



Goldman Sachs Biotech
Symposium

London September 6, 2019



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

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Hansa Biopharma's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Hansa Biopharma's strategy and its ability to further grow, risks associated with the development and/or approval of Hansa Biopharma's products candidates, ongoing clinical trials and expected trial results, the ability to commercialize imlifidase, technology changes and new products in Hansa Biopharma's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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

Continued progress on strategic agenda; Imlifidase highlighted at ATC

Highlights for the second quarter 2019

- Good progress on strategic agenda
 - Guillain Barré Syndrome (GBS) study started - expansion outside transplantation and into auto-immune diseases continues
 - Divestment of equity holding in Genovis
 - Advancement across pipeline
 - Expanding our presence in Europe and the U.S
- High level of excitement at the 2019 American Transplant Congress, with imlifidase highlighted in three presentations. Plenary abstract by Dr. Huang won the “People’s Choice Award”
- Advancing imlifidase toward commercialization for kidney transplantation in highly sensitized patients. MAA under review by EMA; complementary analysis being conducted in the U.S.
- All resolutions were passed at the AGM 2019
- Cash position stood at SEK 763m (~USD 80m) end of June 2019



Continued advancement toward commercialization

Imlifidase in kidney transplantation

Europe (EMA)

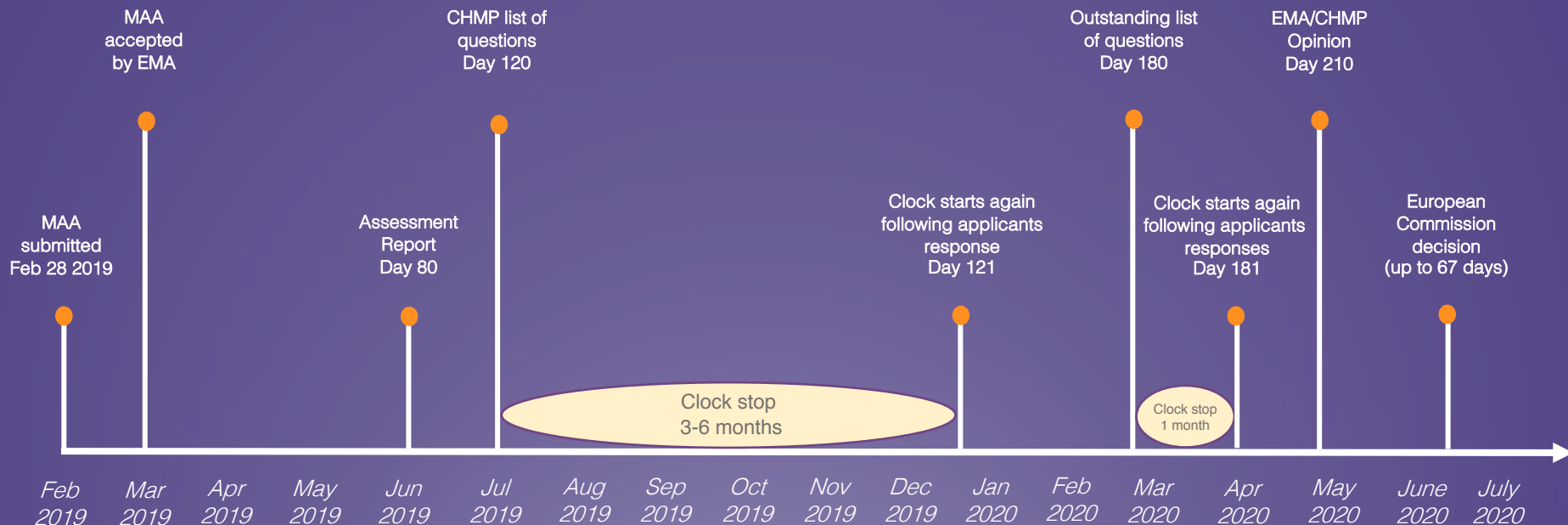
- MAA for imlifidase accepted end of Feb'19; regulatory review progressing
- Opinion from EMA expected within 210 working days, plus clock stops

U.S. (FDA)

