April 2, 2025
StemRIM Inc.

StemRIM Announces the Interim Analysis Results for the Global Phase 2b Clinical Trial in Patients with Acute Ischemic Stroke

Osaka, Japan, April 2, 2025 – StemRIM Inc. (TSE:4599, President and CEO: Masatsune Okajima; "StemRIM" or "Company") announces that the interim analysis results for the global Phase 2b 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, we conducted an interim futility analysis by dose group in AIS patients for whom endovascular reperfusion therapy could not be performed.

In this interim analysis, a predefined futility criterion was established. For each dose group, if the results met the futility criterion compared to the placebo group, the study would be discontinued for that group; if not, it would be continued. To maintain blinding, an independent evaluation committee assessed the data and provided recommendations to Shionogi regarding the continuation or discontinuation of each dose group.

As a result of the interim analysis, the evaluation committee recommended continuing the trial for Redasemtide (1.5 mg/kg) group and discontinuing the trial for Redasemtide (0.75 mg/kg) group. While Redasemtide (1.5 mg/kg) group was originally selected as the expected efficacious dose at the start of the trial, the inclusion of Redasemtide (0.75 mg/kg) group was mandated by regulatory authorities.

The outcome of this interim analysis falls within the anticipated range. With the discontinuation of the lower dose group, the required number of subjects will be reduced, and further progress in the study is expected moving forward.

Going forward, the target number of subjects will be redefined to include the additional cohort; however, the overall study duration is not expected to be extended. The results of this interim analysis hold significant importance in the clinical development of this investigational drug for AIS, and we are very pleased with the outcome.

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

* 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 2b Clinical Trial of the Regeneration-Inducing Medicine™ Redasemtide in Patients with Acute Ischemic 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 ischemic stroke, 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/)