PRESSRELEASE

SHIONOGI

Initiation of a Global Late Phase 2 Clinical Trial of the Regeneration Inducing Medicine® Redasemtide in Patients with Acute Ischemic Stroke

OSAKA, Japan, April 10, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that a global late phase 2 clinical trial in patients with acute ischemic stroke of redasemtide (code No. S-005151), a regeneration inducing medicine® introduced by StemRIM Inc. (Headquarters: Ibaraki City, Osaka; Chairman and CEO: Kensuke Tomita; hereafter "StemRIM"), was initiated.

Based on positive results from the phase 2 clinical trial in Japan, we have been discussing with regulatory authorities in each major region regarding the registration path, originally intending to initiate a global Phase 3 clinical trial[1]. Based on regulatory agency feedback, we have decided to partially revise the development plan and to conduct this trial for the purpose of dose setting.

This trial will evaluate the efficacy and safety of redasemtide (1.5 mg/kg), redasemtide (0.75 mg/kg), and placebo for 5 days in 627 acute ischemic stroke patients aged 18 years or older within 25 hours after onset. This trial has initiated in Japan and is scheduled to be opened subsequently at sites in the US, Europe and China. After obtaining optimal dose information from this study, Shionogi plans to initiate a global phase 3 clinical trial to support manufacturing and marketing approval submission. We expect that the impact of this development plan change on the overall submission timing is insignificant at present.

Shionogi is pursuing its vision toward 2030, "Building Innovation Platforms to Shape the Future of Healthcare" and is striving to contribute to the 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.

About redasemtide

Redasemtide is a regeneration-inducing medicine® under development that regenerates tissues damaged by injury or disease without using living cells. In order to provide healthcare solutions to as many patients as possible by taking advantage of the characteristics of regeneration-inducing medicine®, we are engaging in its development for epidermolysis bullosa, chronic liver disease, knee osteoarthritis, and cardiomyopathy, in addition to acute ischemic stroke.

About the phase 2 clinical trial of redasemtide in patients with acute ischemic stroke in Japan

This trial evaluated the efficacy and safety of redasemtide (1.5 mg/kg) for 5 days in 150 acute ischemic stroke patients. The primary endpoint was assessed on the modified Rankin Scale* (mRS) 90 days after administration. As a result, the rate of improvement to a socially independent level that does not require assistance (the rate of achieving mRS ≤ 2) increased approximately twice as much in the redasemtide group as in the placebo group at 90 days after administration (redasemtide group: 34%, placebo group: 18%)[2].

* 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

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. StemRIM 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.

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.

Reference

1. Shionogi R&D Meeting (October 12, 2022) More information on redasemtide, refer to: p62-64
2. Shionogi press release (December 13, 2021)
   SHIONOGI Announces Positive Results from a Phase 2 Clinical Trial of the Regeneration Inducing Medicine S-005151 (Redasemtide) in Patients with Acute Ischemic Stroke

For Further Information, Contact:

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html