PRESSRELEASE

SHIONOGI

Positive Interim Analysis Results from Phase 3 Clinical Trial of Tapinarof Cream 0.5%, Aryl Hydrocarbon Receptor (AhR) Modulating Agent, in Infant Patients with Atopic Dermatitis in Japan

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OSAKA, Japan, May 19, 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; hereafter "Torii"), a wholly owned subsidiary of Shionogi, announced today positive interim analysis results (data cutoff: March 2026) of a Phase 3 trial in infant patients with atopic dermatitis in Japan for tapinarof cream 0.5%, an Aryl hydrocarbon Receptor (AhR) modulating agent.

This Phase 3, an open-label, uncontrolled trial evaluates the efficacy and safety of tapinarof cream 0.5% over 52 weeks in infant patients (aged 3 months to <24 months) with atopic dermatitis, in Japan[1].
The interim analysis results show the cream's effect in improving skin eczema. The safety of the cream within the treatment period was also confirmed. Based on these results and other clinical studies, Shionogi and Torii aim to expand the use of tapinarof for infant patients with atopic dermatitis in Japan.

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

About tapinarof
In 2020, Japan Tobacco Inc. (whose pharmaceutical business has since been transferred to Shionogi; hereafter "JT") previously entered into an exclusive license agreement with Dermavant Sciences GmbH (which was later acquired by Organon & Co.) for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. JT also signed an exclusive license agreement with Torii for the co-development and commercialization of tapinarof in Japan.
In June 2024, JT received manufacturing and marketing approval in Japan for tapinarof cream 1% (VTAMA® Cream 1%) for the treatment of atopic dermatitis in patients aged 12 years and older and plaque psoriasis in adults. VTAMA® Cream 1% has been distributed in Japan by Torii since October 2024 and is currently being co-promoted by Shionogi and Torii.
Furthermore, JT submitted a manufacturing and marketing authorization application in Japan in October 2025 for tapinarof cream 0.5% for the treatment of atopic dermatitis in pediatric patients aged 2 to <12 years.

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)[2].

Reference:

1. Japan Registry of Clinical Trials（jRCT2031250138）
2. Japanese guidelines for atopic dermatitis (ADGL) 2024

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