Sumitomo Pharma

News Release

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Sumitomo Pharma Co., Ltd.

Sumitomo Pharma Builds Cell-Processing Center in U.S.

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that it has decided to construct a cGMP-compliant cell processing center (CPC) in the U.S.

Sumitomo Pharma's consolidated U.S. subsidiary Enzyvant Therapeutics Ltd. obtained approval for RETHYMIC® (allogeneic processed thymus tissue-agdc) from the U.S. Food and Drug Administration (FDA) in October 2021. The facility is designed for the manufacturing of RETHYMIC®.

In addition, Sumitomo Pharma plans to expand the CPC so that it can be used for the production of allogeneic iPS cell-derived regenerative medicine and cell therapy products that the Company plans to commercialize in the future.

Sumitomo Pharma and Enzyvant plan to begin the construction of the CPC (total floor area: 3,385m^2) this summer in the Research Triangle Park area near Durham, North Carolina. Completion is scheduled during fiscal 2023 and the total investment is planned to be approximately $34 million.

Sumitomo Pharma has a manufacturing plant for regenerative medicine and cell therapy products (common name: SMaRT (Sumitomo Pharma Manufacturing Plant for Regenerative Medicine & Cell Therapy)) within its Central Research Laboratories (Suita, Osaka). Furthermore, the plan is to construct the CPC for use as a base for the regenerative medicine and cell therapy business in the U.S.

Reference

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.

About allogeneic iPS cell-derived regenerative medicine and cell therapy products

In the field of regenerative medicine and cell therapy, Sumitomo Pharma is engaged in collaborative research and development projects with industry and academia partners using allogeneic iPS cells (from healthy individuals) for age-related macular degeneration, Parkinson's disease, retinitis pigmentosa, spinal cord injury, etc.

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