

## **StemRIM Announces Initiation of Phase 2 Clinical Trial for Redasemtide in Ischemic Cardiomyopathy**

**Osaka, Japan, March 13, 2024** – StemRIM Inc. (TSE: 4599, President and CEO: Masatsune Okajima; “StemRIM”) announces that a clinical trial plan for Phase 2 investigator-initiated clinical trial, targeting ischemic cardiomyopathy using Redasemtide, has been submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) by Osaka University. Redasemtide is a drug under development that has been licensed out to Shionogi & Co., Ltd. (TSE: 4507, Chief Executive Officer: Isao Teshirogi, Ph.D.). This clinical trial will be initiated with the submission of this clinical trial plan notification.

This clinical trial will be conducted as an investigator-initiated clinical trial at Osaka University Hospital and several other facilities. The main objective of this clinical trial is to evaluate the efficacy and safety of Redasemtide in patients with ischemic cardiomyopathy who have undergone coronary artery bypass grafting. This clinical trial will evaluate various cardiac function tests such as echocardiography at 52 weeks after treatment with either Redasemtide or placebo (10 patients each) for 5 days.

"Regeneration-Inducing Medicine™" Redasemtide is a completely new concept in medicine that induces functional regeneration of organs and tissues damaged by injury or disease. The ectodermal mesenchymal stem cells induced by administration of Redasemtide can differentiate into diverse tissues and are expected to be effective in a variety of disease areas, including ischemic cardiomyopathy. Furthermore, as it is administered through intravenous infusion and does not involve the use of live cells, this pharmaceutical product is industrially producible. Unlike traditional regenerative medical products that utilize live cells, it avoids quality control issues during manufacturing and product transport. It is anticipated to have a cost advantage and widespread adoption due to its simple administration method.

In clinical trials to date, the safety and efficacy of Redasemtide have been confirmed in dystrophic epidermolysis bullosa (additional Phase 2 clinical trial ongoing at Osaka University Hospital and other institutions), acute ischemic stroke (global Phase 2b clinical trial ongoing in Japan, the United States, and Europe), knee osteoarthritis (Phase 2 investigator-initiated clinical trial completed at Hirosaki University Hospital), and chronic liver disease (Phase 2 investigator-initiated clinical trial I completed at Niigata University Medical and Dental Hospital). Ischemic cardiomyopathy will be the 5th indication for Redasemtide in a Phase 2 clinical trial.

The impact on the financial performance for the fiscal year ending July 31, 2024, is nothing. Nevertheless, we believe it contributes to the medium to long-term improvement of our overall performance.

## **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 extrapulmonary mesenchymal stem cells is promising.

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