HANSA BIOPHARMA

Presentation
SEB Nordic Seminar

Copenhagen January 8, 2020

Christian Kjellman, SVP and CSO

Forward-looking statement

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

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Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- 74 employees (~3/4 in R&D) at Dec 31, 2019
- Operations in Sweden, US & Europe
- Market cap: SEK ~3.5bn (USD ~350m) Dec 31 , 2019
- Listed on Nasdaq OMX Stockholm (HSNA)

Leader in immunomodulatory enzymes for rare IgG-mediated diseases

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

Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients (MAA under review by EMA)
- 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

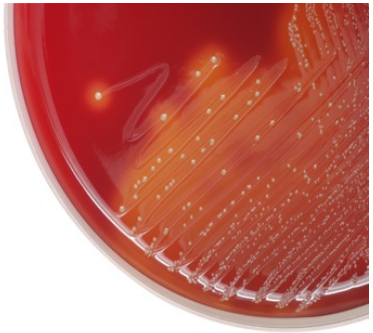
• Cash position	9m'19 SEK 680m
• Operating Cash Flow	9m'19 SEK -260m
• R&D cost	9m'19 SEK -135m
• Net Profit	9m'19 SEK -249m

…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

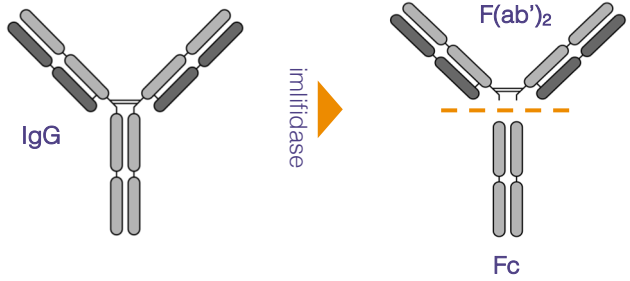
Origins from Streptococcus pyogenes

- Species of Gram-positive, spherical bacteria
- known to cause e.g. strep throat infection (*pharyngitis*)



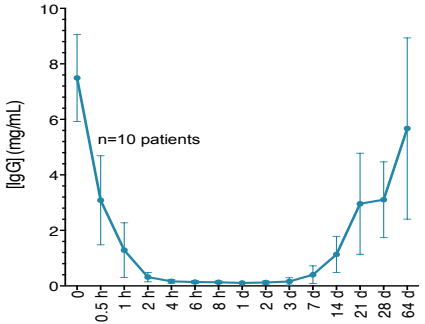
Imlifidase, a unique IgG antibody-cleaving enzyme