- Conducting complementary transplantability analyses comparing imlifidase-treated patients and matched controls from U.S. transplant registry
- Upon completion of analyses, Hansa to request FDA meeting to determine U.S. regulatory path forward. Meeting expected in H2'19
- U.S. administration announced initiatives to increase transplant rate and quality of life for dialysis patients and also reduce expenditure to treat chronic and end-stage renal disease



EMA – The process towards approval



EMA/CHMP Assessment

- Evaluation of benefit and risks
- Assessment of Risk Management Plan
- Assessment of product information
- Assessment on need for post safety/efficacy studies
- Preparation of Risk Management Plan Summary

Anti-GBM enrolling; AMR & GBS receives CTA approval. NiceR lead candidate selected

Advancement across our pipeline in 1H 2019

Anti-Glomerular Basement Membrane Disease (Anti-GBM)

- 9 patients enrolled out of targeted 15. Adding more sites and expect the study to be fully enrolled by year-end

Antibody Mediated Rejection (AMR) in kidney transplant

- Phase 2 study with imlifidase in AMR received CTA approval in March'19. Recruitment of up to 30 patients initiated from eight sites in the U.S., Europe and Australia.
- Study is a randomized, open-label multi-center, active control study, designed to evaluate the safety and efficacy of imlifidase in eliminating DSA in acute AMR

Guillain-Barré Syndrome (GBS)

- Phase 2 study with imlifidase in GBS received CTA in April'19

NiceR

- Lead candidate selected in next-generation program for repeat dosing
- Development of a GMP process initiated; preparations for toxicology studies are ongoing



New GBS study marks continued expansion outside transplantation

Initiation of GBS Phase 2 study in Europe

- Guillain Barré Syndrome (GBS) is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system affecting 1-2 in 100,000 people annually
- CTA approval obtained for Phase 2 study in GBS in April
- Recruitment of up to 30 patients initiated at ten clinics in France, U.K. and the Netherlands.
- 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
- In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS



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				*)		MAA review by EMA Follow-up meeting with FDA
	Anti-GBM antibody disease						Complete enrolment
	Antibody mediated kidney transplant rejection (AMR)						Complete enrolment
	Guillain-Barré syndrome						Complete enrolment
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 et al. (2015) PLOS ONE 10(7).

² Lorant et al American Journal of Transplantation and 03+04 studies (Jordan et al New England Journal of Medicine)

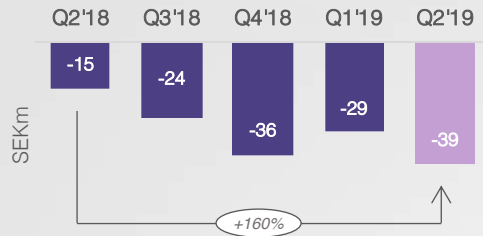
*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2.

A confirmatory study would need to be executed in case of approval.

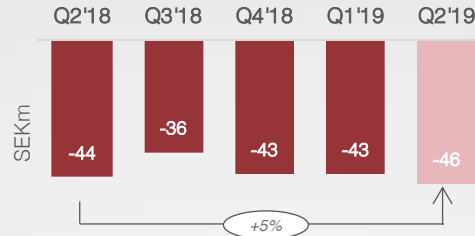
FDA: Discussion on path forward in the US is still ongoing.

SG&A and R&D spending increase with commercial preparation and pipeline advancement

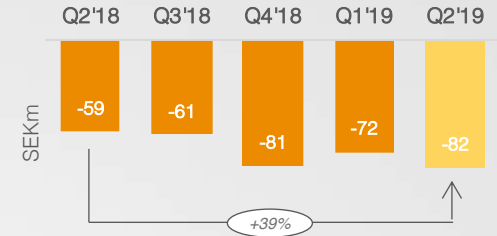
SG&A expenses (Q/Q)



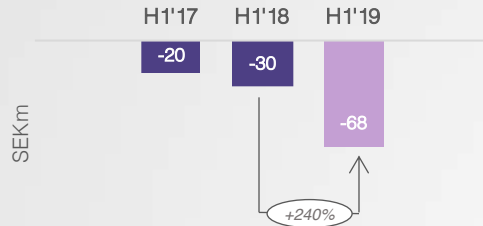
R&D expenses (Q/Q)



