April 10, 2023
StemRIM Inc.

StemRIM Announces Preliminary Results from Phase 2 Clinical Trial of Redasemtide in Patients with Chronic Liver Disease

Osaka, Japan, 10th April, 2023 – StemRIM Inc. (TSE: 4599, Chairman and CEO: Kensuke Tomita; "StemRIM") announced today, that the primary endpoint of its investigator-initiated Phase 2 clinical trial of Redasemtide in patients with chronic liver disease who had undergone prescribed surgical procedures, has been achieved.

In this study, Redasemtide was administered to two groups (cohorts) of patients by using different dosing methods, to evaluate its safety and exploratory efficacy during treatment and follow-up periods of 4 and 20 weeks, respectively. The primary endpoint was to assess the safety of the drug during administration, and it was confirmed to be well-tolerated. Specifically, out of 10 patients in both cohorts, only one patient experienced a serious adverse event (bleeding during liver biopsy), and two patients experienced adverse events that could not be definitively attributed to the drug (one case of hoarseness and one case of fever, both mild).

The secondary endpoint was to evaluate the efficacy of the drug after administration, and is currently being analyzed. A reduction of 8–12% in liver stiffness was observed in one of the cohorts after drug administration, by using MR elastography, which is the most reliable method for evaluating liver fibrosis in chronic liver disease.

An overview of this study can be found in the Japan Registry of Clinical Trials (jRCT2031200232), a clinical research database.

This matter is progressing as planned and has no impact on our financial results for the fiscal year ending July 31, 2023.

About StemRIM Inc.

StemRIM Inc. is a biotech venture which began in 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 stems 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/)