- 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

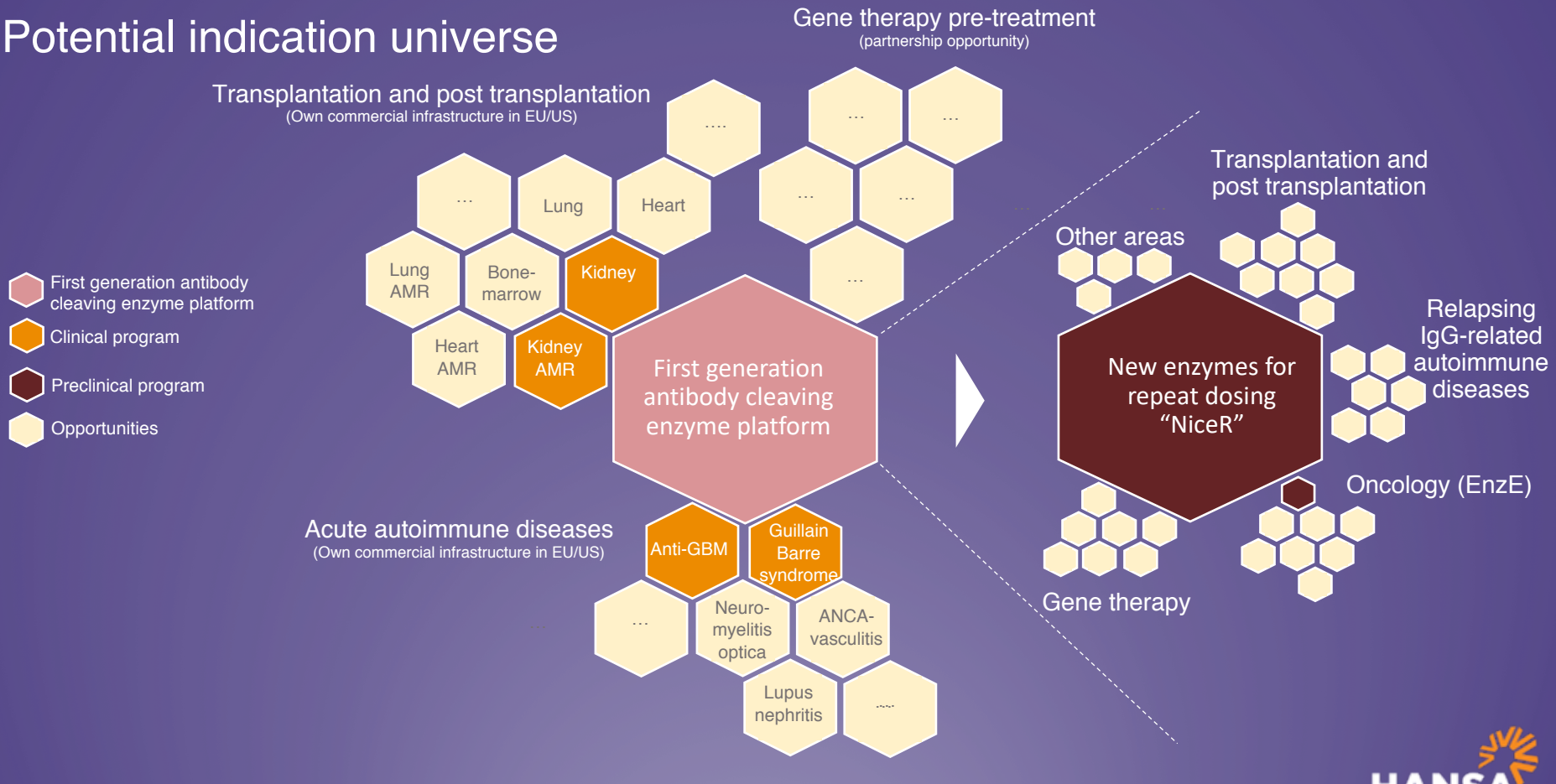


Imlifidase inactivates IgG in 2 hours

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



Potential indication universe



Imlifidase may enable transplantation in highly sensitized kidney patients

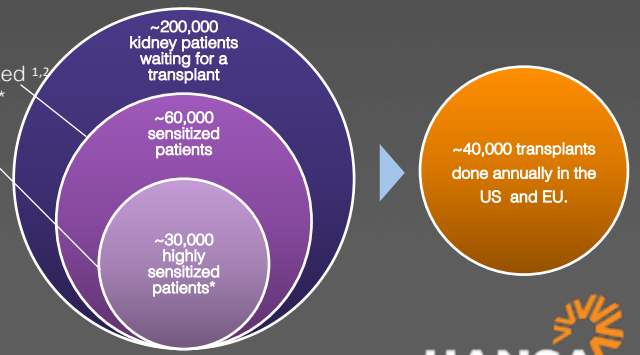
Creating equity for highly sensitized patients

- 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

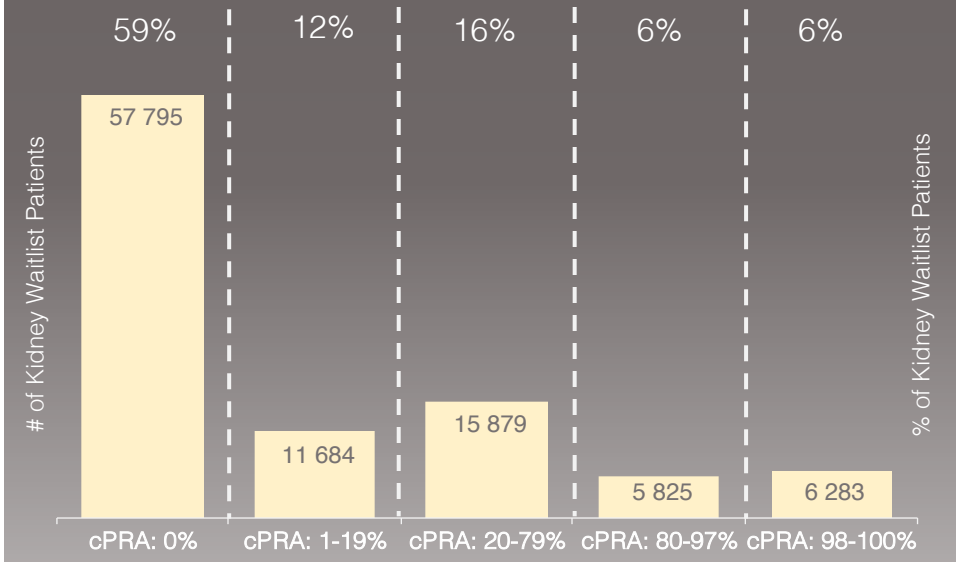
Approximately 10-15% of patients on wait list are highly sensitized

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 transplant of highly sensitized patients
- Allocation Systems such as KAS and Eurotransplant relies on cPRA score to characterize patients for transplant