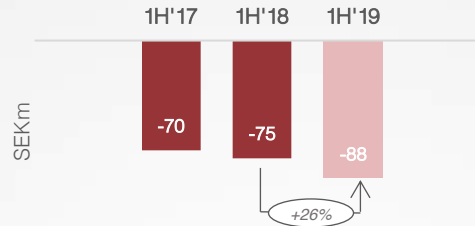
Net loss (Q/Q)



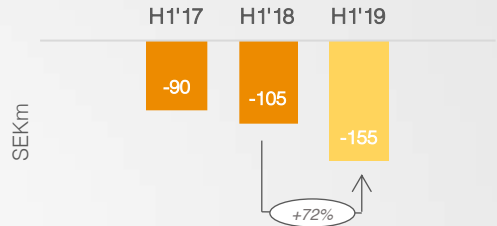
SG&A expenses (Y/Y)



R&D expenses (Y/Y)

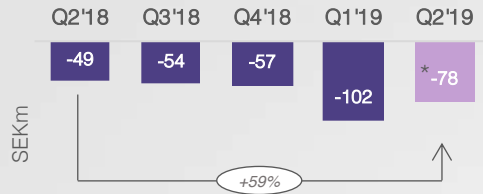


Net loss (Y/Y)

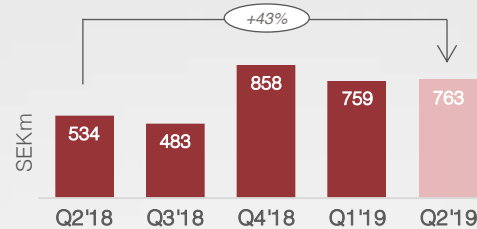


Cash flow follows increased activity level; positively impacted by the divestiture of equity stake in Genovis.

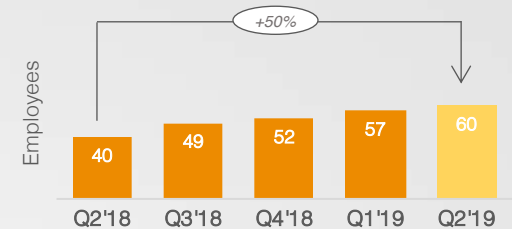
Operating cash flow (Q/Q)



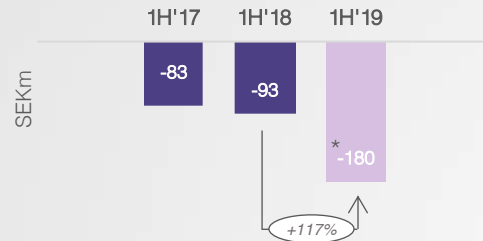
Cash & short term investments (Q/Q)



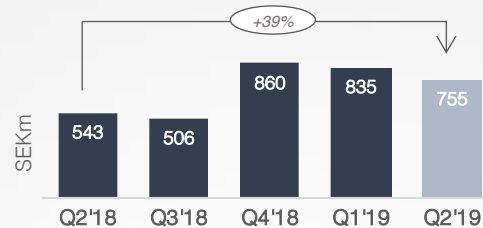
Number of employees (Q/Q)



Operating cash flow (Y/Y)

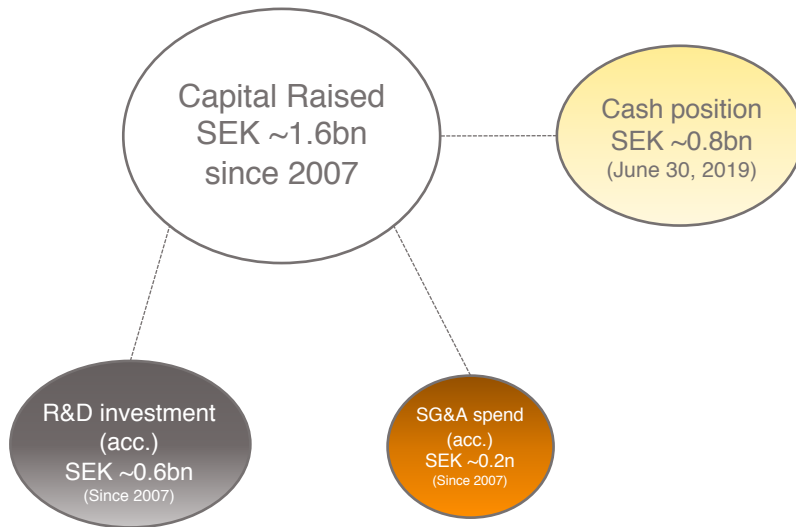


Shareholders equity (Q/Q)

