



**FOR IMMEDIATE RELEASE**

Tokyo, May 31, 2024

**Positive Top-line Results of Phase 3 Clinical Study (Comparative Study) of JTE-061 (tapinarof) Cream, Aryl hydrocarbon Receptor (AhR) agonist, in Pediatric 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 in pediatric patients with atopic dermatitis in Japan for JTE-061.

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 pediatric patients (aged 2 to  $\leq 11$  years) with atopic dermatitis. The top-line results show that the EASI75 achievement rate\* at week 8, the primary endpoint of efficacy, has met statistical superiority to 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 this and other clinical studies.

In addition, the new drug application in patients with plaque psoriasis and atopic dermatitis (aged  $\geq 12$ ) was filed on September 15, 2023. Tapinarof cream developed by Dermavant has been approved for the 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

---

\* 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.

of the skin (dry skin and abnormal skin barrier function).

###

*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/>.*

Contact for Japan Tobacco Inc.:

Ichiro Kawai, 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)