US Kidney Waitlist Patients by cPRA 2018



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

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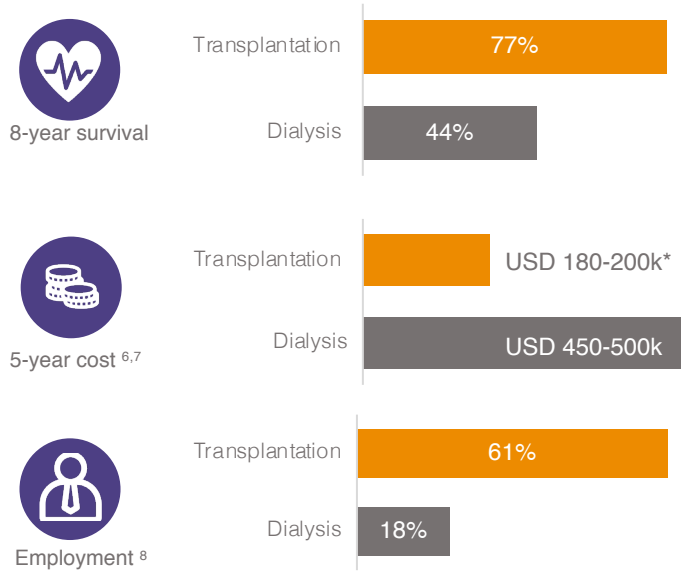
Kidney transplantation saves lives, reduce costs and increase quality of life incl. societal gains for the society

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. Age, gender and co-morbidity differences did not explain the large work capacity benefit of transplantation[4]
- Lastly, extended dialysis is also a high-risk factor for removal from the transplant wait list[5]

[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] www.usrds.org
[7] Shehata et al, Transfus Med Rev 201, 24 Suppl 1: S7-S27
[8] Jarl et al. Transplantation, 2018, 102:1375-1381

Transplantation leads to better outcomes



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

Imlifidase has in 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	8 patients
	Design	Multicenter, multinational, single-arm, open-label
	Main objective	Efficacy in creating a negative crossmatch test

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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

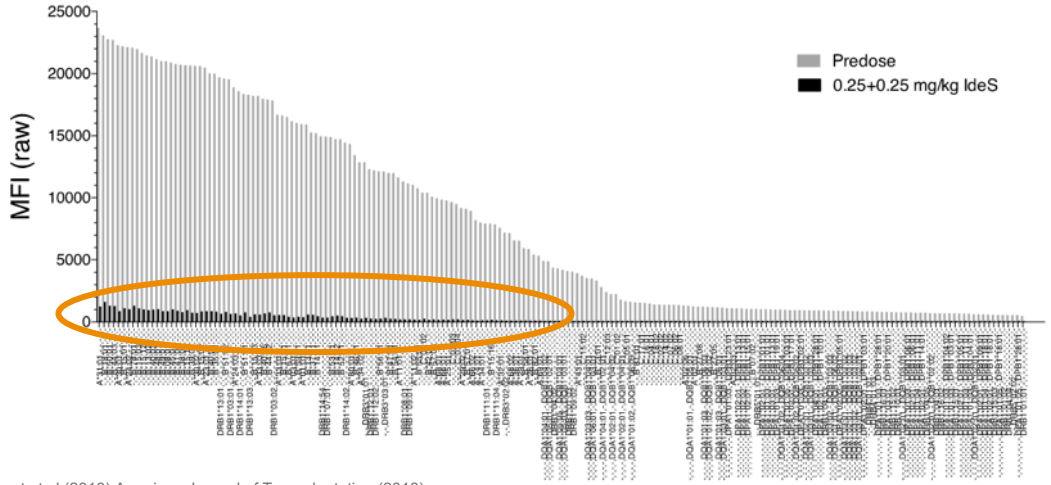
- Single-center, Single arm with ascending doses, open-label
- Transplantation not part of protocol

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 proofed 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

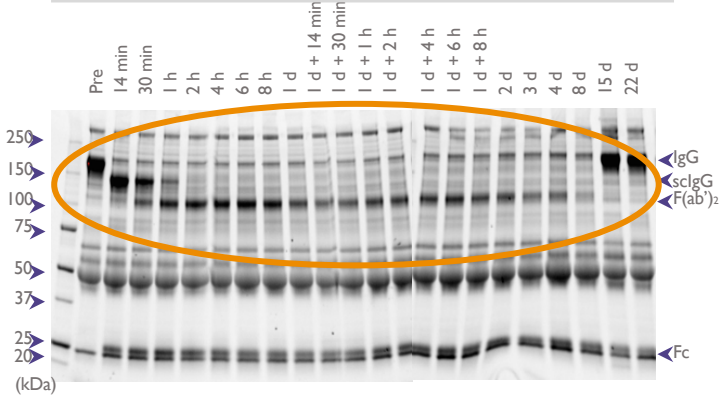
- Single-center, single-arm, open-label, no prior desensitization
- Similar design as 13-HMedIdeS-02 but transplantation part of protocol
- In deceased and living donors