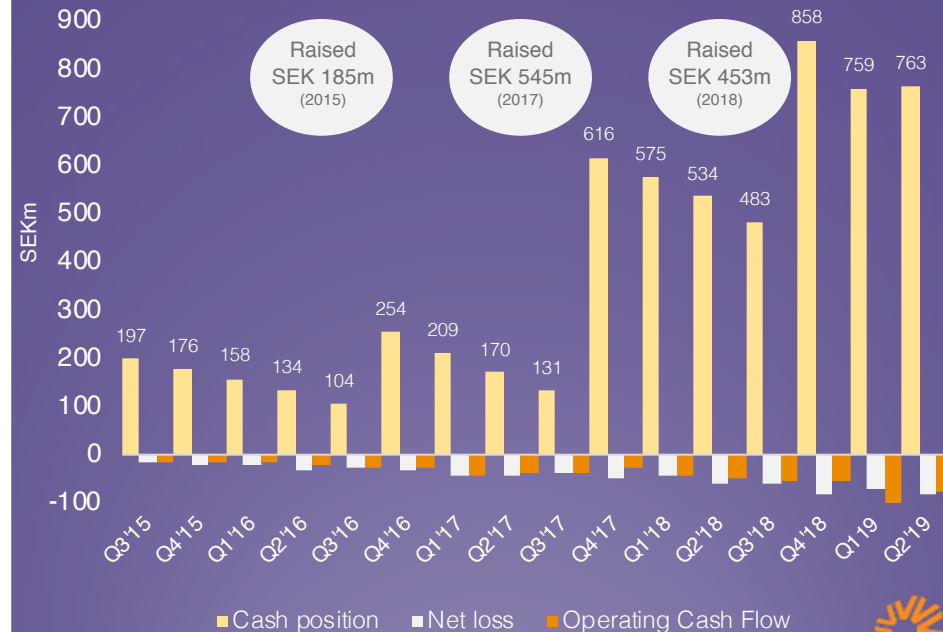


Hansa Biopharma is financed through 2020

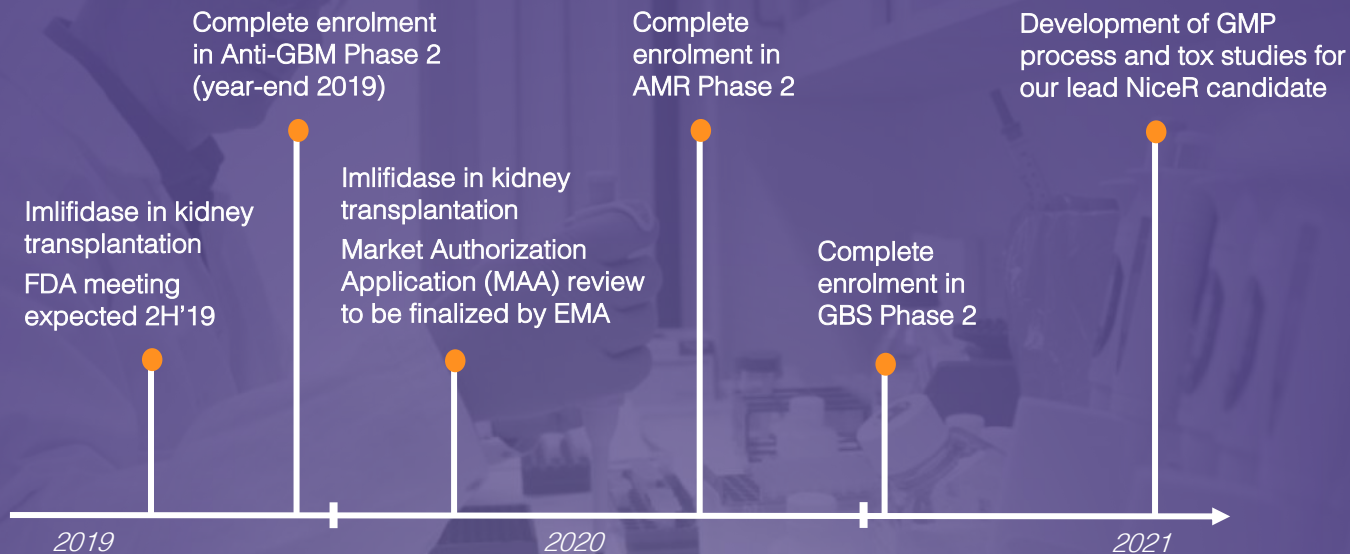
Significant capital raised since 2007



Solid cash position end of first half 2019



Milestones and near-term news flow



Appendix



Hansa Biopharma at a glance



Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- 60 employees (~3/4 in R&D) at June 30, 2019
- Operations in Sweden, US & UK
- Market cap: SEK 7.4bn (USD 791m)
- Listed on Nasdaq OMX Stockholm (HSNA)



Leader in immunomodulatory enzymes for rare IgG-mediated diseases

- Imlifidase can help meet a large unmet need by transforming the lives of people with rare disease
- A novel approach to specifically and effectively eliminate pathogenic IgG
- Opportunity in transplantation to increase survival rate and quality of life for dialysis patients
- Strong data from five clinical studies (one phase 1 and four phase 2 studies)
- PoC demonstrated in five clinical studies and published in peer-reviewed journals (e.g. NEJM & AJT)



Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients (MAA under review)
- 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	1H'19 SEK 763m	(FY'18 SEK 858m)
• Operating Cash Flow	1H'19 SEK -78m	(FY'18 SEK -205m)
• R&D cost	1H'19 SEK -46m	(FY'18 SEK -155m)
• Net Profit	1H'19 SEK -82m	(FY'18 SEK -248m)

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



Hansa Biopharma

- a unique immunomodulatory enzyme technology with near-term commercial opportunity



Imlifidase works!

