



Investor Presentation
Pareto Healthcare Conference

Stockholm, September 3, 2020

Søren Tulstrup, President & CEO



*...at Hansa Biopharma we envision a world where all patients
with rare immunologic diseases can lead long and healthy lives...*

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Hansa Biopharma's business, financial condition and results of operations. The terms "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 statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Hansa Biopharma's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Biopharma's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize imlifidase, 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.

No assurance can be given that such expectations will prove to have been correct. Hansa Biopharma disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Hansa Biopharma at a glance



Company background

- Founded 2007 with HQ in Lund, Sweden
- Søren Tøllstrup, CEO – Ulf Wiinberg, Chairman
- ~80 employees (~2/3 in R&D) at June 30, 2020
- Operations in Sweden, US & across Europe
- Market cap: SEK ~12bn Aug 2020
- Listed on Nasdaq OMX Stockholm (HNSA)



Leader in immunomodulatory enzymes for rare IgG-mediated diseases

- Imlifidase is a unique IgG antibody-cleaving enzyme. If approved, imlifidase may have the potential to meet a large unmet need and preserve and transform the lives of people with rare diseases
- Imlifidase has been studied in five clinical studies in kidney transplantation
- Imlifidase has been published in peer-reviewed journals (e.g. New England Journal of Medicine and the American Journal of Transplantation)



Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients
 - The European commission has granted conditional approval for Idefix™ (imlifidase) in highly sensitized kidney transplant patients in the European Union
 - US: Study protocol for RCT submitted June 2020, discussions with FDA ongoing
- Anti-GBM antibody disease (Phase 2)
- Antibody mediated kidney transplant rejection (AMR) (Phase 2)
- Guillain-Barré syndrome (GBS) (Phase 2)
- NiceR - Recurring treatment in autoimmune disease, transplantation and oncology (Preclinical)
- EnzE – Cancer immunotherapy (Preclinical)



Key financials*

• Cash & short-term inv.	H1'20* SEK 400m / SEK 1.5bn post capital raise	FY'19 SEK 601m
• Operating Profits/Loss	H1'20* SEK -193m (H1'19 SEK -156m)	FY'19 SEK -360m
• Operating cash flow	H1'20* SEK -199m (H1'19 SEK -180m)	FY'19 SEK -335m

* Unaudited

*...at Hansa Biopharma we envision
a world where all patients with rare
immunologic diseases can lead
long and healthy lives...*



Imlifidase – a novel approach to eliminate pathogenic IgG



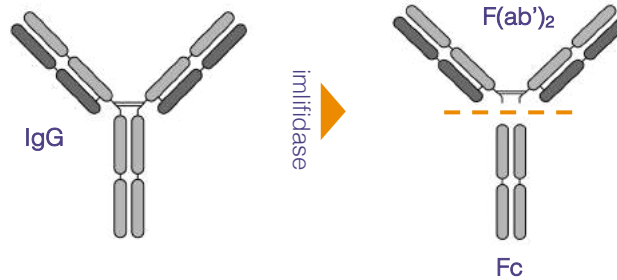
Origins from *Streptococcus pyogenes*

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



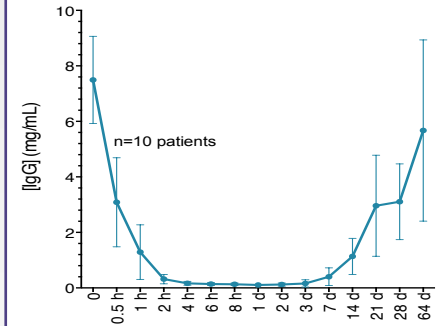
Imlifidase, a unique IgG antibody-cleaving enzyme

- 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

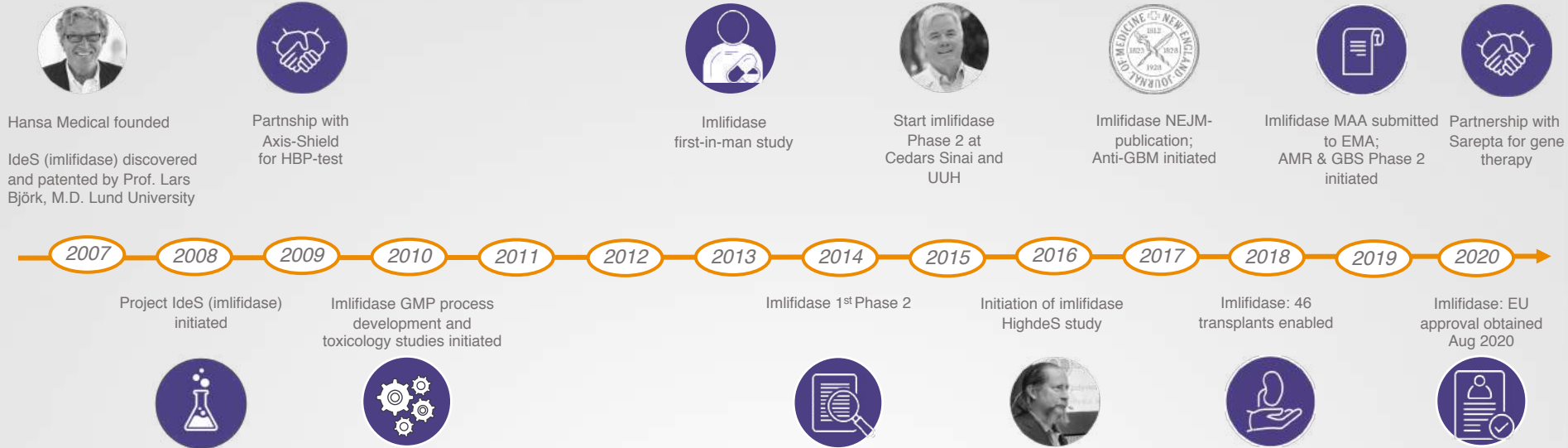


Imlifidase inactivates IgG in 2 hours

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



From technology development to expected commercialisation in 13 years



Our Equity Story



Targeting rare diseases with a high unmet medical need



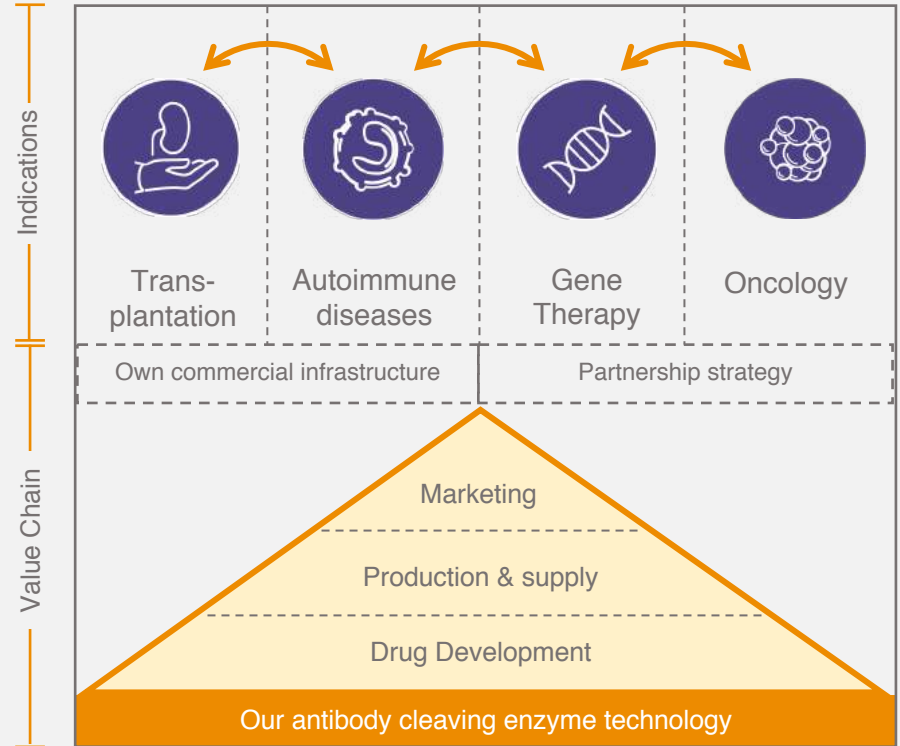
Preparing for commercialization



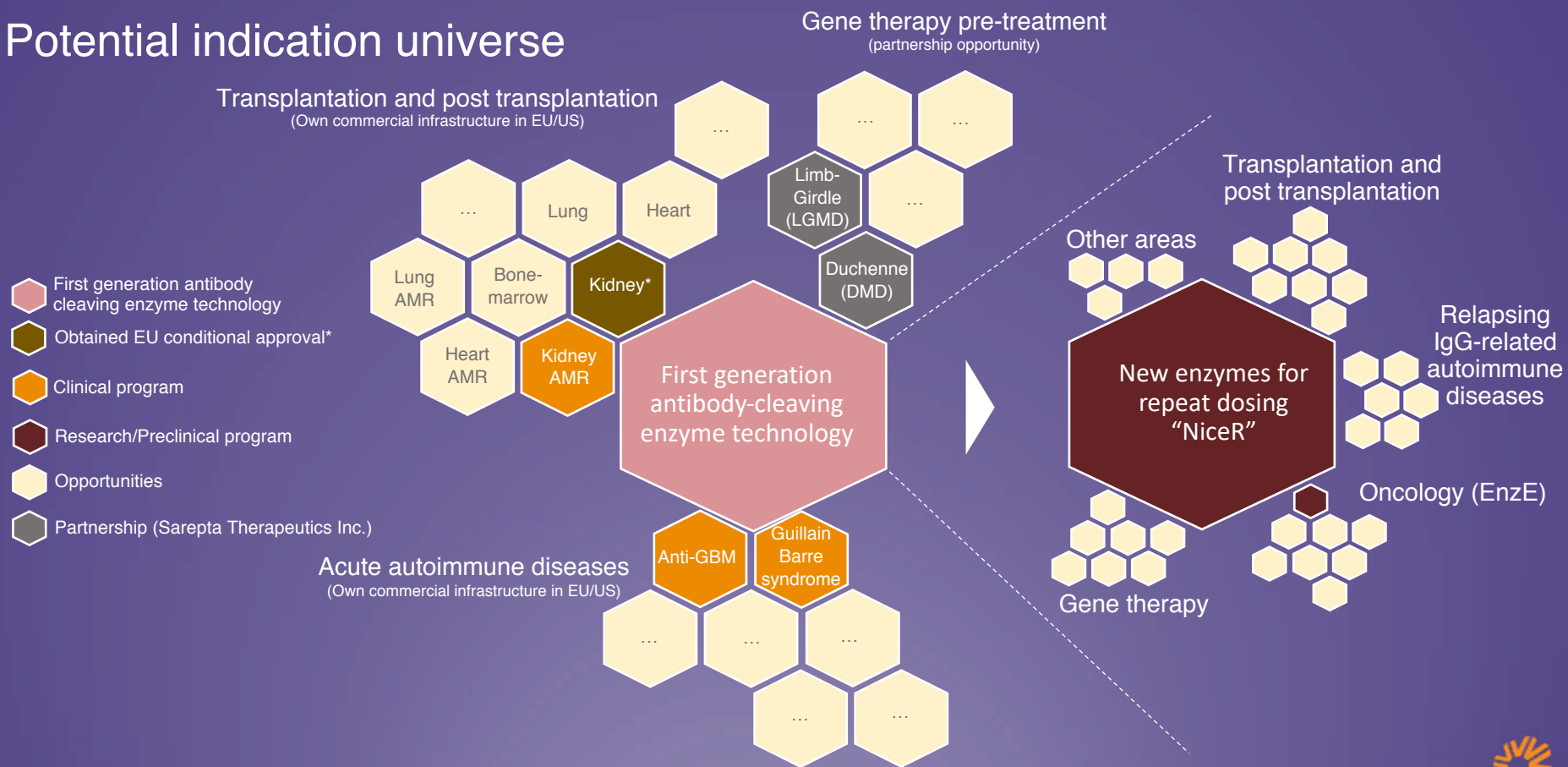
Evolution into a fully integrated biopharmaceutical company



