March 3, 2025
StemRIM Inc.

StemRIM Announces the Protocol Amendment for the Global Phase 2b Clinical Trial in Patients with Acute Ischemic Stroke

Osaka, Japan, March 3, 2025 – StemRIM Inc. (TSE:4599, President and CEO: Masatsune Okajima; "StemRIM" or "Company") announces that the protocol amendment for the global late-stage Phase 2 clinical trial of Redasemtide, which was previously out-licensed from our company to Shionogi & Co., Ltd (TSE:4507, Representative Director, President and CEO: Isao Teshirogi ; "Shionogi") for the treatment of acute ischemic stroke(AIS).

This clinical trial is being conducted in 18 countries worldwide, including Japan, the United States, and Europe, to evaluate the efficacy and safety of Redasemtide in AIS patients who are not eligible for endovascular recanalization therapy. The trial consists of 3 cohorts, with patients receiving Redasemtide at a dose of 1.5 mg/kg, Redasemtide at a dose of 0.75 mg/kg, or a placebo for 5 days. *

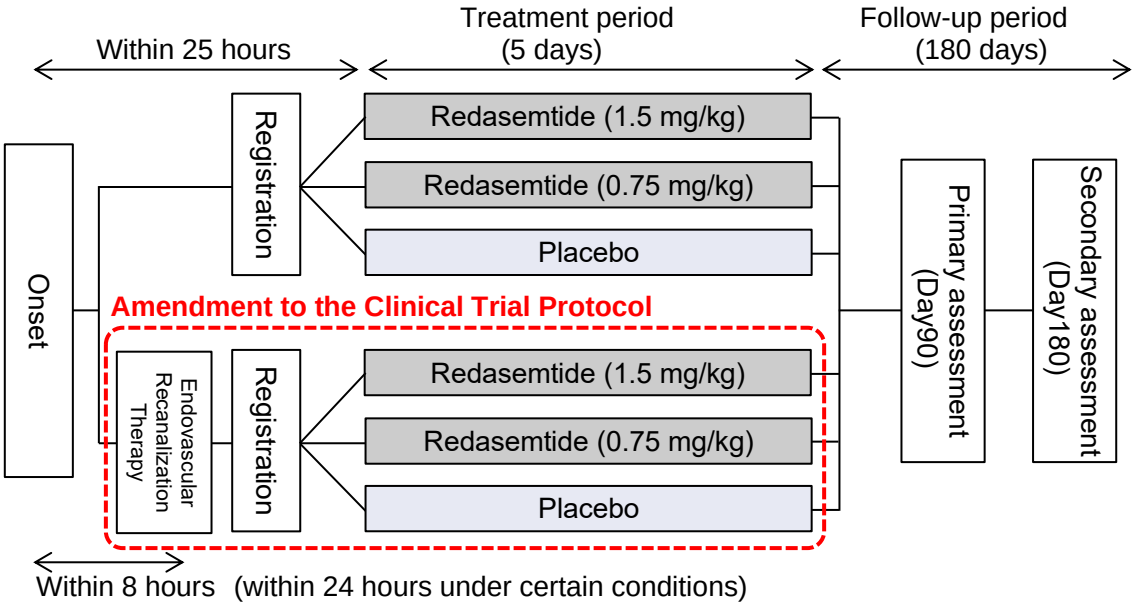
With advances in medical technology, the treatment paradigm for AIS has undergone significant changes, and the proportion of patients eligible for treatment with endovascular recanalization therapy has been rapidly increasing. To adapt to these changes and enable broader patient access to Redasemtide after its market approval, an interim analysis will be conducted to confirm the reproducibility of Redasemtide efficacy in patients with AIS who are not eligible for endovascular recanalization therapy. Based on this analysis, a new cohort of patients who have undergone endovascular recanalization therapy will be added to the study.

The total number of cases and study groups will be determined based on the results of the interim analysis. Although the total number of enrolled cases in the trial will increase due to the addition of this new cohort, the eligibility criteria for both the existing and additional cohorts will be relaxed, lowering the NIHSS** score requirement from 8 or higher to 6 or higher. Furthermore, the new cohort will include patients who were initially ineligible for the trial, thereby allowing a larger number of patients to participate. As a result of these modifications, a significant extension of the trial period is not expected.

The market size for ischemic stroke in global markets, including Japan, the United States, five European countries, and China, is estimated to reach $10.56 billion by 2027. With the rapid expansion of endovascular recanalization therapy, the market environment is expected to undergo significant changes. In this context, the amendment to the clinical trial protocol is of critical importance in adapting to these changes, and we are very pleased to proceed with this adjustment.

At this time, there is no impact on the financial results for the fiscal year ending July 31, 2025, due to this matter.

Cohort Addition Overview



* For details of this clinical trial, please refer to the announcement made by Shionogi & Co., Ltd. on April 10, 2023, titled "Initiation of a Global Phase II Late-Stage Clinical Trial of the Regeneration-Inducing Medicine™ Redasemtide in Patients with Acute Ischemic Stroke."
** NIHSS (National Institutes of Health Stroke Scale): The NIHSS consists of 11 items assessing various neurological functions, including the level of consciousness, consciousness disorders (orientation and memory), gaze, visual fields, facial palsy, motor function of both upper and lower limbs, limb ataxia, sensory function, speech, extinction, and inattention. Each item is scored on a scale ranging from 0 to 4. The total score ranges from a minimum of 0 to a maximum of 40, with the overall score indicating the severity of the stroke.

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.

Inquiries:
StemRIM Inc.
Management & Administrator Dept.
E-Mail: stemrim-ir@stemrim.com
Twitter: @StemRIM_Inc

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