PRESS RELEASE 2 May 2023

FDA approves the manufacture of new microbiome-based therapeutic VOWST™ at Recipharm site

Recipharm, a global contract development and manufacturing organization (CDMO), has announced today that its subsidiary, GenIbet Biopharmaceuticals, has been approved by the US Food and Drug Administration (FDA) as a manufacturing site of VOWST, a breakthrough orally administered fecal microbiota product for the prevention of *Clostridioides difficile* recurrent infection (CDI) in adults following antibacterial treatment for recurrent CDI.

Recipharm will manufacture VOWST at its GenIbet site in Oeiras, Portugal on behalf of Seres Therapeutics.

In the US, CDI has been classified as one of the greatest microbial threats to human health by the Centers for Disease Control and Prevention (CDC) and is associated with approximately 30,000 deaths annually.

Raquel Fortunato, CEO of GenIbet, said: "FDA's approval is a major development in the biologics market. It will help shift the perception of microbiome medicines and open the door for new opportunities for patients around the world.

I would like to thank colleagues, past and present, who have been involved in the VOWST project. Their hard work and perseverance over almost ten years have enabled this major milestone which has the potential to improve patients' health and save lives. I can't think of a better example to illustrate our mission, to be the bridge between innovators and patients."

A Recipharm company, GenIbet specializes in the manufacture of biological clinical trial material and novel modalities such as viral vectors, RNA and microbiome therapeutics. GenIbet started working on the VOWST Tech Transfer and GMP manufacturing in 2014, supporting Seres Therapeutics throughout the clinical trial supply, process validation and BLA submission. GenIbet currently supports customer projects in the preclinical and Phase 1/2 stages, and has a track record of developing novel production processes.

The FDA decision will provide Recipharm with a platform on which to build out its manufacturing capabilities for new modalities in the Biologics space.

Seres Therapeutics is a commercial-stage biotech working to revolutionize a wide range of diseases by modulating the function of the human microbiome.

Contact information

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About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) in the pharmaceutical and biopharmaceutical industry employing almost 9,000 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material and APIs, pharmaceutical and biologics product development, and development and manufacturing of medical devices. Recipharm manufactures several hundred different products for customers ranging from big pharma to smaller research and development companies. The company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and is headquartered in Stockholm, Sweden.
For more information on Recipharm and our services, please visit www.recipharm.com