HANSA BIOPHARMA

Investor Presentation

RBC Global Healthcare Conference
New York City
May 19, 2020

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

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Q1’20 Business Update

EMA process on track; CHMP opinion expected in the second quarter 2020

Highlights for the first quarter 2020

- Imlifidase in kidney transplantation
  - Formal adoption of outstanding questions expected in April; CHMP opinion expected in the second quarter 2020
  - Discussions with the FDA on the design of a new trial in kidney transplantation in the US is progressing according to plan
  - Long-term follow-up data demonstrate two-year graft survival of 89% after imlifidase treatment and transplantation
- Progress in our pipeline
  - Anti-GBM study fully enrolled; Completion marks an important milestone for the Company outside transplantation
  - Four patients have been treated in GBS and AMR respectively.
- COVID-19 pandemic may impact parts of the business
  - Recruitment in AMR and GBS expected to be delayed 3-6 months
  - Initiation of US imlifidase trial
  - Potential European launch of imlifidase in kidney transplantation
  - Financing strategy
- Cash position stood at SEK 477m (~USD 47m) end of March; Hansa Biopharma is financed through mid 2021

EMA: Formal adoption of outstanding questions expected at April meeting. CHMP Opinion expected in Q2 2020

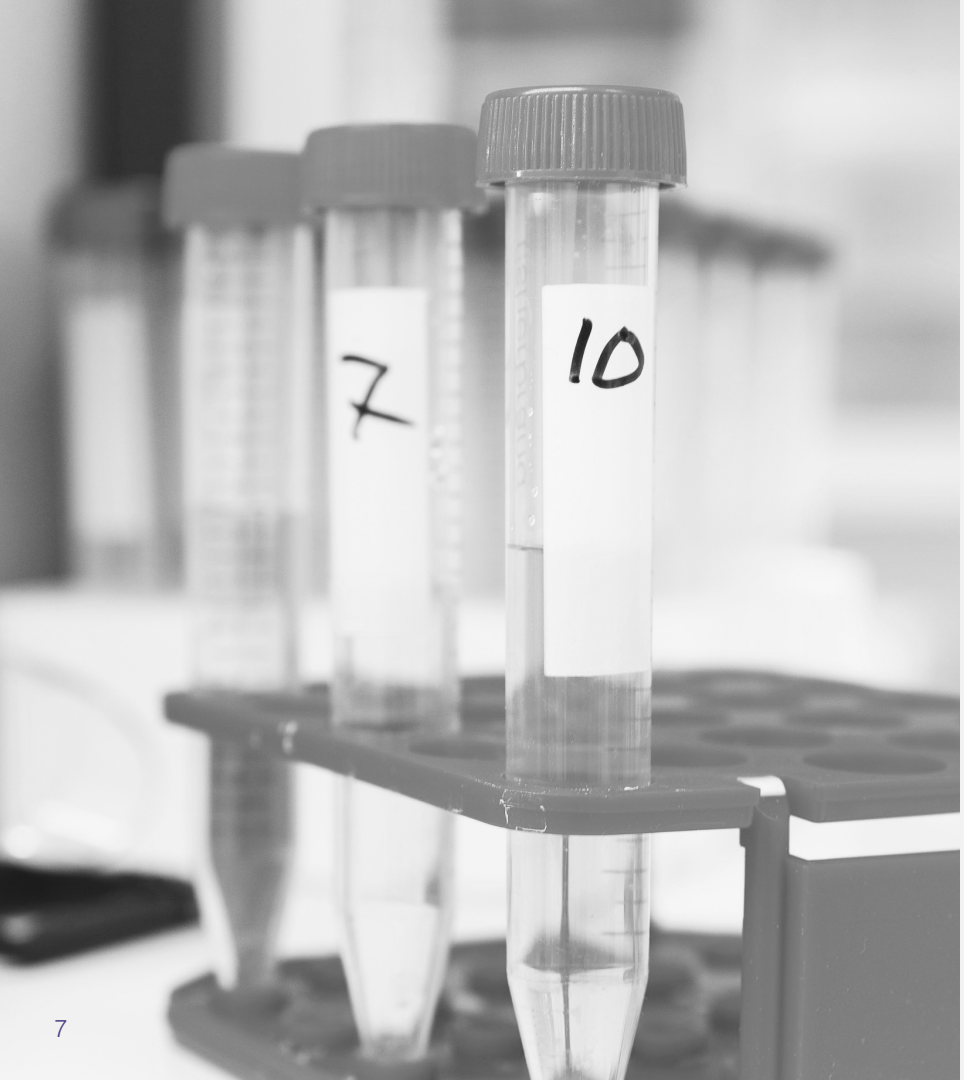
EU: Imlifidase in kidney transplantation

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

Launch strategy

- Our launch strategy involves targeting of leading kidney transplantation centers with the potential to become early adopters and centers of reference
- COVID-19 impact: Our potential launch may be affected by the pandemic, incl. limited access to market access authorities, potentially delaying pricing and reimbursement
- It remains, however, our aim to launch imlifidase this year



FDA: Discussions around new US trial design progressing as planned; New study planned to be initiated in Q4

US: Imlifidase in kidney transplantation

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
- COVID-19 impact: Potential reprioritization of activities by the FDA may impact the timeline for the initiation of our new US trial
- It remains our aim to start recruitment in Q4 2020 following receipt of the necessary ethical approvals and setting up of trial centers in the US

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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

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]					*)		CHMP Opinion Q2 2020
	US: Kidney transplantation in highly sensitized patients [1,2]				**)			Finalization of study design Q2 2020 / first patient dosed Q4 2020
	Anti-GBM antibody disease							Data read-out Q3 2020
	Antibody mediated kidney transplant rejection (AMR)							Complete enrolment of 30 patients
	Guillain-Barré syndrome (GBS)							Complete enrolment of 30 patients
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology							Development of CMC process / Tox studies
EnzE	Cancer immunotherapy							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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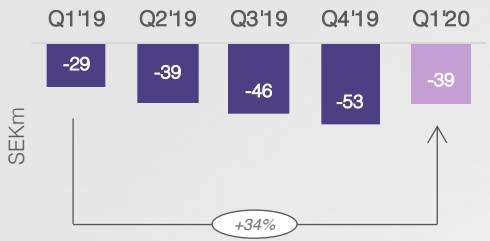
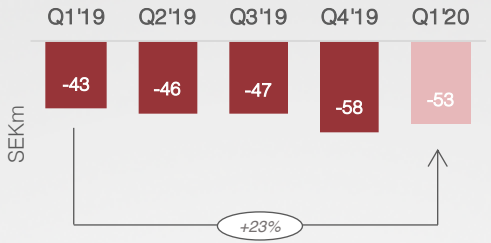
Investments in SG&A and R&D increased in preparation for potential conditional approval in EU and due to pipeline advancement

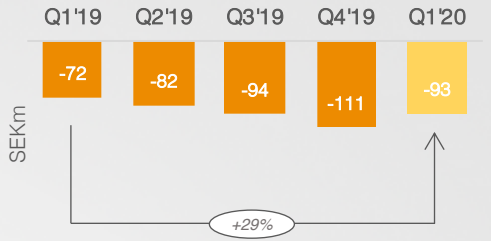
SG&A expenses (Q/Q)



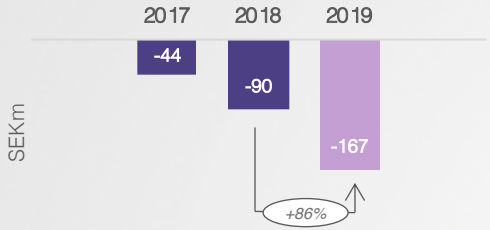
R&D expenses (Q/Q)



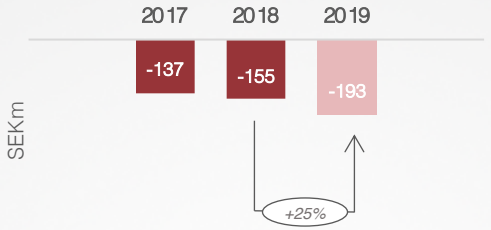
Net loss (Q/Q)



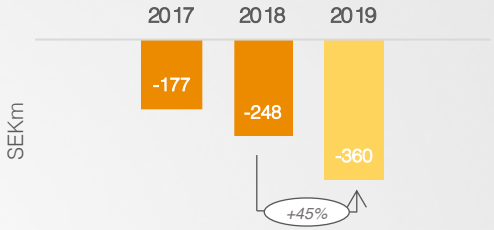
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

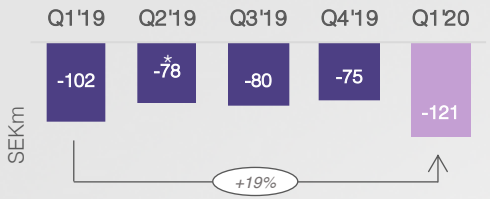


Net loss (Y/Y)

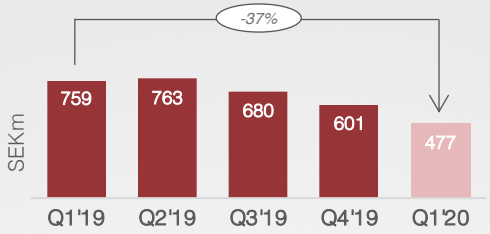


Cash position stood at SEK 477m (~USD 47m) end of Q1 2020; Hansa Biopharma is financed through mid 2021

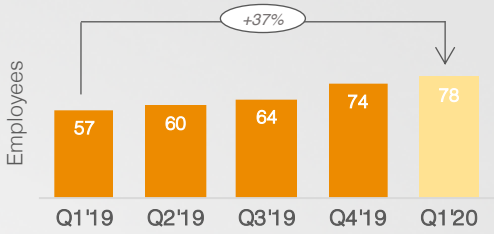
Operating cash flow (Q/Q)



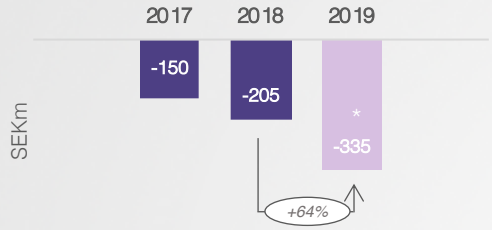
Cash & short term investments (Q/Q)



