HANSA BIOPHARMA

Investor Presentation
UBS Global Health Care Conference

New York City, May 18, 2020

Søren Tulstrup, President & CEO

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

Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- ~78 employees (~3/4 in R&D) at Mar 31, 2020
- Operations in Sweden, US & Europe
- Market cap: SEK ~5bn (USD ~500m) April 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 transforming the lives of people with rare disease
- 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
  (EU: CHMP Opinion expected Q2 2020 US: New clinical study to support BLA submission in 2023)
- Anti-GBM antibody disease (Phase 2)
- Antibody mediated kidney transplant rejection (AMR) (Phase 2)
- Guillain-Barré syndrome (Phase 2)
- NiceR - Recurring treatment in autoimmune disease, transplantation and oncology (Preclinical)
- EnzE – Cancer immunotherapy (Preclinical)

Key Financials

• Cash position	Q1'20*	SEK 477m	FY'19 SEK 601m
• R&D expenses	Q1'20*	SEK -53m	FY'19 SEK -193m
• Operating Profits/Loss	Q1'20*	SEK -91m	FY'19 SEK -360m
• Operating cash flow	Q1'20*	SEK -121m	FY'19 SEK -335m

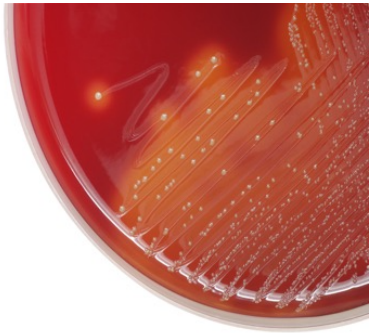
*Unaudited financials

…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

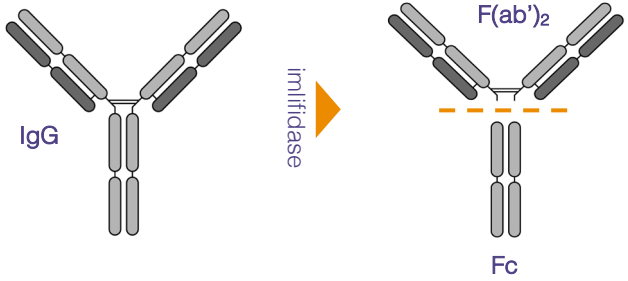
Origins from Streptococcus pyogenes

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



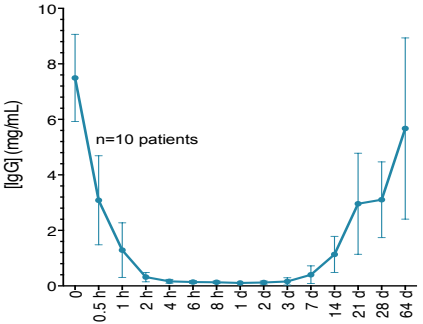
Imlifidase, a unique IgG antibody-cleaving enzyme

- 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 potential commercialisation in 13 years

Hansa Medical founder

IdeS (imlifidase) discovered and patented by Prof. Lars Björk, M.D. Lund University

Partnship with Axis-Shield for HBP-test

Imlifidase First-in-man study

Start Imlifidase Phase II at Cedars Sinai and UUH

NEJM-publication Anti-GBM initiated

MAA submitted to EMA AMR & GBS Phase 2 initiated

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

Project IdeS (Imlifidase) initiated

GMP development and toxicology studies initiated

Imlifidase 1st Phase II

Initiation of HighdeS

46 transplants enabled

Potential EMA approval in 2020

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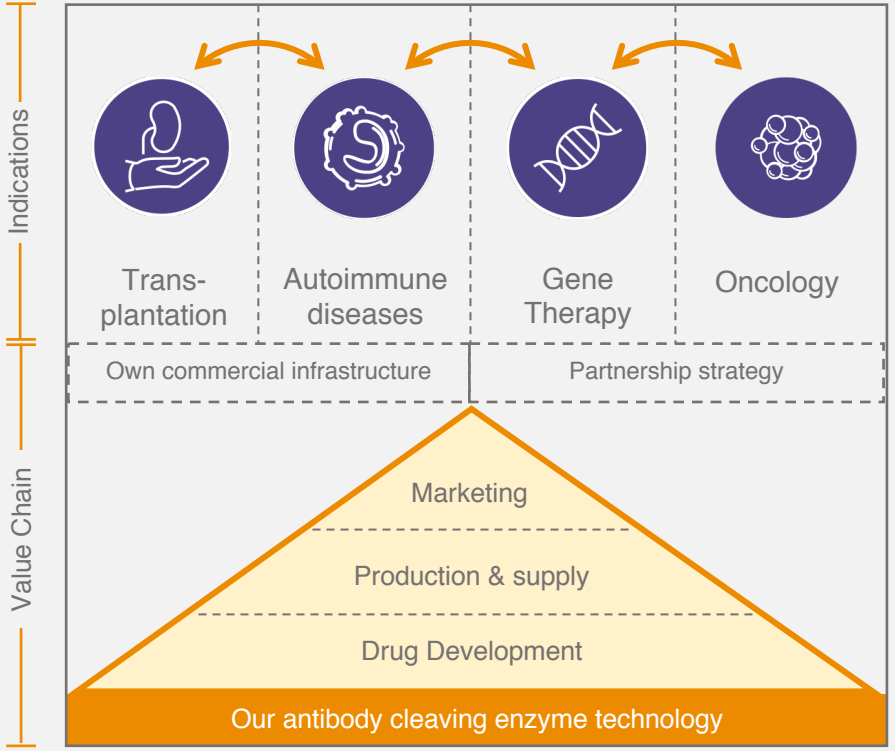
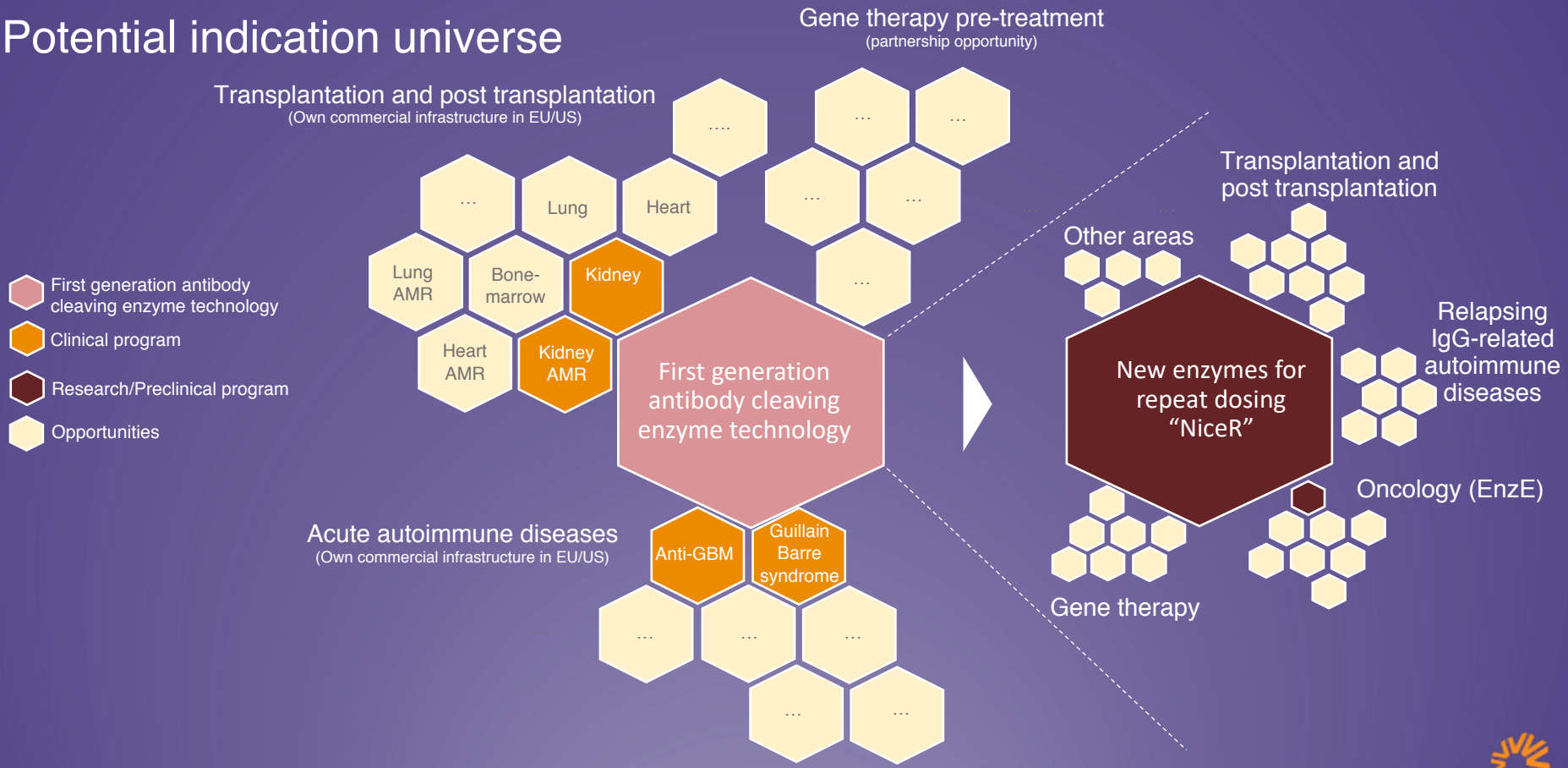
Our Equity Story

