



Announcement Regarding Torii Pharmaceutical's Announcement Regarding New Drug Application for JTE-061 Cream, Aryl hydrocarbon Receptor (AhR) modulating agent, for the Treatment of Pediatric Atopic Dermatitis in Japan

OSAKA, Japan, October 10, 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.) hereby announces that its group company, Torii Pharmaceutical Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; President and Chief Executive Officer: Nobumasa Kondo), has issued a press release regarding a new drug application for JTE-061 Cream, aryl hydrocarbon receptor modulating agent, for the treatment of pediatric atopic dermatitis in Japan.

Below is the announcement released by Torii Pharmaceutical.

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) announced today that JT has filed a New Drug Application for JTE-061 (generic name: tapinarof) cream 0.5%, a therapeutic aryl hydrocarbon receptor modulating agent, for the treatment of pediatric patients aged 2 to <12 years with atopic dermatitis.

In 2020, 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. Under this agreement, JT and Torii are jointly developing tapinarof cream 0.5% for pediatric patients with atopic dermatitis, and Torii will be responsible for marketing the product in Japan subsequent to JT's obtaining manufacturing and marketing approval.

In the Phase 3 clinical study conducted in Japan in pediatric patients aged 2 to <12 years with atopic dermatitis, tapinarof cream 0.5% met the primary efficacy endpoint, demonstrating superiority over vehicle. Furthermore, the safety of tapinarof cream 0.5% was confirmed during long-term treatment. JT and Torii expect that tapinarof cream 0.5% will offer a new treatment option for pediatric patients with atopic dermatitis in Japan.

In addition, in June 2024, JT received manufacturing and marketing approval in Japan for tapinaorf 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.

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 in patients with a physiological abnormality of the skin (dry skin and abnormal skin barrier function).

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>