STATUS

Completed

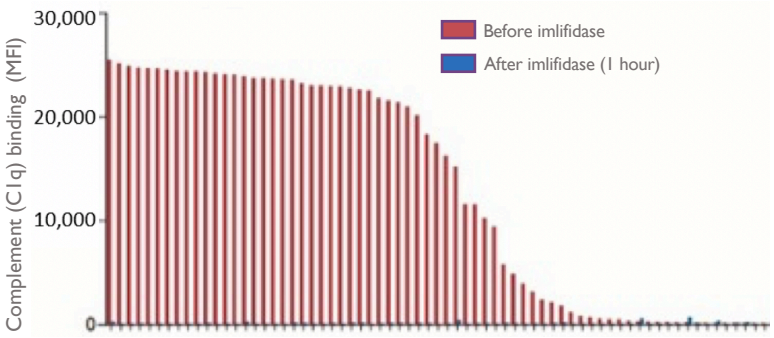
- Proofed safety and efficacy with HLA antibodies at acceptable levels; enabling transplantation in all patients

Analysis of IgG in patient serum before and after imlifidase treatment



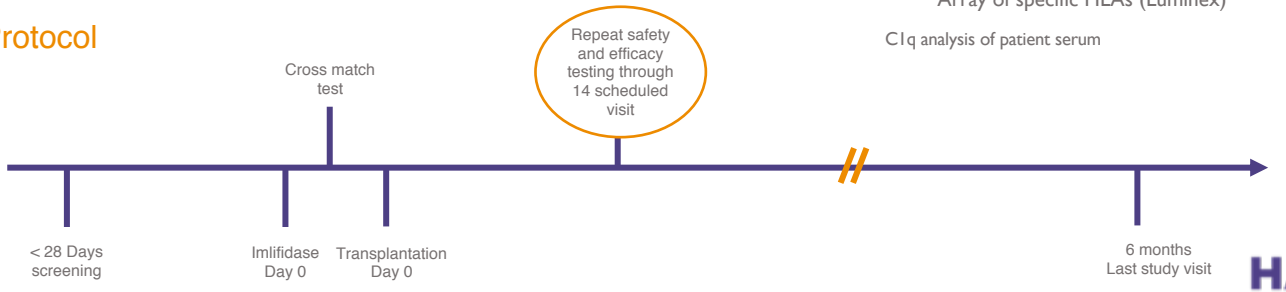
SDS-PAGE analysis of patient serum

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 proofed 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

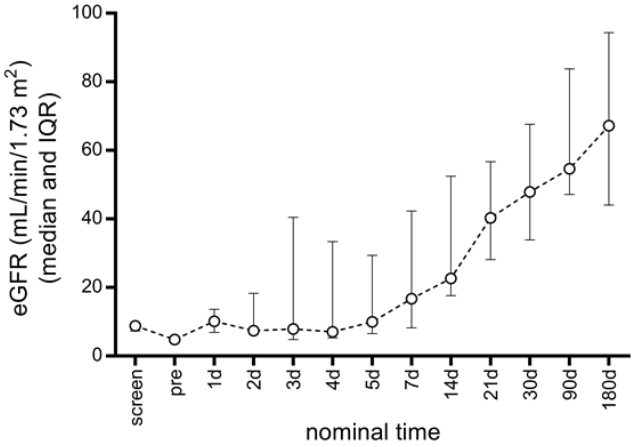
COMMENTS

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

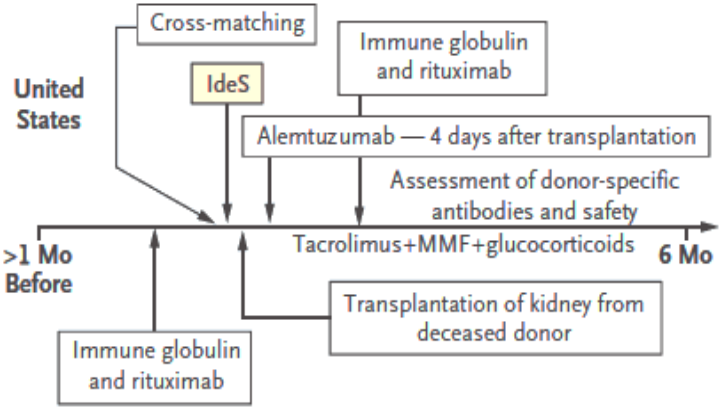
STATUS

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 proofed safety and efficacy thereby 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