- Proven mechanism of action with a consistently demonstrated ability to rapidly and effectively deplete IgG across five clinical studies
- Clearly demonstrated ability to remove the immunological barrier to kidney transplantation



Addresses a clear unmet need

- Enables kidney transplantation for a new segment of patients advancing them to standard of care
- Additional indications in rare, autoimmune diseases with no approved treatment options
- US administration is working on a new kidney care reform to increase survival rate and quality of life for dialysis patients



Well positioned for commercial success

- Highly concentrated transplant center market, reachable by a small commercial organization of rare disease experts
- Expanding commercial infrastructure
- MAA under review by EMA potential launch in 2020
- Strong protection
 - 11 patent families
 - Orphan drug status
 - Significant knowhow



Rich pipeline with significant potential

- Leveraging a strong technology platform
- Three phase 2 projects in other IgG-mediated indications incl. Anti-GBM, AMR and GBS – all with Orphan Drug status
- Path to develop less immunogenic enzymes to enable repeat dosing and further commercial opportunities

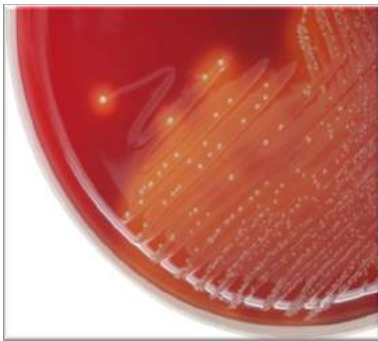
Technology snapshot

– *imlifidase, a novel approach to specifically and effectively eliminate pathogenic IgG*



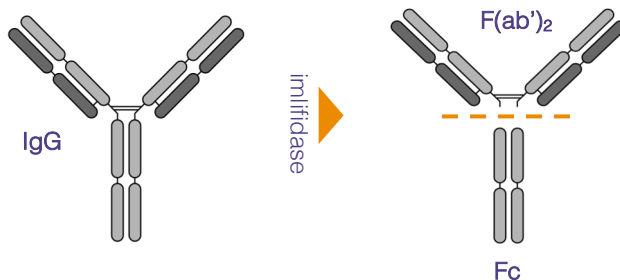
Origins from *Streptococcus pyogenes*

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



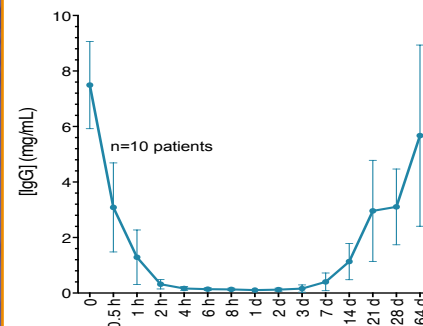
Imlifidase, a unique IgG antibody-degrading enzyme with proven mechanism of action

