

Hansa Biopharma  
P.O. Box 785  
SE-220 07 Lund, Sweden  
Phone: +46 46 16 56 70  
Fax: +46 46 12 77 75

(Visiting address)  
Scheelevägen 22  
223 63 Lund, Sweden

[www.hansabiopharma.com](http://www.hansabiopharma.com)



## **Hansa Biopharma Receives Ethics and Regulatory Clearance to Start Phase 2 Study of Imlifidase in Guillain Barré Syndrome**

**Lund, Sweden, April 15, 2019**– Hansa Biopharma AB (NASDAQ Stockholm: HNSA), the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, announced today that it received Clinical Trial Application and Ethics Committee approvals in Europe for the company’s Phase 2 study of imlifidase in Guillain Barré Syndrome (GBS). The study will enroll up to 30 patients at approximately ten clinics in France, U.K. and the Netherlands over the next 18 months.

GBS is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system that affects 1-2 in 100,000 people annually. GBS is an aggressive neurological disease, with many patients deteriorating despite standard of care treatment. Two thirds of GBS patients have severe symptoms resulting in their inability to walk unaided, and 20-30% require mechanical ventilation for weeks or months. In 2018, the U.S. Food and Drug Administration granted Orphan Drug Designation to imlifidase for the treatment of GBS.

*“Our novel IgG degrading enzyme, imlifidase, has potential in an array of acute autoimmune diseases, including Guillain Barré Syndrome. We believe that imlifidase’s rapid inactivation of IgG has the potential to halt GBS disease progression, accelerate recovery and decrease disease severity overall,”* said Søren Tulstrup, Chief Executive Officer of Hansa Biopharma.

The 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 30 GBS patients enrolled in the study will be compared to a matched control group of GBS patients treated with IVIg from the International Guillain-Barré Syndrome Outcome Study (IGOS) database. All subjects in Hansa’s study will receive a single, 30-minute infusion of imlifidase as soon as possible after diagnosis, followed by standard of care IVIg treatment two days later. Safety and efficacy,

primarily measured as improvement on the GBS functional scale, will be monitored over a 12-month period post treatment, with an initial end point read out at six months.

More information about the study will be available at ClinicalTrials.gov under the study title *An open-label, single arm, multi-centre, phase II study investigating safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of imlifidase (IdeS) in patients with Guillain-Barré Syndrome (GBS), in comparison with matched control patients.*

Hansa has submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for IDEFIRIX™ (INN: imlifidase) for the treatment of highly sensitized patients to enable kidney transplantation. The submission was accepted for review by EMA on February 28, 2019. A dialogue is ongoing with FDA regarding a potential Biologic License Application (BLA).

*This is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below at 08:30am CET on April 15, 2019.*

## **About Guillain-Barré Syndrome**

Guillain-Barré Syndrome is a rare, acute, paralyzing disease of the peripheral nervous system, affecting 1-2 in 100,000 people per year. GBS is usually preceded by an infection or other immune stimulation that induces an aberrant autoimmune response, with IgG-antibodies targeting the peripheral nervous system. It is the most frequent cause of acute neuromuscular weakness in the Western world and can occur at any age. GBS is a rapidly progressive monophasic disorder, often leading to a severe paralysis of the arms and legs. Most GBS patients have sensory disturbance (tingling or numbness or ataxia) and pain, and some patients have double vision or problems with swallowing. GBS may also paralyze the respiratory muscles, leading to intensive care unit admission and mechanical ventilation. While patients are typically treated with either IVIg or plasmapheresis, there remains a significant unmet medical need.

## **About imlifidase**

Imlifidase is an enzyme that specifically cleaves immunoglobulin G (IgG) antibodies, thereby inhibiting the IgG-mediated immune response. Hansa is developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplant surgery due to the presence of Donor Specific Antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling transplantation. In addition to transplantation, imlifidase is being evaluated in a Phase 2 clinical study in anti-GBM

antibody disease, a rare autoimmune disorder, and imlifidase has potential applications in a variety of additional autoimmune diseases. Imlifidase is protected by a strong patent portfolio and results of studies with imlifidase have been published in multiple peer reviewed scientific journals.

## **About Hansa Biopharma**

Hansa Biopharma AB (NASDAQ Stockholm: HNSA) is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product, IDEFIRIX (imlifidase), is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune indications. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden.

## **For further information, please contact:**

### *Company:*

Emanuel Björne, Vice President Business Development and Investor Relations

Hansa Biopharma AB (Publ)

Mobile: +46 70 717 5477

E-mail: [emanuel.bjorne@hansabiopharma.com](mailto:emanuel.bjorne@hansabiopharma.com)

<http://hansabiopharma.com>

### *Swedish Investor and Media Relations:*

Cord Communications

Mikael Widell

+46 70-311 99 60

### *U.K. Investor and Media Relations:*

FTI Consulting

Simon Conway / Natalie Garland-Collins

+44 (0)20 3727 1000

### *U.S. Investor and Media Relations:*

Argot Partners

Stephanie Marks / David Rosen (media)

+1 212 600 1902