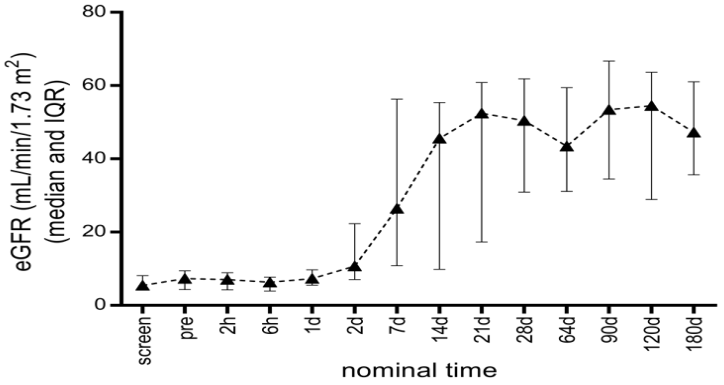
STUDY DESGIN

- 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

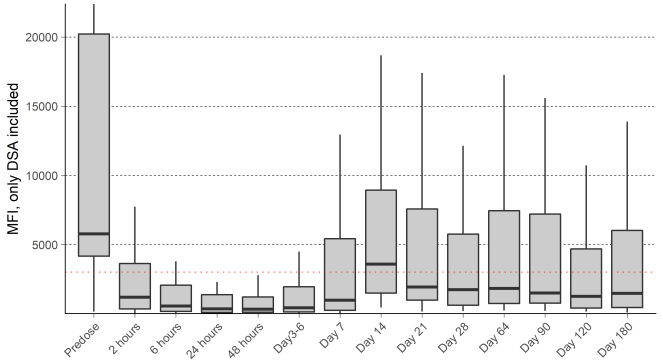
STATUS

Completed

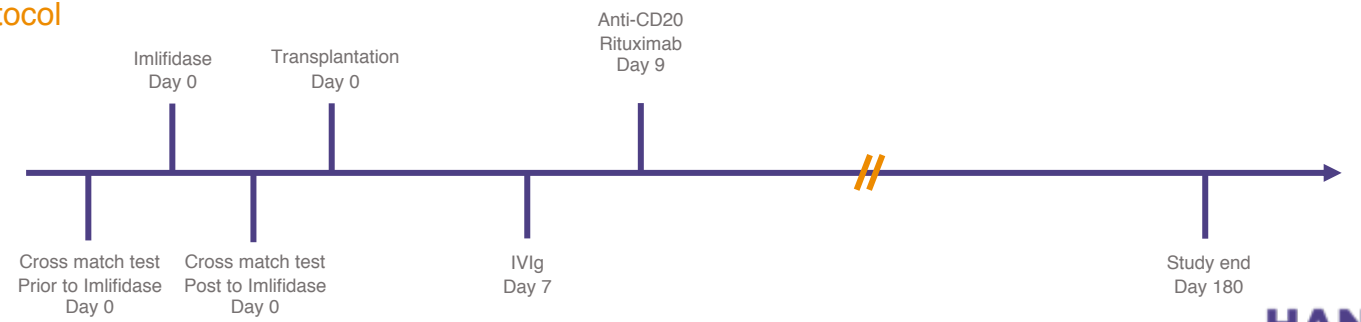
Graft function (eGFR) post imlifidase



DSA level pre-dose and post imlifidase



Protocol



Montgomery (ATC, Boston 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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Agreement with the FDA on a regulatory path forward in the US; EMA review process on track

Imlifidase in kidney transplantation

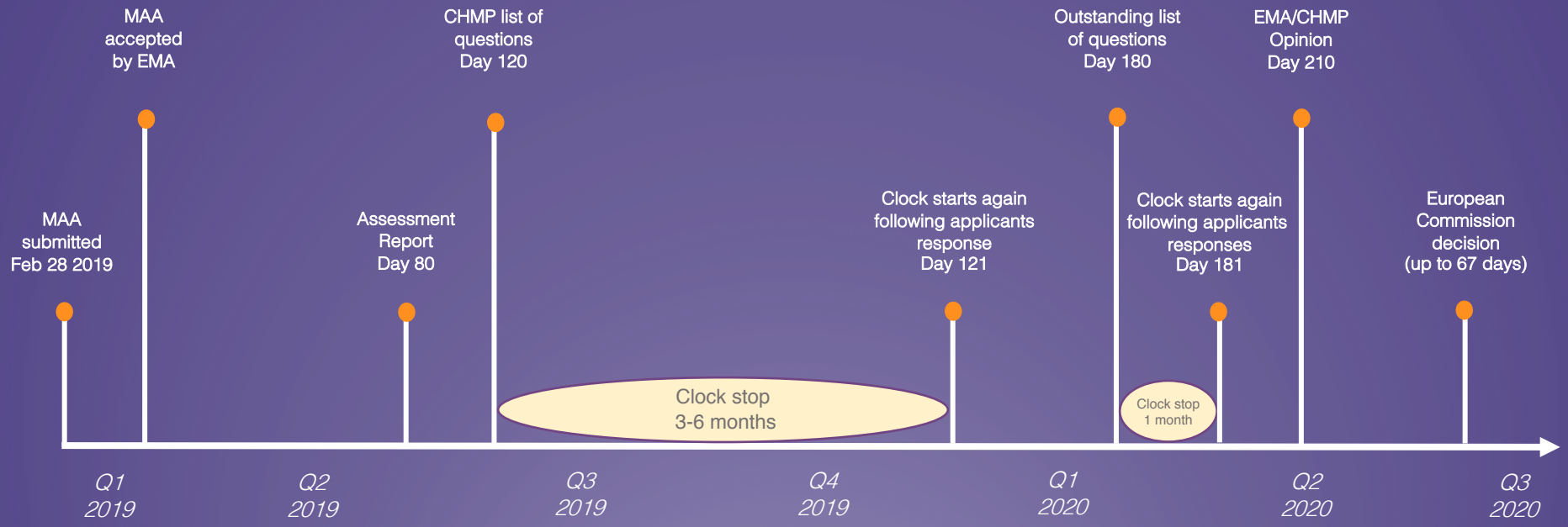
U.S. (FDA)