- 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



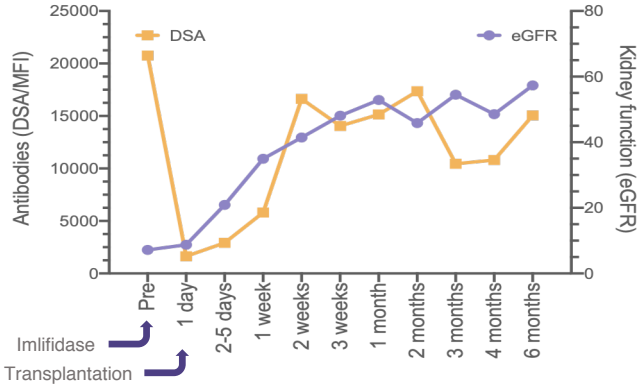
Potential indication universe



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
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

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EMA: CHMP Opinion expected in Q2
FDA: New study planned to be initiated in Q4 2020

Imlifidase in kidney transplantation

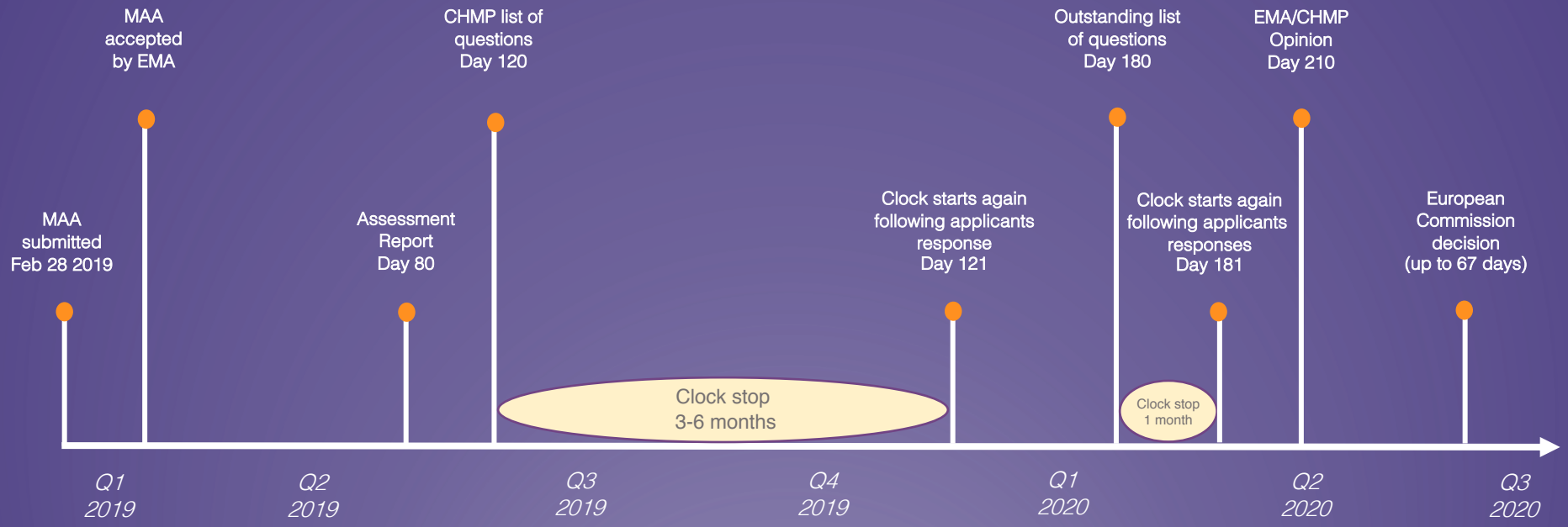
Europe (EMA review)

- Regulatory review process progressing as expected. Day 180 responses submitted end of Q1 2020
- Good dialogue with EMA; expect formal adoption of list of outstanding questions at the April CHMP session
- CHMP Opinion expected at subsequent CHMP meeting in Q2
- Decision by European Commission expected in Q3 2020

U.S. (FDA)

- Discussions with the FDA on the design of a new US trial in kidney transplantation is progressing according to plan. Submission of the study protocol is expected in Q2 2020
- The new trial is expected to include ~50 patients with a cPRA score of 99.9% or above. eGFR (kidney function) will be used as a surrogate endpoint to demonstrate a clinical benefit of imlifidase therapy vs. patients being waitlisted
- New study planned to be initiated in Q4 2020 following the necessary ethical approvals and setting up trial centers in the US

The EMA process towards marketing authorization

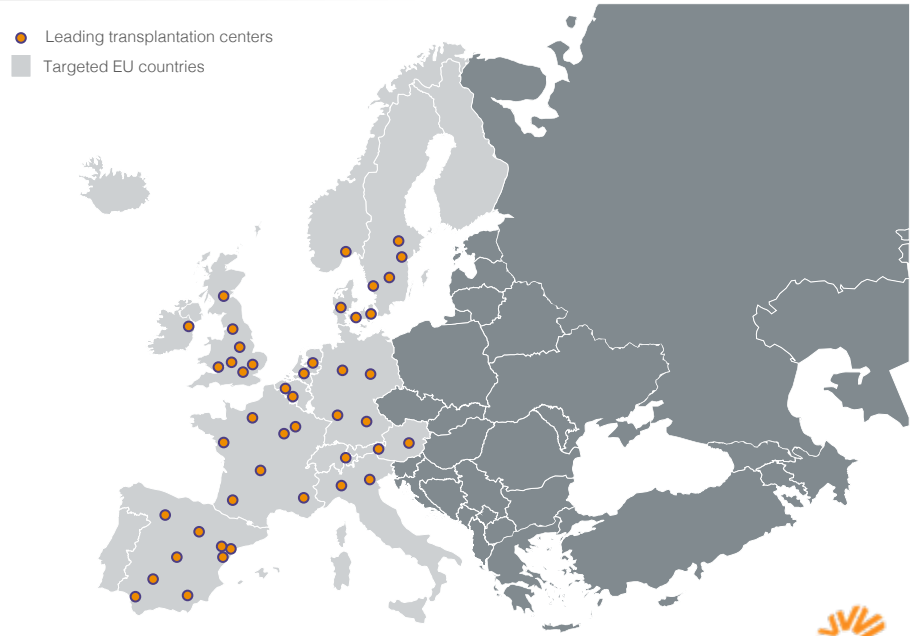


Focused launch strategy targeting leading kidney transplantation centers to ensure positive experience

Potential 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 potential marketing authorization - an opportunity to generate relevant experience and broaden out the experience with imlifidase

