HANSA BIOPHARMA

BAML Global Health Care Conference

London September 20, 2019

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Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- ~70 employees (~3/4 in R&D)
- Operations in Sweden, US & UK
- Market cap: SEK~6bn (USD 600m)
- 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 to increase transplantation 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 investments	1H'19 SEK -46m	(FY'18 SEK -155m)
• Net Profit	1H'19 SEK -82m	(FY'18 SEK -248m)

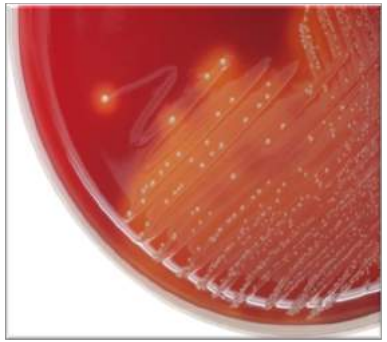
…at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...

Technology snapshot

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

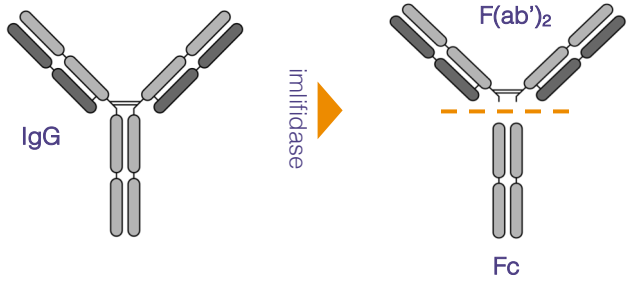
Origins from Streptococcus pyogenes

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



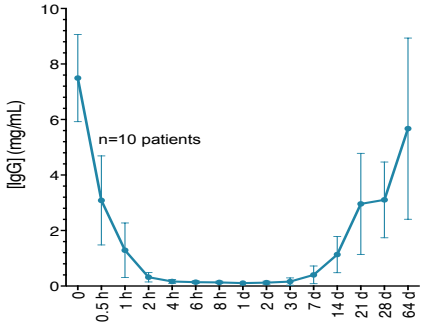
Imlifidase, a unique IgG antibody-degrading enzyme with proven mechanism of action

- 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



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- 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
- 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 programs 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

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Continued advancement toward commercialization

Imlifidase in kidney transplantation

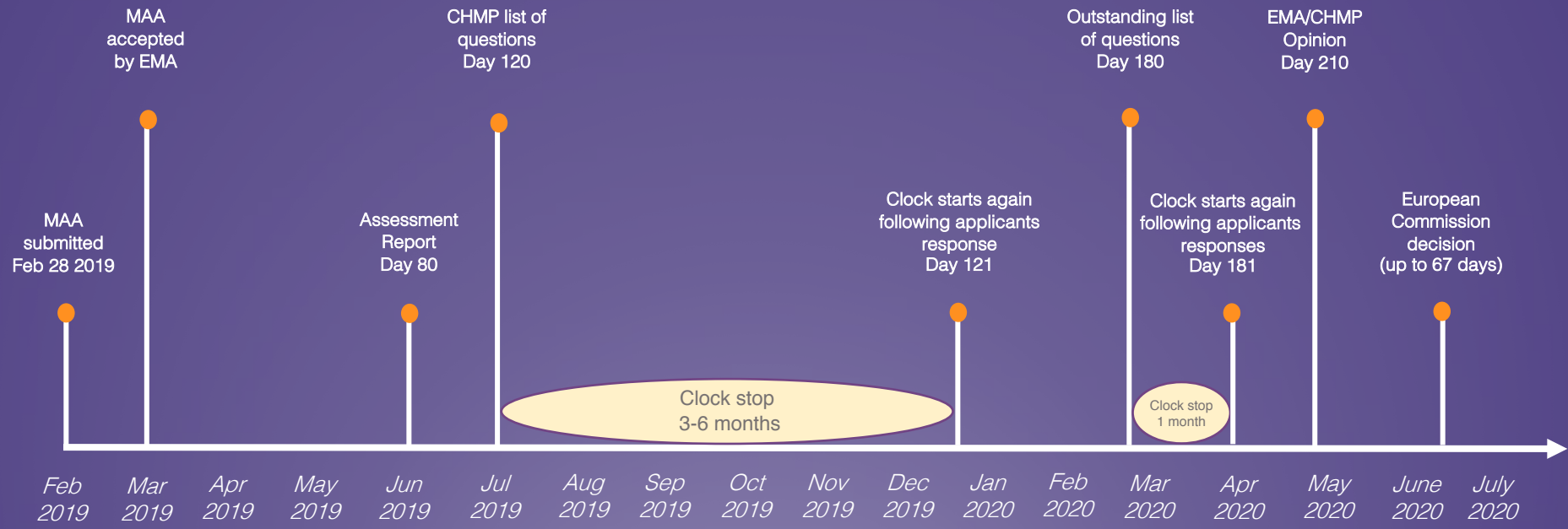
Europe (EMA)

