



**FOR IMMEDIATE RELEASE**

Tokyo, September 15, 2023

**JT Files New Drug Application of JTE-061 Cream,  
Aryl hydrocarbon Receptor (AhR) agonist,  
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 today that JT has filed a New Drug Application for JTE-061 (generic name: tapinarof) cream, a therapeutic aryl hydrocarbon receptor agonist, for separate indications in atopic dermatitis and plaque psoriasis on 15 September, 2023.

JT signed an exclusive license agreement with Dermavant Sciences GmbH (Dermavant) for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. JT also signed an exclusive license agreement with Torii for co-development and commercialization of tapinarof in Japan. Under this agreement, tapinarof is being developed for patients with atopic dermatitis or plaque psoriasis by JT and Torii in Japan, and Torii will market tapinarof cream in Japan, subsequent to JT's obtaining manufacturing and marketing approval.

In each of the Phase 3 clinical studies of tapinarof cream in patients with atopic dermatitis (aged  $\geq 12$ ) and in patients with plaque psoriasis conducted in Japan, the primary endpoint of efficacy has met superiority to the vehicle. Furthermore, the safety of tapinarof cream was confirmed in long-term treatment in both patient populations. JT and Torii expect tapinarof cream to be a new option for the treatment of atopic dermatitis and plaque psoriasis patients in Japan.

Separately, Phase 3 clinical studies in pediatric patients (aged 2 to  $\leq 11$  years) with atopic dermatitis are ongoing and being conducted in Japan. Tapinarof cream was developed by Dermavant and approved by the U.S. Food and Drug Administration (FDA) for the treatment of plaque psoriasis in May 2022 in the U.S.

**ABOUT Atopic Dermatitis**

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to develop through exposure to various irritation 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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