EU launch will focus on leading transplantation centers



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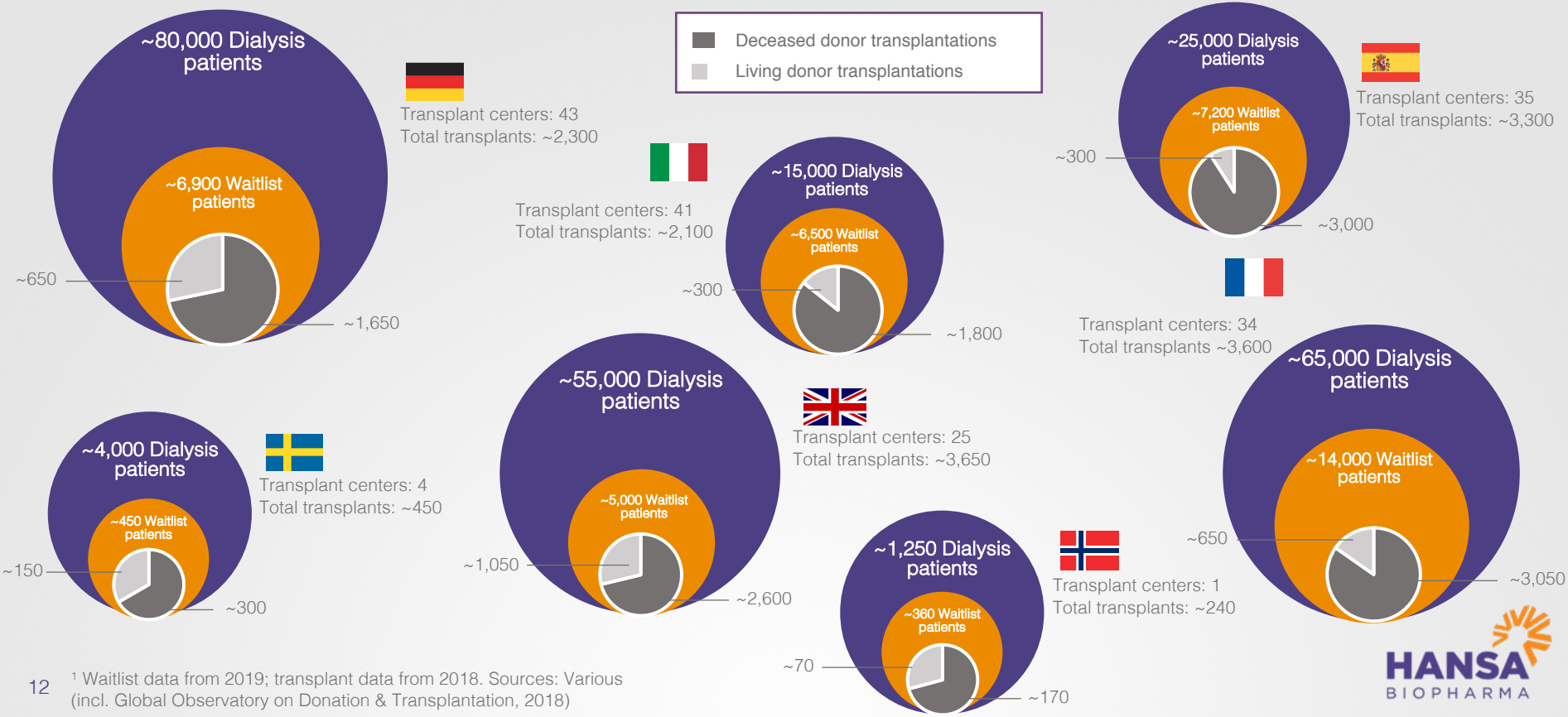
Approximately 16,000 kidney transplants in EU5 plus Sweden and Norway[1] with 70-80% performed at leading transplantation centres in each country



[1] Waitlist data from 2019; transplant data from 2018. Sources: Various (incl. Global Observatory on Donation & Transplantation, 2018)

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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]	Completed	Completed	Completed	Completed →	*)		CHMP Opinion Q2 2020
	US: Kidney transplantation in highly sensitized patients [1,2]	Completed	Completed	Completed	**)			Finalization of study design Q2 2020 / first patient dosed Q4 2020
	Anti-GBM antibody disease	Completed	Completed	Ongoing				Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing				Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing				Complete enrolment of 30 patients
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	Ongoing						Research phase

Completed Ongoing

[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).

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A post-approval study would need to be executed in case of approval.

**) FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study could support BLA submission by 2023

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Enrollment in Anti-GBM completed; Four patients recruited in each of the AMR and GBS studies

Ongoing Phase 2 studies

Enrollment status end Q1'2020

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.
- COVID-19 expected to delay the recruitment of AMR patients by 3-6 months. Enrollment is now expected to be completed H1 2021

Guillain-Barré Syndrome

- 4/30 patients enrolled
- COVID-19 expected to delay the recruitment of GBS patients by 3-6 months. Enrollment is now expected to be completed in H2 2021

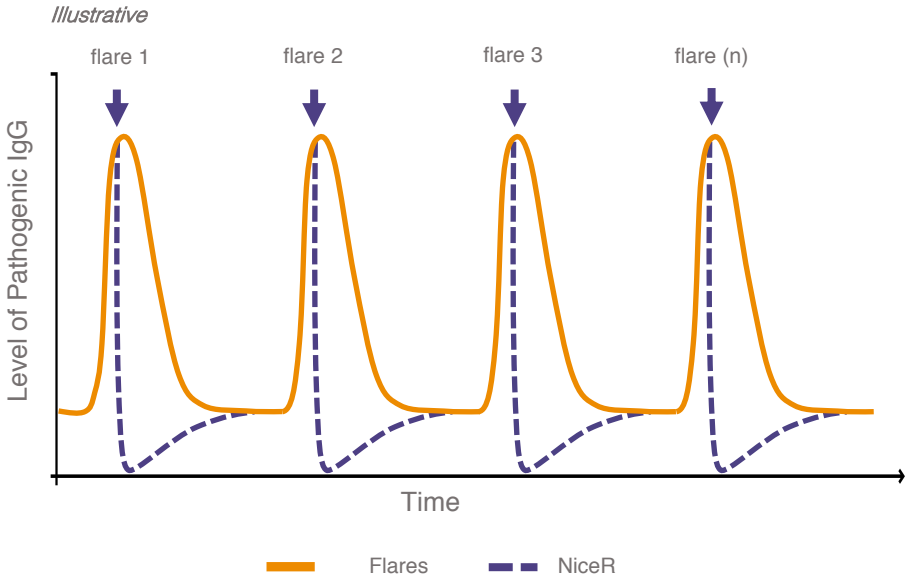
▪ Patients enrolled
▪ Patients left

“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



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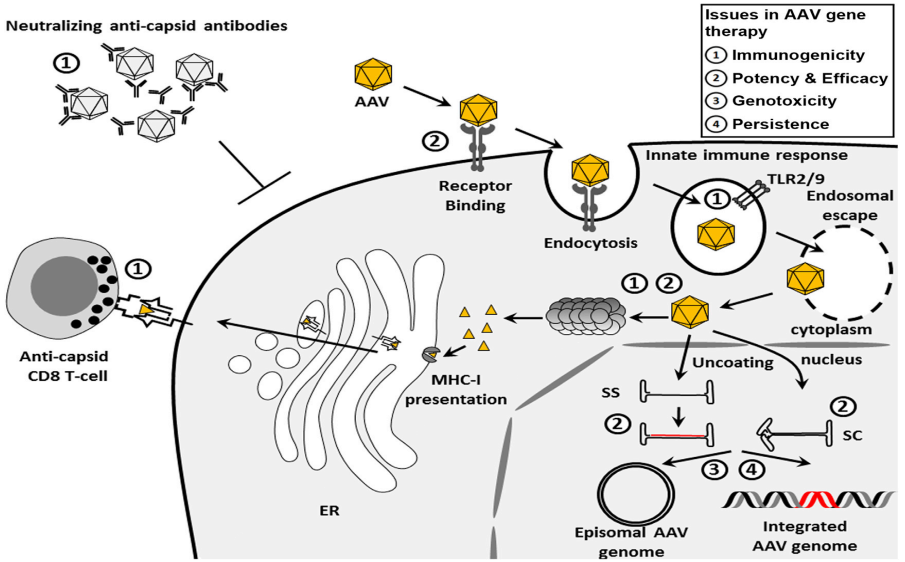
Exploring imlifidase in gene therapy as a potential pre-treatment to inactivate neutralizing antibodies

Nabs are immunological barriers in gene therapy

- Gene therapy programs may exclude up to 40% of patients from clinical studies and approved treatments due to presence of neutralizing antibodies[1]
- Most gene programs use viral vectors originating from Adeno-Associated Viruses (AAV) for gene insertions *in vivo*; however in many cases the human immune system have developed preformed neutralizing anti-AAV that prevents effective and safe use
- 187 in vivo programs are ongoing in gene therapy including 73 clinical stage programs, while two *in vivo* gene therapy products have been approved by FDA (Luxturna from Spark Therapeutics and Zolgensma from Novartis)

