

StemRIM Announces Selection for the AMED Project "FY2024 Project for Fundamental Technology Development toward Industrialization of Regenerative Medicine and Gene Therapy"

Osaka, Japan, December 6, 2024 – StemRIM Inc. (TSE:4599, President and CEO: Masatsune Okajima; "StemRIM" or "Company") announces that our company has been selected for the "FY2024 Project for Fundamental Technology Development toward Industrialization of Regenerative Medicine and Gene Therapy (Project to Promote Industrialization of Regenerative, Cellular, and Gene Therapies)" conducted by the Japan Agency for Medical Research and Development (AMED). The overview of the selected research is as follows:

Project Title	: Development of Curative Gene Therapy Technology for Severe Dystrophic Epidermolysis Bullosa
Grant Period	: December 2024 – March 2027
Total Research Budget / Maximum Grant Amount	: 269,750 thousand yen / 179,833 thousand yen
Lead Organization	: StemRIM Inc.
Collaborating Organizations	: Osaka University Hospital Graduate School of Medicine, Osaka University

Dystrophic epidermolysis bullosa is a rare and severe disease. It is caused by a genetic deficiency in type VII collagen, which is essential for the adhesion of epidermal tissues in the outermost layer of the skin. From birth, patients suffer from blistering, erosions, and ulcerations resembling severe burns throughout their lives. Over time, the skin becomes scarred (fibrosis), leading to complications such as fused fingers, limited mouth opening, and esophageal strictures, resulting in a significant decline in their quality of life (QOL). At present, there is no curative treatment for dystrophic epidermolysis bullosa, and its development remains a pressing challenge in modern medicine.

Our company, in collaboration with the Graduate School of Medicine at Osaka University, is advancing the development of a stem cell gene therapy (development code: PJ5). This therapy is based on our proprietary low-invasive technology to harvest mesenchymal stem cells from the skin of epidermolysis bullosa patients. Using a lentiviral vector, the therapy efficiently introduces the type VII collagen gene into mesenchymal stem cells derived from the patient's skin, which are then reintroduced to provide a sustained supply of type VII collagen. This represents a potential curative treatment for epidermolysis bullosa.

In this study, we aim to rapidly transition to physician-led clinical trials by establishing an investigational drug manufacturing system with clinical application in mind. This builds on the gene-modified cell product manufacturing system established in AMED's Step 1 phase and incorporates guidance from the Risk-Based Approach (RS) consultation with the Pharmaceuticals and Medical Devices Agency (PMDA).

The project is eligible to receive AMED subsidies covering two-thirds of the expenses, with a maximum total grant of 179 million yen over three years.

The impact on the financial performance for the fiscal year ending July 31, 2025, is insignificant. We will promptly disclose any additional information that needs to be disclosed.

About StemRIM Inc.

StemRIM Inc. is a biotech venture which began at Osaka University with the goal of realizing a new type of medicine called "Regeneration-Inducing Medicine™". The overall aim is to achieve regenerative therapy effects equivalent to those of regenerative medicine, solely through drug administration, without using living cells or tissues. Living organisms have inherent self-organizing abilities to repair and regenerate tissues that have been damaged or lost due to injury or disease. This ability arises from the presence of stem cells in the body that exhibit pluripotency i.e., can differentiate into various types of tissues. When tissues are damaged, these cells, therefore, exhibit proliferative and differentiative capabilities, promoting functional tissue regeneration. "Regeneration-Inducing Medicine™" is aimed at maximizing the tissue repair and regeneration mechanisms already present in the body. With this aim, StemRIM is currently developing one of its most advanced regenerative medicine products. Specifically, this product is designed to release (mobilize) mesenchymal stem cells from the bone marrow into the peripheral circulation upon administration, thus increasing the number of stem cells circulating throughout the body and promoting their accumulation in damaged tissues. Here, these stem cells should accelerate tissue repair and regeneration. Certain disease areas expected to benefit from "Regeneration-Inducing Medicine™" include epidermolysis bullosa (EB), acute phase cerebral infarction, cardiomyopathy, osteoarthritis of the knees, chronic liver disease, myocardial infarction, pulmonary fibrosis, traumatic brain injury, spinal cord injury, atopic dermatitis, cerebrovascular disease, intractable skin ulcers, amyotrophic lateral sclerosis (ALS), ulcerative colitis, non-alcoholic steatohepatitis (NASH), systemic sclerosis, and any other areas where treatment with ectomesenchymal stem cells is promising.

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For more information, please visit the StemRIM website (<https://stemrim.com/english/>)