

StemRIM Announces Milestone Achievement in Development of Therapeutic Drug (Redasemtide) Targeting Acute Ischemic Stroke

Osaka, Japan, April 10, 2023 – StemRIM Inc. (TSE: 4599, Chairman and CEO: Kensuke Tomita; "StemRIM") announced the commencement, from today, of a global late Phase 2 clinical trial of Redasemtide in patients with acute ischemic stroke in Japan. This developmental milestone was achieved after receiving approval from PMDA, in response to a clinical trial plan submitted by Shionogi & Co., Ltd. (TSE: 4507, Chief Executive Officer: Isao Teshirogi, Ph.D; "Shionogi") on March 27, 2023

Originally, a global Phase 3 trial was planned, but, for the purpose of dose setting, a global Phase 2 trial was chosen instead. For further details, please refer to the disclosure made by Shionogi today titled "Initiation of a Global Late Phase 2 Clinical Trial of the Regeneration Inducing Medicine Redasemtide in Patients with Acute Ischemic Stroke" for details. The trial is expected to start sequentially in the United States, Europe, and China.

We have received a milestone payment of 450 million yen from Shionogi, based on our license agreement, which we have recorded in the business revenue disclosed in today's "Notice of Earnings Forecasts for the Fiscal Year Ending July 31, 2023".

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 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/>)