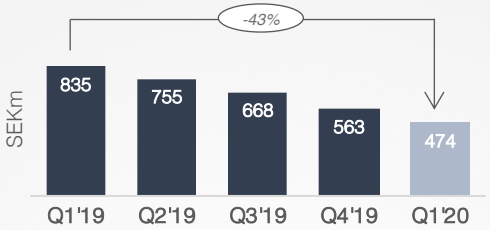
Number of employees (Q/Q)



Operating cash flow (Y/Y)

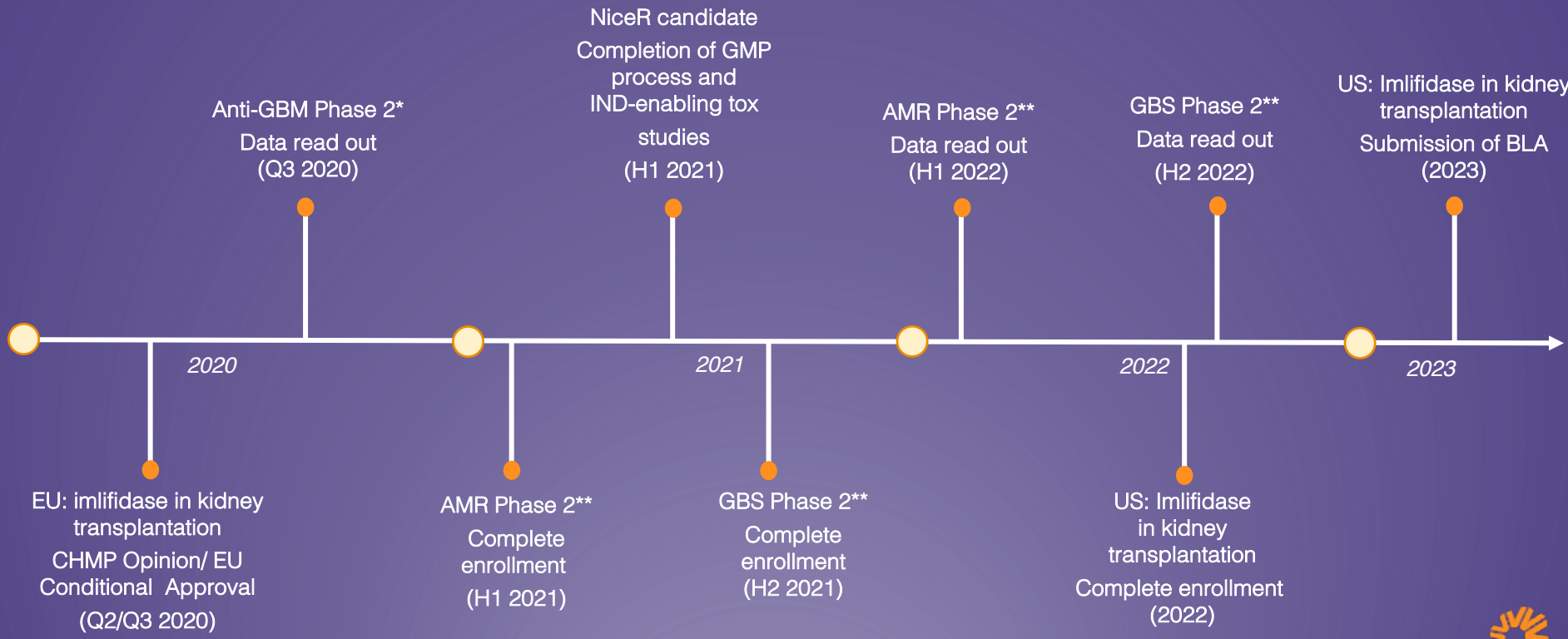


Shareholders equity (Q/Q)



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

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)

HANSA BIOPHARMA

Company Overview

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

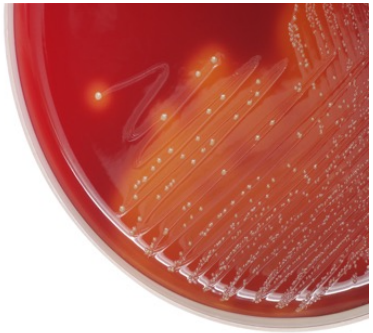
*Unaudited financials

…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

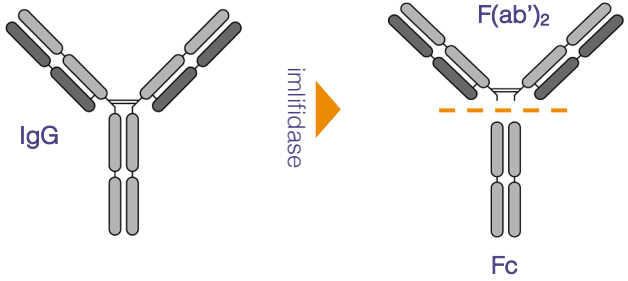
Origins from Streptococcus pyogenes

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



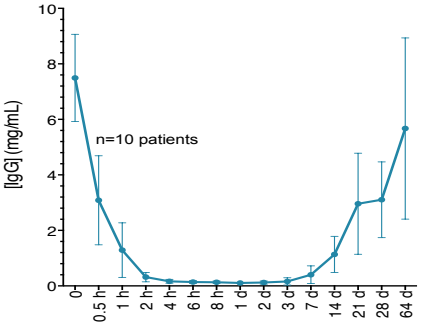
Imlifidase, a unique IgG antibody-cleaving enzyme

- 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



Our Equity Story

Targeting rare diseases with a high unmet medical need

- Imlifidase is a unique IgG antibody-cleaving enzyme with a rapid onset of action and high specificity for inactivation of IgG in patients with rare immunologic diseases

Preparing for commercialization

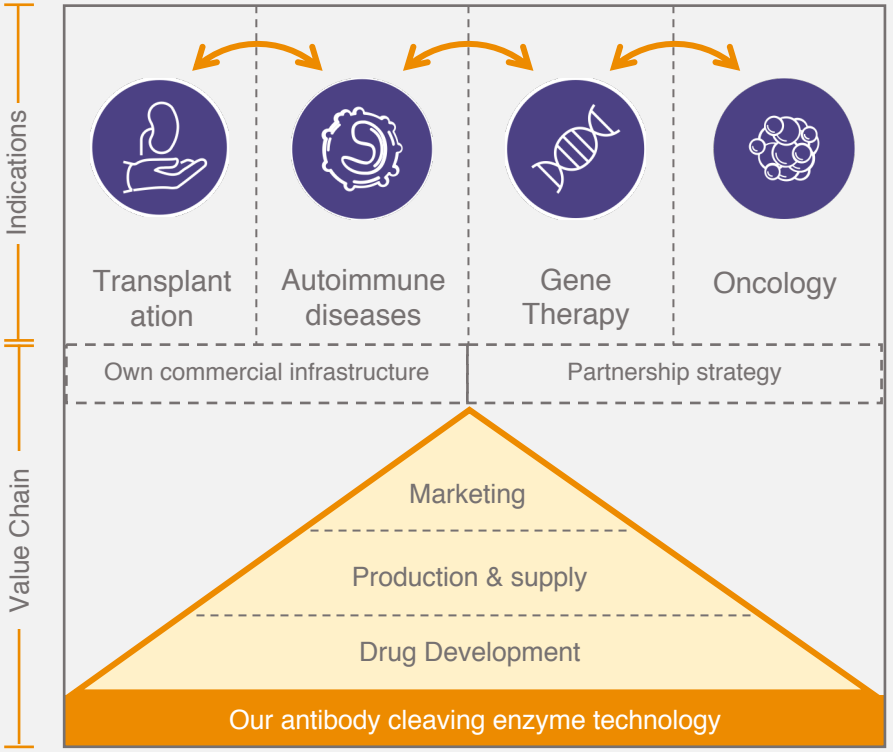
- Preparing for potential European launch of imlifidase under conditional approval in 2020. MAA under review by EMA with a CHMP Opinion expected in Q2 2020
- Imlifidase to be launched through Hansa´s own medical and commercial organization, while the company is expected to pursue a partnership strategy outside core markets
- In the US a clear regulatory path has been agreed with the FDA that could support potential submission of a BLA in 2023 under the accelerated approval pathway
- Broad technology protection with patent coverage throughout 2035 in key markets and orphan drug designation in both the US/EU in our lead indications

