PRESSRELEASE

SHIONOGI

StemRIM and Shionogi Announce Topline Results of Clinical Trials of Redasemtide in Patients with Dystrophic Epidermolysis Bullosa and Acute Ischemic Stroke

- Additional Phase 2 trial in dystrophic epidermolysis bullosa[1]: The primary endpoint of refractory ulcer closure was met in three out of four patients. Additionally, improvement in systemic symptoms was also observed in certain cases.
- Global Phase 2 trial in acute ischemic stroke[2]: The primary endpoint—measured by the modified Rankin Scale at Day 90— did not demonstrate a statistically significant difference compared to the placebo group; the primary endpoint was not met.
- Safety: Both trials identified no safety concerns related to redasemtide, and tolerability was confirmed to be favorable.

OSAKA, Japan, September 9, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced the results of an additional Phase 2 clinical trial in patients with dystrophic epidermolysis bullosa and a global Phase 2 clinical trial in patients with acute ischemic stroke for redasemtide (a peptide drug created from HMGB1[1)]; development code: S-005151), a regeneration-inducing medicine® candidate in-licensed from StemRIM Inc. (Head Office: Osaka, Japan; President and CEO: Masatsune Okajima; hereafter "StemRIM").

In the additional Phase 2 clinical trial in patients with dystrophic epidermolysis bullosa, the primary endpoint of closure of refractory ulcers was met in 3 of 4 patients. In addition, in certain cases, favorable results were also observed for clinical symptoms, including the total body ulcer area. No new safety concerns were identified for redasemtide, and tolerability was confirmed to be favorable.

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In the global Phase 2 clinical trial in patients with acute ischemic stroke, the efficacy and safety of redasemtide or placebo were evaluated in patients with acute ischemic stroke within 25 hours of onset. In the cohort that did not undergo endovascular recanalization therapy[2)], the primary endpoint was the modified Rankin Scale (mRS)[3)] at 90 days after the start of study drug administration, which indicates the degree of prognosis toward returning to social life. As a result, the redasemtide group did not show a statistically significant improvement compared with the placebo group, and this trial did not achieve its primary endpoint.
A trend toward improvement in mRS was observed in the redasemtide group in this Phase 2b study, similar to the previous Phase 2 trial conducted in Japan. Furthermore, in the Phase 2b study, an exploratory subgroup analysis suggested a trend toward improvement in mRS in the redasemtide group among patients with higher severity at onset within the cohort that did not undergo endovascular recanalization therapy. In addition, the incidence of adverse events was comparable between the redasemtide and placebo groups; no new safety concerns were identified in this trial either and tolerability was confirmed to be favorable.

Dystrophic epidermolysis bullosa is a serious rare disease with limited effective treatment options. Based on the results obtained in this trial, Shionogi will continue discussions with StemRIM and relevant parties, and will continue to consider its future development policy, so that this drug can be delivered as soon as possible to

the patients who need it. Regarding the development for acute ischemic stroke, Shionogi will continue to consider its future policy after conducting a detailed analysis of the results obtained in this trial.

1) HMGB1 (High Mobility Group Box 1): one of the nuclear proteins of cells that recruits mesenchymal stem cells in the body to the affected area.
2) Endovascular recanalization therapy: a general term for thrombolytic therapy and mechanical thrombectomy. Thrombolytic therapy is a treatment that dissolves the thrombus and restores blood flow by intravenously administering a thrombolytic agent (t-PA), and is selected within 4.5 hours of onset. Mechanical thrombectomy is a treatment that retrieves the thrombus using a catheter and thrombus-retrieval device and is selected within 8 hours of onset (within 24 hours if various conditions are met).
3) 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 neurological impairment.

About Redasemtide
Redasemtide is a regeneration-inducing medicine® candidate that regenerates tissue damaged by injury or disease through the administration of a drug, without using living cells. Leveraging the characteristics of regeneration-inducing medicine®, Redasemtide is in development in chronic liver disease, osteoarthritis, and cardiomyopathy, in addition to dystrophic epidermolysis bullosa and acute ischemic stroke.

About Dystrophic Epidermolysis Bullosa
The skin consists of three layers: the epidermis, the dermis, and the subcutaneous tissue. Between the epidermis and the dermis, there are proteins necessary for adhesion, forming a structure that does not easily separate even when external force is applied to the skin. However, in epidermolysis bullosa, mutations in the genes encoding these structural proteins of the skin mean that even slight stimulation in daily life causes erosions and blisters on the skin and mucous membranes, significantly affecting daily life. Epidermolysis bullosa is classified according to the type of causative protein gene, and dystrophic epidermolysis bullosa is the most common type, accounting for approximately 50% of all cases. In severe cases, the risk of digital fusion, esophageal stricture, iron-deficiency anemia, and the development of scar cancer also increases. The number of patients with epidermolysis bullosa in Japan is estimated to be approximately 500 to 1,000, but there is currently no fundamental treatment.
Reference: Japanese Dermatological Association / Japan Intractable Diseases Information Center

About Acute Ischemic Stroke
Acute ischemic stroke occurs when cerebral blood flow decreases due to occlusion or stenosis of a cerebral blood vessel. Treatments for cerebral infarction include endovascular recanalization therapies such as intravenous thrombolytic therapy using tissue plasminogen activator (t-PA), intra-arterial thrombolytic therapy, and thrombectomy; however, the patients eligible for these treatments are limited, and even when applied, the effect is limited in some patients. Therefore, the development of new treatments for acute ischemic stroke is anticipated.

About StemRIM
StemRIM Inc. is a "drug-discovery R&D-type" biotech company that originated from Osaka University. It was established in 2006 with the aim of developing, as a pharmaceutical, the bone-marrow-derived pluripotent stem cell mobilization factor identified by Professor Katsuto Tamai and colleagues at the Graduate School of Medicine, Osaka University. Since then, through joint research with Osaka University, it has been engaged in research and development aimed at realizing regeneration-inducing medicine®, which promotes the functional regeneration and healing of biological tissues that have been damaged and lost their function due to injury or disease. Under its corporate mission of "overcoming intractable diseases through regeneration

induction," it continues to take on challenges to become a world-leading bioventure. For details, please visit StemRIM's website.

Reference:
1. Japan Registry of Clinical Trials (jRCT2031220378)
2. Japan Registry of Clinical Trials (jRCT2031230083)

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.

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