

StemRIM Announces Conclusion of Agreement for the Initiation of a Phase2 Clinical Trial for Redasemtide in Ischemic Cardiomyopathy

Osaka, Japan, December 4, 2023 – StemRIM Inc. (TSE: 4599, President and CEO: Masatsune Okajima; "StemRIM") announces that we have entered into a contract for the implementation of a Phase 2 investigator-initiated clinical trial targeting ischemic cardiomyopathy using Redasemtide, in collaboration with Osaka University Hospital and Shionogi & Co., Ltd. (TSE: 4507, Chief Executive Officer: Isao Teshirogi, Ph.D.; "Shionogi")

This clinical trial will be conducted as an investigator-initiated clinical trial mainly at Osaka University Hospital and is planned to start in the first half of 2024, with the primary objective of evaluating the efficacy and safety of Redasemtide in patients with ischemic cardiomyopathy.

Under the terms of the agreement, StemRIM and Shionogi will support the implementation of the clinical trial by providing the investigational drug, information necessary for the submission of the notification of clinical trial, and support for the preparation of various materials related to the clinical trial.

Redasemtide is a candidate for the development of "Regeneration-Inducing Medicine[™]", which regenerates tissue damaged by injury or disease through the administration of medication without the use of living cells. Ischemic cardiomyopathy will be the fifth indication for which Redasemtide is being tested in Phase 2 clinical trials, following dystrophic epidermolysis bullosa, acute ischemic stroke, osteoarthritis of the knee, and chronic liver disease.

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[™]"</sup> 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/)