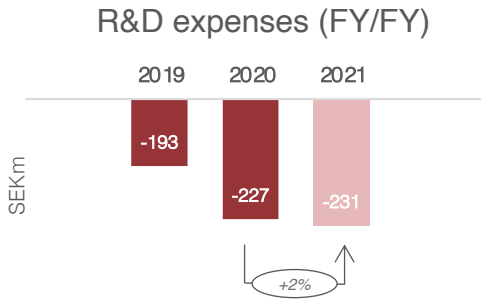
Continued investments in our commercialization and pipeline

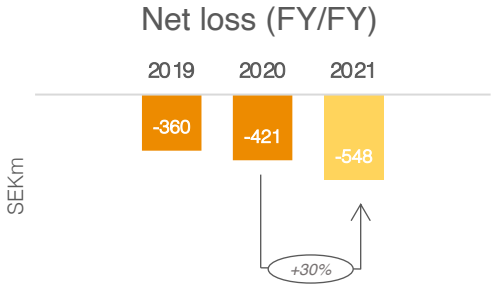






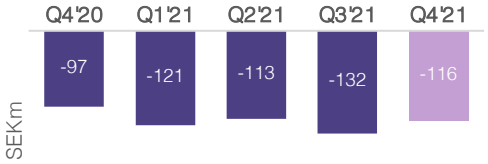




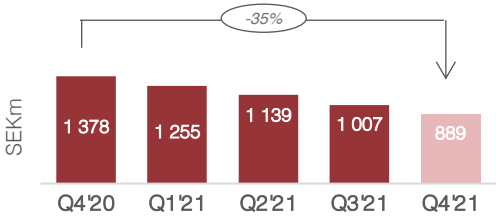


With current cash position and projected burn-rate, operations is financed into 2023

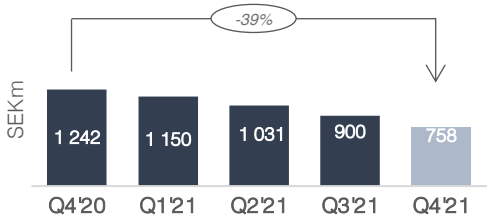
Operating cash flow (Q/Q)



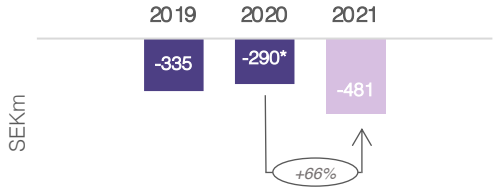
Cash & short-term investments (Q/Q)



Shareholders' equity (Q/Q)

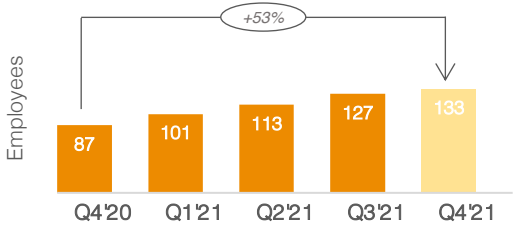


Operating cash flow (FY/FY)



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

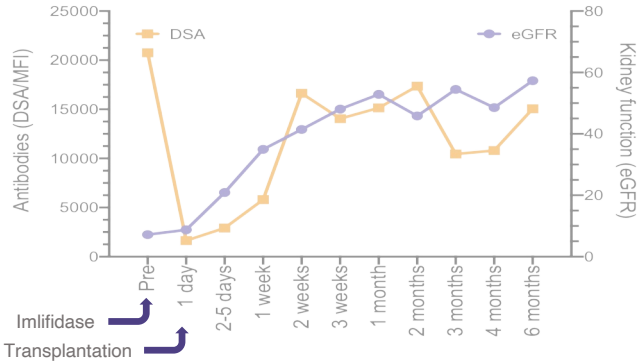
Number of employees (Q/Q)