Evolution into a fully integrated biopharmaceutical company

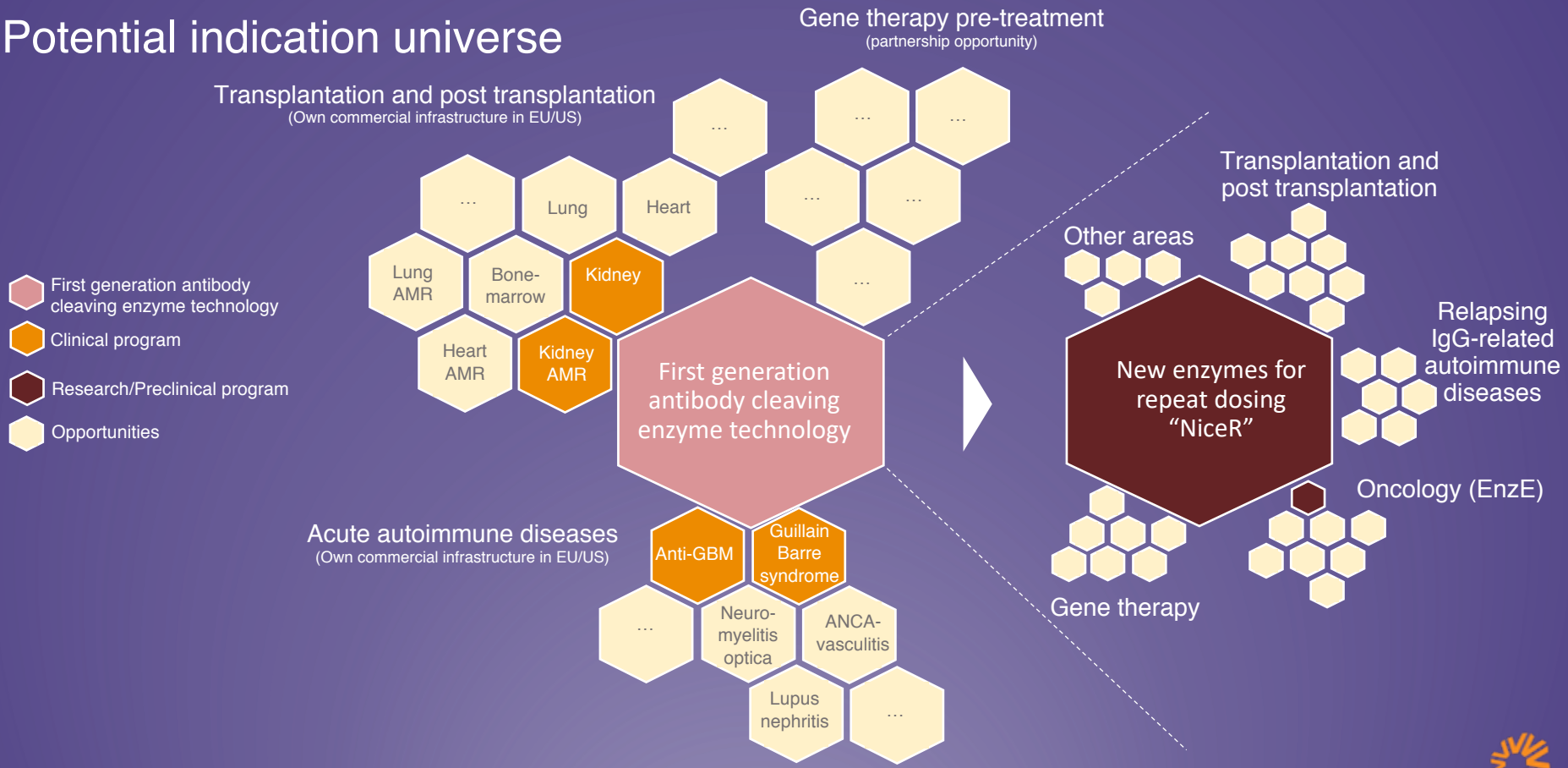
- Controlling the full value chain from early discovery through commercialization to maximize the value creation and capture

Leveraging our proprietary antibody cleaving enzyme technology

- Advancing our pipeline with three phase 2 programs in transplantation and acute autoimmune diseases.
- New set of modified enzymes under development (NiceR program) for repeat dosing; potentially enabling treatment in relapsing diseases and oncology
- Exploring potential combination therapies in oncology with IgG-modulating enzymes and gene therapy in patients with neutralizing antibodies through potential partnerships



Potential indication universe

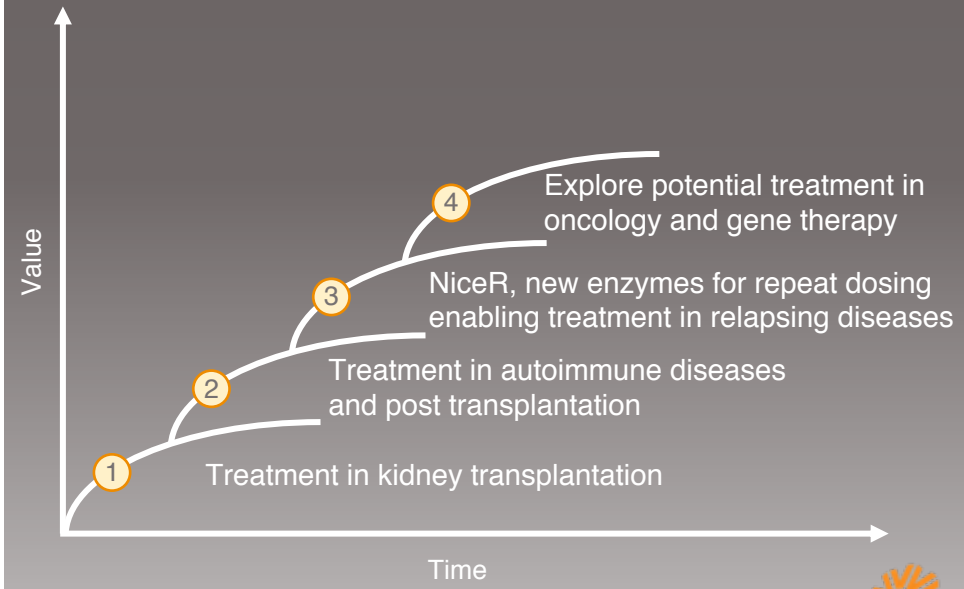


Our unique enzyme technology platform offers significant potential for growth and expansion

Our strategic priorities

- Establish a commercial and medical infrastructure in Europe
- Attain marketing authorization 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



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 BioInvent,
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

Henk D. van Troostwijk

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

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

Anne Säfström Lanner

VP, Global HR (2019)
Ex-Head of HR European Spallation Source
Ex-Head of HR Cellavision

Board of Directors

Ulf Wiinberg

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

Birgit Stattin Norinder

Borad 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 Renumeration Committee.

HANSA BIOPHARMA

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

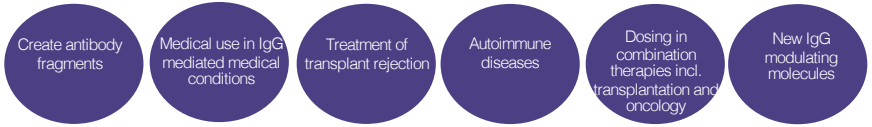
Potential EMA approval in 2020

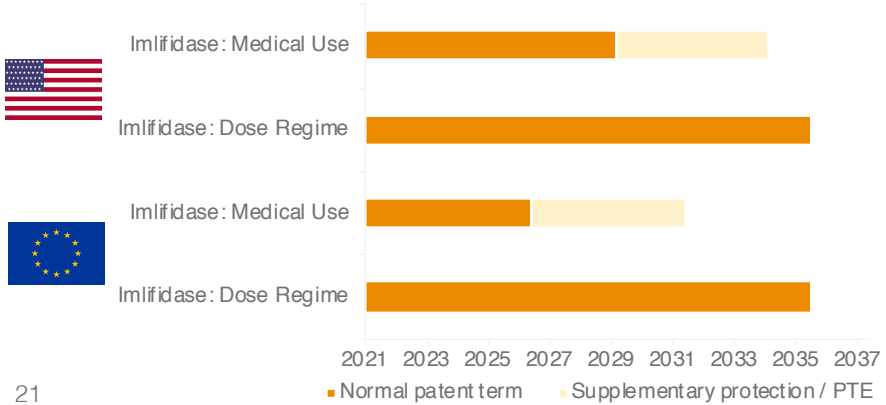
HANSA BIOPHARMA

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)

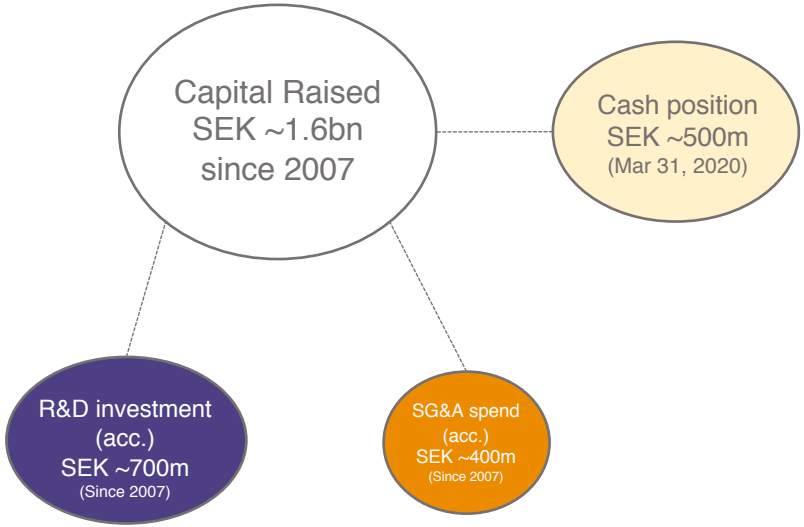
FDA

Orphan drug designation

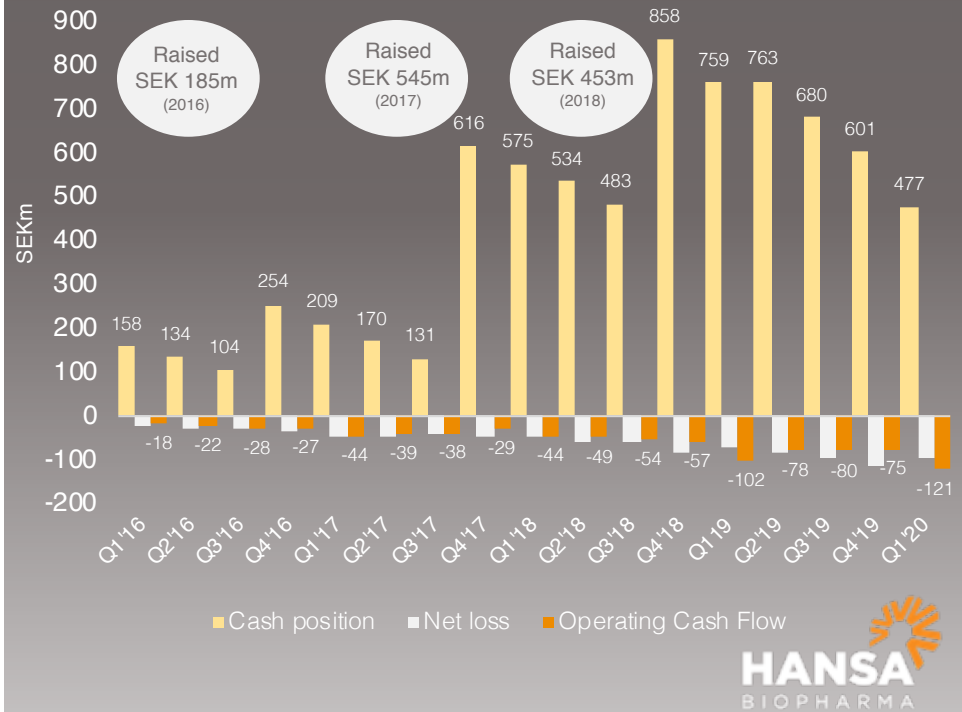
- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
- Imlifidase for the treatment of Guillian-Barré Syndrome (2018)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

