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Application for Manufacturing and Marketing Approval of a New Lotion Formulation for the Atopic Dermatitis Treatment "CORECTIM®" in Japan

OSAKA, Japan, February 27, 2026 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and Torii Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan; President and CEO: Nobumasa Kondo; hereinafter "Torii"), a wholly owned subsidiary of the SHIONOGI Group, are pleased to announce the submission of an application for manufacturing and marketing approval for a 0.5% lotion formulation (hereinafter "this product") of the atopic dermatitis treatment CORECTIM® (generic name: delgocitinib), which we are jointly developing.

CORECTIM® is a non-steroidal, JAK inhibitors that are expected to improve autoimmune and allergic diseases by inhibiting the action of JAKs, which play key roles in immune activation signaling in cells, by suppressing the overactivation of immune responses. In Japan, the ointment formulation has been approved for the treatment of atopic dermatitis in adults and children^{1,2} and is now also available for use in infants³.

Atopic dermatitis is a chronic disease that repeatedly worsens and improves, making stable symptom control over the long term essential. Therefore, a therapeutic drug that can be used over the long term and can control symptoms is needed. This application for approval of the additional formulation is based on the positive results of a Phase 1 skin safety study ([jRCT2031230570](#)) and a Phase 3 bioequivalence study ([jRCT2031230713](#)). The Phase 1 skin safety study confirmed safety, while the Phase 3 bioequivalence study confirmed bioequivalence to CORECTIM® 0.5% Ointment and safety.⁴ Generally speaking, the lotion formulation can be easily applied to the scalp and other hairy areas where ointments are difficult to use. Its low greasiness and pleasant, lightweight texture are expected to support improved patient adherence to treatment.

Shionogi has identified "contributing to a healthy and prosperous life" as a key materiality and is committed to building a society where everyone can live longer, healthier, and more fulfilling lives in their own way. Shionogi and Torii Pharmaceutical will continue to work hard to deliver this drug as soon as possible to contribute to the treatment and improvement of the quality of life of patients suffering from atopic dermatitis.

About Atopic Dermatitis

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to develop through exposure to various irritants or allergens for patients with a physiological abnormality of the skin (dry skin and abnormal skin barrier function).

About Delgocitinib

Delgocitinib, under the product name "CORECTIM[®] Ointment," was approved in Japan in January 2020 as the world's first non-steroidal topical JAK inhibitor. Currently, Shionogi is the manufacturer and distributor, and Torii Pharmaceutical is the distributor, with both companies co-promoting the drug in Japan. In 2014, LEO Pharma signed a license agreement for the exclusive development and commercialization of topical skin preparations worldwide except for Japan. LEO Pharma has obtained approval for the treatment of chronic hand eczema in Europe and the United States, and is selling the product under the name "Anzupgo[®] Cream."

Reference:

1. [Torii Pharmaceutical Co., Ltd. Press Release: January 23, 2020](#)
2. [Torii Pharmaceutical Co., Ltd. Press Release: March 23, 2021](#)
3. [Torii Pharmaceutical Co., Ltd. Press Release: December 14, 2021](#)
4. [Torii Pharmaceutical Co., Ltd. Press Release: May 14, 2025](#)

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>