

StemRIM Announces the Initiation of Global Late Phase 2 Clinical Trials for Redasemtide (HMGB1 Peptide) Targeting Acute Ischemic Stroke (Europe, China)

Osaka, Japan, July 25, 2023 – StemRIM Inc. (TSE: 4599, Chairman and CEO: Kensuke Tomita; “StemRIM”) announced the commencement, from today, of a global late Phase 2 clinical trial for Redasemtide in patients with acute ischemic stroke in the Europe and China. Shionogi & Co., Ltd. submitted the Clinical Trial Plan Notification for the global Phase 2 clinical trial to the European Medicines Agency on March 31, 2023, and to the National Medical Products Administration in China on April 28, 2023. Today, we have received confirmation that the approval for the trial has been obtained in each respective region.

Originally, a global Phase 3 trial was planned, but a global late Phase 2 trial was chosen instead for dose setting. For further details, please refer to the disclosure made by Shionogi on April 10, 2023, 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 has already been underway in Japan and the United States, and it has just started in Europe and China.

This development is progressing as planned and is not expected to have any impact on the financial performance for the fiscal year ending July 31, 2023. However, we believe that it will contribute to the improvement of our performance in the medium to long term.

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/>)