Leveraging our proprietary antibody cleaving enzyme technology



Potential indication universe

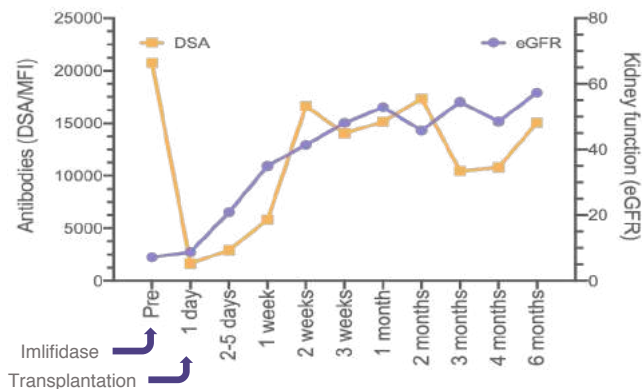


* US: Study protocol submitted June 2020, discussions with FDA ongoing







Imlifidase has enabled kidney transplantation in 46 highly sensitized patients

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
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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
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Study 06 Phase 2	Subjects	18 patients   
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Imlifidase has received conditional approval in the European Union

Imlifidase in kidney transplantation

EMA (Europe)

- imlifidase received conditional approval for *“desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor”*
- The MAA for imlifidase in kidney transplant was accepted for review by EMA back in 2019 based on data from four completed phase 2 studies across Sweden, France and the US

FDA (US)

- Given the existence of the US Kidney Allocation System (KAS), FDA has requested a Randomized Controlled Trial to be completed prior to potential submission of a BLA (Exp. 2023)
- Proposed study protocol submitted June 2020 and discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients
- Given the continued impact of the COVID-19 pandemic in the US affecting patient enrollment and the timeline for the finalization of the study protocol Hansa expects recruitment of the first patient to be in H1 2021 (previously Q4 2020)

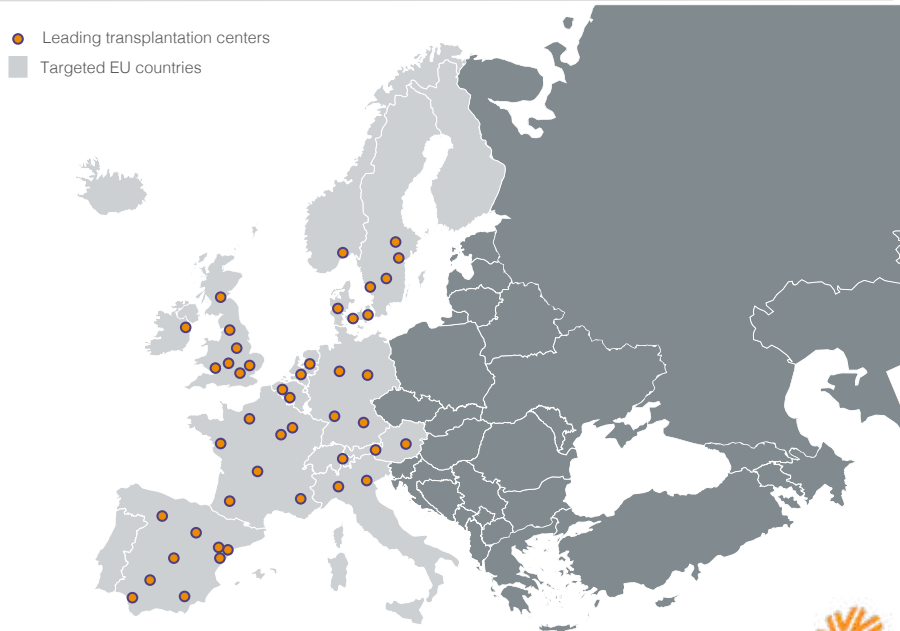


Focused launch strategy targeting leading kidney transplantation centers to ensure positive experience

EU launch under conditional approval

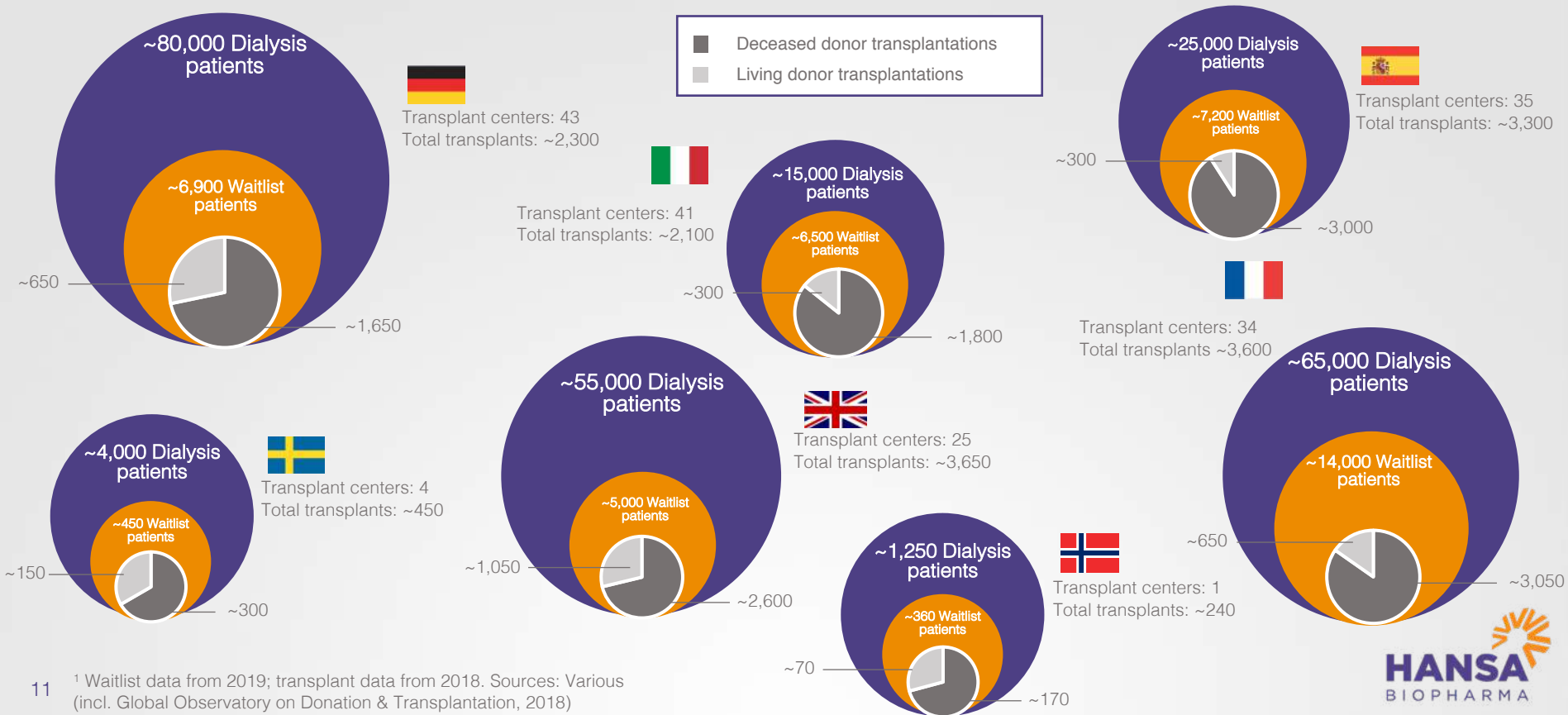
- A sequenced and focused strategy to launch imlifidase
 - Well defined and concentrated target audience
 - Center-focused launch strategy targeting leading clinics with the potential to become early adopters
 - Key to secure early positive experience in right patients; sales ramp-up as leading centers and clinicians gain experience
- Building awareness and Key Opinion Leader advocacy through Medical Science Liaisons (MSLs) in key European markets
- Post-approval study to be initiated following marketing authorization - an opportunity to generate relevant experience and broaden out the experience with imlifidase

EU launch will focus on leading transplantation centers



European transplantation landscape

Approximately 16,000 kidney transplants in EU5 plus Sweden and Norway¹ with 70-80% performed at leading transplantation centres in each country



Broad pipeline in transplantation and auto-immune diseases

Candidate / Project	Indication	Research/ Preclinical	Phase 1	Potentially Pivotal/ Phase 2	Phase 3	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	EU: Kidney transplantation in highly sensitized patients ^{1,2}	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div>*)</div>	EU: Commercial launch Q4 2020
	US: Kidney transplantation in highly sensitized patients ^{1,2}	<div></div>	<div></div>	<div></div>	<div>**)</div>	<div></div>	<div></div>	First patient dosed H1 2021
	Anti-GBM antibody disease ³	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	High-level data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	Complete enrolment of 30 patients H2'21
	Guillain-Barré syndrome (GBS)	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	Complete enrolment of 30 patients H2'21
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	Research phase

Completed

Ongoing

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

*) 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

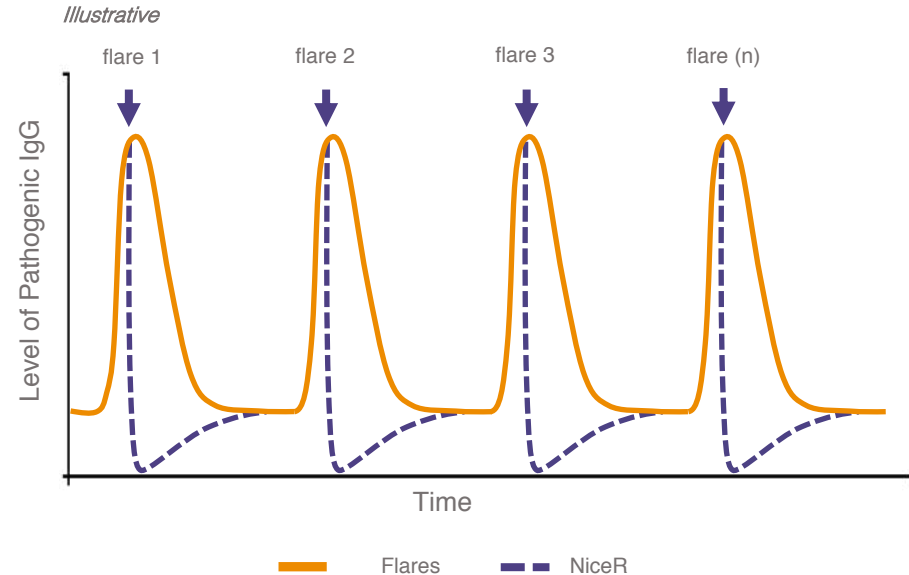
**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