- Hansa Biopharma will conduct a randomized, controlled clinical study in a limited and well-defined group of very highly sensitized kidney patients using eGFR (kidney function) after 12 months as a surrogate endpoint
- Results from this clinical study should support BLA submission by 2023 under the accelerated approval pathway

Europe (EMA)

- Regulatory review process progressing as expected; Day 120 answers submitted on December 22, 2019
- Opinion from Committee for Medicinal Products for Human Use (CHMP) expected during the second quarter of 2020
- Decision by European Commission expected during the summer 2020

The EMA process towards marketing authorization



Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1[1]	Pivotal program/ Phase 2[2]	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients	Completed	Completed	Completed	Ongoing *)		EU: CHMP Opinion US: Initiation of clinical study to support BLA submission by 2023
	Anti-GBM antibody disease	Completed	Completed	Ongoing			Complete enrolment
	Antibody mediated kidney transplant rejection (AMR)	Completed	Completed	Ongoing			Complete enrolment
	Guillain-Barré syndrome	Completed	Completed	Ongoing			Complete enrolment
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 to support BLA submission by 2023

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Appendix

Anti-GBM, a rare acute autoimmune disease affecting kidneys and lungs

2/3 of Anti-GBM patients lose their kidneys[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 one in a million annually (~900 worldwide[1,2]) with majority of patients lose kidneys[2], requiring chronic dialysis and kidney transplantation.
- The study is an open label investigator-initiated Phase 2 with Professor Mårten Segelmark at Linköping 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 on top of standard care consisting of plasmapheresis, steroids and cyclophosphamide.
- 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

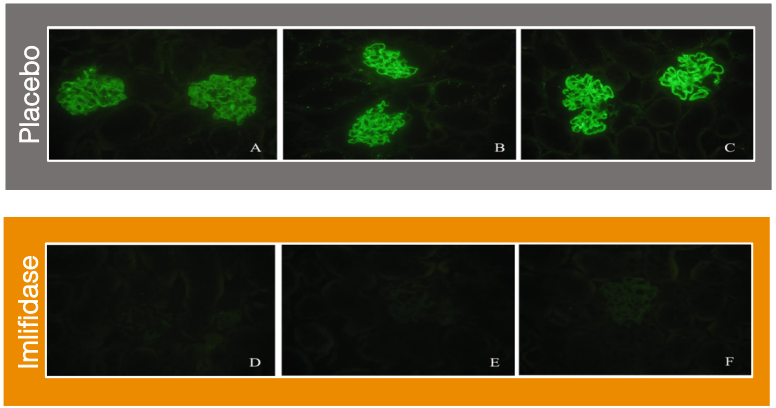
STUDY DESIGN

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

STATUS

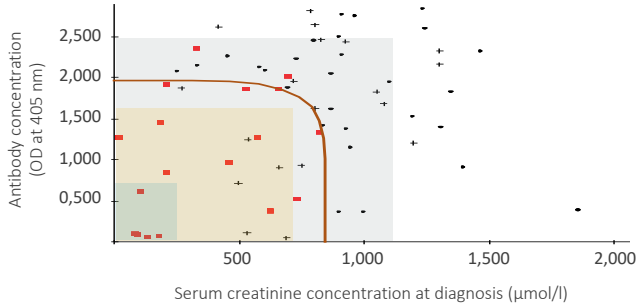
Ongoing

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] 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.
- The first patient out of targeted 30 patients was treated with imlifidase in Q3 2019. Enrollment is planned to take 12 months with an expected topline data read out 2H 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