Hansa Biopharma is financed into mid-2021

Significant capital raised since 2007



Cash position end of March 2020



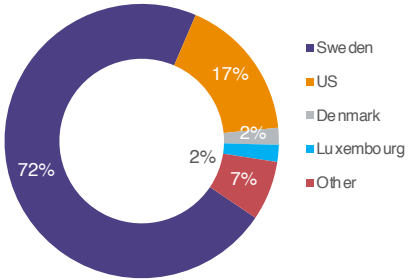
Ownership in Hansa Biopharma

Top 10 ownership as per March 31, 2020

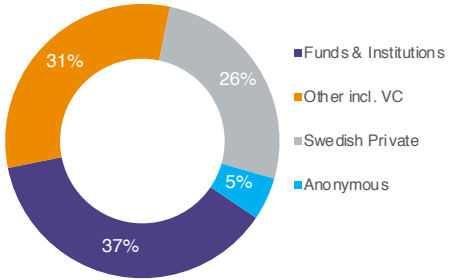
Name	No. of shares	Ownership in pct.
NXT2B	5 755 379	14.4
Invesco	2 116 818	5.3
Consonance Capital Management LP	2 088 285	5.2
Thomas Olausson	1 713 474	4.3
Gladiator	1 530 014	3.7
Avanza Pension	1 372 236	3.3
Third Swedish National Pension Fund	1 316 470	3.2
Fourth Swedish National Pension Fund	1 112 044	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

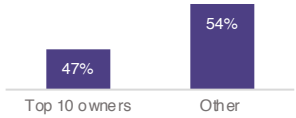
Ownership by country



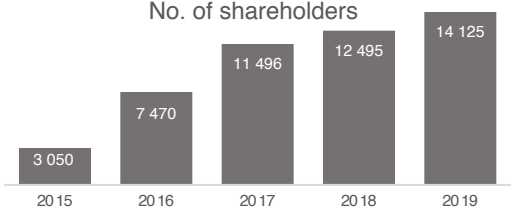
Ownership by type



Top 10 represents 46.5%



No. of shareholders



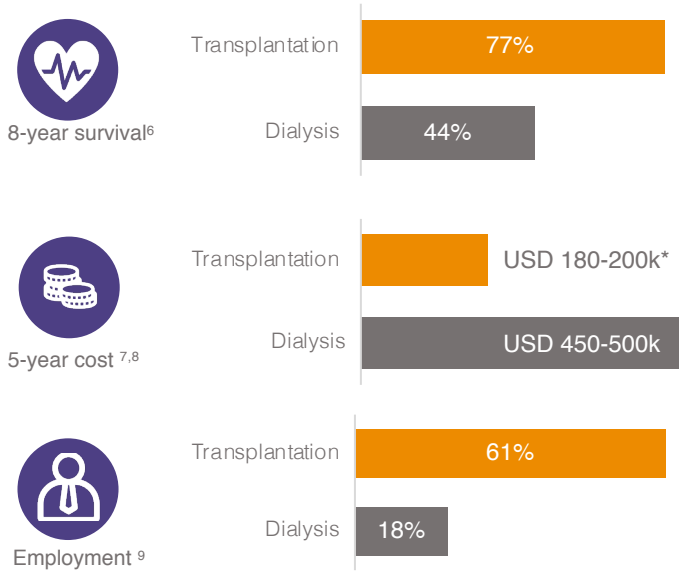
Imlifidase in kidney transplantation

Kidney transplantation saves lives, reduce costs and increase quality of life incl. societal gains for the society

Several complications and risks with dialysis

- Undergoing dialysis treatment is associated with many complications and side effects incl. cardiovascular diseases[1]. In the long term, patients may also eventually lose access to dialysis as a result of failed ports, bad veins, and other factors[2]
- In general, patients on the kidney transplant waiting list and who are on dialysis have a lower quality of life than non-dialysed patients or patients who have been transplanted[3]
- First study in Europe on labor market outcomes demonstrates societal gains of enabling transplantation with three times as many transplant patients employed vs. dialysis patients.
- Lastly, extended dialysis is also a high-risk factor for removal from the transplant wait list[6]

Transplantation leads to better outcomes



*Cost of kidney transplantation and 5 years of immuno-suppression treatment[6,7]

[1] Cozzolino et al., 2018
[2] Sinnakirouchenan and Holley, 2011 Shenoy, 2017
[3] Wyld et al., 2012
[4] Jarl et al. Transplantation, 2018, 102:1375-1381
[5] NHS blood and transplant, 2018.
[6] Orandi et al. N Engl J Med 2016;374:940-50
[7] www.usrds.org
[8] Shehata et al, Transfus Med Rev 201, 24 Suppl 1: S7-S27
[9] Jarl et al. Transplantation, 2018, 102:1375-1381

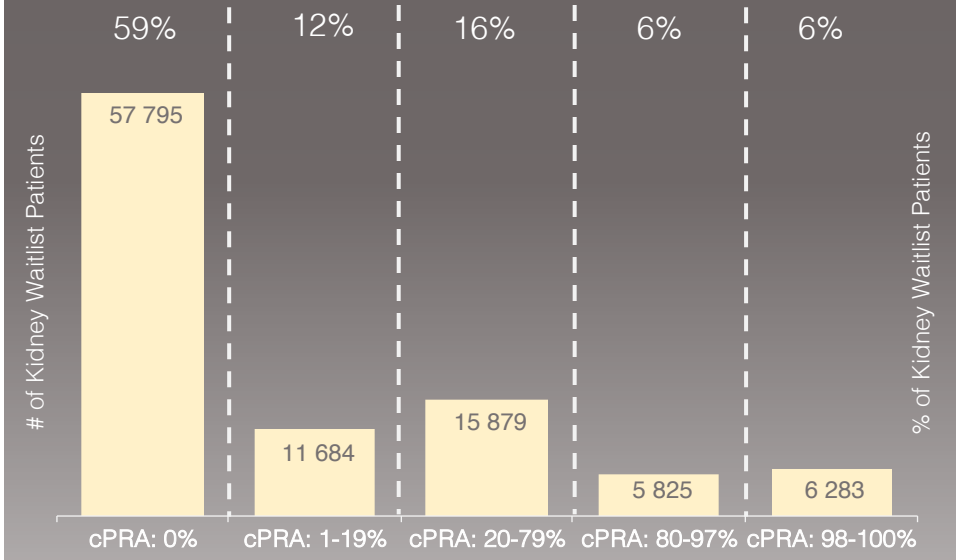
Approximately 10-15% of patients on wait list are highly sensitized

Highly sensitized patients are difficult to match

- Causes of sensitization include

- Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization
- Inability to match or effectively desensitize patients remains a barrier for transplantation in highly sensitized patients
- Allocation Systems such as KAS and Eurotransplant rely on cPRA score to characterize patients for transplant

US Kidney Waitlist Patients by cPRA in 2018



Source: Organ Procurement and Transplant Network, Advanced Report. Analysis as of September 25, 2018

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Imlifidase may enable transplantation in highly sensitized kidney patients

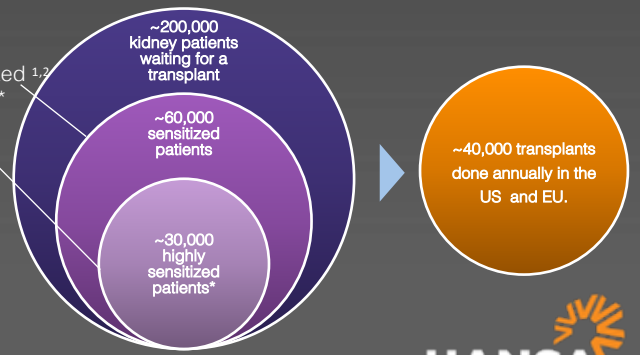
Creating equity for highly sensitized patients

- Allocation systems increase transplantation rates, however the rates for highly sensitized patients are still very low compared with average or non-sensitized patients
- If approved, imlifidase may potentially:
  - Complement allocation systems (e.g. KAS, Euro-transplant) to reduce time to transplant in highly sensitized patients
  - Reduce the need for antibody matching and give sensitized patients access to a larger pool of organs
  - Reduce the risk for co-morbidities and mortality associated with dialysis and waiting time
  - Increase transplant rates in highly sensitized patients
  - Help reduce the number of discarded kidneys (1,000 donated kidneys are discarded in the U.S. alone every year[3])

Delilah, a 23 years old highly sensitized kidney transplant patient from California

U.S. + EU Kidney Transplant Waitlist Breakdown

>30% of waitlist patients are sensitized
- 15% moderately sensitized [1,2]
- 15% highly sensitized[1,2] *



