



**FOR IMMEDIATE RELEASE**

Tokyo, June 24, 2024

**JT Receives Manufacturing and Marketing Approval of  
VTAMA<sup>®</sup> Cream 1%  
for the Treatment of Atopic Dermatitis and Plaque Psoriasis in Japan**

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that JT has today received manufacturing and marketing approval for VTAMA<sup>®</sup> Cream 1% (generic name: tapinarof), an aryl hydrocarbon receptor (AhR) modulating agent, for the indications of atopic dermatitis and plaque psoriasis in Japan.

VTAMA<sup>®</sup> Cream 1% is a nonsteroidal, small molecule therapeutic 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, a cytosolic ligand-dependent transcription factor. Based on this mechanism of action, VTAMA<sup>®</sup> Cream 1% exerts its therapeutic effect on atopic dermatitis and plaque psoriasis. In each Phase 3 comparative clinical study in patients with atopic dermatitis (≥12 years old) and adults with plaque psoriasis for VTAMA<sup>®</sup> Cream 1% conducted in Japan, the primary endpoint of efficacy demonstrated superiority to the vehicle control. Furthermore, the safety of VTAMA<sup>®</sup> Cream 1% has been confirmed in long-term treatment in both patient populations.

JT and Torii expect VTAMA<sup>®</sup> Cream 1% to be a new option for the treatment of atopic dermatitis and plaque psoriasis in Japan. Under the terms of the agreement on January 2020 between JT and Torii, the drug will be sold exclusively by Torii in Japan, following its inclusion in the National Health Insurance (NHI) price list. The drug's launch date will be announced as soon as a decision is made.

Currently, the Phase 3 clinical study in pediatric patients with atopic dermatitis (2 to <12 years old) for tapinarof cream is being conducted in Japan.

Also, VTAMA<sup>®</sup> (tapinarof) cream 1%, being marketed by Dermavant Sciences, Inc. (Dermavant) in the U.S., was approved for the topical treatment of plaque psoriasis in adults in May 2022, and in April 2024, the U.S. Food and Drug Administration (FDA) accepted Dermavant's Supplemental New Drug Application (sNDA) for VTAMA<sup>®</sup>

(tapinarof) cream, 1% for the topical treatment of atopic dermatitis in adults and children (≥2 years old).

### **Outline of Approval**

Product name: VTAMA® Cream 1%

Generic name: Tapinarof

Indications: Atopic dermatitis, plaque psoriasis

Dosage and administration:

<Atopic dermatitis>

For adults and pediatric patients (≥12 years old), apply an appropriate amount of cream to the affected areas once daily.

< Plaque psoriasis >

For adults, apply an appropriate amount of cream to the affected areas once daily.

### **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 Plaque Psoriasis**

Plaque psoriasis is a chronic, systemic, inflammatory skin disease characterized by red patches and plaques with silvery scales on the skin.

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*Japan Tobacco Inc. is a leading international tobacco and vaping company and its products are sold in over 130 markets. With approximately 53,000 employees, it manufactures and sells some of the world's best-known brands including Winston, Camel, MEVIUS and LD. The JT Group is committed to investing in Reduced-Risk Products (RRP) and currently markets its heated tobacco products under its Ploom brand and various e-cigarette products under its Logic brand. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit <https://www.jt.com/>.*

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