“NiceR” – new set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases

IgG-cleaving enzyme 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.
- Development of a GMP-manufacturing process has been initiated

NiceR can potentially inactivate flares

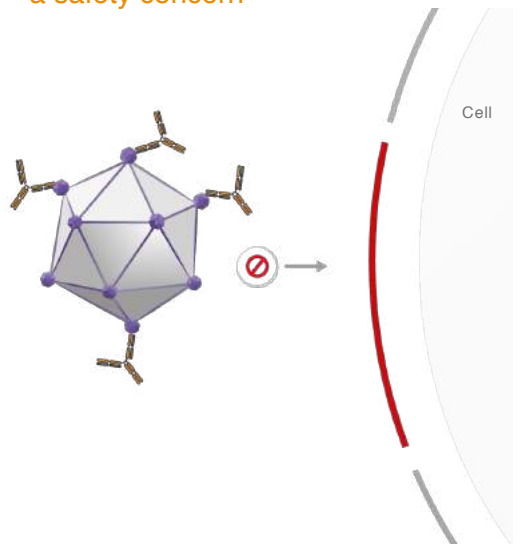


Neutralizing antibodies (Nabs) are immunological barriers in gene therapy

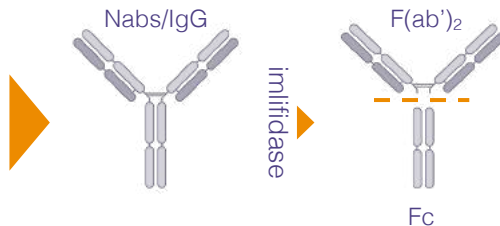
Between approximately 5% and 70%^{1,2} of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

Our hypothesis is that imlifidase has the potential to eliminate neutralizing antibodies as a pre-treatment, prior to the introduction of gene therapy

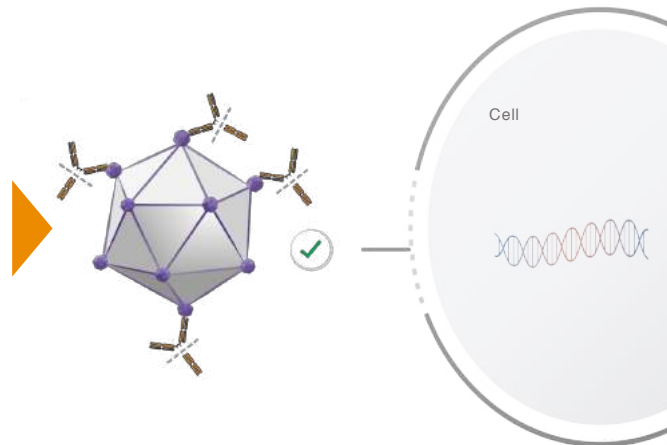
- 1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



- 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



Exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

A unique opportunity to combine efforts...

...and to use the unique features of imlifidase to potentially enable gene therapy treatment in patients who today aren't eligible for these breakthrough therapies due to pre-existing neutralizing antibodies in two indications with a very high unmet medical need

Structure of the partnership

Sarepta will be responsible for conducting

- Pre-clinical/clinical studies with imlifidase
- Regulatory approvals
- Promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval

Hansa will supply product, support with know-how and involve in the regulatory approval process

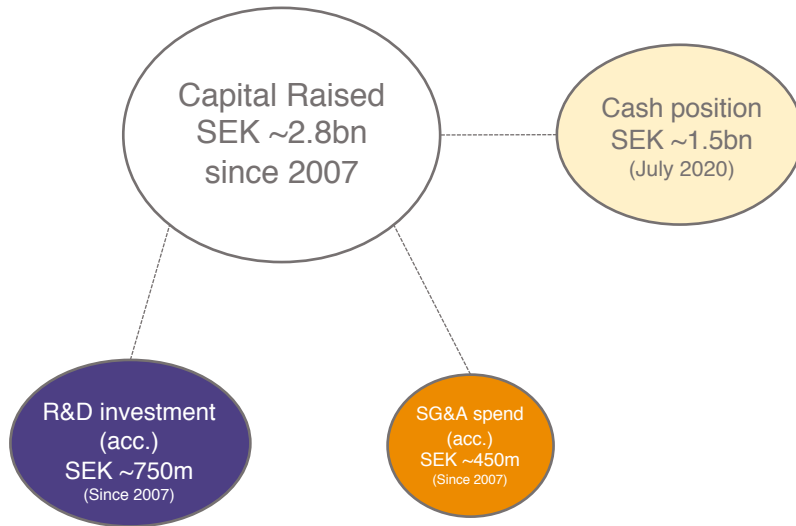
Hansa's financial participation

Potential total deal value for Hansa amounts to up to USD ~400m plus royalties and incremental imlifidase sales

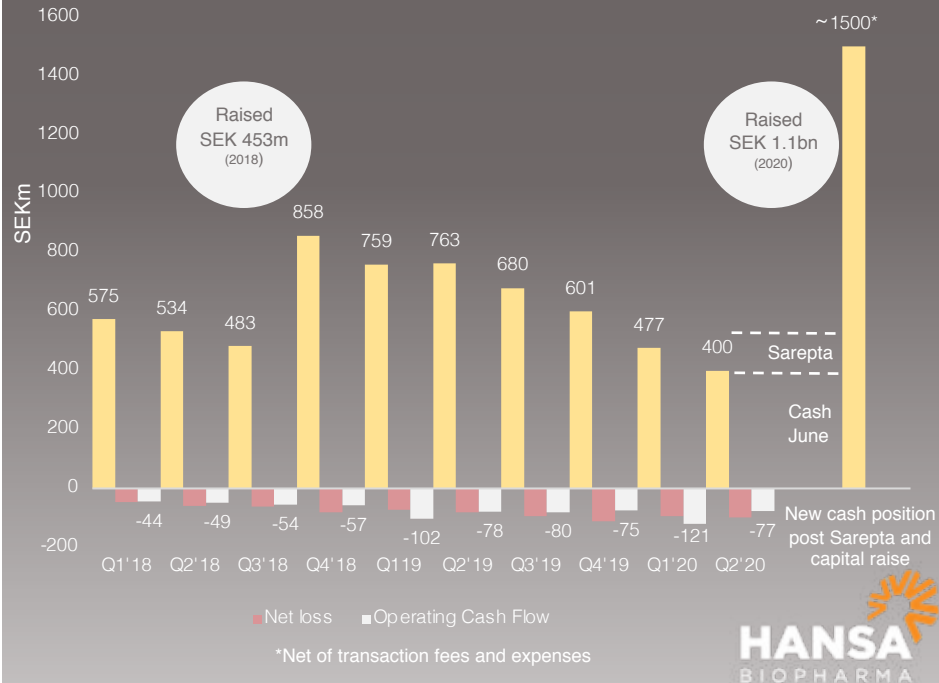


With the recent capital injection Hansa Biopharma is financed into 2023

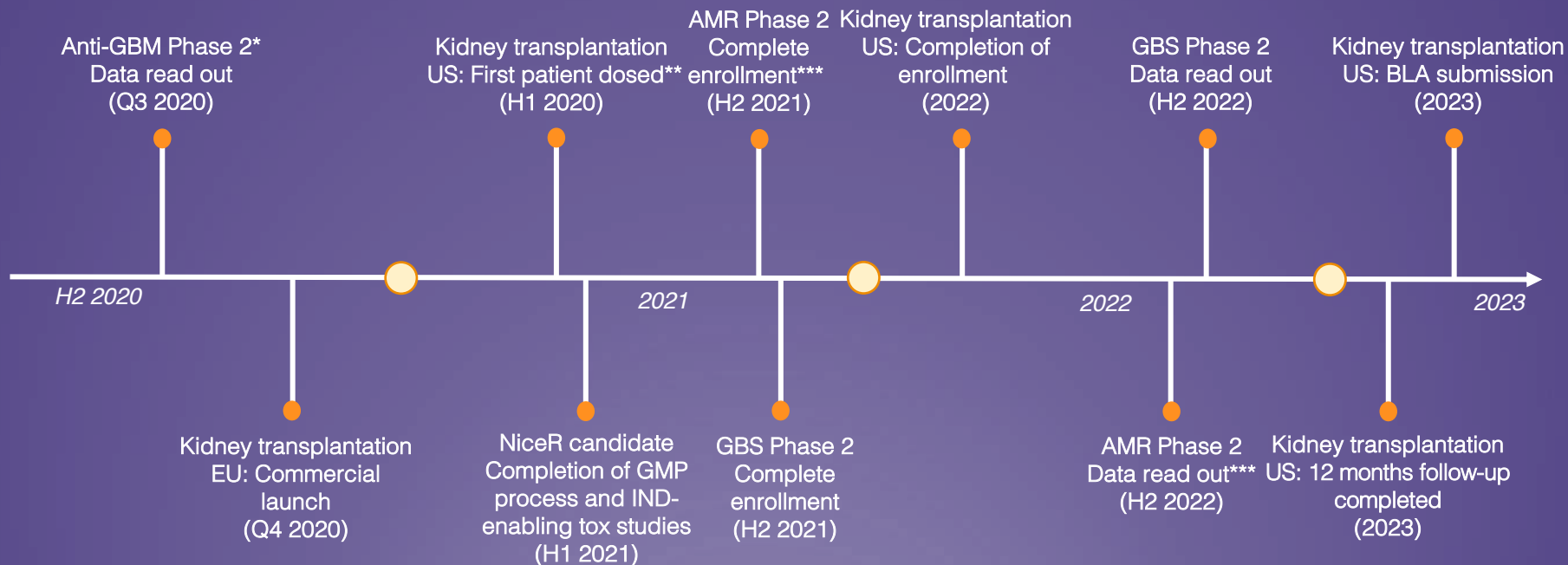
Since 2007 Hansa has mainly been backed by VCs funding the development of our enzyme platform



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



Upcoming milestones



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

**) FDA: Proposed study protocol submitted June 2020. Discussions are currently ongoing with the FDA. Once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients. Given the continued impact of the COVID-19 pandemic and the timeline for the finalization of the study protocol Hansa expect recruitment of the first patient to be in H1 2021

***) AMR/GBS Due to the impact from the COVID-19 pandemic, the enrollment in GBS and AMR were temporarily halted for the past six months. Hansa Biopharma expects to reinstate enrollment of these studies in Q4 2020 under a risk-based, site-by-site approach. Enrollment of patients in the AMR study is now expected to be completed in the second half of 2021, while completion of patient enrollment in the GBS study is still expected in the second half of 2021. High-level data readout for both studies are expected in the second half of 2022.