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

Pooled analysis from four Phase 2 trials

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



Study design of our four Phase 2 trials

Study 02 Phase 2

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

Study 03 Phase 2

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

Study 04 Phase 2

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

Study 06 Phase 2

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

HANSA BIOPHARMA

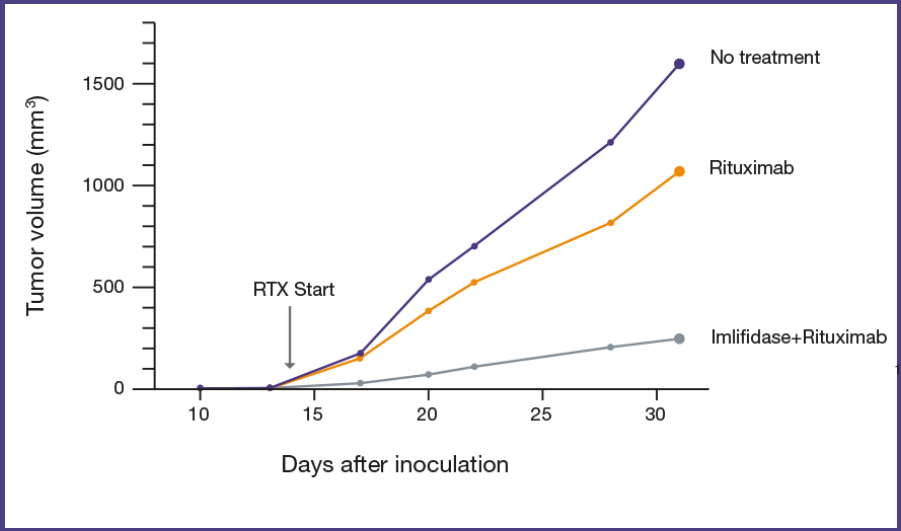
Our antibody cleaving enzymes

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

HANSA BIOPHARMA

Antibody Mediated Rejection

Long term graft survival is challenged by AMR post transplantation

There is no approved treatment for AMR

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

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

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AMR Phase 2

Ongoing AMR Phase 2 study

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

CLINICALTRIALS.GOV ID

NCT03897205 (2019)

SUBJECTS

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

DOSES/FOLLOW UP TIME

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

MAIN OBJECTTIVES

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

STUDY DESIGN

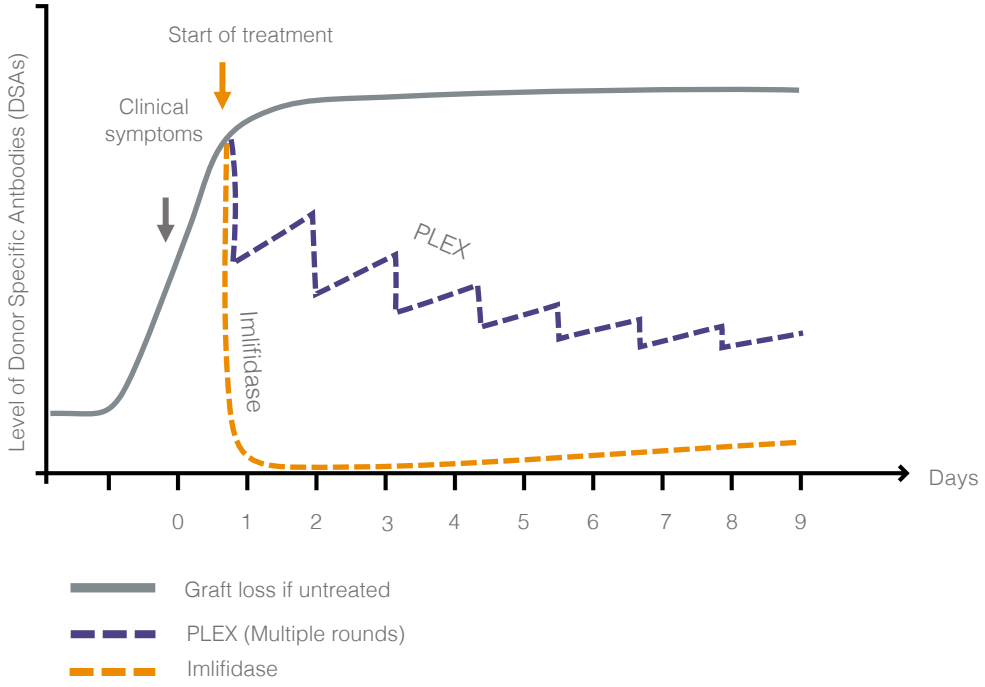
- Randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

STATUS

Ongoing recruitment

Potential of using imlifidase vs. PLEX in AMR

Illustrative



HANSA BIOPHARMA

Guillain-Barré syndrome

GBS is an acute autoimmune attack on the peripheral nervous system

GBS can affect anyone at any age

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

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

GBS
Phase 2

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

CLINICALTRIALS.GOV ID

NCT03943589 (2019)