*Patients with sensitivity above cPRA 80%

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

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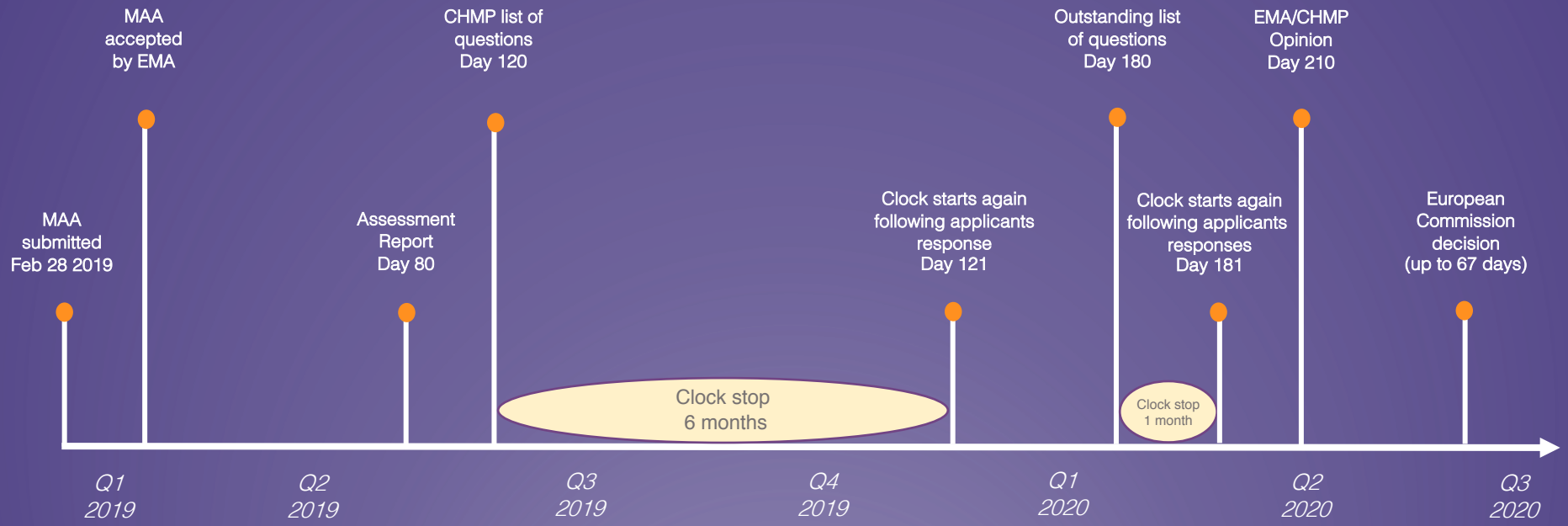
[1] Jordan et al. British Medical Bulletin, 2015, 114:113–125
[2] Orandi et al. N Engl J Med 2016;374:940-50
[3] Organ Procurement and Transplantation Network (OPTN)
[4] Jordan et al. British Medical Bulletin, 2015, 114:113-125

The EMA process towards marketing authorization

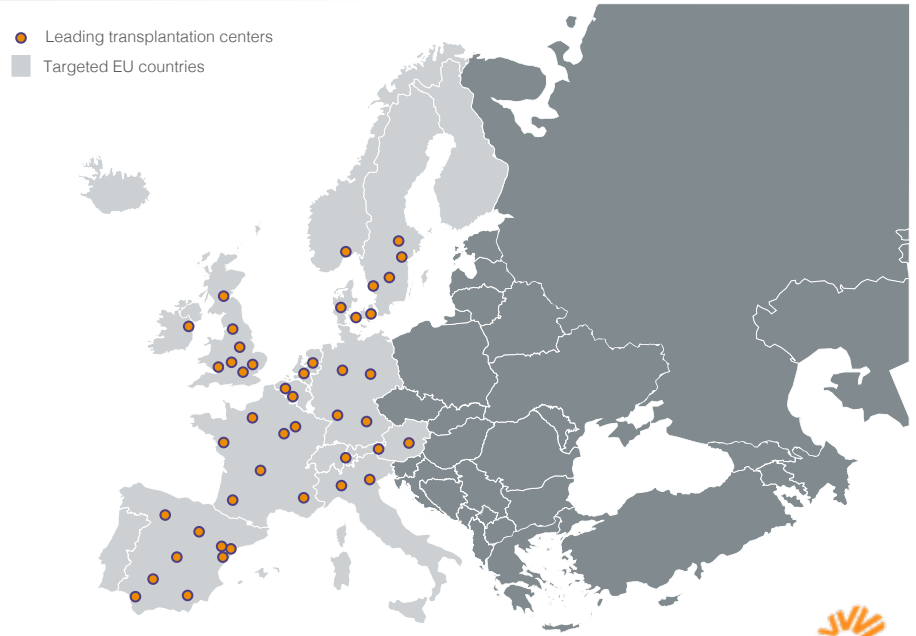


Focused launch strategy targeting leading kidney transplantation centers to ensure positive experience

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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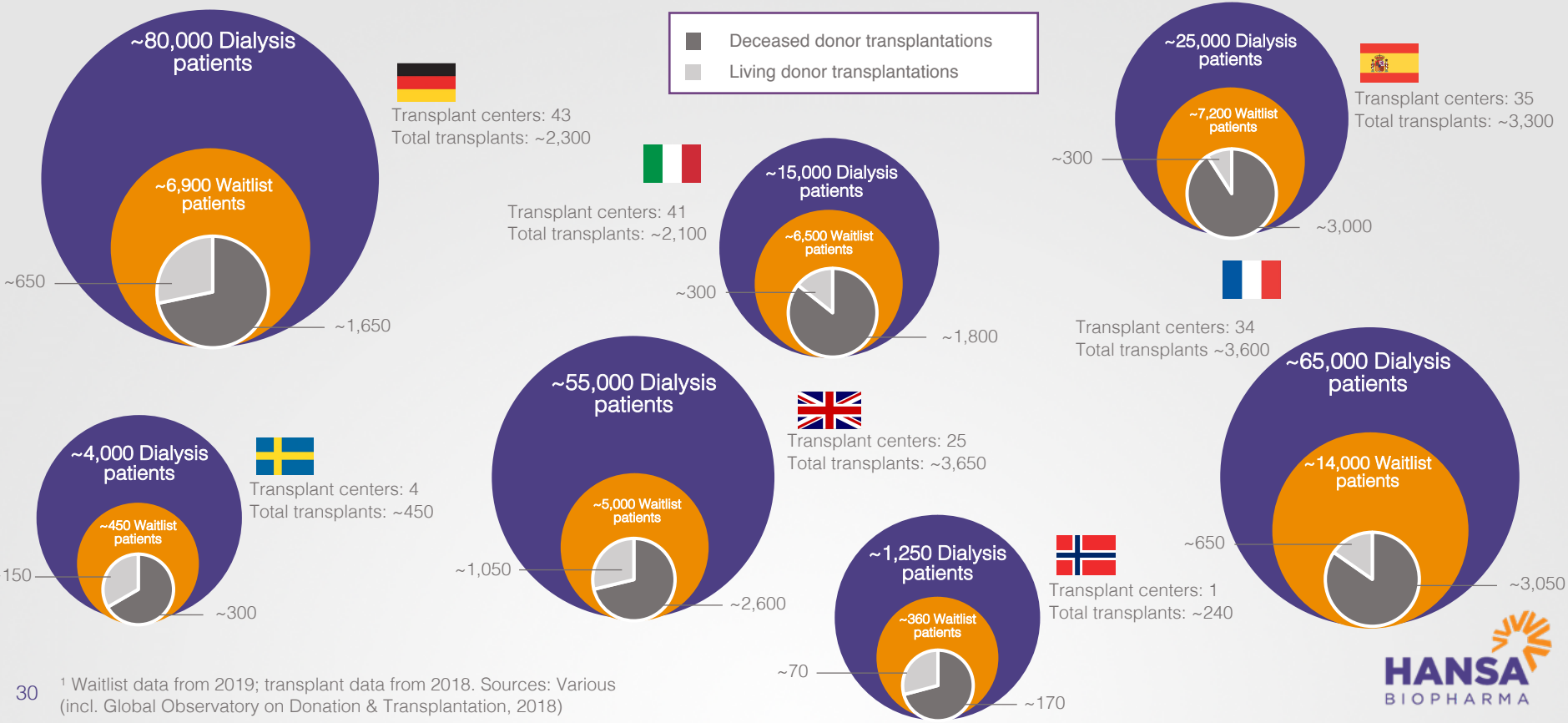
European transplantation landscape

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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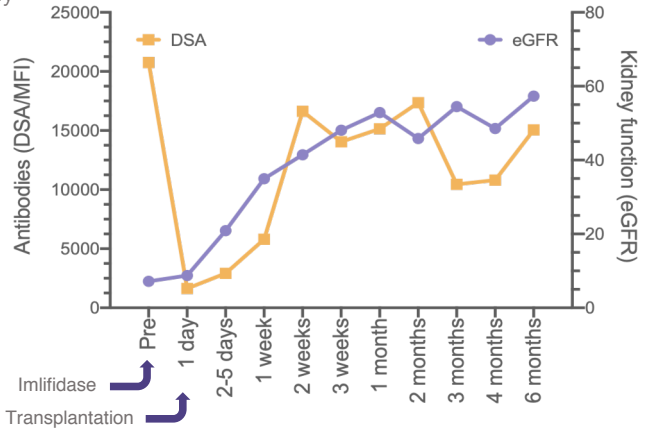
Completed and ongoing studies in kidney transplantation

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 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. Patients are followed up to five years in a separate study



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. 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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Study 01
Phase 1

CLINICALTRIALS.GOV ID

NCT01802697 (2013/2014)

SUBJECTS

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

DOSES/FOLLOW UP TIME

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

MAIN OBJECTTIVES

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

STUDY DESIGN

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

STATUS

Completed

- The 01 study showed complete removal of IgG and that Imlifidase was considered safe to use