Appendix



Corporate



Our unique enzyme technology platform offers significant potential for growth and expansion

Our strategic priorities



Establish a commercial and medical infrastructure in Europe ahead of commercial launch



Marketing authorization obtained in Europe for imlifidase as a treatment for highly sensitized patients to enable kidney transplantation. Conduct a new randomized, controlled study in the US in the context of KAS to support a BLA filing by 2023



Investigate the potential of imlifidase in autoimmune indications and post transplantation

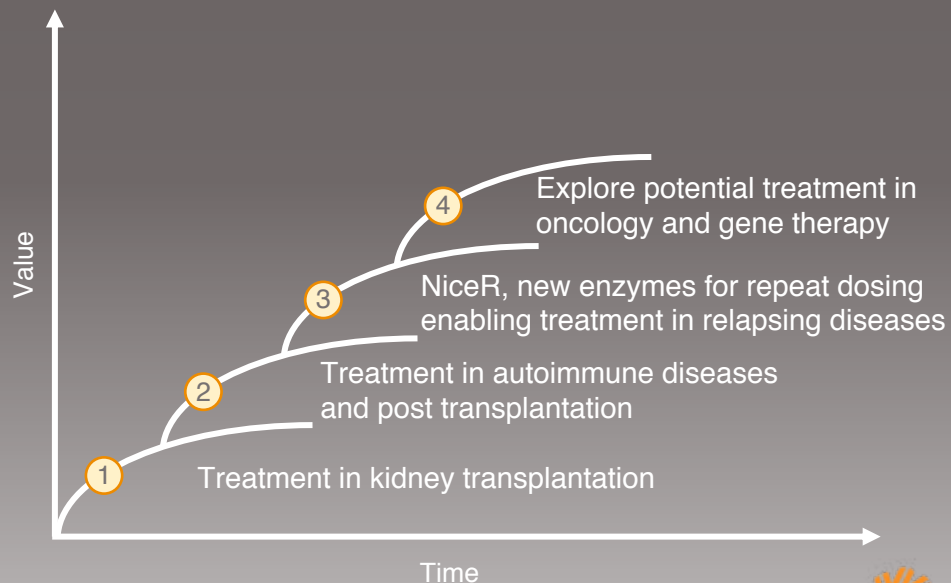


Advance a new set of immunomodulatory enzymes designed for repeat dosing in relapsing diseases (NiceR) into clinical development



Explore potential combination therapies with imlifidase in oncology and in gene therapy

Our road map for growth and expansion



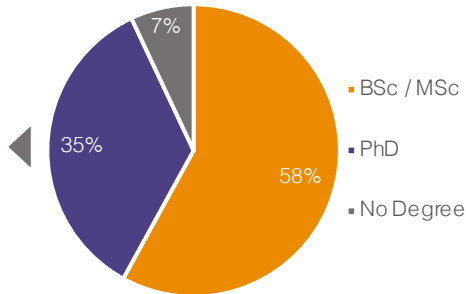
The Hansa team has extensive experience from international life science industry and academia

Highly educated team with more than 1,100 “man years” in the life science industry and academia

More than 1/3 of the team holds a relevant life science PhD

PhD specializations include

- Applied Microbiology
- Biotechnology
- Cell and Molecular Biology
- Clinical Infection Medicine
- Engineering
- Experimental Clinical Chemistry
- Experimental Medicine
- Immune Technology
- Medical Microbiology
- Medical Science
- Physiological Chemistry



Vast experience from life science; +50% has worked in Big Pharma

Biotech

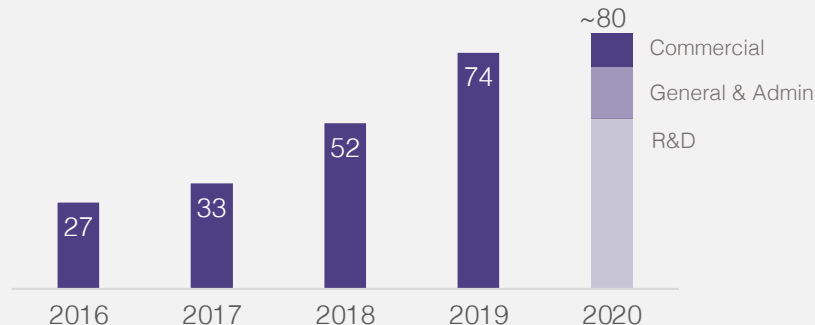


Commercial-stage/Big pharma



We are building an organization in preparation to become a commercial-stage biopharma company

Staff has tripled in 5 years as new competences are being added



Addition of new functions & positions



Experienced Board and Executive Committee with many years in the global healthcare industry

Executive Committee



Sören Tulstrup

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



Christian Kjellman

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



Donato Spota

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



Achim Kaufhold

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



Max Sakajja

VP, Corporate Strategy (2017)
Ex-M&A Director at SOBI
Ex-Global Product and Service
Development Manager at
EnviroTainer
Ex-independent life science
industry management consultant



Henk D. van Troostwijk

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



Anne Säfström Lanner

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



Ulf Wiinberg

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



Birgit Stattin Norinder

Board Member (2012)
Ex-CEO and Chairman at Prolifix Ltd.
Ex- SVP, Pharmacia & Upjohn
Member of Hansa Biopharma Scientific
Committee and Remuneration Committee



Anders Gersel Pedersen

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



Eva Nilsagård

Board Member (2019)
interim CFO at OptiGroup AB
CEO of Nilsagård Consulting AB
Ex-CFO of Vitrolife and Plasta
Chairman of Hansa Biopharma's
Audit Committee



Mats Blom

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



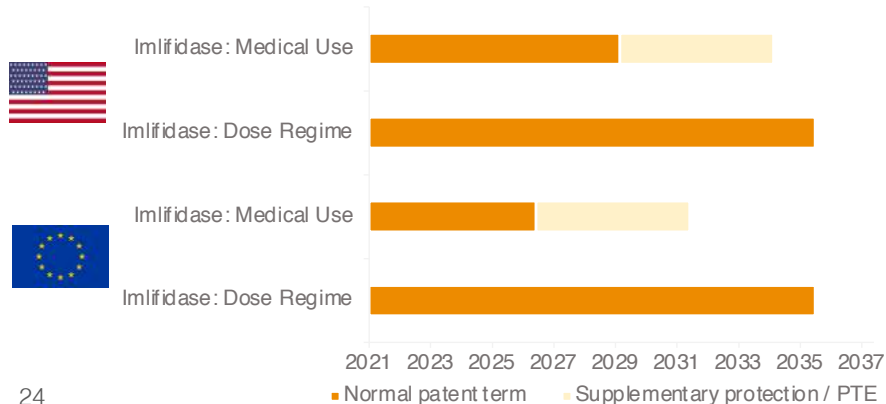
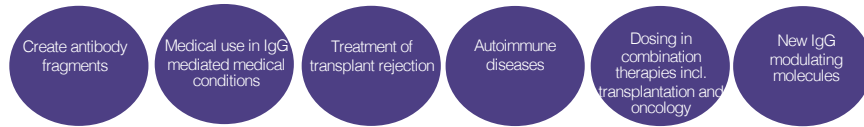
Andreas Eggert

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

Strong technology protection through patents and orphan drug designation

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

EMA

Orphan drug designation

- Imlifidase for the prevention of graft rejection following solid organ transplantation (2017)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

FDA







Orphan drug designation

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

Completed and ongoing studies in kidney transplantation



Overview of all 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

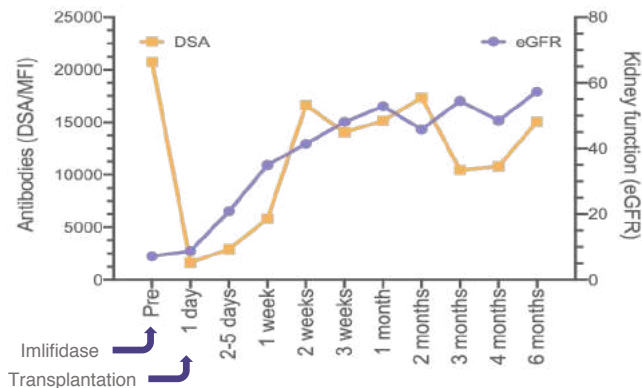
³ Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation", N Engl J Med 2017;377:442-53.

⁴ Montgomery et al., "Safety And Efficacy Of Imlifidase In Highly-sensitized Kidney Transplant Patients: Results From A Phase 2 Study" ATC Abstract, 2019







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Study design of our four Phase 2 trials

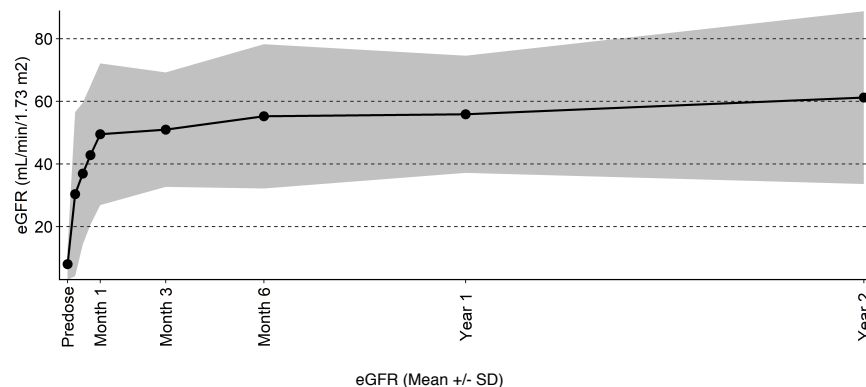
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Study 06 Phase 2	Subjects	18 patients   
	Design	Multicenter, multinational, single-arm, open-label
	Main objective	Efficacy in creating a negative crossmatch test

Two year follow-up data show graft survival of 90% and well functioning kidneys in 92% of these patients

AMR frequency in line with less sensitized patients

- Two-year follow-up data post imlifidase treatment and transplantation show 90% graft survival for 31 patients
- Of the patients with data at two years, 92% had a well functioning kidney with median eGFR of 61ml/min/1.73 m²
- 33% of the patients experienced active antibody mediated rejections (AMR) within the first six months, which compares with 25-60% of patients in the literature for this group of highly sensitized patients¹
- Only one patient experienced an AMR episode later than six months after transplantation
- The analysis concludes that the AMR frequency was comparable with other studies with less sensitized patients in crossmatch positive patients

