PRESSRELEASE

SHIONOGI

Notice Regarding Approval of an Additional Dosage and Administration of VTAMA® Cream for Pediatric Atopic Dermatitis (Under Age12) in Japan

---

OSAKA, Japan, September 16, 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: Nobumasa Kondo; hereafter "Torii"), a SHIONOGI Group company, announced that they have today obtained manufacturing and marketing approval for VTAMA® Cream 0.5% (generic name: tapinarof; hereafter "the drug"), for the indication of atopic dermatitis in pediatric patients under 12 years of age.

The drug is a nonsteroidal, small molecule therapeutic aryl hydrocarbon receptor (AhR) modulating agent that suppresses the production of inflammatory cytokines and induces gene expression of skin barrier function-related and antioxidant molecules through the activation of AhR. In Japan, VTAMA® Cream 1% has obtained manufacturing and marketing approval for atopic dermatitis in adults and pediatric patients aged 12 years and older, as well as for plaque psoriasis in adults.[1]

This approval is based on the results of a domestic Phase 3 clinical trial[2] conducted in pediatric patients with atopic dermatitis (aged 2 to under 12 years). In the trial, the efficacy and safety of the drug administered once daily for 8 weeks were evaluated in comparison with the vehicle cream, and the long-term safety of administration for up to 60 weeks was also evaluated. As a result, the primary efficacy endpoint was met, with the drug showing superiority over the vehicle cream, and favorable tolerability was also confirmed with respect to long-term safety. Atopic dermatitis frequently develops in childhood, and with this approval, the drug is expected to become a new treatment option for pediatric patients.

The SHIONOGI Group has identified "Contributing to a healthier and enriched life" as one of its material issues and is advancing initiatives toward realizing a society in which everyone can live longer, more vibrant lives that are true to themselves. Shionogi and Torii will continue to strive to deliver the drug as quickly as possible, in order to contribute to the treatment and quality of life (QOL) of pediatric patients with 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 in patients with a physiological abnormality of the skin (dry skin and abnormal skin barrier function).

About Tapinarof

In 2020, Japan Tobacco Inc. (whose pharmaceutical business has since been transferred to Shionogi; hereafter "JT") and Dermavant Sciences GmbH (which was later acquired by Organon & Co.) entered into an agreement for the exclusive development and commercialization rights of tapinarof for dermatological diseases in Japan, and JT and Torii Pharmaceutical entered into an agreement for its co-development and marketing in Japan. Tapinarof was approved in Japan in 2024 under the product name "VTAMA® Cream 1%."[1] Currently, Shionogi is the manufacturer and distributor, and Torii Pharmaceutical is the distributor, with both companies co-promoting the product in Japan.

Reference:

1. Japan Tobacco Inc. Press Release, June 24, 2024 — [JT News] Regarding the Acquisition of Manufacturing and Marketing Approval in Japan for the Atopic Dermatitis Treatment and Plaque Psoriasis Treatment "VTAMA® Cream 1%"
2. Japan Registry of Clinical Trials (jRCT2031230139)

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