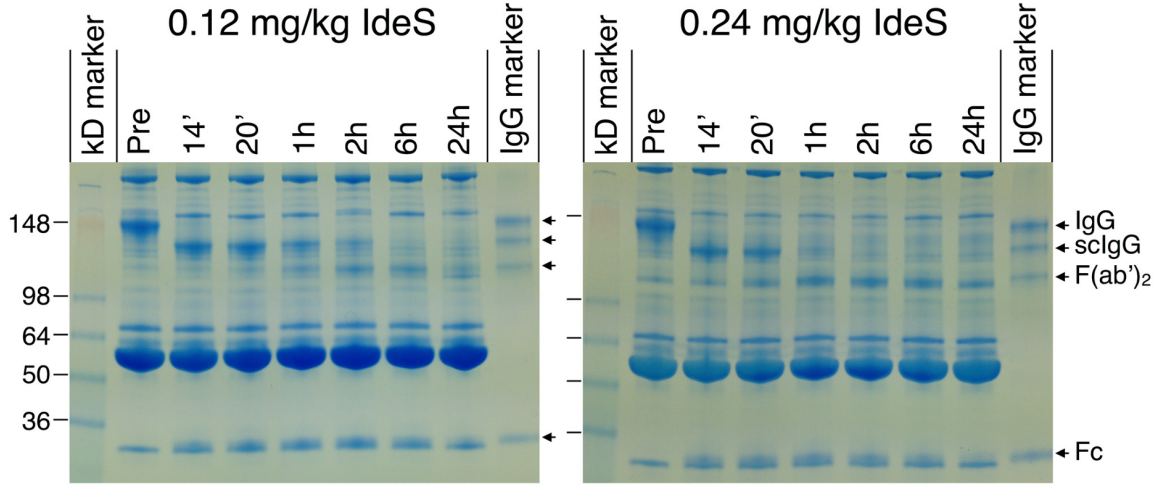
The 01 study showed complete removal of IgG and a good tolerability profile

Efficacy

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

Safety

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



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

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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

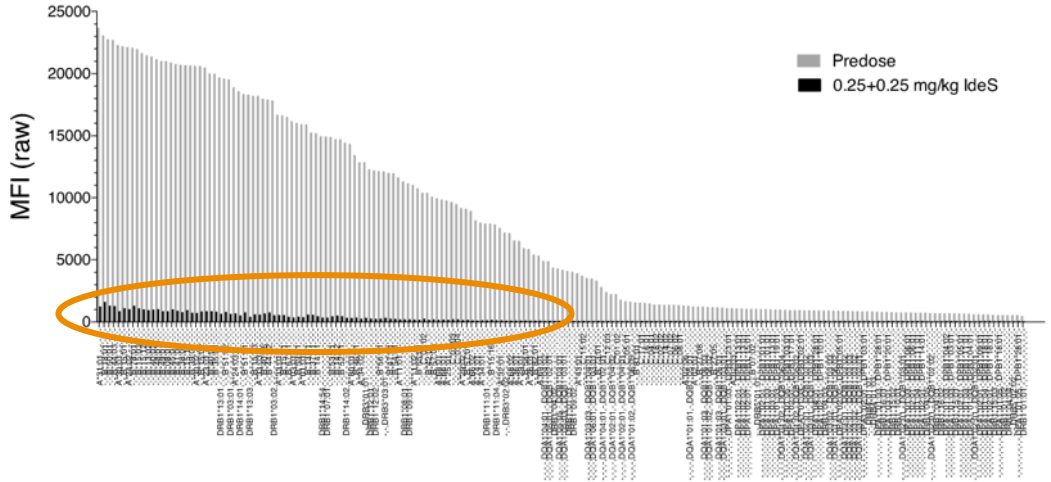
- Single-center, Single arm with ascending doses, open-label
- Transplantation not part of protocol

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)

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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

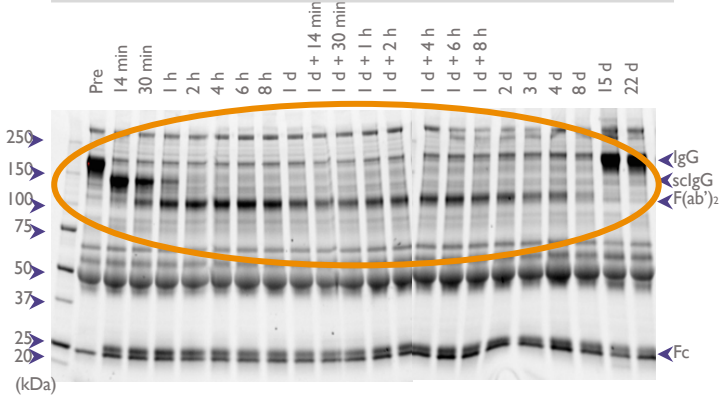
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

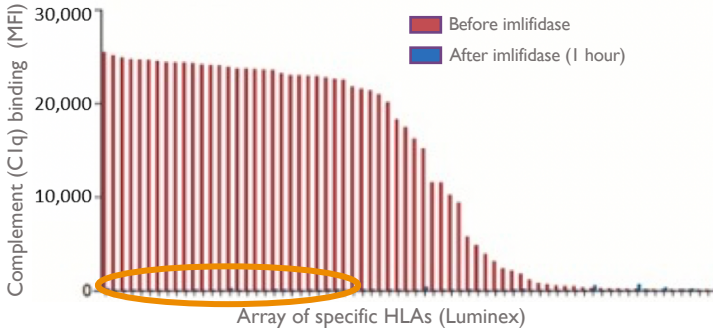
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment



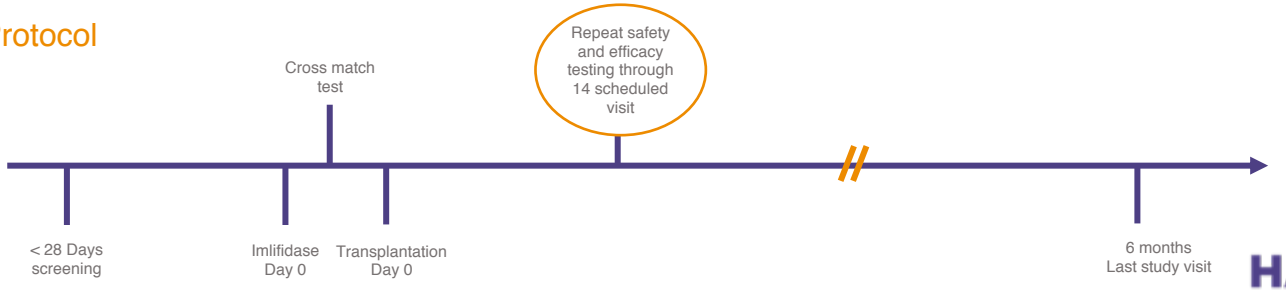
SDS-PAGE analysis of patient serum

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

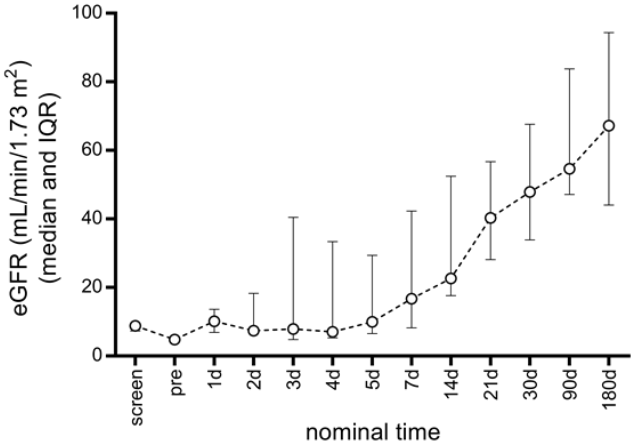
STUDY DESIGN

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

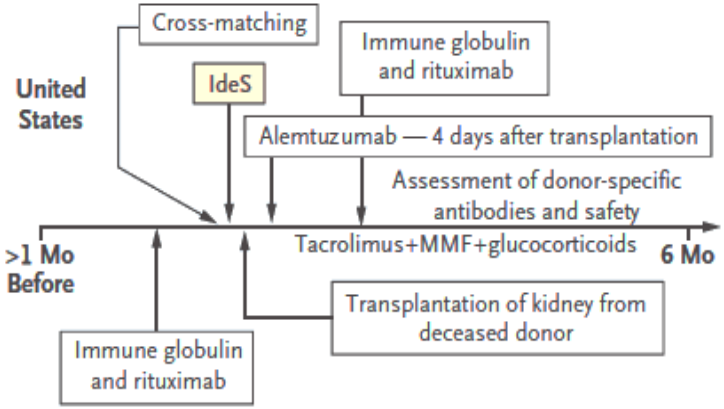
STATUS

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

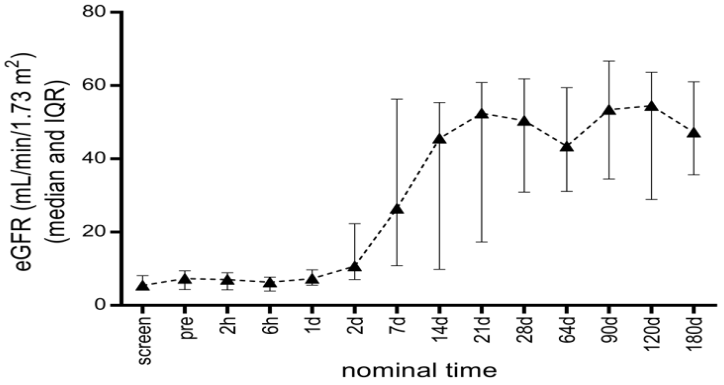
STUDY DESGIN

- 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

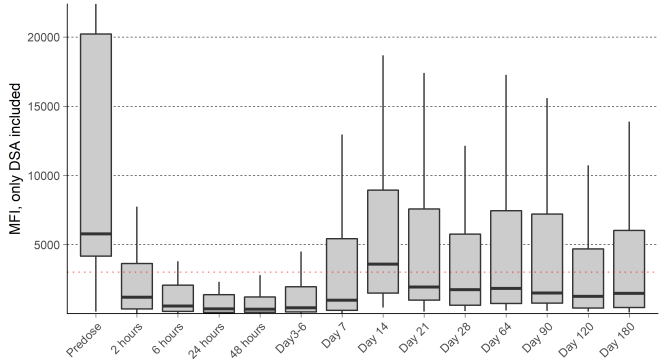
STATUS

Completed

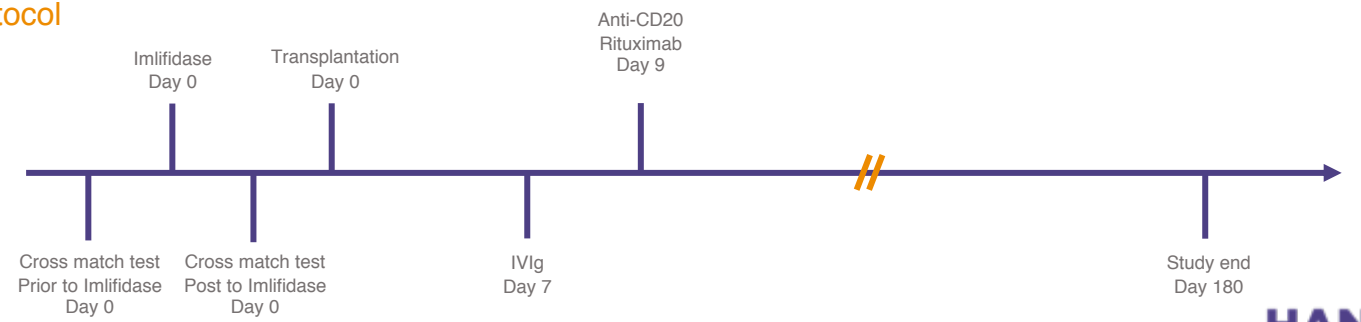
Graft function (eGFR) post imlifidase



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.