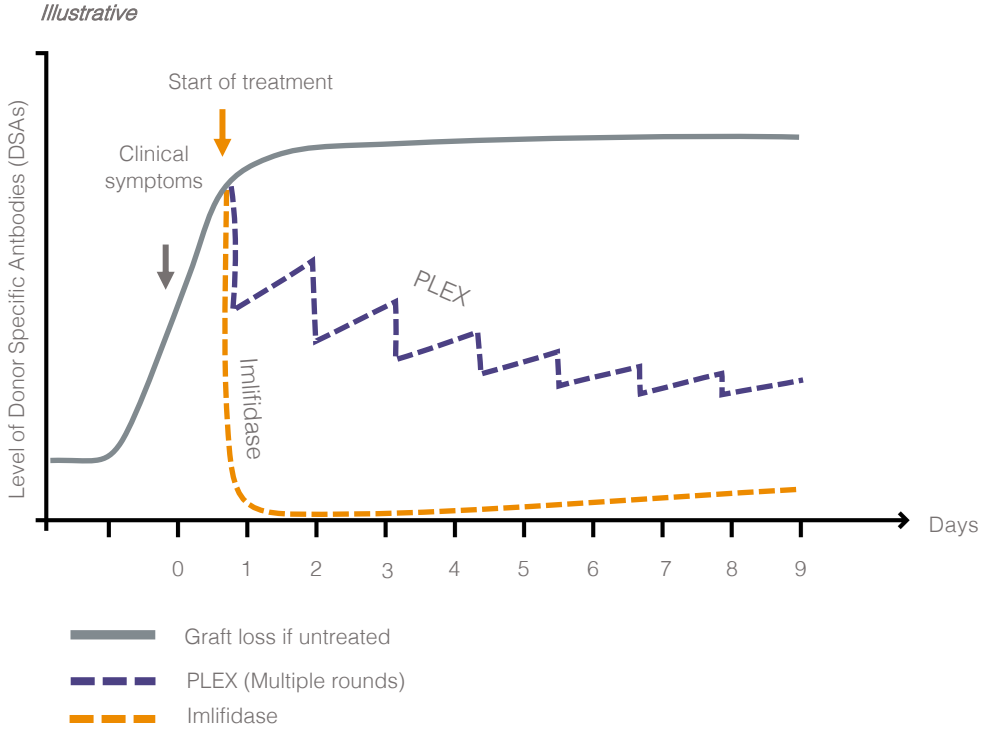
STUDY DESIGN

- 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



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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)
- The GBS study aims at enrolling up to 30 patients at ten clinics in the EU over 18 months. Topline data is expected in H1 2022
- 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

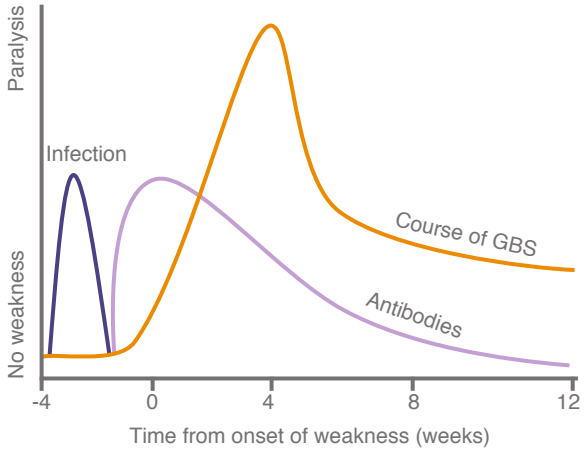
- Study is an open-label, single arm, multi-center trial evaluating safety, tolerability and efficacy of imlifidase, in combination with standard of care, IVIg, to treat GBS