Median eGFR at 61ml/min/1.73 m² after year 2

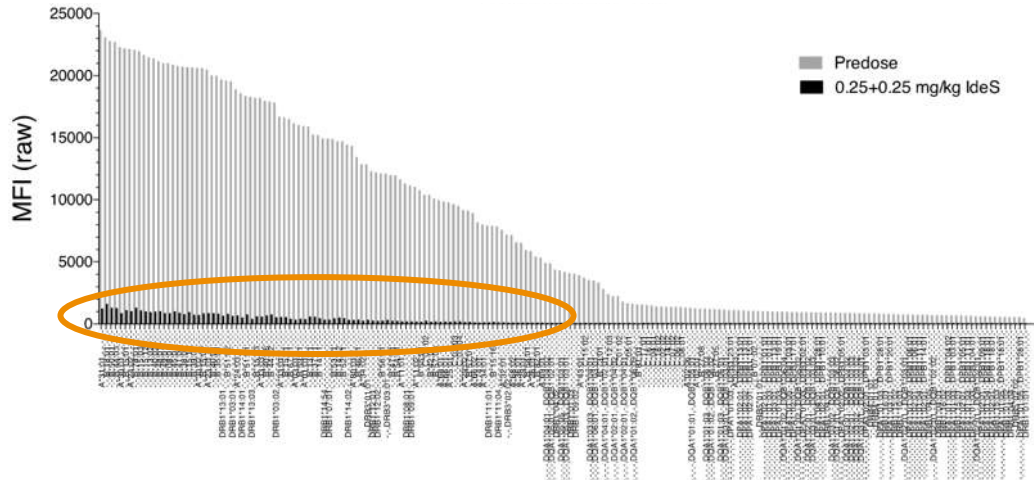


Study 02 Phase 2

The 02 study 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

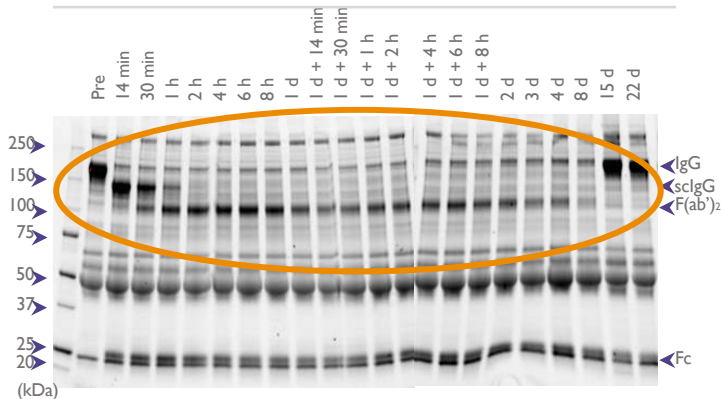


¹ Lorant et al (2018) American Journal of Transplantation (2018)

Study 03 Phase 2

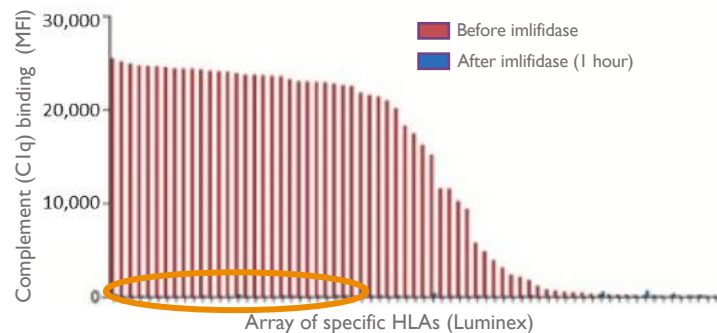
The 03 study proved safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

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



CLiQ analysis of patient serum

Protocol

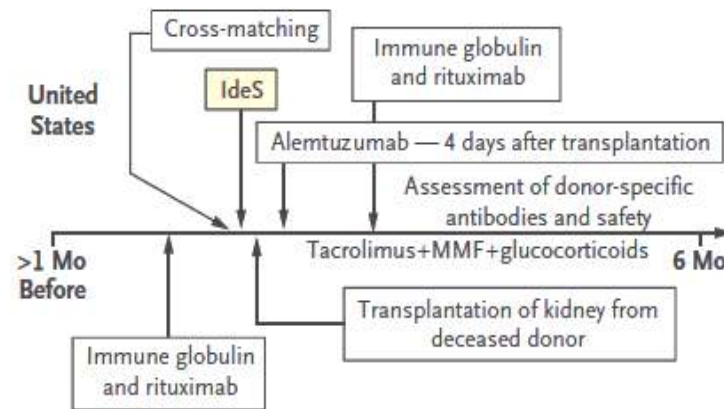
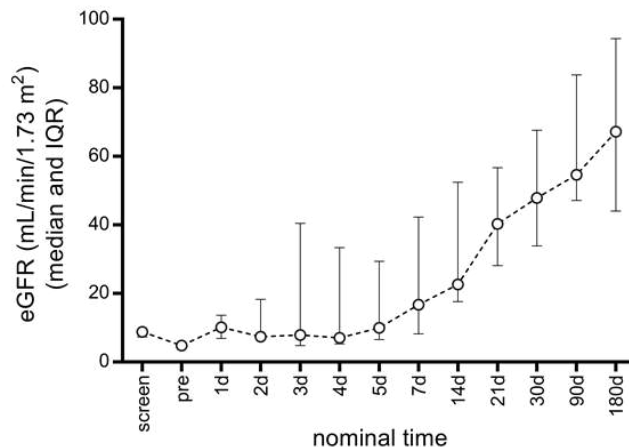


Study 04 Phase 2

The 04 study proved safety and efficacy with Cedar Sinai's standard protocol (rituximab and IVIg)

Cedar's desensitization protocol in combination with imlifidase

Graft function (eGFR) post six months



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

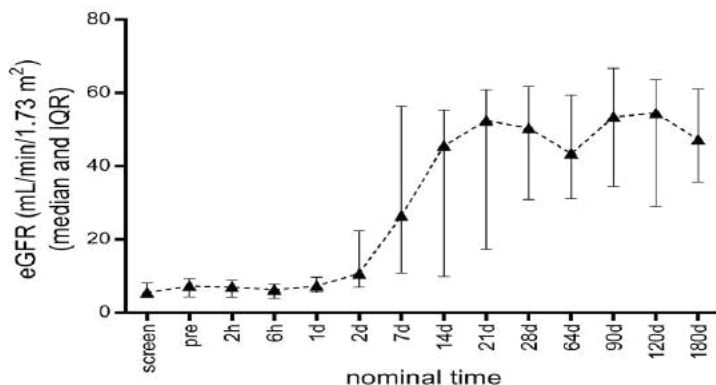
STATUS

Completed

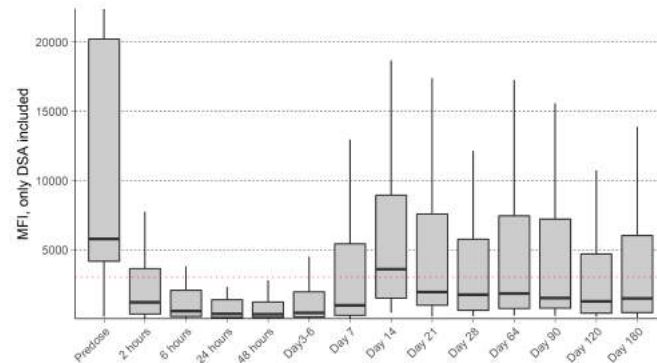
Study 06 Phase 2

The 06 study showed proved safety and efficacy in making highly sensitized patients eligible for kidney transplantation

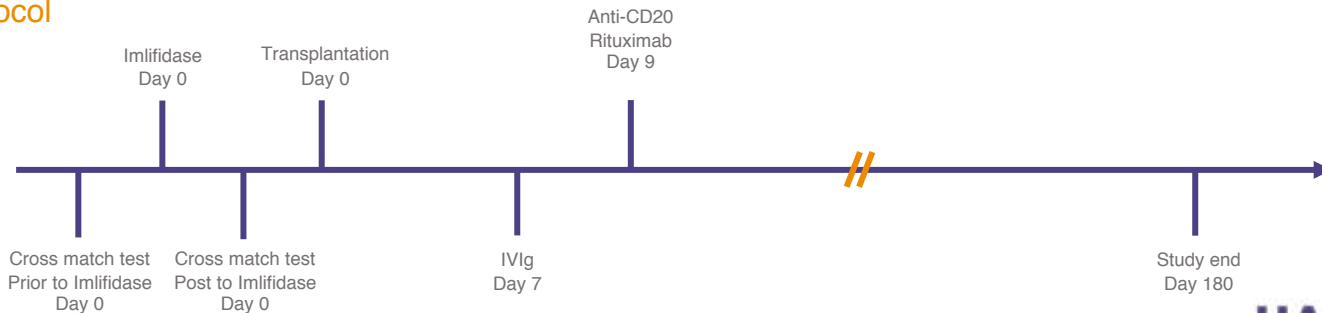
Graft function (eGFR) post imlifidase



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.

Clinical development programs



First read-out in the Anti-GBM study in Q3'20. Recruitment in AMR & GBS expected to be reinitiated in Q4'20

Ongoing Phase 2 programs

Enrollment status
end Q2'2020



Anti-GBM (investigator-initiated study)

- 15/15 patients enrolled in anti-GBM across 5 European countries
- First data read-out expected in Q3 2020



Antibody Mediated Rejection

- 4/30 patients enrolled in AMR study.
- Recruitment is expected to be reinitiated in Q4 2020*
- Enrollment is expected to be completed H2 2021



Guillain-Barré Syndrome

- 4/30 patients enrolled in GBS study
- Recruitment is expected to be reinitiated in Q4 2020*
- Enrollment is expected to be completed in H2 2021

■ Patients enrolled
■ Patients left

* Recruitment process was been impacted in Q2 following the COVID-19 virus pandemic causing a 3-6 months delay



Anti-GBM, a rare acute autoimmune disease affecting kidneys and lungs; Enrollment completed in Q1 2020

2/3 of Anti-GBM patients lose kidney function²

- Indication: Antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM) causing acute injury of kidney and/or lung
- Anti-GBM affects 1.6 in a million people annually with majority of patients losing their kidney function^{1,2}, requiring chronic dialysis and kidney transplantation.
- The study is an open label investigator-initiated Phase 2 with Professor Mårten Segelmark at Linköping- and Lund University Hospital as the sponsor and principal investigator
- The study is designed to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM disease on top of standard care consisting of plasmapheresis, steroids and cyclophosphamide.
- 15/15 patients enrolled in anti-GBM across 5 European countries. First data read-out expected in Q3 2020.
- Our Anti-GBM program obtained Orphan Drug designation from both FDA and European Commission (2018)



Favourable pre-clinical studies show that imlifidase degrades IgG bound to the GBM in vivo; preventing renal damage in animals

CLINICALTRIALS.GOV ID

NCT03157037 (Since March 2017)

SUBJECTS

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

DOSES/FOLLOW UP TIME

Dosage 0.25mg/kg 180 days follow up

MAIN OBJECTIVES

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

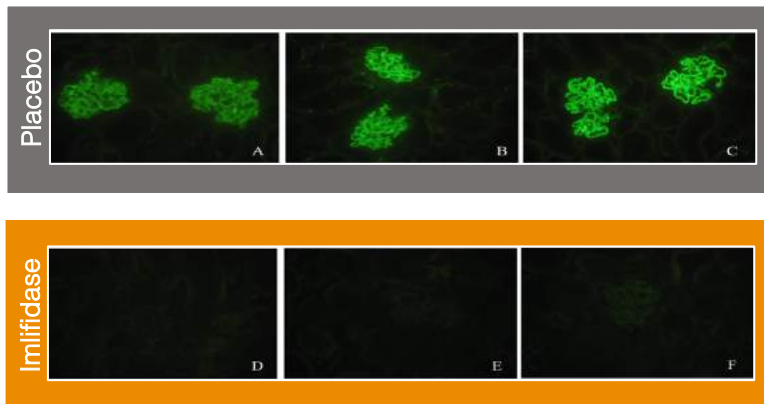
STUDY DESIGN

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

STATUS

Ongoing

Mouse anti-rabbit IgG (Fc specific)



Inclusion criteria

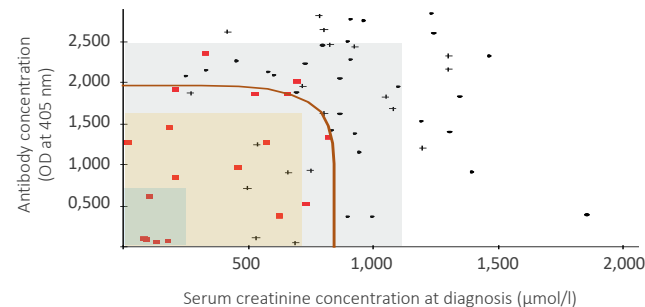
Inclusion: Toxic anti-GBM antibodies level as considered by the investigator. eGFR < 15 ml/min/1.73 m² or if the patient is non-responsive to standard treatment, and has lost >15 ml/min/1.73 m² after start of treatment

Exclusion: Anuria for more than 2 days (less than 200 ml during last 48 hours); Dialysis dependency for more than 5 days

Yang et al. Favorable pre-clinical studies: "Imlifidase degrades IgG bound to the GBM in vivo, thereby preventing renal damage in this animal model. Nephrology Dialysis Transplantation, 2010;25(8): 2479-86.

