Press Release

SHIONOGI Announces Positive Results from a Phase 2 Clinical Trial of the Regeneration Inducing Medicine S-005151 (Redasemtide) in Patients with Acute Ischemic Stroke

OSAKA, Japan, December, 13, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that the primary endpoint in a Phase 2 clinical trial of redasemtide in patients with acute ischemic stroke (hereafter "this trial") was achieved. Redasemtide is a regeneration-inducing development compound introduced by StemRIM Inc. (Headquarters: Ibaraki City, Osaka; Chairman and CEO: Kensuke Tomita; hereafter "StemRIM").

This trial was a phase 2 placebo-controlled, double-blind, randomized, controlled trial in patients with acute ischemic stroke within 4.5 to 24 hours after onset who were not candidates for revascularization therapy (thrombolytic therapy or mechanical thrombectomy). The primary objective of this trial was to examine the efficacy and safety of redasemtide. The primary endpoint, assessed on the modified Rankin Scale* (mRS) 90 days after administration, was achieved. The incidence of adverse events was similar between the redacemtide group and the placebo group, confirming the favorable tolerability of redasemtide.

Redasemtide is a development-stage regeneration-inducing medicine that regenerates tissue damaged by injury or disease by administration of a drug without using living cells. Shionogi is advancing development of this compound in dystrophic epidermolysis bullosa, chronic liver disease, knee osteoarthritis and cardiomyopathy, in addition to acute ischemic stroke. Based on the results of this trial, Shionogi will prepare for the transition to global Phase 3 clinical trials for acute ischemic stroke.

Shionogi is pursuing its vision toward 2030, "Building Innovation Platforms to Shape the Future of Healthcare" and is striving to contribute to the better health and quality-of-life of people all over the world, in partnership with academia and innovative companies, in addition to our own R&D activities.

* modified Rankin Scale: A scale commonly used to measure the degree of disability or dependence in the daily activities of people suffering from stroke or other causes of neuropathy

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack

of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:
SHIONOGI Website Inquiry Form：https://www.shionogi.com/global/en/contact.html

About StemRIM
StemRIM is a drug discovery research and development oriented biotech company originating from Osaka University. It was established in 2006 with the aim of developing a myelomultiactive stem cell recruitment factor as a pharmaceutical product, which was identified by Professor Tamai and his colleagues at the Graduate School of Medicine, Osaka University. Since then, through joint research with Osaka University, StemRIM has been consistently pursuing the development of “regeneration-inducing medicine”, which is medicine promoting functional tissue regeneration and enabling the treatment of previously intractable diseases. StenRIM is continuing to undertake the challenge of becoming a world-leading bioventure company with the corporate mission of "overcoming intractable diseases with regeneration-inducing medicine." For more information, please refer to the StemRIM website.

Reference
1. Shionogi R&D Meeting (September 29, 2021) More information on redasemtide , refer to : p57-65
2. Press release(June 30, 2020)
   Signing of a new contract with StemRIM -Toward Investigator-initiated Clinical Study Implementation of S-005151 [Generic Name: Redasemtide] -