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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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Medical Advisory Board

Professor Stanley Jordan

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Professor Kathryn Wood

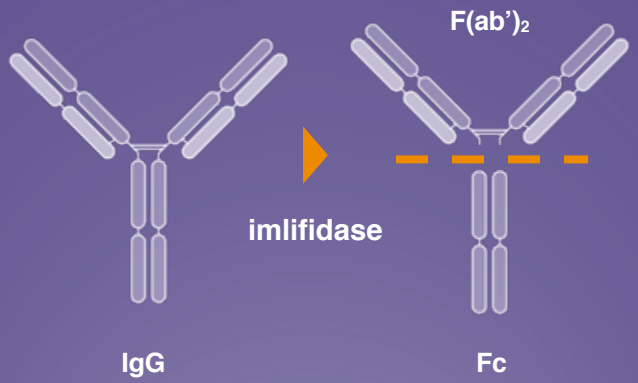
Ph.D. Fellow of the Academy of Medical Sciences, Professor of Immunology in the Nuffield Department of Surgical Sciences, University of Oxford, England, runs the Transplantation Research Immunology Group

CMC - Imlifidase

Imlifidase, a novel approach to effectively eliminate pathogenic IgIG

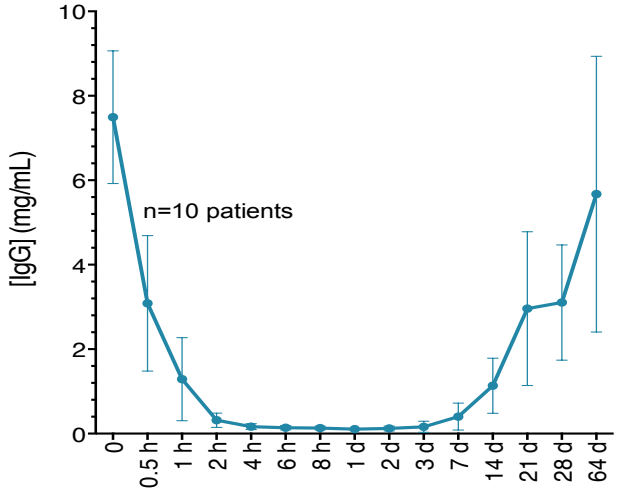
Proven mechanism of action

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one $F(ab')_2$ fragment and one homo-dimeric Fc-fragment



Inactivation of IgG in human serum

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

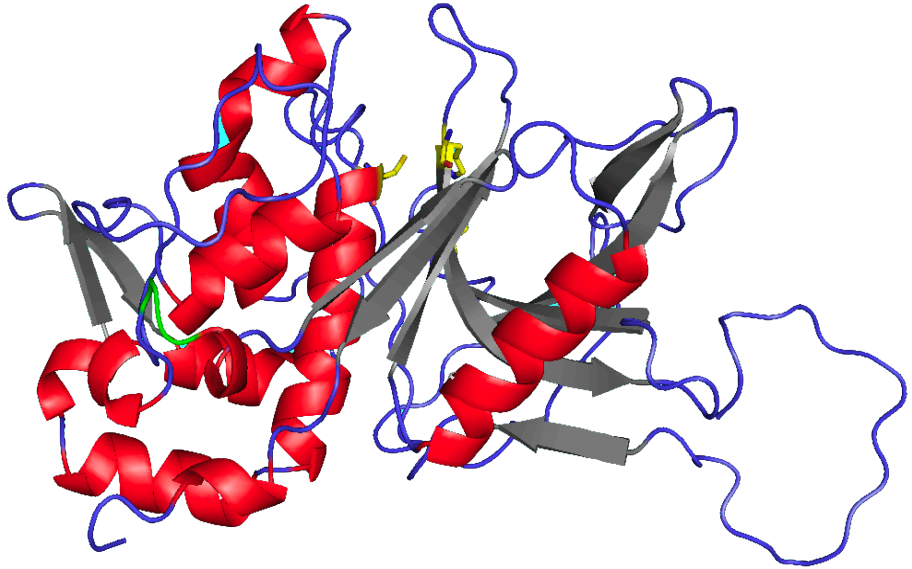


Our IgG antibody-cleaving enzyme

Origins from Streptococcus pyogenes

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

Imlifidase consists of 311 amino acids



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Imlifidase is a lyophilized product formulation with a shelf life of 12 months at 2-8° Celsius storage

Imlifidase will be infused in 15 minutes

- The product for commercial supply will be a lyophilized (cold chain) powder concentrate (11 mg solution) for infusion currently with a claimed shelf life of 12 months at 2-8°C storage. Ongoing stability studies indicate a shelf life of at least 24 months.
- Each vial is filled with 1.2 mL of a 10 mg/mL solution before freeze drying (=12 mg). Extractable volume after reconstitution with 1.2 mL sterile water is 1.1 mL of 10 mg/mL solution - resulting in 11 mg product
- The protein concentration,10 mg/mL, has desirable characteristics with respect to not form aggregates
- Continuous stability programs ongoing to study changes in protein characteristics and performance.
- Imlifidase dose is clinically set to 0.25 mg/kg bodyweight (11 mg / 0.25 mg/kg = 44 kg (BW) / vial content) 2R vial size is suitable for the content

Supply Chain for imlifidase in kidney transplantation

Drug Development

Drug substance Manufacturer (API)

Logistics of bulk product
- handling of drug substance product

Final product (packaging and labelling)

Distribution

Clinics and hospitals

Patients

Drug product manufacturer (upscaling)

Manufacturing will be done in close collaboration with highly experienced European based third party CMOs

Drug substance production process (API)

Biotechpharma

Fermentation/ harvesting
- Working Cell Bank
- Pre-Cultivation
- Main Cultivation
- Cell Harvest

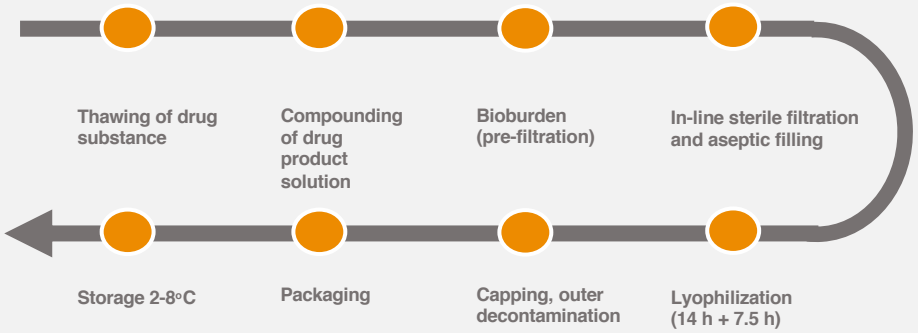
Protein purification
- Cell Disruption
- Protein Release

Protein purification cont.
- Ion Exchange Chromatography
- Ceramic Hydroxy Apatite Chromatography
- Hydrophobic Interaction Chromatography
- Ultrafiltration/ Diafiltration

Filling
- Formulation, filtration, filling and storage (-80°C)

Drug product production process (upscaling)

Baxter



biotechpharma

Facts
- Based in Vilnius, Lithuania
- Start-up Year: 2004
- Capacity: 300 L fermentor (1000 L fermentor in 2020)
- Certifications: GMP compliance, Manufacturing authorization license
- Inspections: National regulatory agency (EU), EU/US customer inspections, FDA mock inspection

Baxter

Facts
- Based in Halle/Westfalen Germany
- Start-up Year: 2001 (contract manufacturing)
- Capacity: 6-35 L drug product solution per batch (5,000-30,000 vials)
- Certifications: GMP compliance, Manufacturing authorization license
- Inspections: National regulatory agency (EU), FDA, EU/US customer inspections

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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

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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

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

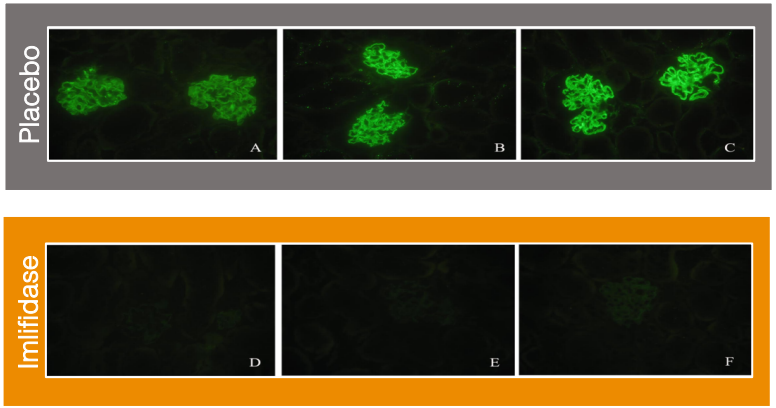
STUDY DESIGN

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

STATUS

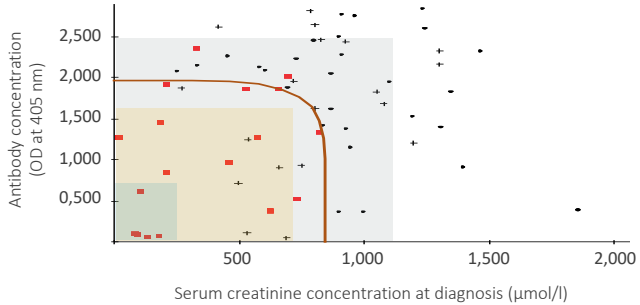
Ongoing

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.