Idea is to enable gene therapy despite Nabs



1 http://www.ijcem.com/files/ijcem0094241.pdf

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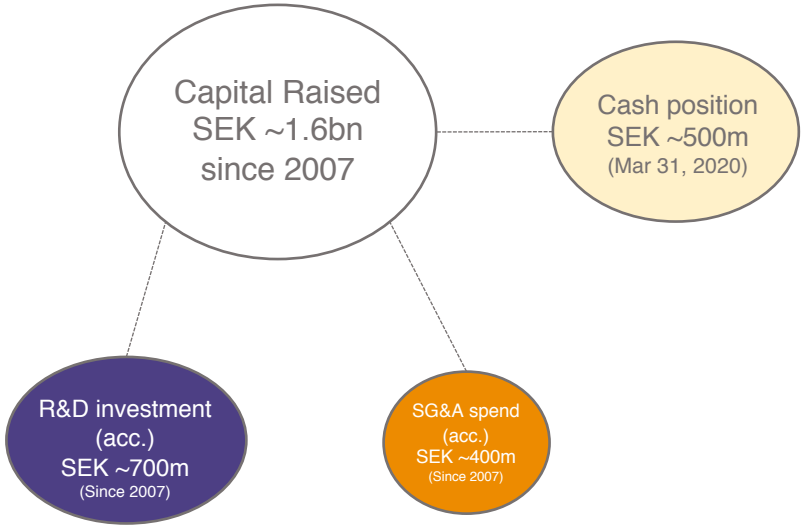
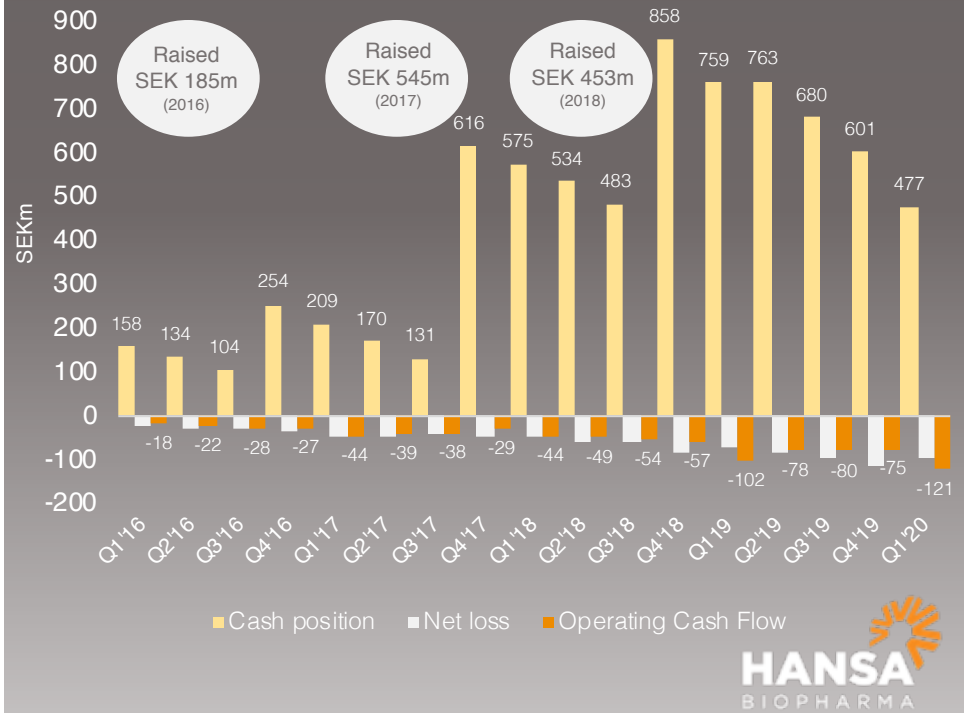
Hansa Biopharma is financed into mid-2021

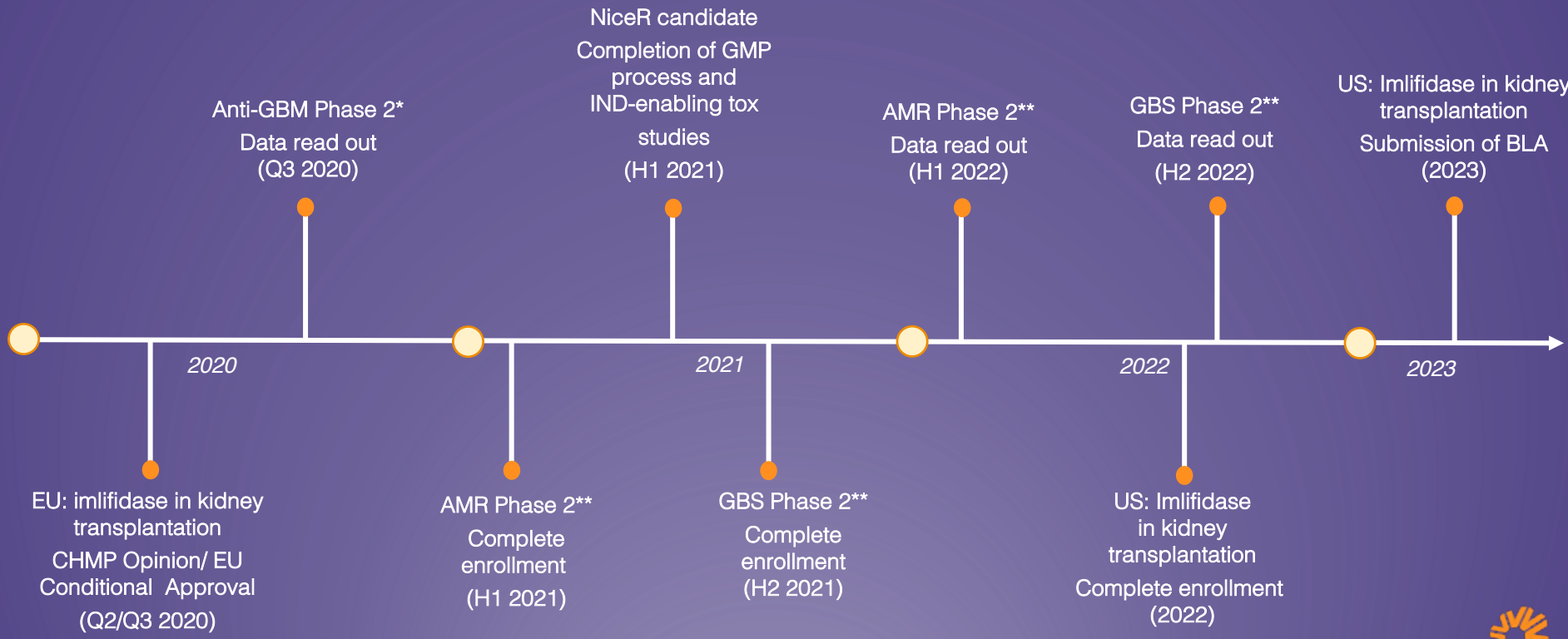
Significant capital raised since 2007



Cash position end of March 2020



Upcoming milestones



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

** An expected delay in the recruitment of patients of 3-6 months in the AMR and GBS studies have been incorporated following COVID-19 (Corona)

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Appendix

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	• Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects	• Safety and tolerability	• Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase	Complete PLOS ONE (2015)[1]
Study 02 Phase 2	8 subjects	• Single-center, single-arm, open-label	• Dosing resulting in HLA-antibody reduction (MFI<1100)	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete Lorant et al (2018) American Journal of Transplantation[2]
Study 03 Phase 2	10 subjects	• Single-center, single-arm, open-label • No prior desensitization	• Safety: AEs, clinical laboratory tests, vital signs, ECGs	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete The New England Journal of Medicine (2017)[3]
Study 04 Phase 2	17 subjects	• Investigator initiated study, Single-center, single-arm, open-label • All patients had prior desensitization with IVIG and/or plasmapheresis	• Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients • Assessment of safety • Assessment of efficacy/kidney function	• Serum creatinine (0-6 months) • Proteinuria (0-6 months) • DSA at multiple timepoints posttransplant (day 0, D30, D90, D180)	Complete The New England Journal of Medicine (2017)[3]
Study 06 "Highdes" Phase 2	18 subjects	• Multicenter, multinational, single-arm, open-label Included pts who may have had prior unsuccessful desensitization or pts in whom it was unlikely to be effective	• Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD	• DSA reduction at multiple timepoints (2, 6, 24, 48 h after imlifidase) • Time to create negative CDC XM test and/or flow cytometry (FACS) XM test • Safety	Complete Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019)[4]
Long-term follow-up study	Up to 46 subjects	• A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation	• Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration	• Patient survival, kidney function, comorbidity, treatments and QoL • Safety • DSA • Immunogenicity	Ongoing

