Hansa Biopharma provides updated guidance on its clinical programs

- Idefirix™ recently granted formal approval by the EU Commission; First treatments expected in select countries in Q4 2020 in the EU
- Updating clinical timelines for ongoing and planned imlifidase trials due to continued impact from the COVID-19 pandemic
- High-level data read-out from the investigator initiated phase 2 study in anti-GBM expected in Q3, 2020, as previously guided

Lund, Sweden September 1, 2020. Hansa Biopharma ("Hansa"), the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced updated guidance regarding its ongoing and planned clinical trial program ahead of Management's participation at upcoming investor conferences in September.

Following the conditional approval recently granted by the EU Commission for Idefirix™ (imlifidase) in highly sensitized kidney transplant patients in the European Union, Hansa Biopharma expects the first treatments with Idefirix to be available to patients in select European countries during the fourth quarter 2020, as communicated earlier.

As part of the conditional approval, a post-approval study will be initiated following the market authorization. The post-approval study is expected to commence in the second half of 2021 following ongoing site selection and alignment on country specific requirements. The transplantation centers participating in the study will embark on a mutual learning experience, and the post-approval study will run in parallel with the Company's commercial roll-out activities.

The proposed study protocol for a randomised controlled trial (RCT) targeting highly-sensitized kidney patients in the US was submitted to the US Food and Drug Administration (FDA) in June, 2020. Discussions are currently ongoing with the FDA and, once the final protocol has been agreed upon, Hansa Biopharma will proceed to set up centers in the US and start to enroll patients.

Given the continued impact of the COVID-19 pandemic in the US affecting patient enrollment, and the timeline for finalization of the study protocol, Hansa Biopharma now expects recruitment of the first patient to be in the first half of 2021 (previously Q4 2020). Completion of enrollment is still expected to be in 2022 with a potential Biologics License Application (BLA) submission by 2023 under the accelerated approval path.

In the investigator initiated Phase 2 trial in anti-glomerular basement membrane (anti-GBM) disease, the last patient last visit took place in July and the Company expects to report high level data from this study during the third quarter of 2020, as previously guided. Anti-GBM is the first IgG mediated disease outside transplantation, where imlifidase is being investigated to potentially stop an immunologic attack.

Due to the widespread impact from the COVID-19 pandemic, the enrollment in the phase 2 programs in Guillain Barré Syndrom (GBS) and Antibody-mediated kidney transplant rejection (AMR) were temporarily halted for the past months. Hansa Biopharma expects to reinitiate enrollment of these studies in Q4 2020 under a risk-based, site-by-site approach. As a consequence, enrollment in the AMR study is now expected to be completed in the second

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About Hansa Biopharma

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications.

Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth quarter of 2020.

Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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half of 2021 (previously H1 2021). Enrollment in the GBS study is still expected to be completed in the second half of 2021, as previously guided. High-level data readout for both studies are now expected in the second half of 2022.

Upcoming milestones and news flow

Q3 2020	Anti-GBM Phase 2 study: High-level data read out
Q4 2020	Kidney transplantation EU: Commercial launch
H1 2021	Kidney transplantation US: First patient dosed
H1 2021	NiceR candidate: Completion of GMP process and IND-enabling tox studies
H2 2021	AMR Phase 2 study: Complete enrollment
H2 2021	GBS Phase 2 study: Complete enrollment
H2 2022	AMR Phase 2 study: Data read out
H2 2022	GBS Phase 2 study: Data read out
2022	Kidney transplantation US: Complete enrollment
2023	Kidney transplantation US: 12 months follow-up completed
2023	Kidney transplantation US: BLA submission

Disclaimer regarding the ongoing COVID-19 pandemic: Clinical trials are being impacted by the COVID-19 Pandemic. Challenges may arise, for example, from self-isolation, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected with COVID-19. These challenges may lead to difficulties in meeting recruitment as well as protocol-specified procedures, including administration or use of the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing.

This is information that Hansa Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation (MAR).