BIOPHARMADIVE

DIVE BRIEF

Novo Nordisk parent backs cell therapy manufacturing facility

As cell therapies for cancer and diabetes grow, the Novo Nordisk Foundation will spend up to $136 million to build a plant at a Danish university.

Published Sept. 21, 2023

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Dive Brief:

- The Novo Nordisk Foundation, the controlling owner of the Danish drugmaker, will spend up to 950 million kroner, or roughly $136 million, to build a cell therapy manufacturing facility that can support development of treatments for use in human testing, according to an announcement Thursday.
- To be built at Technical University of Denmark in Lyngby, the facility will be available for use by private companies as well as academic researchers. Its main function will be to help the final development steps and upscaling of production to initiate clinical trials. Construction is slated to begin in 2024, with the facility expected to be operational in 2027.
- After decades of research, cell therapies have become a reality, with six immune cell therapies now available in blood cancers and a pancreatic cell replacement therapy recently approved for Type 1 diabetes. The Novo foundation hopes to usher more

treatments to patients by helping developers advance their experimental projects into human trials.

Dive Insight:

Cell therapies are viewed as potential one-time treatments able to cure or at least reduce the burden of disease in chronic or fatal conditions. Emily Whitehead, who, in 2012, became the first pediatric leukemia patient given the cancer-fighting CAR-T cell therapy Kymriah, has been in remission since her treatment.

Other conditions that could see benefit from cell therapies include chronic heart failure, Type 1 diabetes, Parkinson's disease and kidney disease, according to the Novo foundation.

In Type 1 diabetes, which is caused by the autoimmune destruction of insulin-secreting pancreatic cells, a replacement therapy could relieve patients of the burden of managing their insulin levels, especially as their disease advances. The cell therapy Lantidra — approved by the Food and Drug Administration in June — is intended for Type 1 diabetes patients who have trouble managing blood sugar levels and have experienced repeated episodes of hypoglycemia.

Novo, the drugmaker, itself has invested in development of cell therapies, building a stem cell facility in California in 2018. More recently, it partnered with a Japanese company called Heartseed to develop a heart failure treatment that has entered clinical trials, and with the Canadian company Aspect Biosystems for bioprinting of cell therapies for Type 1 diabetes and obesity.

The new Novo foundation-backed cell therapy plant will serve more than the drugmaker's projects, however. It aims to be able to aid in the manufacturing of multiple types of cells, including embryonic stem cells, induced pluripotent stem cells and adult

stem cells. Some of the services the plant will provide include optimization of manufacturing processes, quality assurance and regulatory support.

A few hospitals in Denmark have small-scale cell therapy production capabilities. The foundation said establishment of its plant should help concentrate cell therapy expertise in one place to create a large-scale production facility.

The facility can serve as a “critical link” that “enables ground-breaking stem cell discoveries to be taken all the way to proof-of-concept in human chronic disease trials,” said Mads Krogsgaard Thomsen, the foundation’s CEO who was formerly the drugmaker’s science chief, in a statement.