HANSA BIOPHARMA

Presentation
Redeye Life Science Day

Stockholm, November 19, 2019

Klaus Sindahl, Head of IR

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Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- 64 employees (~3/4 in R&D) at Sep 30, 2019
- Operations in Sweden, US & Europe
- Market cap: SEK ~6bn (USD ~600m) Oct, 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

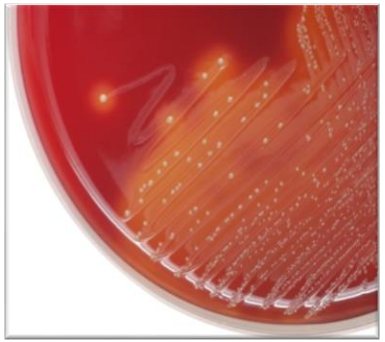
• Cash position	9m'19 SEK 680m
• Operating Cash Flow	9m'19 SEK -260m
• R&D cost	9m'19 SEK -135m
• Net Profit	9m'19 SEK -249m

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

Imlifidase, a novel approach with a rapid onset of action to eliminate pathogenic IgG with high specificity

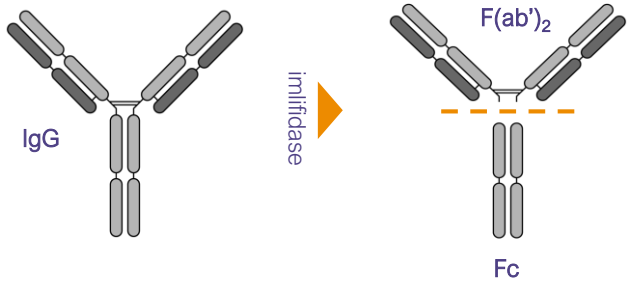
Origins from Streptococcus pyogenes

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



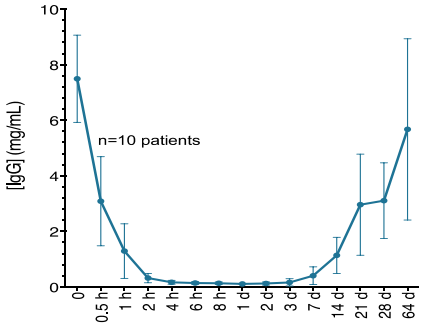
Imlifidase, a unique IgG antibody-cleaving enzyme

- 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



Imlifidase enabled kidney transplantation in highly sensitized patients

Pooled analysis of four Phase 2 trials presented

- 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.

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Imlifidase may enable transplantation in highly sensitized kidney patients

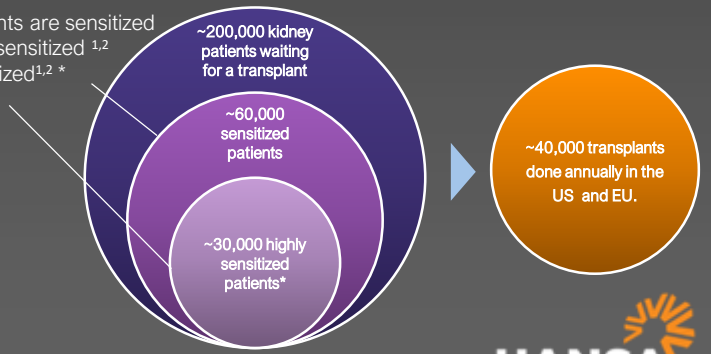
Creating equity for highly sensitized patients