[1] Winstedt el al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)
[2] Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762
[3] Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation", N Engl J Med 2017;377:442-53.
[4] Montgomery et al., "Safety And Efficacy Of Imlifidase In Highly-sensitized Kidney Transplant Patients: Results From A Phase 2 Study" ATC Abstract, 2019

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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 transplantation[1]

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

CLINICALTRIALS.GOV ID

NCT02224820

SUBJECTS

8 Patients with chronic kidney disease (Sweden)

DOSES/FOLLOW UP TIME

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

MAIN OBJECTTIVES

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

STUDY DESIGN

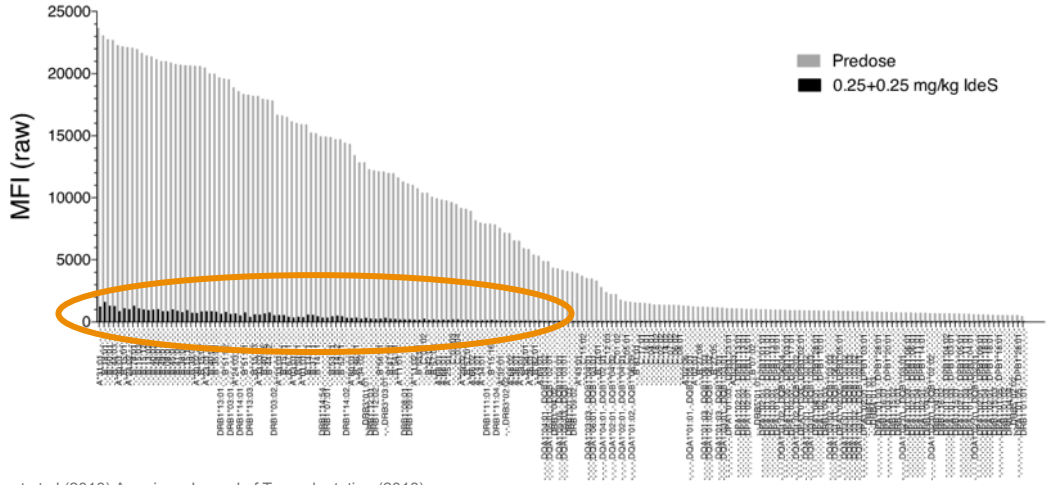
- Single-center, Single arm with ascending doses, open-label
- Transplantation not part of protocol

STATUS

Completed

- Primary efficacy endpoint reached
- Safe and well tolerated

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

CLINICALTRIALS.GOV ID

NCT02475551

SUBJECTS

10 Patients (Sweden)

DOSES/FOLLOW UP TIME

0.25 and 0.50 mg/kg during 180 days

MAIN OBJECTTIVES

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

STUDY DESIGN

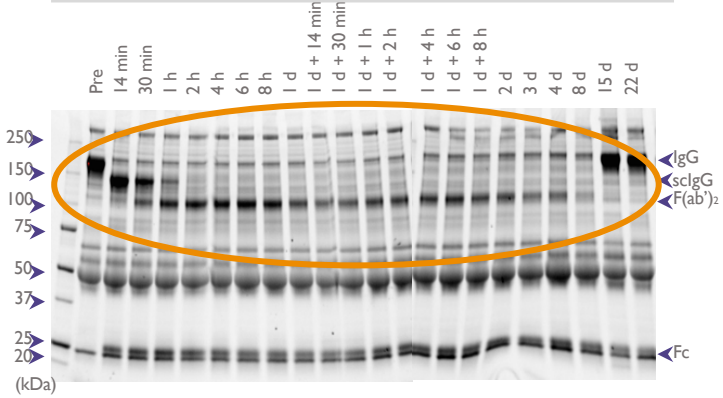
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

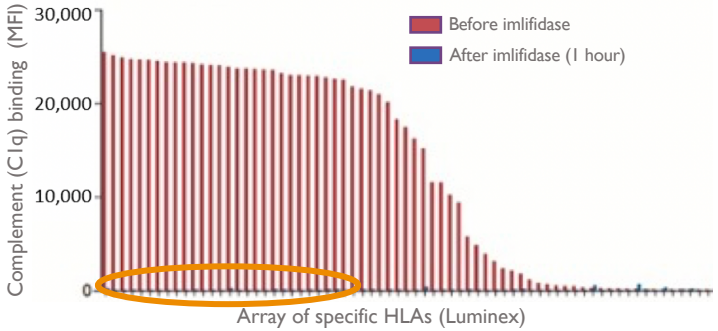
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment



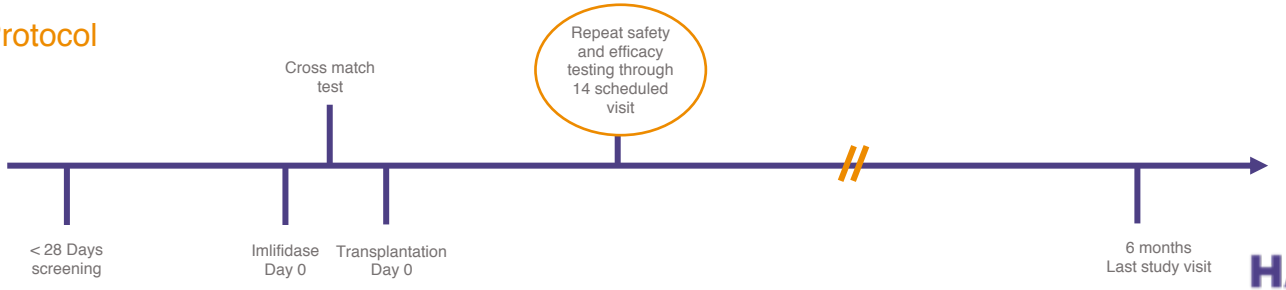
SDS-PAGE analysis of patient serum

Analysis of complement binding HLA antibodies before and after imlifidase



C1q analysis of patient serum

Protocol



Jordan SC, *et al.* (2017) NEJM Aug 3;377(5):442-453.

Study 04
Phase 2

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

CLINICALTRIALS.GOV ID

NCT024226684

SUBJECTS

17 Patients (US)

DOSES/FOLLOW UP TIME

0.24 mg/kg 180 days

MAIN OBJECTTIVES

- Safety in combination with Cedars Sinai's "standard protocol" for desensitization of highly sensitized patients
- Efficacy in preventing AMR

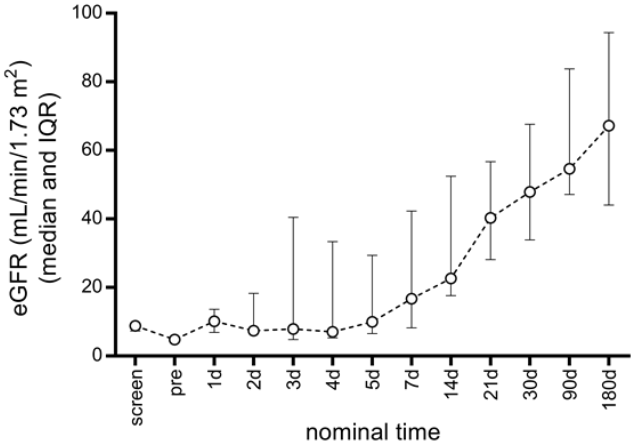
STUDY DESIGN

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

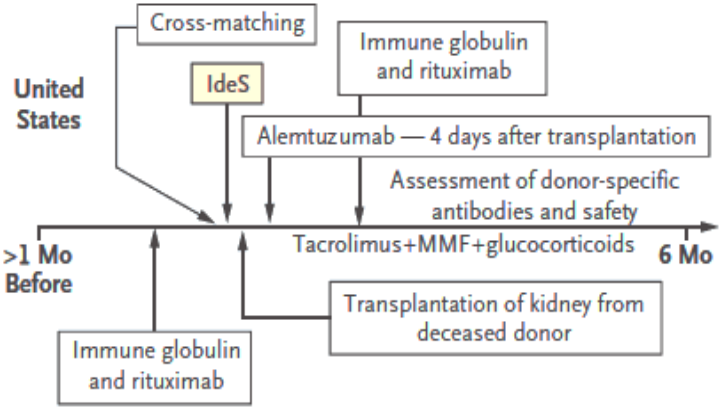
STATUS

Completed

Graft function (eGFR) post six months



Cedar's desensitization protocol in combination with imlifidase



Jordan SC, *et al.* (2017) NEJM Aug 3;377(5):442-453.
Huang E, *et al.,* (2019). Three-year outcomes of highly-sensitized kidney transplant recipient desensitized with imlifidase (IdeS). Abstract at ATC.

