



FOR IMMEDIATE RELEASE

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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 ≤ 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 ≥ 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).

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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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