- 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

High unmet medical need in spite of updated Kidney Allocation System

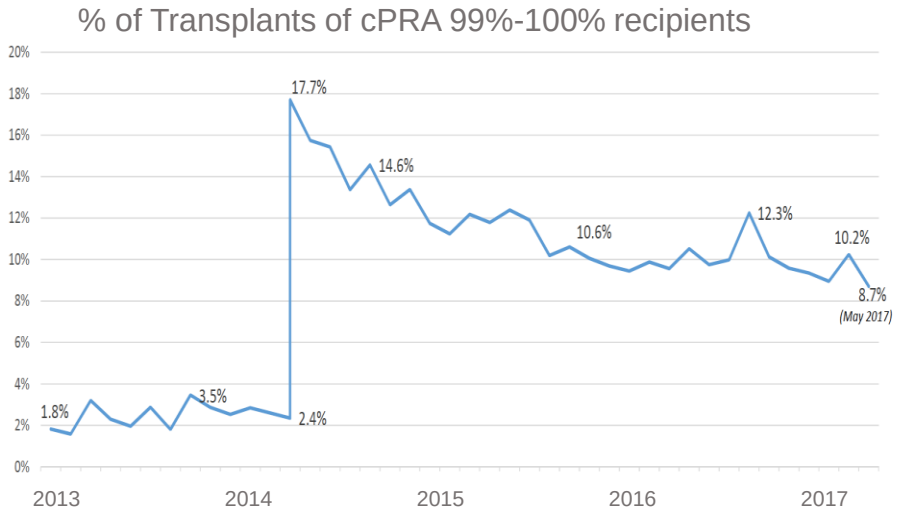
Imlifidase may potentially complement KAS

- The Kidney Allocation System (KAS) in U.S. was updated in 2014 to prioritize national allocation for highly sensitized patients
- Implementation initially resulted in a bolus effect; however a group of highly sensitized patients are still not helped due to lack of matched organs
- If approved, imlifidase may potentially complement allocation systems like KAS and Euro-transplant and reduce time to transplant in highly sensitized patients

"We thought the KAS would be very good, but the experience was different. I don't think you can have a bureaucratic solution for an immunologic problem, we have to face that we do need drugs to deal not only with acute antibodies but also with the rebound."

Stanley Jordan M.D., Director Kidney Transplantation and Transplant Immunology at the Cedars-Sinai Medical Center in LA.

Significant number of highly sensitized patients remains on the waiting list post KAS



Source:
OPTN/UNOS
Darren Stewart, MS,
UNOS Research Department

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Regulatory review with EMA is progressing as expected

Imlifidase in kidney transplantation

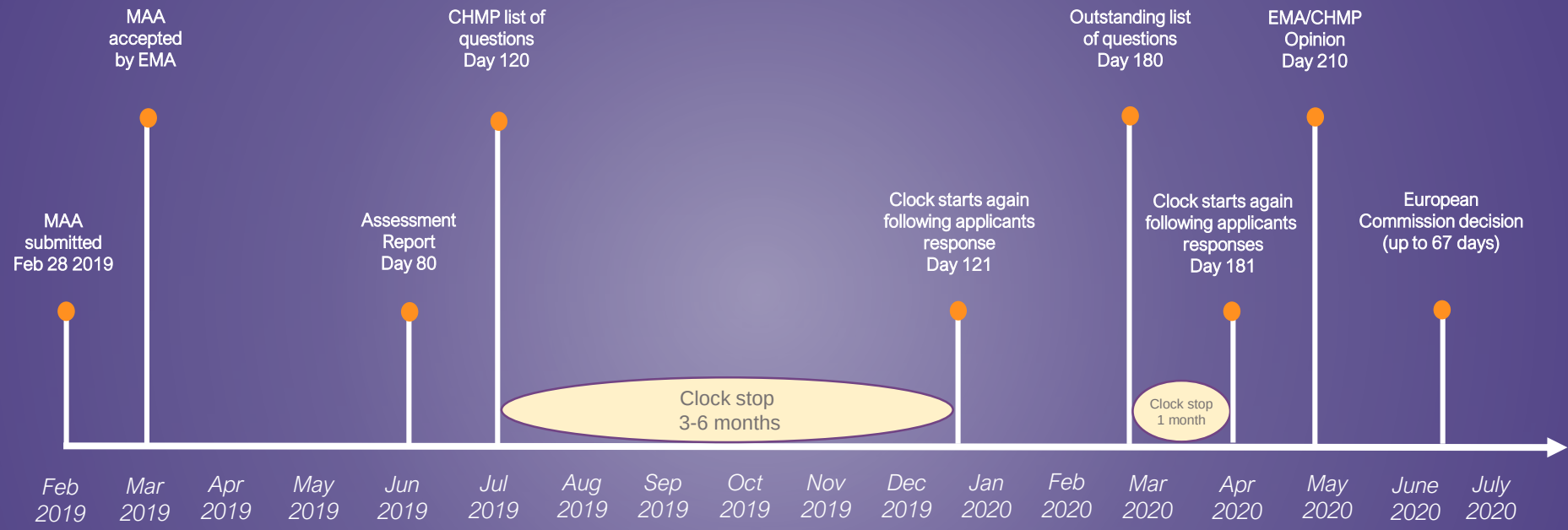
Europe (EMA)