Anti-GBM creatinine and antibody concentration

- Both creatinine and levels of antibodies predict outcome and we expect that imlifidase can treat the disease by degrading IgG bound to the GBM



Long term graft survival is challenged by antibody mediated rejection post transplantation

There is no approved treatment for AMR

- Active antibody mediated rejection after transplantation occurs in 10-15% of kidney transplants¹ or ~ 3,200^{2,3} new patients annually⁴ 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.
- 4/30 patient treated with imlifidase in AMR. 6/8 sites have been initiated to recruit patients in the US, Europe and Australia.
- Enrollment is expected to be completed H2 2021

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

² Jordan et al., British Medical Bulletin, 2015, 114:113-125.

³ <http://www.irodat.org>.

⁴ Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan



AMR Phase 2

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 8 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 OBJECTIVES

- 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

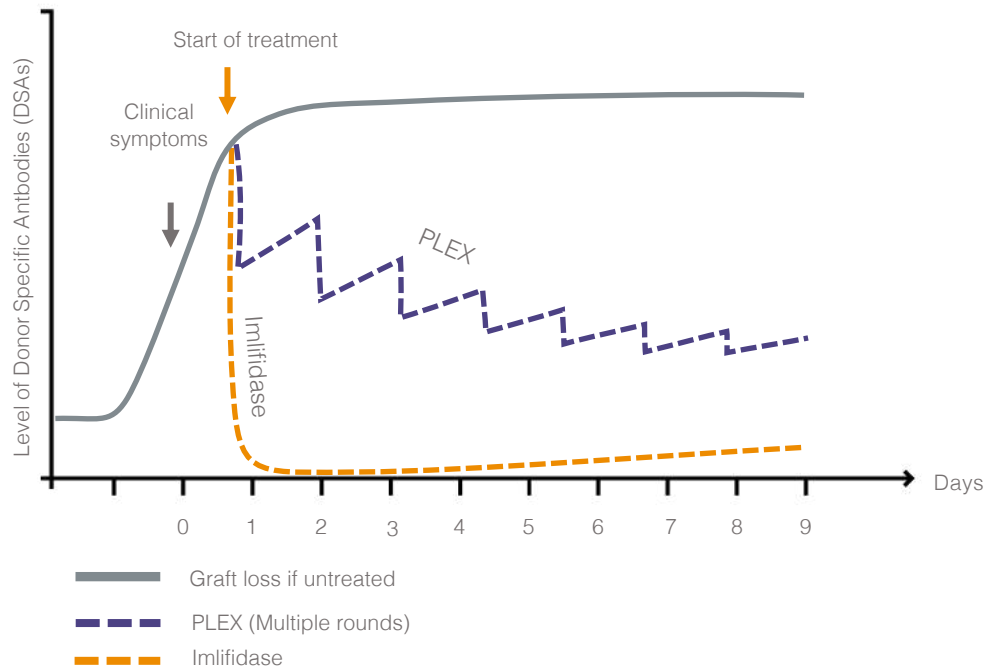
- Randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in active AMR

STATUS

Ongoing
38

Potential of using imlifidase vs. PLEX in AMR

Illustrative



Guillain-Barré syndrome 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 ~ 11,000¹ per year in 7MM²
- 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)
- 4/30 patients enrolled. 6/10 sites are recruiting patients across France, UK and the Netherlands. Enrollment is expected to be completed in H2 2021
- 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 OBJECTIVES

- safety and effectiveness of imlifidase in patients diagnosed with GBS

STUDY DESIGN

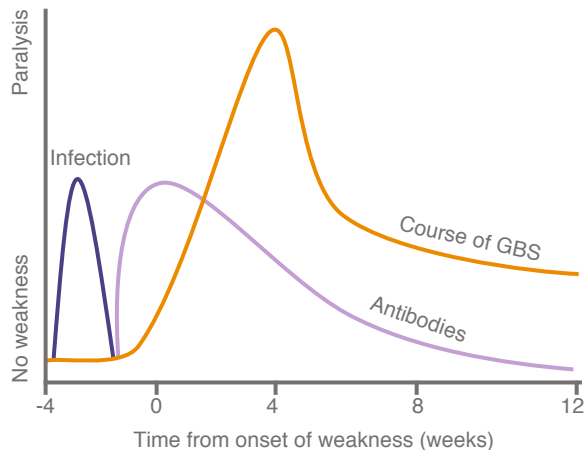
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing

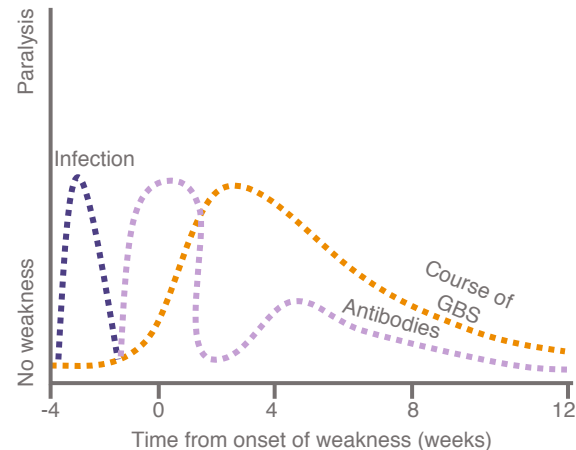
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



Pre-clinical programs

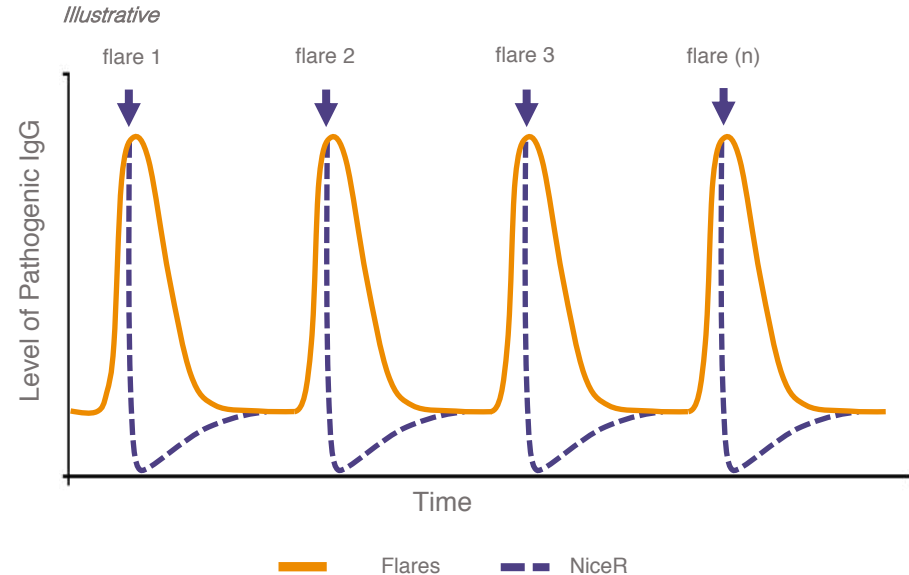


“NiceR” – new set of enzymes for repeat dosing; potentially enabling treatment of relapsing diseases

IgG-cleaving enzyme 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.
- Development of a GMP-manufacturing process has been initiated

NiceR can potentially inactivate flares

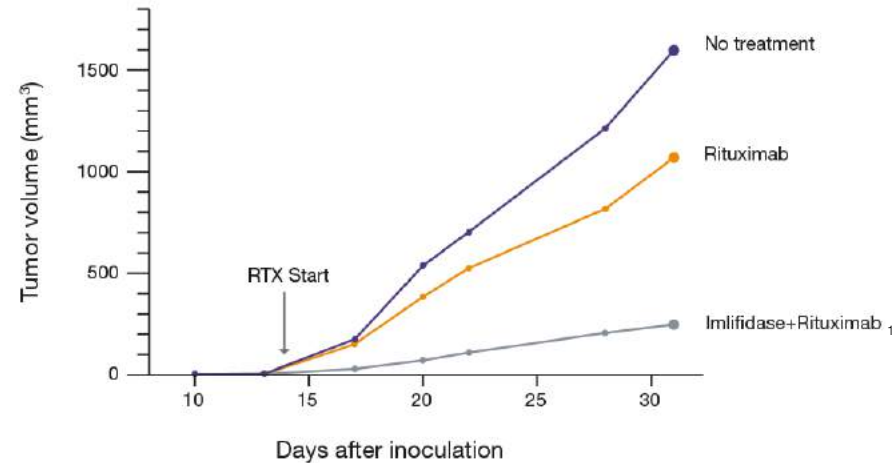


EnzE can potentially improve the therapeutic effect in oncology

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)



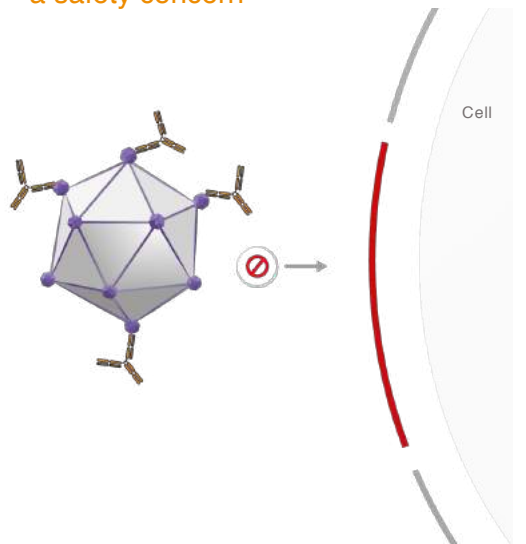
¹ Järnum et al. Mol Cancer Ther 2017;16:1887-1897

Neutralizing antibodies (Nabs) are immunological barriers in gene therapy

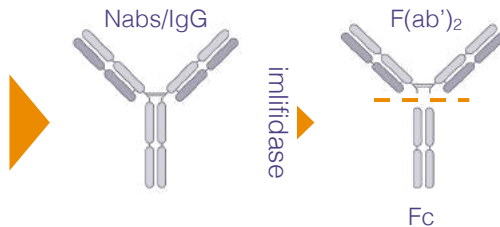
Between approximately 5% and 70%^{1,2} of patients considered for gene therapy treatment carry neutralizing anti-AAV antibodies forming a barrier for treatment eligibility