STATUS

Ongoing

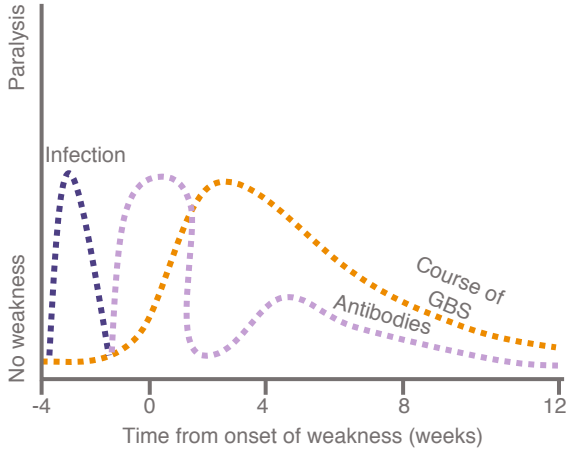
Today's Standard of Care IVIg or PLEX

Illustrative



Potential with imlifidase

Illustrative



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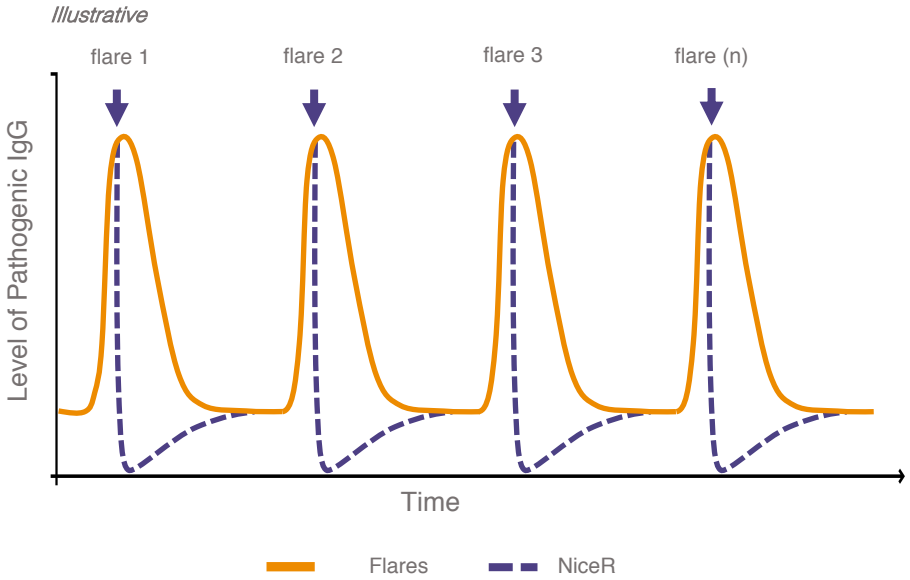
“NiceR” – new enzymes for repeat dosing; potentially enabling treatment of relapsing diseases

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 enable repeat dosing for inactivation of flares

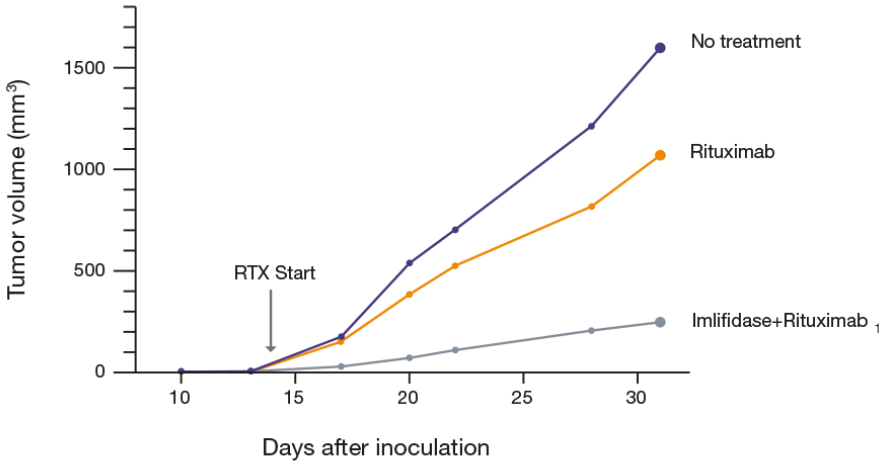


EnzE can potentially improve the therapeutic effect in oncology

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)



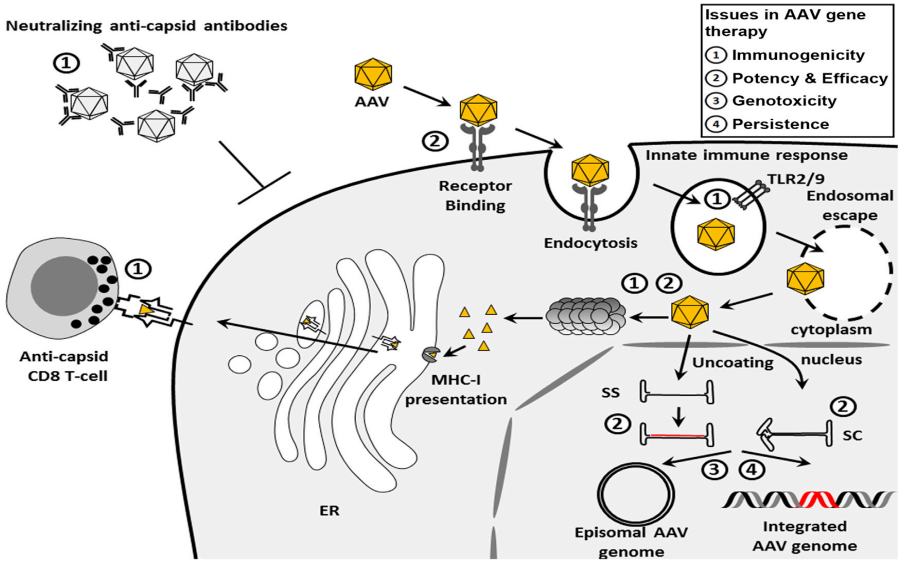
[1] Järnum et al. Mol Cancer Ther 2017;16:1887-1897

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 expression *in vivo*; however in many cases the human immune system have developed preformed neutralizing anti-AAV that prevents effective and safe use
- Today experimental protocols are used based on plasma-pheresis, or with immunosuppressants; however these protocols protocols have not demonstrated sufficient efficacy and safety
- 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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