- 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

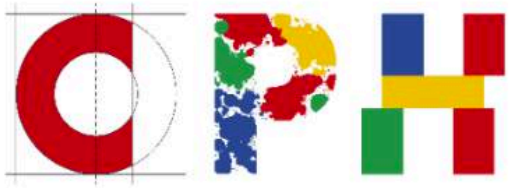


Positive results presented at ESOT; imlifidase enabled transplantation in 46 sensitized patients

Pooled analysis of four Phase 2 trials

- Analysis included 46 patients
  - 50% had a cPRA of 100% (Average 99%)
  - 85% were crossmatch positive
  - 70% were retransplanted
- DSA levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation of all patients
- DSA rebound post transplantation; no strong correlation between DSA levels and AMR. AMR episodes occurred in 33% of patients - all treated with Standard of Care
- Three patients experienced graft loss unrelated to imlifidase
- Conclusion:
  - Imlifidase is a promising drug candidate which can rapidly convert positive crossmatch tests to negative and thus enable deceased donor transplantation in highly sensitized patients who would otherwise remain on dialysis

ESOT CONGRESS 2019
INSPIRING MINDS, DRIVING PROGRESS
in COPENHAGEN



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Imlifidase enables life-saving kidney transplantation that would otherwise not be possible

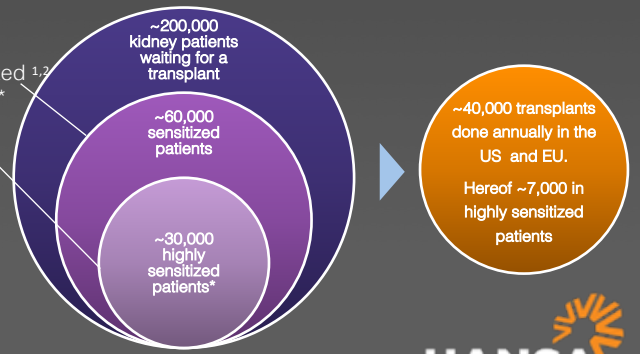
Creating equality on the waitlist

- Imlifidase complements the new KAS system and can help facilitate reduced time to kidney transplantation in highly sensitizedpatients
- Reduces the need for antibody matching and enables highly sensitized patients to be transplanted
- Reduces co-morbidities and mortality associated with dialysis and wait time
- Adjusted for current rate of organ donation, ~ 12K sensitized patients annually could benefit from imlifidase
- Around 1,000 donated kidneys are discarded in the U.S.[3]

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

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 in the 98-100 range

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

Broad pipeline in transplantation and auto-immune diseases

Candidate / Program	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 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 confirmatory study would need to be executed in case of approval.

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

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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

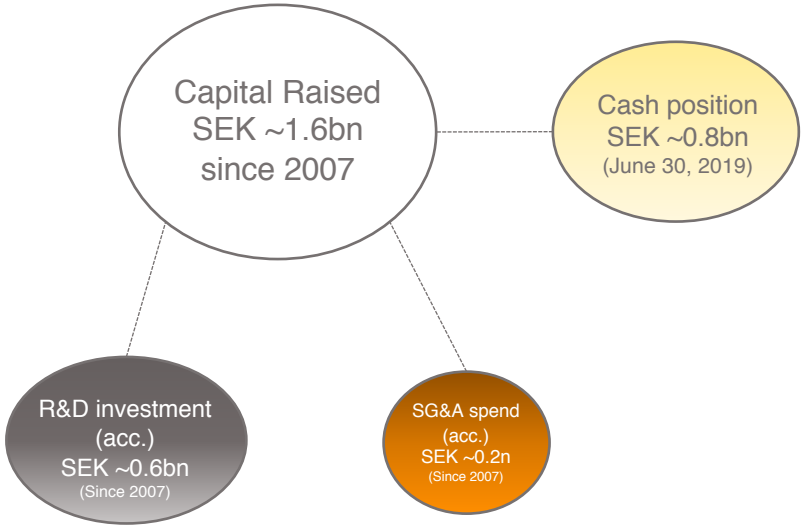
New GBS study marks continued expansion outside transplantation