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Study 06
Phase 2

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

CLINICALTRIALS.GOV ID

NCT02790437

SUBJECTS

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

DOSES/FOLLOW UP TIME

0.25 mg/kg 180 days

MAIN OBJECTTIVES

- Efficacy in creating a negative crossmatch test

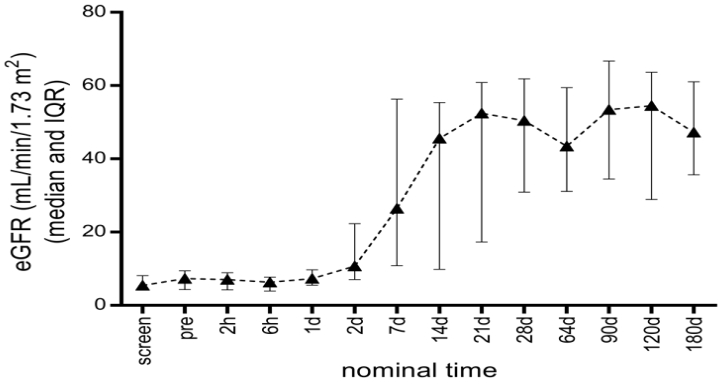
STUDY DESGIN

- Multicenter, multinational, single-arm, open-label Included patients who may have had prior unsuccessful desensitization or patients in whom it was unlikely to be effective

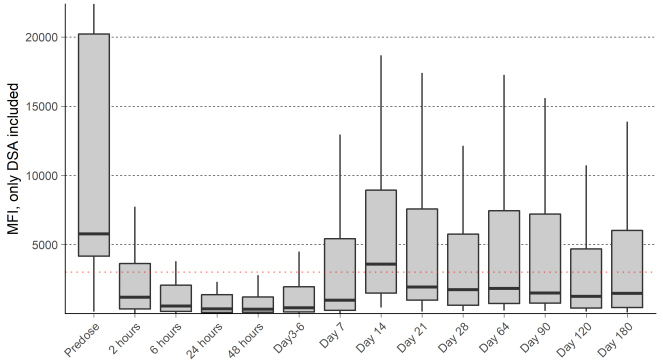
STATUS

Completed

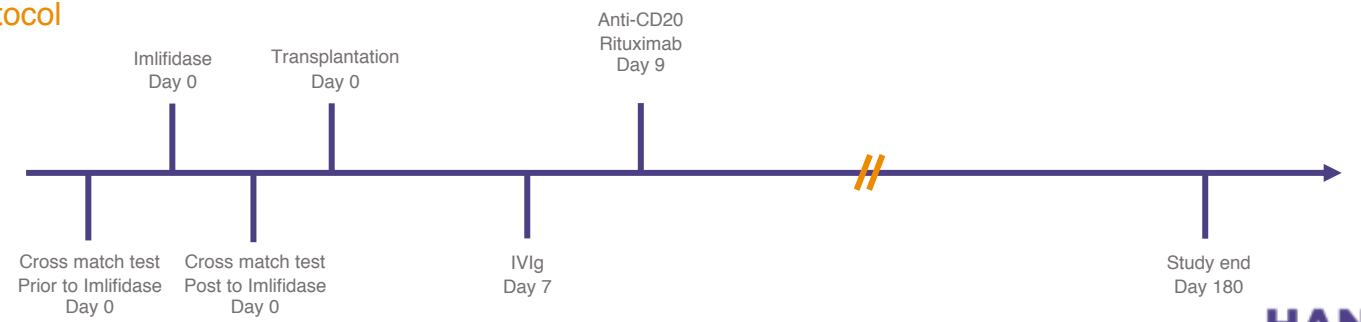
Graft function (eGFR) post imlifidase



DSA level pre-dose and post imlifidase



Protocol



Jordan SC, *et al.* (2019).
Results from the international phase II study on the safety and efficacy of imlifidase in highly-sensitized kidney transplant patients. Abstract presented at ATC.

Clinical development programs

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]	Completed	Completed	Completed	Completed →	*)		CHMP Opinion Q2 2020
	US: Kidney transplantation in highly sensitized patients [1,2]	Completed	Completed	Completed	**)			Finalization of study design Q2 2020 / first patient dosed Q4 2020
	Anti-GBM antibody disease	Completed	Completed	Ongoing				Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing				Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)	Completed	Completed	Ongoing				Complete enrolment of 30 patients
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology	Ongoing						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy	Ongoing						Research phase

Completed Ongoing

[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).

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A post-approval study would need to be executed in case of approval.

**) FDA: Agreement with the FDA on a regulatory path forward in the US. New clinical study could support BLA submission by 2023

HANSA BIOPHARMA

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

2/3 of Anti-GBM patients lose kidney function[2]

- 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)

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

Anti-GBM Phase 2

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 OBJECTTIVES

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

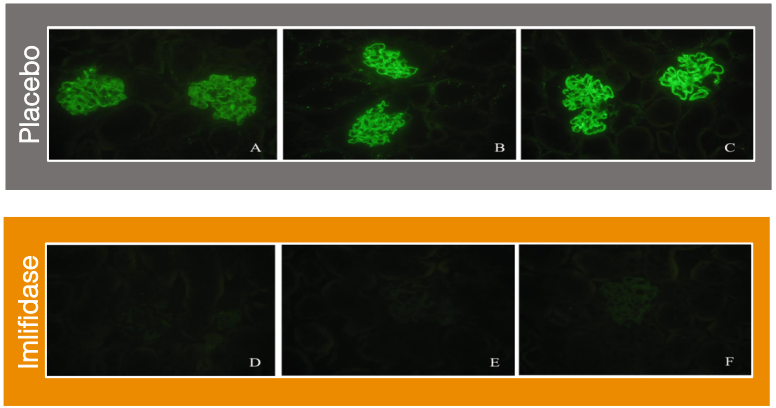
STUDY DESIGN

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

STATUS

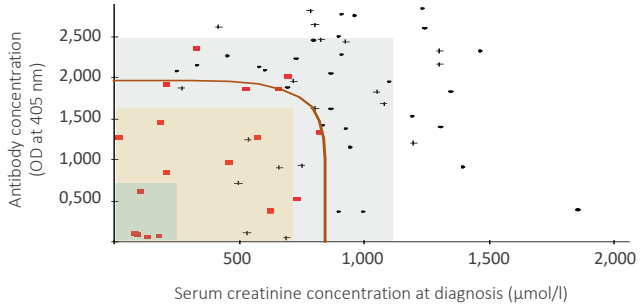
Ongoing

Mouse anti-rabbit IgG (Fc specific)



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



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.

HANSA BIOPHARMA

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 transplants[1] or ~ 3,200[2,3] new patients 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.
- 4/30 patient treated with imlifidase in AMR. 6/8 sites have been initiated to recruit patients in the US, Europe and Australia.
- COVID-19 expected to affect recruitment of AMR patients by 3-6 months. Enrollment is now expected to be completed H1 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 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

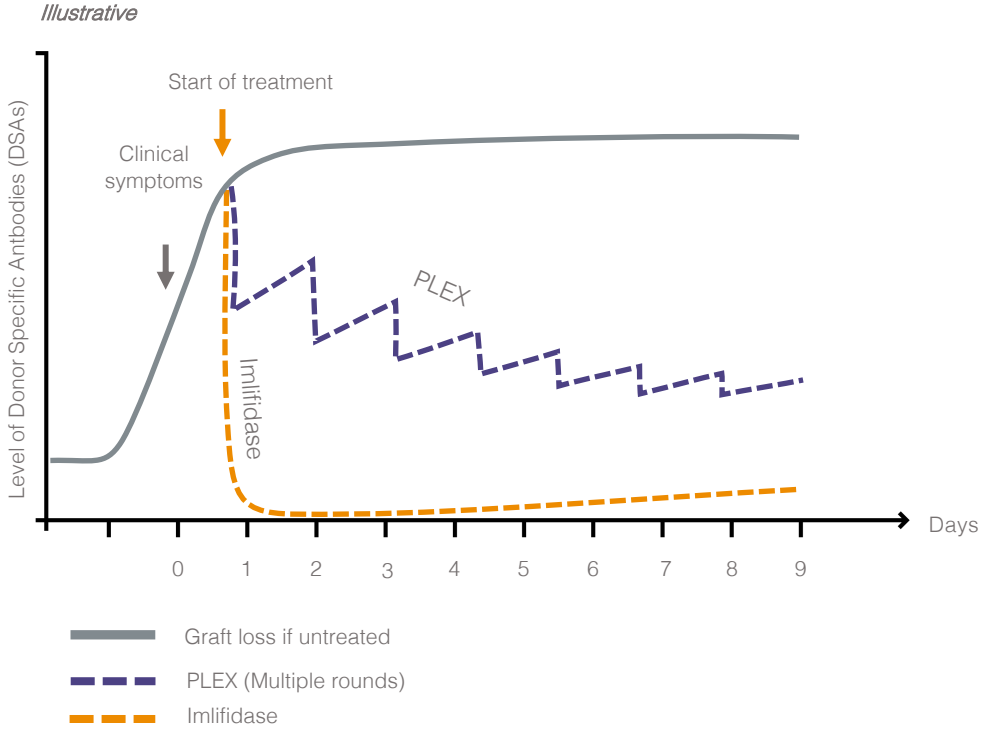
STUDY DESIGN

- 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

Potential of using imlifidase vs. PLEX in AMR



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 ~ 11,000[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)
- 4/30 patients enrolled. COVID-19 expected to affect recruitment of GBS patients by 3-6 months. 6/10 sites are recruiting patients across France, UK and the Netherlands. Enrollment is now 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 OBJECTTIVES

