



**FOR IMMEDIATE RELEASE**

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## **Top-line Results of Phase 3 Clinical Study (Comparative Study) of JTE-061 (tapinarof) Cream, Aryl hydrocarbon Receptor (AhR) agonist, in Adult and Adolescent Patients with Atopic Dermatitis in Japan**

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced today the top-line results of a Phase 3 comparative study for JTE-061, conducted in Japan, for the treatment of atopic dermatitis.

JT signed an exclusive license agreement with Dermavant Sciences GmbH (Dermavant) for the development and commercialization of tapinarof, a topical, therapeutic aryl hydrocarbon receptor agonist (JTE-061), for dermatological diseases and conditions in Japan. JT also signed an exclusive license agreement with Torii for co-development and commercialization of JTE-061 in Japan. JTE-061 is being developed for patients with atopic dermatitis and plaque psoriasis.

This study is a double blind, randomized and parallel-group comparison study to evaluate the efficacy and safety of JTE-061 cream in comparison to vehicle over 8 weeks in adult and adolescent patients with atopic dermatitis. The top-line results show that the IGA response<sup>1</sup> at week 8, the primary endpoint of efficacy, has met statistical superiority to vehicle. In addition, JTE-061 cream demonstrated higher EASI75 achievement rate<sup>2</sup> at Week 8, key secondary endpoint of efficacy, compared with vehicle. The safety of JTE-061 cream was confirmed and there were no observed issues of tolerability for the cream.

JT and Torii will aim to submit a manufacturing and marketing application for JTE-061 cream in Japan, based on the results of the study and other Phase 3 studies currently being conducted.

Separately, Phase 3 clinical studies in patients with plaque psoriasis and Phase 2 clinical studies in pediatric patients (aged 2 to ≤11 years) with atopic dermatitis are ongoing and being conducted in Japan. Tapinarof cream developed by Dermavant has been approved for the

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<sup>1</sup> Proportion of subjects which achieve an Investigator's Global Assessment (IGA) score of 0 (Clear) or 1 (Almost clear) with a minimum of 2-grade improvement from baseline. IGA score is a tool used to measure the extent area and severity of atopic dermatitis (IGA=0: Clear, 1: Almost clear, 2: Mild, 3: Moderate, 4: Severe).

<sup>2</sup> Proportion of subjects with a minimum of 75% improvement in Eczema Area and Severity Index (EASI) score from baseline. EASI score is a tool used to measure the extent area and severity of atopic dermatitis.

treatment of plaque psoriasis on May 23, 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 company selling its products in more than 130 countries and regions. With approximately 55,000 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/>.*

Contact for Japan Tobacco Inc.:

Dinesh Babu Thotakura, General Manager  
Media and Investor Relations Division  
Japan Tobacco Inc. Tokyo: +81-3-6636-2026  
E-mail: [jt.media.relations@jt.com](mailto:jt.media.relations@jt.com)

Contact for Torii Pharmaceutical Co., Ltd.:

Corporate Planning Department  
(Public Relations)  
Torii Pharmaceutical Co., Ltd. Tokyo: +81-3-3231-6814  
E-mail: [webmaster@torii.co.jp](mailto:webmaster@torii.co.jp)