Our hypothesis is that imlifidase has the potential to eliminate neutralizing antibodies as a pre-treatment, prior to the introduction of gene therapy

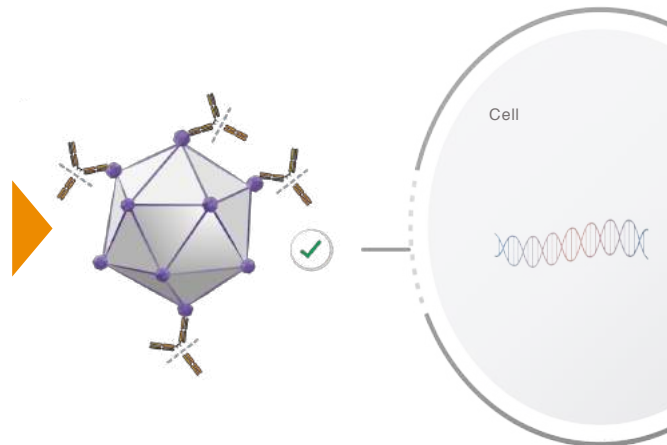
- 1 Antibodies prevent effective transfer of healthy gene sequence and can be a safety concern



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

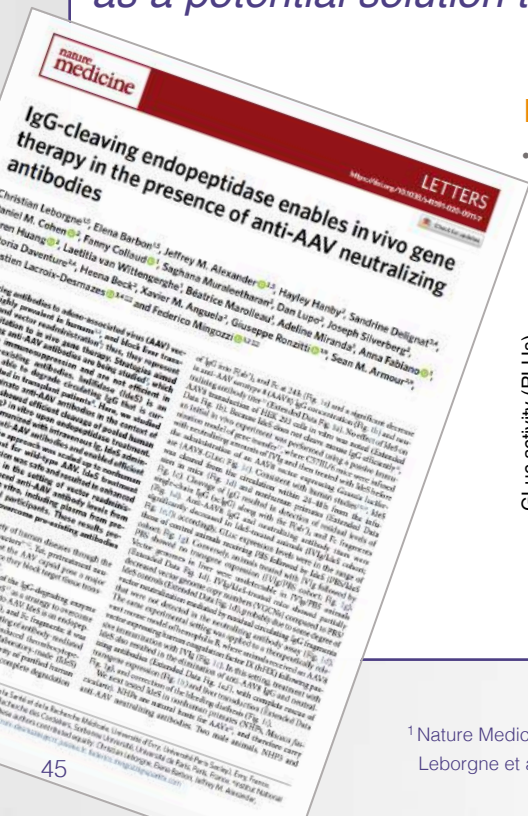


- 3 The idea is to eliminate the neutralizing antibodies as a pre-treatment to enable gene therapy



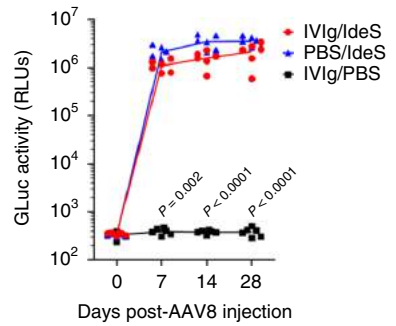
Imlifidase (IdeS) was highlighted in Nature Medicine¹ with encouraging outcome

Results from preclinical studies with imlifidase (ideS) in gene therapy demonstrate imlifidase as a potential solution to overcome pre-existing antibodies to AAV-based gene therapy



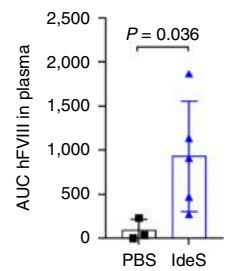
Imlifidase tested in a hemophilia mouse model

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



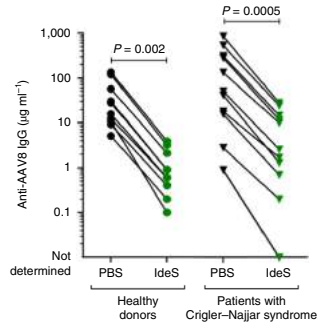
Imlifidase tested in NHP ahead of AAV vector infusion

- 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)

Exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

A unique opportunity to combine efforts...

...and to use the unique features of imlifidase to potentially enable gene therapy treatment in patients who today aren't eligible for these breakthrough therapies due to pre-existing neutralizing antibodies in two indications with a very high unmet medical need

Structure of the partnership

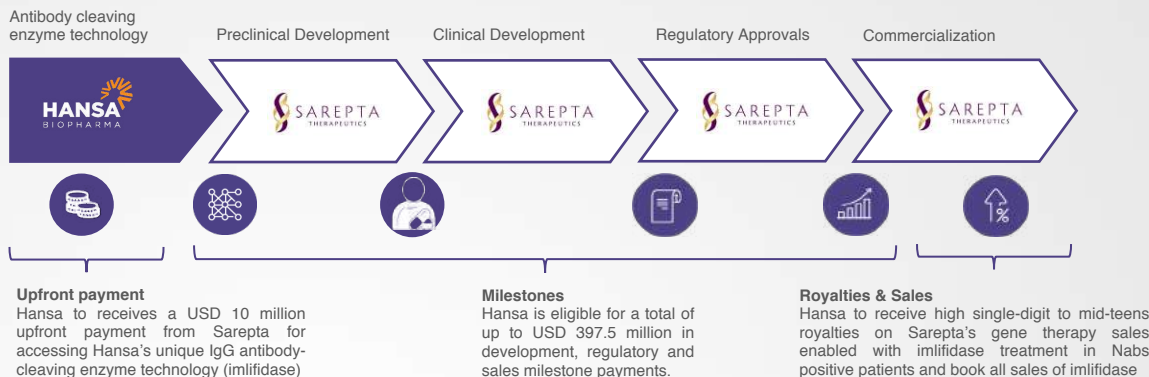
Sarepta will be responsible for conducting

- Pre-clinical/clinical studies with imlifidase
- Regulatory approvals
- Promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval

Hansa will supply product, support with know-how and involve in the regulatory approval process

Hansa's financial participation

Potential total deal value for Hansa amounts to up to USD ~400m plus royalties and incremental imlifidase sales

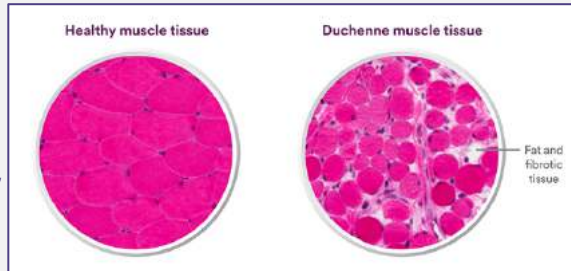


Sarepta obtains a global and exclusive license to imlifidase in DMD and LGMD in gene therapy

About Duchenne muscular dystrophy (DMD)

- Duchenne muscular dystrophy is a rare genetic disease caused by mutation in the DMD gene, encoding for the protein dystrophin
- Muscles in the body become weak and most patients use wheelchair by the age of 12
- Affects one in 3,500 to 5,000 males born worldwide (approximately 400-500 annual male cases in the US) of which approximately 15-20% are estimated to have pre-existing antibodies to AAV-based gene therapy which prevents the patients from being treated with gene therapy

"On average, every day DMD takes the life of a child in the United States..."

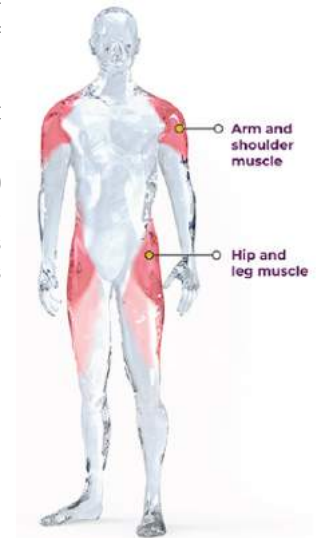


Source: Sarepta Therapeutics

<https://investorrelations.sarepta.com/static-files/0c4aca61-9419-45a5-afb1-ff2092644627>

About Limb-girdle muscular dystrophy (LGMD)

- Limb-girdle muscular dystrophy is a group of diseases that cause weakness and wasting of the muscles
- May be caused by a single gene defect affecting specific proteins within muscle cells
- Global prevalence of 1.63 per 100,000 individuals (of which approximately 15-20% are estimated to have pre-existing antibodies to AAV-based gene therapy which prevents patients from being treated with gene therapy)



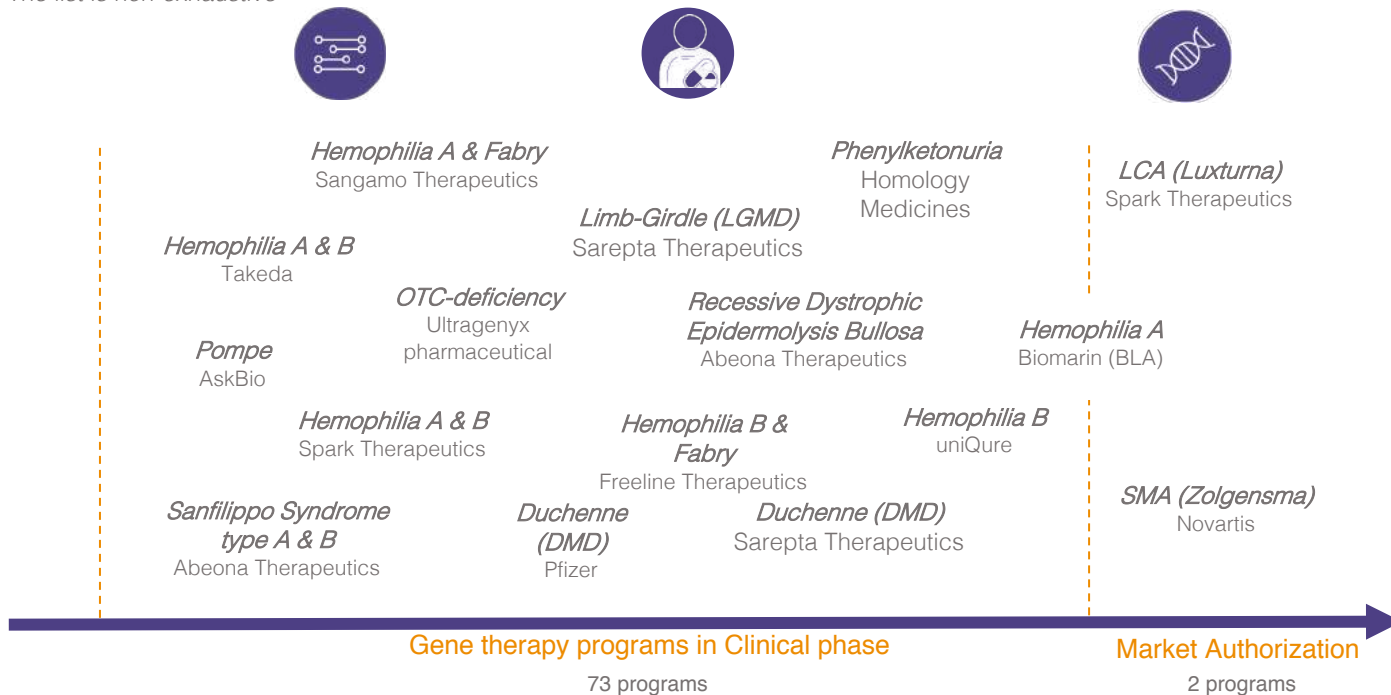
Source: Sarepta Therapeutics

<https://investorrelations.sarepta.com/static-files/0c4aca61-9419-45a5-afb1-ff2092644627>

