Enzyvant Announces Plans to Expand Regenerative Medicine Manufacturing Capabilities

Enzyvant, a commercial-stage biotechnology company with a focus on regenerative medicines for rare diseases, announced today plans to develop a Good Manufacturing Practice (GMP)-compliant regenerative medicine manufacturing facility in Morrisville, NC, part of the Research Triangle Park area.

“Enzyvant is committed to ensuring scalable GMP manufacturing for RETHYMIC® (allogeneic processed thymus tissue-agdc), and we’re looking ahead to potential needs in other indications and in support of other advanced regenerative medicine technologies,” said Enzyvant CEO William Symonds. “This new facility, once completed, will give us the size, flexibility, and nimble processing capability to serve both commercial and research needs.”

The development of the 25,972-square-foot facility is expected to begin this summer and take approximately two and a half years to complete once construction begins. Enzyvant currently has research and development offices in Durham, NC.

“I am very pleased about the novel capabilities this new manufacturing facility will bring to Enzyvant and look forward to the progress ahead as we look to realize efforts,” said Myrtle Potter, CEO of Sumitovant. “This is a great example of three members of the Sumitomo Pharma family of companies working seamlessly together to address the most pressing issues affecting patients and families with the highest unmet medical needs.”

The new manufacturing facility is being co-developed by and operated with Sumitomo Pharma, which owns Enzyvant’s immediate parent company, Sumitovant Biopharma.

“We’re excited that this new site not only expands the range and scope of our manufacturing offerings, but also builds our presence in Research Triangle Park – leveraging our existing employee base and support the local area with new hires,” said Larry Weiner, VP of Pharmaceutical Development & Manufacturing at Enzyvant.

About Enzyvant
Enzyvant is a commercial-stage biotechnology company with a focus on regenerative medicines for rare diseases. The company’s first commercial product is U.S. Food and Drug Administration (FDA)-approved RETHYMIC (allogeneic processed thymus tissue-agdc), a tissue-based regenerative therapy for an ultra-rare and life-threatening pediatric immunodeficiency. Enzyvant has distinctive capabilities in expedited development of regenerative therapies for rare diseases. The company has obtained and leveraged multiple regulatory designations including Regenerative Medicine Advanced Therapy, Breakthrough, Fast Track, Rare Pediatric Disease, Orphan Drug, and Advanced Therapies Medicinal Product. Enzyvant is wholly owned by Sumitovant Biopharma Ltd. (wholly owned by Sumitomo Pharma). For more information about Enzyvant, visit Enzyvant.com.

About Sumitovant Biopharma Ltd.
Sumitovant is a global biopharmaceutical company leveraging data-driven insights to rapidly accelerate development of new potential therapies for unmet patient conditions. Through our unique portfolio of wholly-owned “Vant” subsidiaries—Urovant, Enzyvant, Spirovant, Altavant—and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported the development of FDA-approved products and advanced a promising pipeline of early-through late-stage investigational assets for other serious conditions. Sumitovant, a wholly-owned subsidiary of Sumitomo Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit our website at www.sumitovant.com

About RETHYMIC®
RETHYMIC® (allogeneic processed thymus tissue-agdc) is a novel one-time tissue-based regenerative therapy used for immune reconstitution in pediatric patients with congenital athymia. RETHYMIC is engineered human thymus tissue designed to regenerate the thymic function children with congenital athymia are missing and does not require donor-recipient matching. RETHYMIC has been studied across 10 clinical trials for more than 25 years and was granted multiple U.S. Food and Drug Administration (FDA) designations including Regenerative Medicine Advanced Therapy, Breakthrough Therapy, Rare Pediatric Disease, and Orphan Drug. It also has been granted the Orphan Drug designation and the Advanced Therapy Medicinal Product designation by the European Medicines Agency. RETHYMIC is the first and only treatment approved by the FDA for immune reconstitution in pediatric patients with congenital athymia.

Please see Full Prescribing Information

Indication and Important Safety Information

Indication

RETHYMIC® (allogeneic processed thymus tissue–agdc) is indicated for immune reconstitution in pediatric patients with congenital athymia.

Limitations of Use:
RETHYMIC is not indicated for the treatment of patients with severe combined immunodeficiency (SCID).

Important Safety Information

Immune reconstitution sufficient to protect from infection is unlikely to develop prior to 6-12 months after treatment with RETHYMIC. Given the immunocompromised condition of athymic patients, follow infection control measures until the development of thymic function is established as measured through flow cytometry. Monitor patients closely for signs of infection including fever. If a fever develops, assess the patient by blood and other cultures and treat with antimicrobials as clinically indicated. Patients should be maintained on immunoglobulin replacement therapy until specified criteria are met, and two months after stopping, IgG trough level should be checked. Prior to and after treatment with RETHYMIC, patients should be maintained on *Pneumocystis jiroveci* pneumonia prophylaxis until specified criteria are met.

RETHYMIC may cause or exacerbate pre-existing graft versus host disease (GVHD). Monitor and treat patients at risk for the development of GVHD. Risk factors for GVHD include atypical complete DiGeorge anomaly phenotype, prior hematopoietic cell transplantation (HCT) and maternal engraftment. GVHD may manifest as fever, rash, lymphadenopathy, elevated bilirubin and liver enzymes, enteritis, and/or diarrhea.

Autoimmune-related adverse events occurred in patients treated with RETHYMIC. These events included: thrombocytopenia, neutropenia, proteinuria, hemolytic anemia, alopecia, hypothyroidism, autoimmune hepatitis, autoimmune arthritis, transverse myelitis, albinism, hyperthyroidism, and ovarian failure. Monitor for the development of autoimmune disorders, including complete blood counts with differential, liver enzymes, serum creatinine, urinalysis, and thyroid function.

Pre-existing renal impairment is a risk factor for death.

In the clinical studies of RETHYMIC, 3 out of 4 patients with pre-existing cytomegalovirus infection died. The benefits/risks of treatment should be considered prior to treating patients with pre-existing CMV infection.

Because of the underlying immune deficiency, patients who receive RETHYMIC may be at risk of developing post-treatment lymphoproliferative disorder. Patients should be monitored for the development of lymphoproliferative disorder.

Transmission of infectious disease may occur because RETHYMIC is derived from human tissue and because product manufacturing includes porcine- and bovine-derived reagents.
Immunizations should not be administered in patients who have received RETHYMIC until immune-function criteria have been met.

All patients should be screened for anti-HLA antibodies prior to receiving RETHYMIC. Patients testing positive for anti-HLA antibodies should receive RETHYMIC from a donor who does not express those HLA alleles. HLA matching is required in patients who have received a prior HCT or a solid organ transplant. Patients who have received a prior HCT are at increased risk of developing GVHD after RETHYMIC if the HCT donor did not fully match the recipient.

Of the 105 patients in clinical studies, 29 patients died, including 23 deaths in the first year (< 365 days) after implantation.

The most common (>10%) adverse events related to RETHYMIC included: hypertension, cytokine release syndrome, rash, hypomagnesemia, renal impairment/failure, thrombocytopenia, and graft versus host disease.

To report suspected adverse reactions, please contact the FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch

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https://news.us.sumitomo-pharma.com/2022-04-22-Enzyvant-Announces-Plans-to-Expand-Regenerative-Medicine-Manufacturing-Capabilities