

PRESS RELEASE

Hansa Biopharma announces submission of IND Application to US FDA for HNSA-5487 in GBS

- **The IND submission marks an important milestone in advancing Hansa's novel IgG-cleaving enzyme into clinical development in GBS.**

Lund, Sweden, October 20, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced that it has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for HNSA-5487, Hansa's novel IgG-cleaving enzyme, to support clinical development in Guillain-Barré syndrome (GBS).

Renée Aguiar-Lucander, CEO, Hansa Biopharma said: *"The IND submission for HNSA-5487 represents an important milestone in the development of HNSA-5487 and our pursuit of treating rare diseases. We look forward to initiating the clinical development program and generating the patient data FDA has requested to enable us to move into a pivotal study. HNSA-5487 has demonstrated rapid and effective IgG reduction, and we believe it has the potential to provide clinically meaningful benefits in the treatment of IgG-mediated autoimmune diseases."*

The IND submission advances HNSA-5487 toward clinical evaluation in patients with GBS. The program is supported by a prior clinical study with imlifidase in GBS, which provided clinical evidence for the therapeutic potential of targeting pathogenic IgG in the disease. Subject to FDA review of the IND, Hansa plans to initiate a small Phase 2a single ascending dose (SAD) study of HNSA-5487 in patients with GBS, followed by a pivotal study.

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Notes to editors

About HNSA-5487

HNSA-5487 is a novel IgG-cleaving enzyme. The molecule is being developed with the potential for repeat dosing, which could enable broader application of Hansa's IgG-cleaving technology across IgG-mediated diseases.

In a double-blind, randomized, placebo-controlled Phase 1 study, 36 healthy volunteers received single ascending doses of HNSA-5487 by intravenous infusion. The study assessed safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity. HNSA-5487 demonstrated a rapid and robust reduction of IgG of more than 95% within a few hours.

About Guillain-Barré Syndrome

GBS is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system in which the immune system damages peripheral nerves. The disease is characterised by rapid onset and progression of muscle weakness, which can lead to severe paralysis of the arms and legs. Many patients with GBS also experience sensory disturbances, including tingling, numbness and ataxia, as well as pain, and some patients experience double vision or difficulty swallowing. Early intervention is critical, and there remains a need for new treatment options.

About Hansa Biopharma

Hansa Biopharma AB is a pioneering commercial-stage biopharmaceutical company developing and commercializing novel immunomodulatory therapies to transform care for patients with acute or complex immune disorders. Hansa's proprietary IgG-cleaving enzyme technology platform addresses serious unmet medical needs in transplantation, gene therapy and autoimmune diseases. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients, and HNSA-5487, a next-generation IgG-cleaving molecule that will be developed for Guillain-Barré Syndrome (GBS). Hansa Biopharma is based in Lund, Sweden, and has operations in Europe and the U.S. The company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com and follow us on [LinkedIn](#).

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