

Signing of a new contract with StemRIM - Toward Investigator-initiated Clinical Study Implementation of S-005151 [Generic Name: Redasemtide] -

OSAKA, Japan, June 30, 2020 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi and StemRIM Inc. (Headquarters: Ibaraki City, Osaka; Chairman and CEO: Kensuke Tomita; hereinafter "StemRIM") have entered into a new license agreement for S-005151 [Generic name: Redasemtide] to conduct investigator-initiated clinical studies targeting new indications in the future.

Redasemtide is an innovative new class of medicine named "Regeneration-inducing Medicine" that induces functional regeneration of patient's tissues and organs damaged due to injury or illness by maximizing the human body's innate ability of tissue repairing. Redasemtide increases the amount of circulating mesenchymal stem cells and accumulate them in the damaged tissues by mobilizing bone marrow mesenchymal stem cells into the peripheral blood stream, resulting in acceleration of the reconstruction of damaged tissues. The efficacy in patients with dystrophic epidermolysis bullosa was confirmed by the investigator-initiated Phase II clinical study conducted at Osaka University and other institutions, and Shionogi is preparing for NDA submission. Shionogi is also conducting Phase II clinical study for acute ischemic stroke.

(For more information on redasemtide, please refer to our R&D meeting in March 2020.)

This license agreement enables Shionogi to utilize the evidence of non-clinical research that has been accumulated by StemRIM through joint research with several academia groups. Shionogi and StemRIM will promote investigator-initiated clinical studies for three new indications (chronic liver disease, knee osteoarthritis, and cardiomyopathy).

Shionogi is strengthening Life Cycle Management strategy to maximize the value of the compound in order to provide healthcare solutions to patients under the R&D strategy outlined in our new medium-term business plan "Shionogi Transform Strategy 2030 (STS2030)". Shionogi has its vision toward 2030, "Building Innovation Platforms to Shape the Future of Healthcare" and is striving to contribute to the better health and QOL of people all over the world by utilizing partnership with academia and creative companies in addition to our own R&D activities.

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 myelomulti-active stem cell recruitment factor as a pharmaceutical product, which was identified by Professor Tamai and his colleagues at the Graduate School of Medicine, Osaka

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University. Since then, through joint research with Osaka University, StemRIM has been consistently worked on the development of “regeneration-inducing medicine”, which is medicine promoting functional tissue regeneration and enabling the treatment of intractable diseases. StemRIM is continuing to take on the challenge of becoming a world-leading bioventure with the corporate mission of "overcoming intractable diseases with regeneration-inducing medicine." For more information, see on the [Stemrim website](#).

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, unavailability 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.

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For reference:

1. [Shionogi R&D Meeting \(March 19, 2020\)](#)
More information on redasemtide, see : p78-85