

## PRESS RELEASE

# First patient treated with imlifidase in an investigator-initiated Phase 2 study in ANCA-associated vasculitis

Lund, Sweden 19 July, 2023. Hansa Biopharma ("Hansa"), a pioneer in enzyme technology for rare immunological conditions, today announced first patient treated with imlifidase in an investigator-initiated phase 2 study in anti-neutrophil cytoplasmic antibody ("ANCA")-associated vasculitis. This is the first study evaluating imlifidase, Hansa's first-generation IgG-cleaving enzyme, in this patient population.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "This is an important step forward in the development of our technology platform and pipeline of drug candidates for rare immunologic diseases and conditions. Our lead molecule imlifidase has the potential to address areas of high unmet need in the autoimmune disease space, as demonstrated by our clinical studies in anti-glomerular basement membrane ("anti-GBM")<sup>1</sup> disease and Guillain-Barré syndrome ("GBS"). We look forward to the results of this study in yet another autoimmune disease and are excited about the potential for imlifidase to help even more patients suffering from serious autoimmune diseases and conditions".

The study is a single center, single arm, phase 2 trial led by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany. The primary objective of the study is to assess efficacy and safety of imlifidase together with standard of care in the treatment of patients with pulmonary hemorrhage due to severe ANCA-associated vasculitis.

Dr. Philipp Enghard, Division of Nephrology and Internal Intensive Care Medicine, Charité Universitätsmedizin, Berlin, and co-principal investigator of the study, said, "There are very few treatment options to achieve rapid control of disease activity for patients affected by ANCA-associated vasculitis and we believe imlifidase constitutes a promising opportunity for these antibody-related disorders. Thanks to its almost immediate and highly effective action, imlifidase has the potential to be a powerful candidate as new treatment for ANCA-associated vasculitis, particularly in patients with severely active disease".

A total of 10 patients with severe ANCA-associated vasculitis and Acute Respiratory Distress Syndrome ("ARDS") due to pulmonary hemorrhage will be treated with imlifidase on top of standard of care (consisting of standard immunosuppression as per center protocol and intensive support care). Efficacy and safety of imlifidase will be assessed by evaluating ANCA antibody seroconversion and titers, adverse events, mortality, as well as amelioration of lung and renal function over a 6-month observation period.

ANCA-associated vasculitis is a group of conditions that affect approximately 30 people in a million annually in the EU and US.<sup>2,3</sup> It is characterized by the presence of IgG anti-neutrophil cytoplasmic antibodies<sup>4</sup> directed against antigens expressed by the neutrophils, a type of white blood cell part of the body's immune system response. The consequent activation of neutrophils by the ANCA antibodies causes blood vessel damage<sup>5</sup> that can affect multiple organs, most frequently lungs and kidneys, where it leads to rapidly deteriorating organ function. The progress of the disease results in end stage kidney disease in 25 percent of patients.<sup>6</sup> The most severe cases involving lungs lead to pulmonary hemorrhage with consequent respiratory failure.<sup>7</sup>

More information about the trial is available on EU Clinical Trial Register. EudraCT Number: [2021-004706-22](https://clinicaltrials.gov/ct2/show/study/2021-004706-22)

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Notes to editors

### About Hansa Biopharma

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. 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](http://www.hansabiopharma.com).

### References

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