Emerging landscape in gene therapy

Examples of big pharma and specialized players targeting rare diseases in gene therapy

The list is non-exhaustive



Today experimental protocols are used based on plasmapheresis, or with immunosuppressants; however these protocols have not demonstrated sufficient efficacy and safety

187 *in vivo* programs are ongoing in gene therapy including 73 clinical stage programs¹

Two *in vivo* gene therapy products have been approved by FDA: **Luxturna** from Sparks/Roche and **Zolgensma** from Novartis

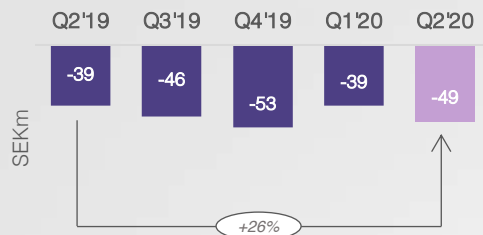
¹ Alacrita Consulting 2019 estimate based on publicly available data

Capital Markets

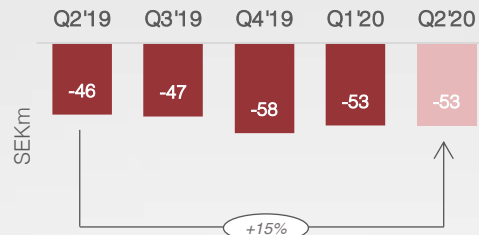


Hansa Biopharma continues to invest in the R&D pipeline and the preparation towards the commercial launch

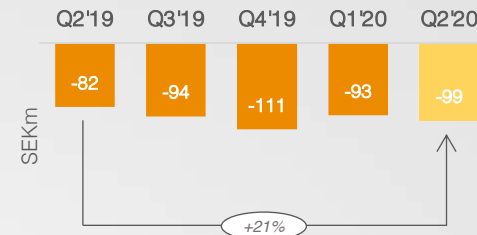
SG&A expenses (Q/Q)



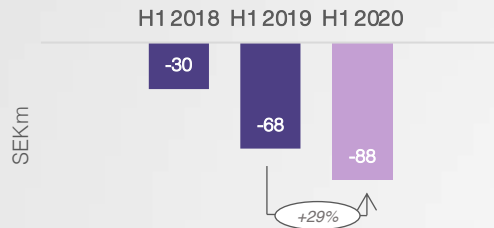
R&D expenses (Q/Q)



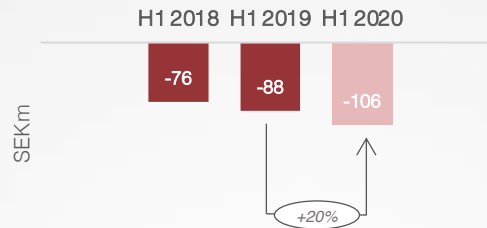
Net loss (Q/Q)



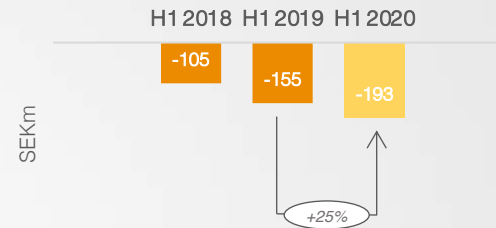
SG&A expenses (H1/H1)



R&D expenses (H1/H1)

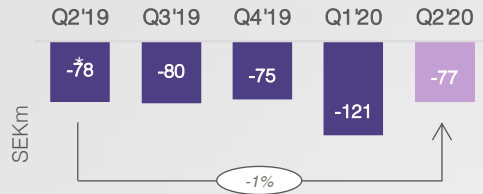


Net loss (H1/H1)

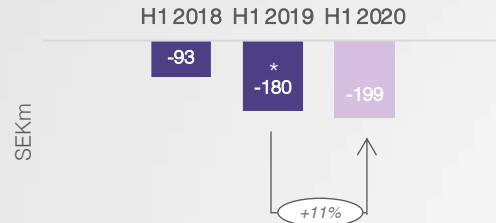


Capital injection from the issue of 4.4m new shares (SEK 1.1bn) and upfront payment from Sarepta (SEK ~100m) will finance Hansa into 2023

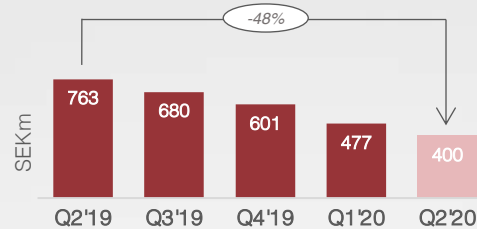
Operating cash flow (Q/Q)



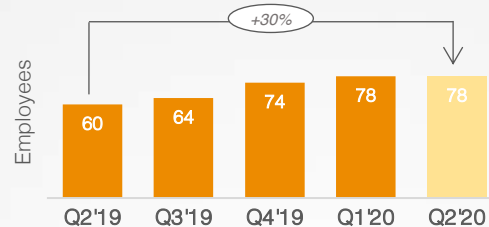
Operating cash flow (H1/H1)



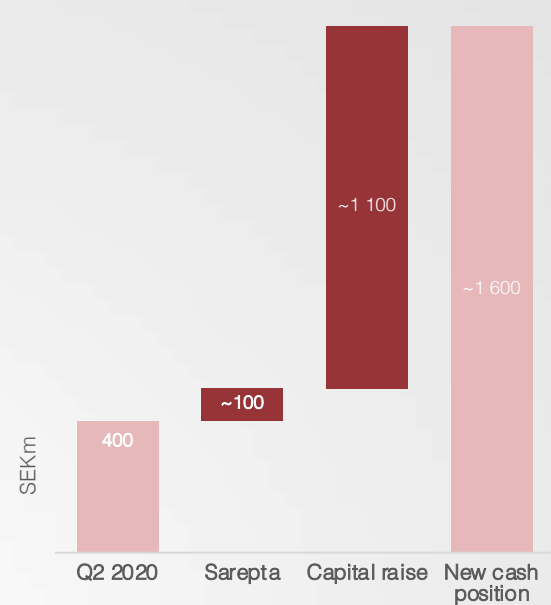
Cash & short term investments (Q/Q)



Number of employees (Q/Q)



Cash position post Sarepta and capital raise



* Excl. positive impact from sale of Genovis shares of SEK 89m in Q2'19

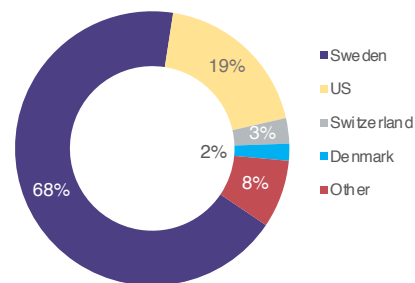
Ownership in Hansa Biopharma

Top 10 ownership as per June 30, 2020

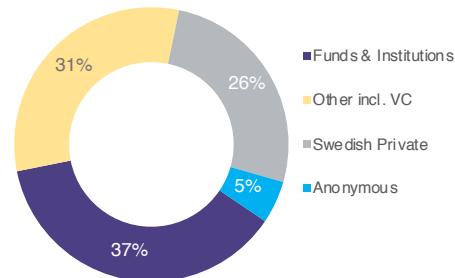
Name	No. of shares	Ownership in pct.
NXT2B	5 755 379	14.4
Consonance Capital Management LP	2 478 177	6.2
Invesco	1 999 188	5.0
Thomas Olausson	1 713 474	4.3
Avanza Pension	1 396 176	3.5
Gladiator	1 260 631	3.1
Fourth Swedish National Pension Fund	1 112 044	2.8
Third Swedish National Pension Fund	1 066 470	2.7
Vanguard	938 933	2.3
ClearBridge, LLC	741 306	1.9
Other	21 564 329	54.0
Outstanding A shares in total	40 026 107	100.0

Classification of ownership

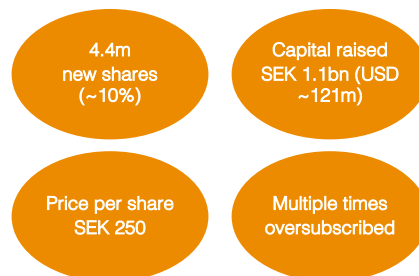
Ownership by country



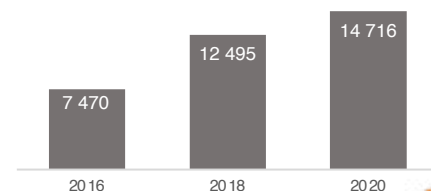
Ownership by type



Capital Raise July 2020



No. of shareholders



Hansa Biopharma - Market data and share price development

Market data

Stock Exchange: Nasdaq, Stockholm since Nov 2015
(First North Oct 2007- Nov 2015)

Ticker HNSA

Market Cap: SEK ~12bn (Aug 2020)

52-week range: SEK 59-282 per share

Avg. Daily Turnover: vol ~400k shares

Shares outstanding: ~45m (post-raise)

Shareholders ~14,700

Top 5 Shareholders: NXT2B 14.4%

As per June 30, 2020 (pre-raise)

Consonance 6.2%

Invesco 5.0%

Thomas Olausson 4.3%

Avanza Pension 3.5%

12 months Share price development (July 2020)



Analysts covering Hansa Biopharma (ticker: HNSA, NASDAQ Stockholm)

Analyst	Bank / Research institution (year of initiation)	Location	Email	Phone
Christopher Uhde	SEB (2016)	Stockholm	christopher.uhde@seb.se	+46 (0) 876-385 53
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Calendar

Sep 3, 2020	Pareto Healthcare Conference, Stockholm (virtual)
Sep 9, 2020	Citi's Annual BioPharma Virtual Conference, Boston (virtual)
Sep 15, 2020	H.C. Wainwright Healthcare Conference, NYC (virtual)
Sep 16, 2020	Bank of America Merrill Lynch Healthcare Conf., London (virtual)
Sept 18, 2020	Morgan Stanley Global Healthcare Conference, NYC (virtual)
Sep 23, 2020	ABG Small & Mid Cap Seminar, Copenhagen and virtual
Oct 22, 2020	Interim Report Jan-Sep 2020
Oct 29, 2020	Hansa Biopharma Capital Markets, Copenhagen and virtual
Nov 17, 2020	Bryan Garnier Healthcare Conference, Paris
Nov 18, 2020	Jefferies Healthcare Conference, London
Nov 25, 2020	Ökonomisk Ugebrev Life Science Conference, Copenhagen
Feb 2, 2021	Interim report Jan-Dec 2020
April 22, 2021	Interim report for Jan-Mar 2021
July 15, 2021	Interim report for Jan-Jun 2021
Oct 21, 2021	Interim report for Jan-Sep 2021