- 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









Imlifidase has proven to be highly efficacious

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



Completed and ongoing studies with imlifidase in kidney transplantation

STUDY	SUBJECTS/ COUNTRY	CLINICAL TRIALS.GOV ID	STUDY DESIGN	PRIMARY ENDPOINT	SECONDARY ENDPOINTS	STATUS	PUBLICATION
Study 01 Phase 1	29 subjects 	NCT01802697 (2013/2014)	<ul style="list-style-type: none"> Randomized placebo controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase 	Complete	PLOS ONE (2015) ¹
Study 02 Phase 2	8 subjects 	NCT02224820	<ul style="list-style-type: none"> Single-center, single-arm, open-label 	<ul style="list-style-type: none"> Dosing resulting in HLA-antibody reduction (MFI<1100) 	<ul style="list-style-type: none"> Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay) 	Complete	Lorant et al (2018) American Journal of Transplantation ²
Study 03 Phase 2	10 subjects 	NCT02475551	<ul style="list-style-type: none"> Single-center, single-arm, open-label No prior desensitization 	<ul style="list-style-type: none"> Safety: AEs, clinical laboratory tests, vital signs, ECGs 	<ul style="list-style-type: none"> Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay) 	Complete	The New England Journal of Medicine (2017) ³
Study 04 Phase 2	17 subjects 	NCT024226684	<ul style="list-style-type: none"> Investigator initiated study, Single-center, single-arm, open-label All patients had prior desensitization with IVIG and/or plasmapheresis 	<ul style="list-style-type: none"> Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients Assessment of safety Assessment of efficacy and kidney function 	<ul style="list-style-type: none"> Serum creatinine (0-6 months) Proteinuria (0-6 months) DSA at multiple timepoints posttransplant (day 0, D30, D90, D180) 	Complete	The New England Journal of Medicine (2017) ³
Study 06 "Highdes" Phase 2	18 subjects 	NCT02790437	<ul style="list-style-type: none"> Multicenter, multinational, single-arm, open-label Included pts who may have had prior unsuccessful desensitization or pts in whom it was unlikely to be effective 	<ul style="list-style-type: none"> Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD 	<ul style="list-style-type: none"> DSA reduction at multiple timepoints (2, 6, 24, 48 h after imlifidase) Time to create negative CDC XM test and/or flow cytometry (FACS) XM test Safety 	Complete	Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019) ⁴
Long-term follow-up study	Up to 46 subjects 	NCT03611621	<ul style="list-style-type: none"> A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation 	<ul style="list-style-type: none"> Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration 	<ul style="list-style-type: none"> Patient survival, kidney function, comorbidity, treatments and quality of life Safety DSA Immunogenicity 	Ongoing	

¹ Winstedt et al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)

² Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762

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

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

Contact our Investor Relations and Corporate Communications team



Klaus Sindahl

Head of Investor Relations

Mobile: +46 (0) 709-298 269

Email: klaus.sindahl@hansabiopharma.com



Rolf Gulliksen

Head of Corporate Communications

Mobile: +46 (0) 733-328 634

Email: rolf.gulliksen@hansabiopharma.com

Calendar

Sep 6, 2019	Goldman Sachs Biotech Symposium, London
Sep 10, 2019	Morgan Stanley Global Healthcare Conference, NYC
Sep 12, 2019	KOL event, San Francisco
Sep 15-18, 2019	ESOT, Copenhagen
Sep 20, 2019	BofAML Global Healthcare Conference, London
Oct 31, 2019	Interim report Jan – Sep 2019
Nov 20-21, 2019	Jefferies Global Healthcare Conference, London
Dec 4, 2019	Evercore Annual HealthCONx Conf, Boston
Dec 5, 2019	DNB Nordic-American Life Science Conf, NYC
Dec 11-12, 2019	CITI Global Healthcare Conference, NYC