SUBJECTS

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

DOSES/FOLLOW UP TIME

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

MAIN OBJECTTIVES

- safety and effectiveness of imlifidase in patients diagnosed with GBS

STUDY DESIGN

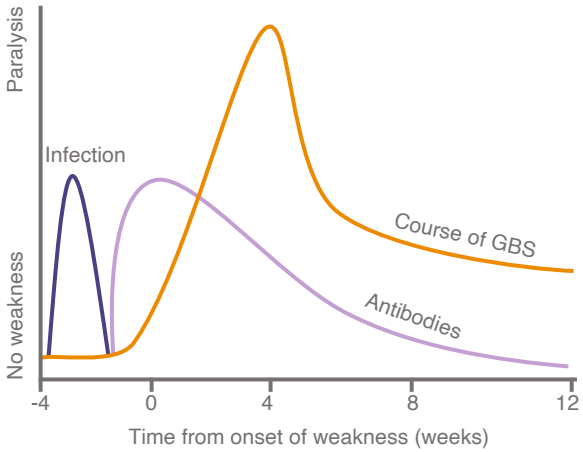
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing recruitment

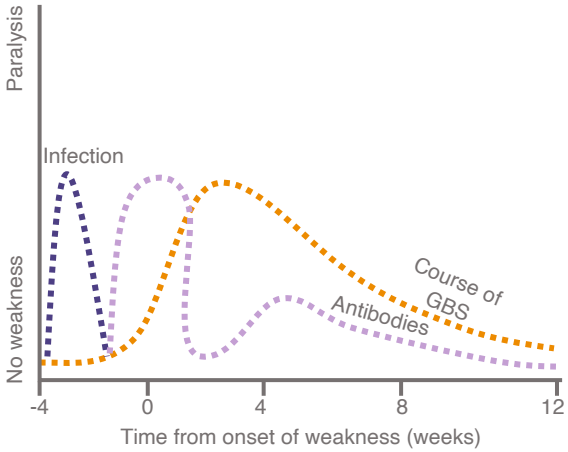
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



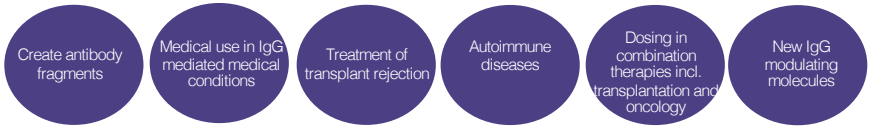
HANSA BIOPHARMA

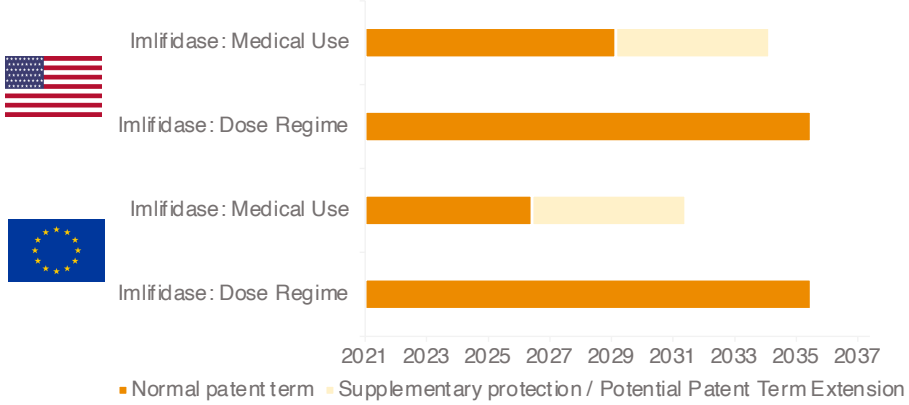
Strong technology protection

through patents and orphan drug designations

Patent coverage out to 2035 in key markets

- Hansa Biopharma's portfolio consist of 11 separate patent families incl. 7 patent families in relations to the use of imlifidase (granted/pending)
- Patents cover use of isolated imlifidase in:





Orphan drug designation

- Orphan drug designation is granted to drugs intended for rare diseases (affecting max 5 patients in 10,000 persons in EU or affecting less than 200,000 patients in the US).
- Designation provides development and commercial incentives incl. 10 years market exclusivity in EU and 7 years in the US, when approved.

EMA

Marketing Approval with orphan drug designation

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

Orphan drug designation

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

FDA

Orphan drug designations

- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
- Imlifidase for the treatment of Guillain-Barré Syndrome (2018)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

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