- safety and effectiveness of imlifidase in patients diagnosed with GBS

STUDY DESIGN

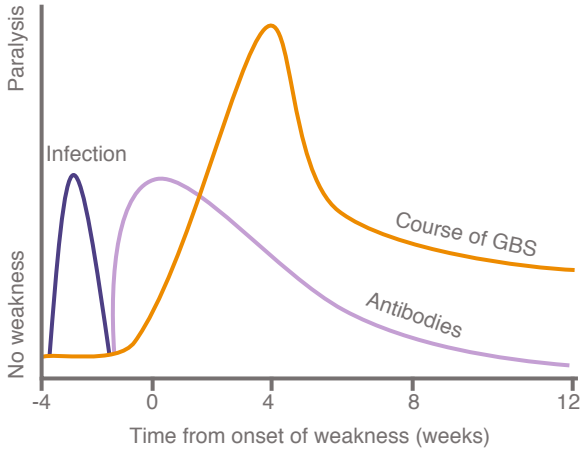
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing

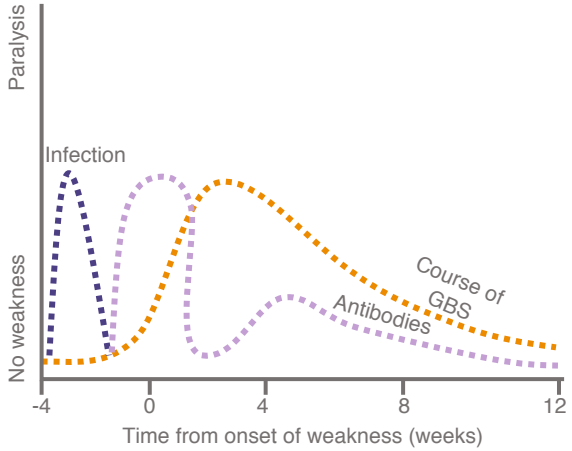
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



HANSA BIOPHARMA

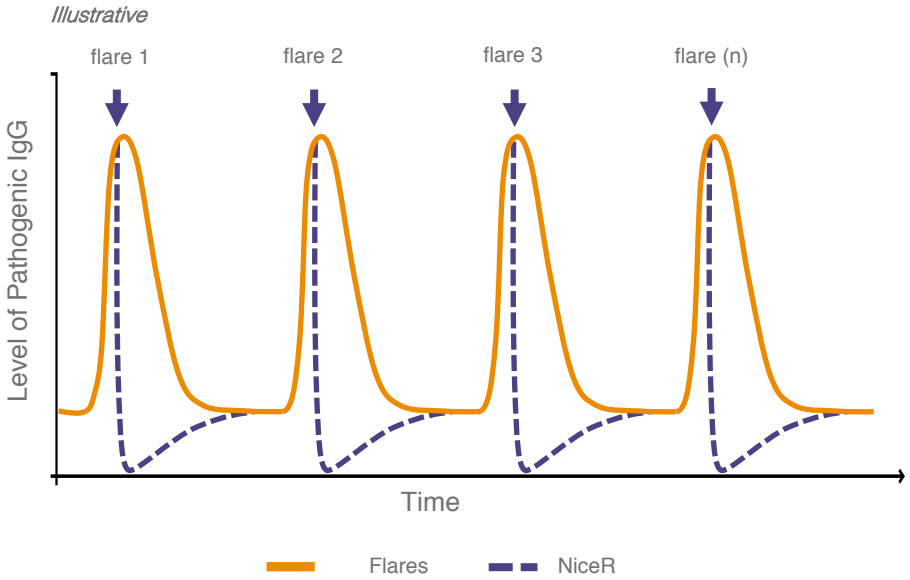
Pre-clinical programs

“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

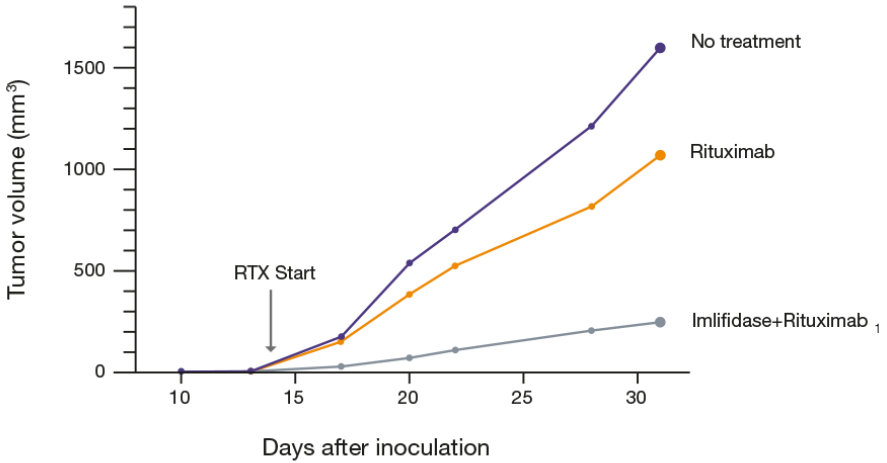


EnzE can potentially improve the therapeutic effect in oncology

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)



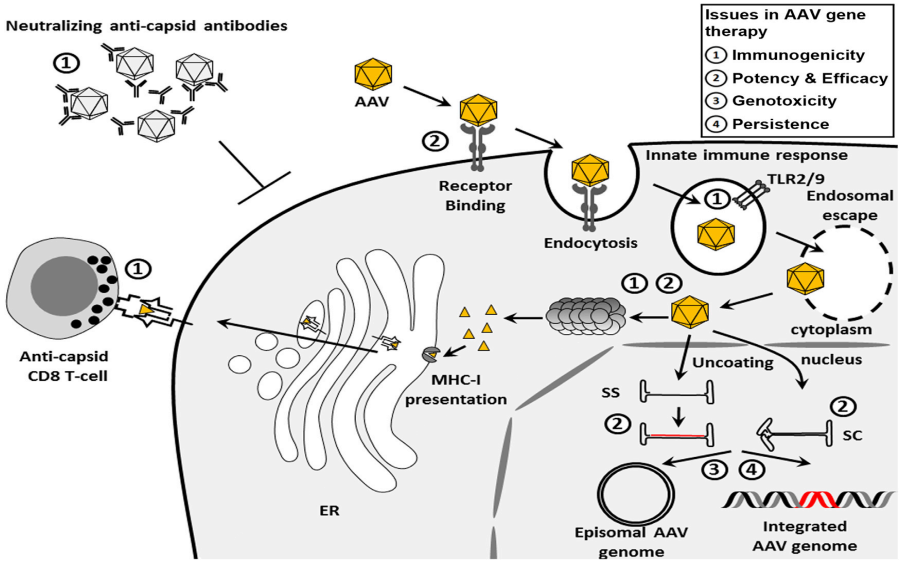
[1] Järnum et al. Mol Cancer Ther 2017;16:1887-1897

Exploring imlifidase in gene therapy as a potential pre-treatment to inactivate neutralizing antibodies

Nabs are immunological barriers in gene therapy

- Gene therapy programs may exclude up to 40% of patients from clinical studies and approved treatments due to presence of neutralizing antibodies[1]
- Most gene programs use viral vectors originating from Adeno-Associated Viruses (AAV) for gene insertions *in vivo*; however in many cases the human immune system have developed preformed neutralizing anti-AAV that prevents effective and safe use
- 187 in vivo programs are ongoing in gene therapy including 73 clinical stage programs, while two *in vivo* gene therapy products have been approved by FDA (Luxturna from Spark Therapeutics and Zolgensma from Novartis)