- MAA for imlifidase accepted end of Feb'19; regulatory review progressing as expected
- Opinion from Committee for Medicinal Products for Human Use (CHMP) expected during the first half of 2020
- Decision by European Commission expected June/July 2020

U.S. (FDA)

- Follow-up meeting with the U.S. Food and Drug Administration scheduled for November 20, 2019 to discuss regulatory path forward in the U.S.
- Minutes from the meeting is expected by end of December

The EMA process towards marketing authorization



Focused launch strategy optimizes patient access to imlifidase

Strong outreach with limited footprint in EU

- Building awareness through MSL and Patient Advocacy
  - MSL organization established in key markets
  - MSLs educate KOLs and physicians at transplantation clinics
  - Reaching out to healthcare providers through Patient Advocacy
- A sequenced and focused launch strategy
  - In EU5, 70-80% of all kidney transplantations are performed at 15-20 centers in each EU5 country
  - Potential Initial launch in early launch countries in the second half of 2020 followed by second wave launch countries

Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1[1]	Pivotal program/ Phase 2	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients				*)		MAA review by EMA Follow-up meeting with FDA Nov 20, 2019
	Anti-GBM antibody disease						Complete enrollment
	Antibody mediated kidney transplant rejection (AMR)						Complete enrollment
	Guillain-Barré syndrome						Complete enrollment
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).

*) 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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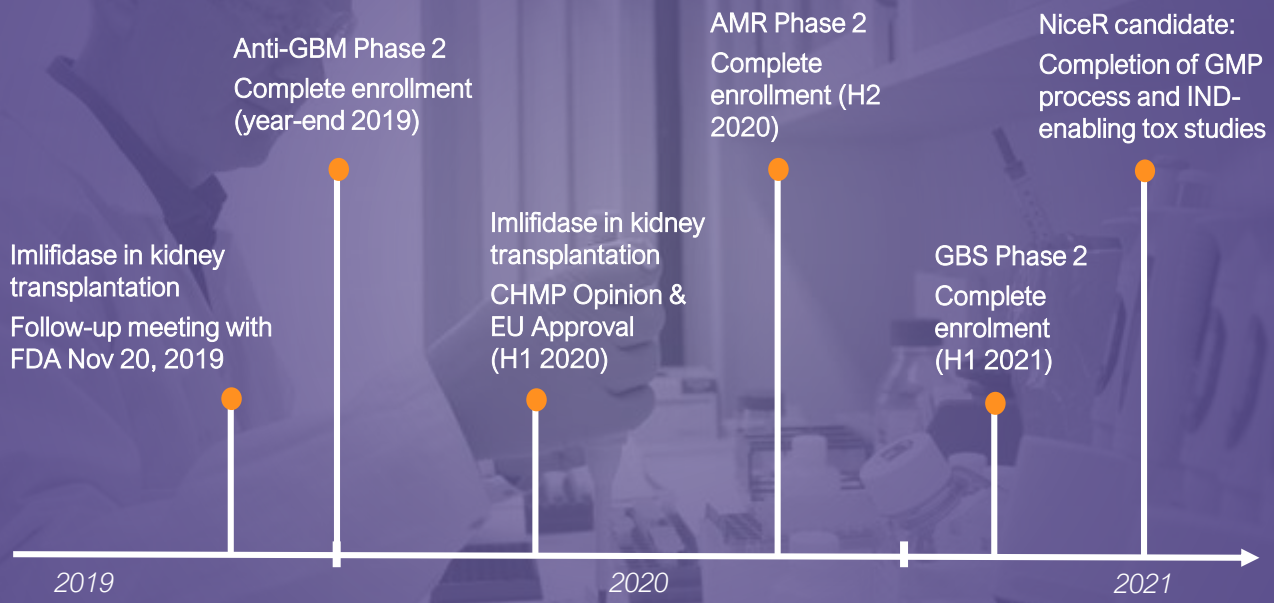
Upcoming milestones

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