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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

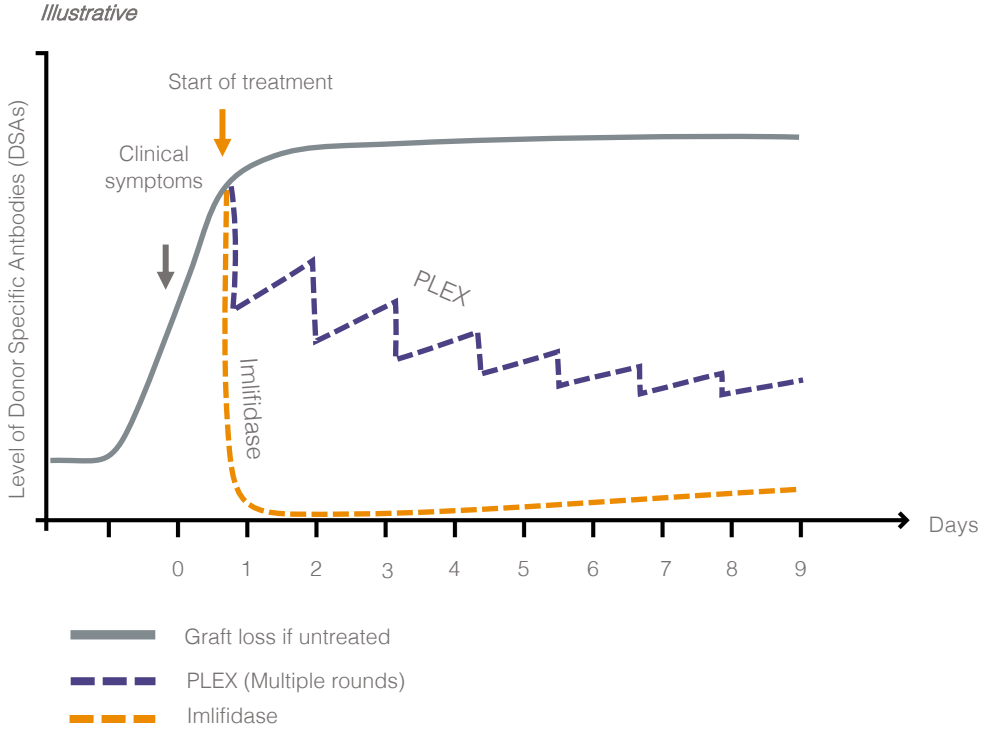
STUDY DESIGN

- 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

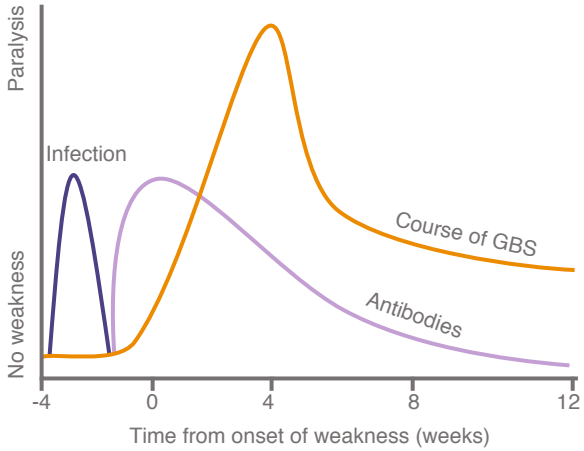
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing

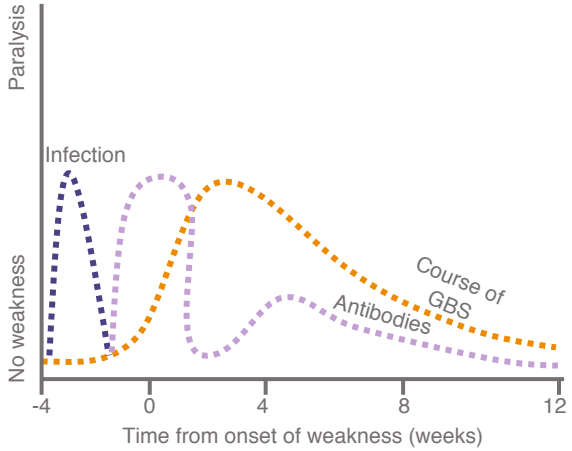
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



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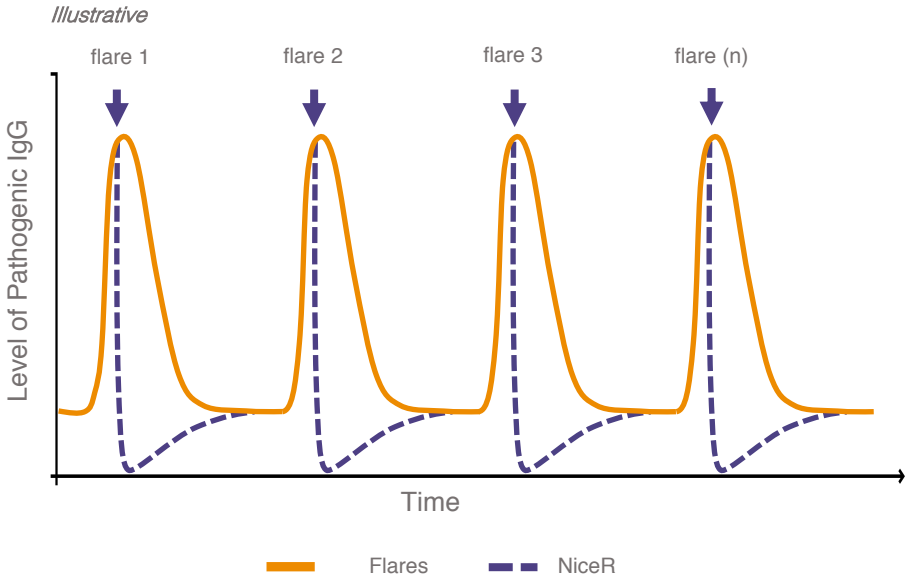
Pre-clinical programs

“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

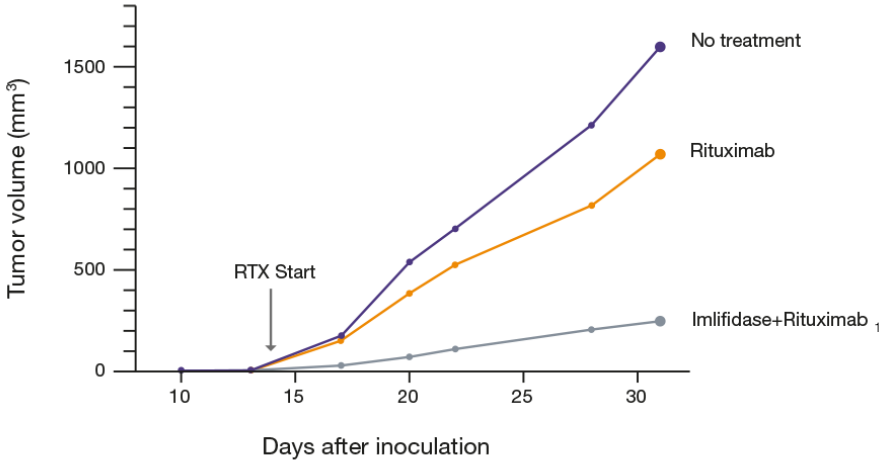


Imlifidase / NiceR can potentially improve the therapeutic effect in oncology (EnzE)

Proof of concept demonstrated in vivo for mice

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

Mice with human IgG (~9mg/mL)



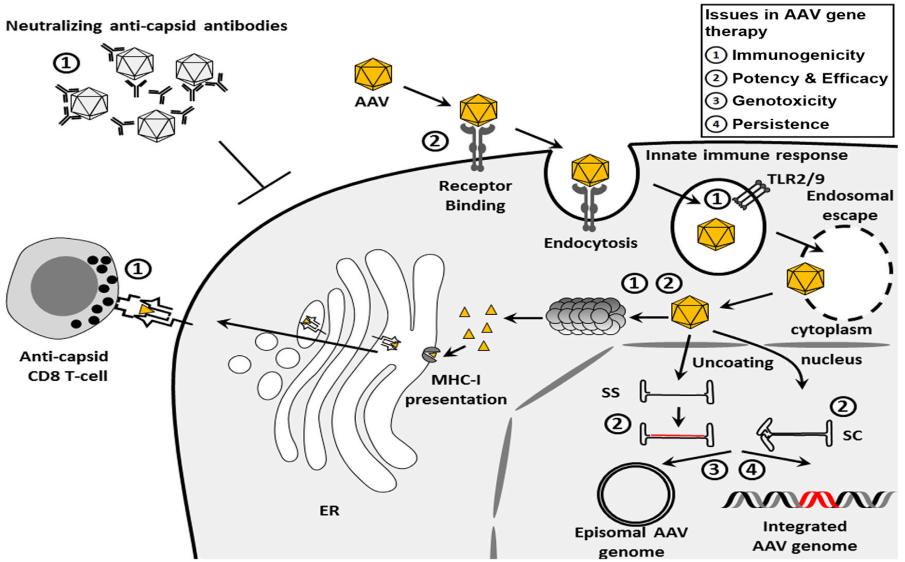
[1] Järnum et al. Mol Cancer Ther 2017;16:1887-1897

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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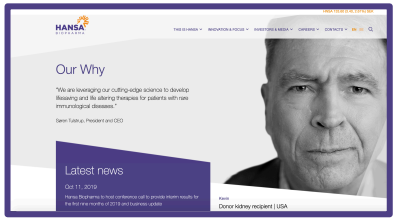

Calendar

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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