Idea is to enable gene therapy despite Nabs



1 http://www.ijcem.com/files/ijcem0094241.pdf

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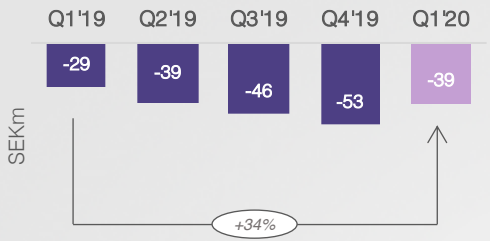
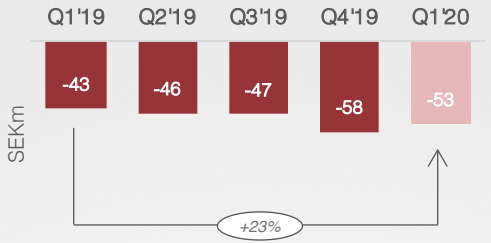
Financials

Investments in SG&A and R&D increased in preparation for potential conditional approval in EU and due to pipeline advancement

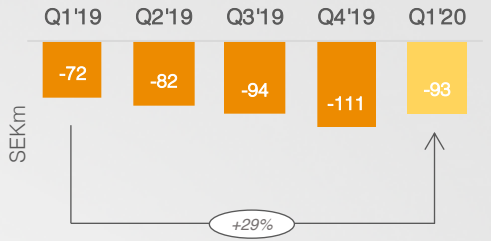
SG&A expenses (Q/Q)



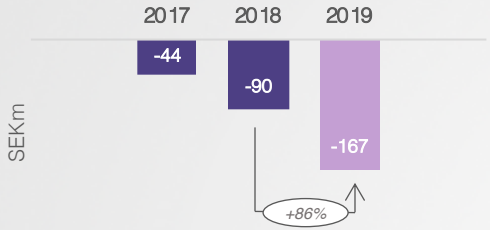
R&D expenses (Q/Q)



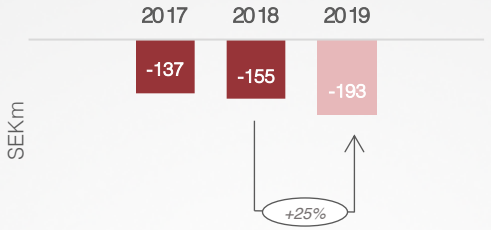
Net loss (Q/Q)



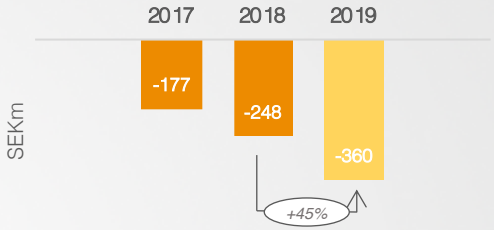
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

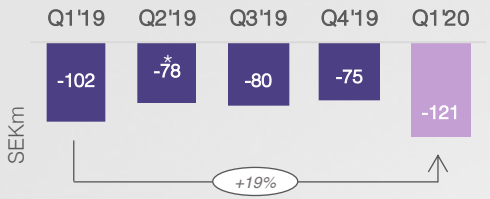


Net loss (Y/Y)

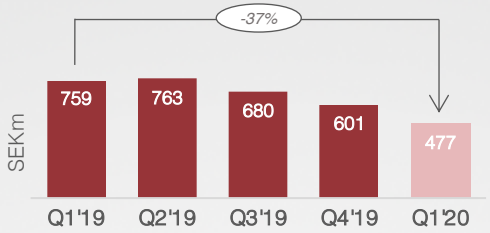


Cash position stood at SEK 477m (~USD 47m) end of Q1 2020; Hansa Biopharma is financed through mid 2021

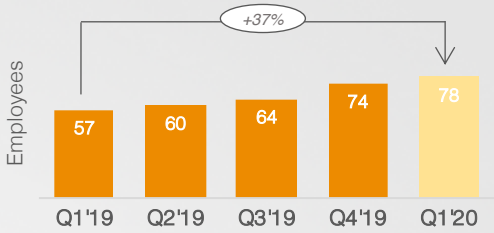
Operating cash flow (Q/Q)



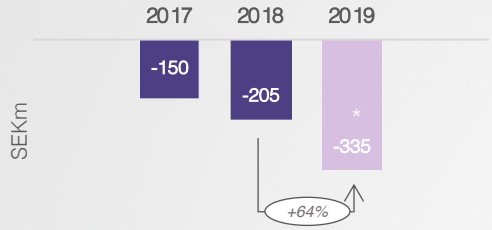
Cash & short term investments (Q/Q)



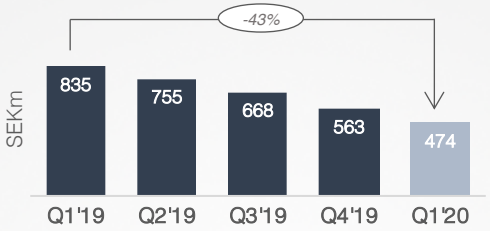
Number of employees (Q/Q)



Operating cash flow (Y/Y)



Shareholders equity (Q/Q)



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

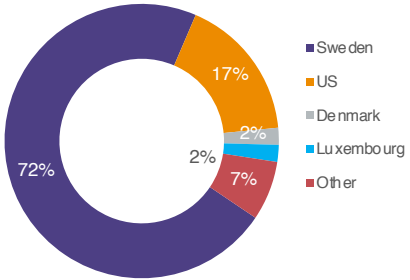
Ownership in Hansa Biopharma

Top 10 ownership as per March 31, 2020

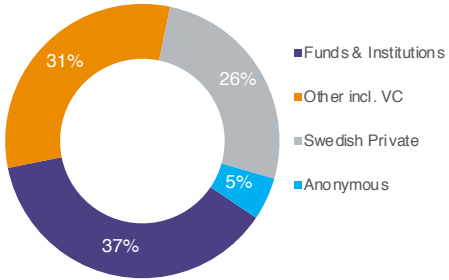
Name	No. of shares	Ownership in pct.
NXT2B	5 755 379	14.4
Invesco	2 116 818	5.3
Consonance Capital Management LP	2 088 285	5.2
Thomas Olausson	1 713 474	4.3
Gladiator	1 530 014	3.7
Avanza Pension	1 372 236	3.3
Third Swedish National Pension Fund	1 316 470	3.2
Fourth Swedish National Pension Fund	1 112 044	2.7
Vanguard	930 811	2.2
ClearBridge, LLC	691 486	1.7
Other	21 444 910	53.5
Outstanding A shares in total	40 026 107	100.0

Classification of ownership

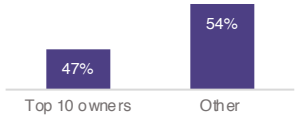
Ownership by country



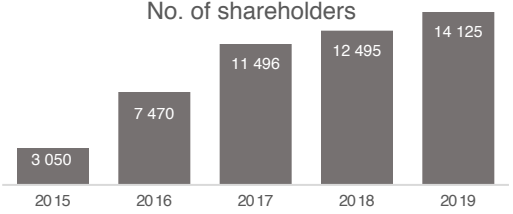
Ownership by type



Top 10 represents 46.5%



No. of shareholders



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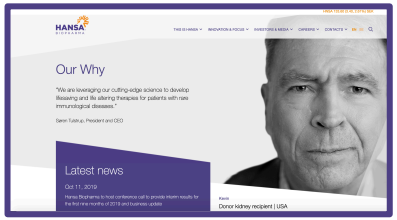
www.hansabiopharma.com



Calendar

May 18, 2020	UBS Global Healthcare Conference, NYC (virtual)
May 19, 2020	RBC Global Healthcare Conference, NYC (virtual)
May 26, 2020	ABG Life Science Summit, Stockholm (virtual)
May 27, 2020	Redeye Orphan Drug Event, Stockholm (virtual)
Jun 16, 2020	Citi's European Healthcare Conference, London (virtual)
Jun 23, 2020	Annual General Meeting
Jul 16, 2020	Interim Report Jan-Jun 2020
Sep 16, 2020	BofAML Global Healthcare Conference, London
Oct 22, 2020	Interim Report Jan-Sep 2020
Nov 25, 2020	Ökonomisk Ugebrev Life Science Conference, Copenhagen

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