Initiation of GBS Phase 2 study in Europe

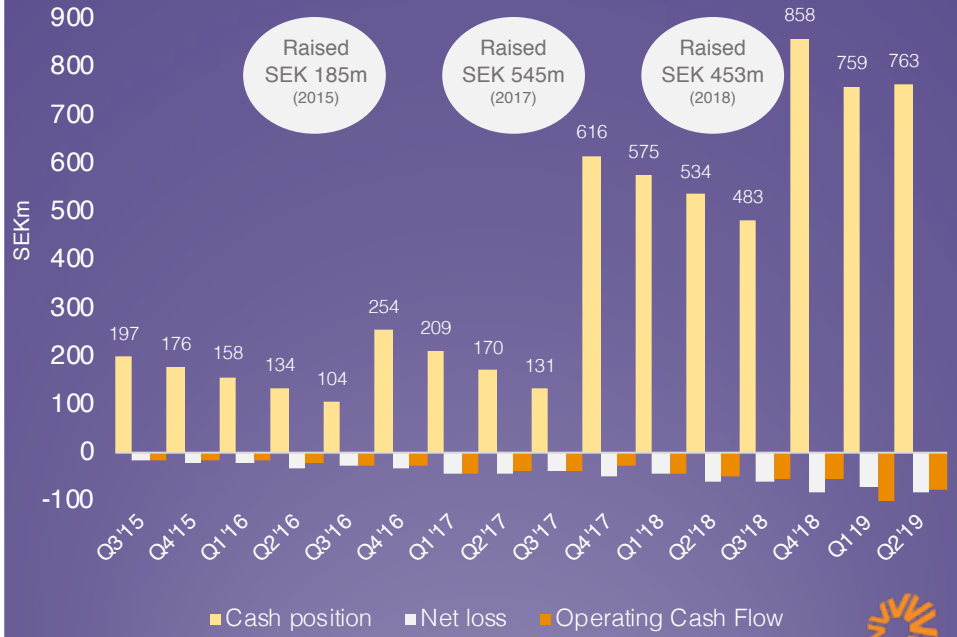
- Guillain Barré Syndrome (GBS) is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system affecting 1-2 in 100,000 people annually
- CTA approval obtained for Phase 2 study in GBS in April
- Recruitment of up to 30 patients initiated at ten clinics in France, U.K. and the Netherlands.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

Hansa Biopharma is financed through 2020

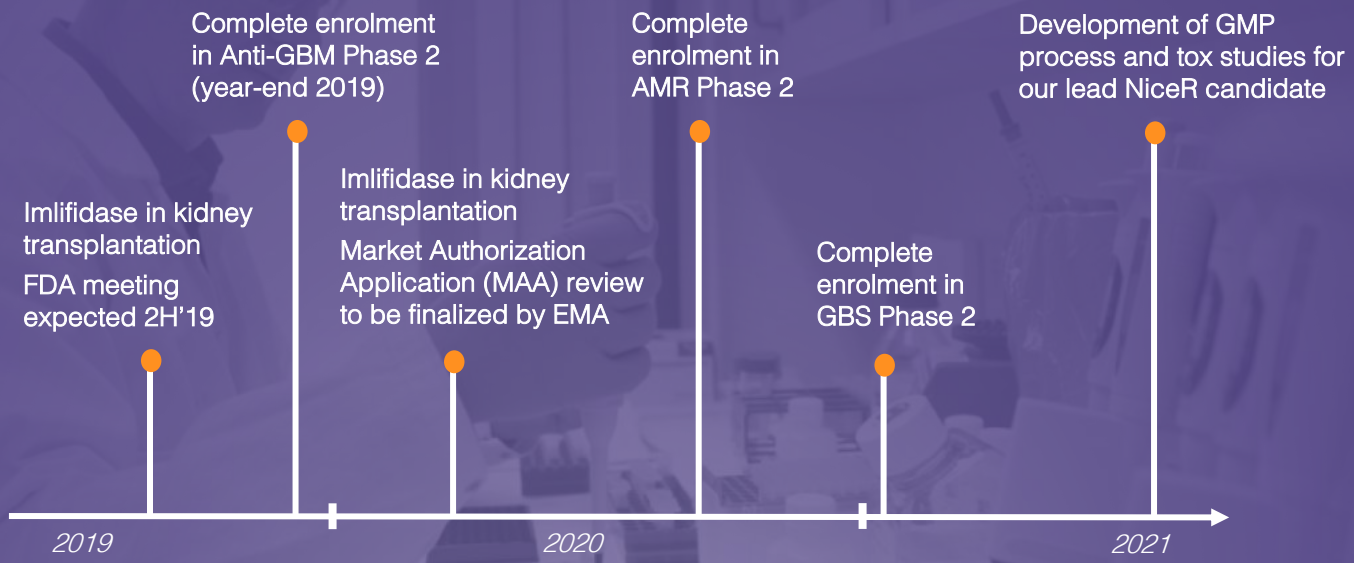
Significant capital raised since 2007



Solid cash position end of first half 2019



Milestones and near-term news flow

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