



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 Patients with Plaque Psoriasis in Japan

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

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, parallel-group comparison study to evaluate the efficacy and safety of JTE-061 cream in comparison to vehicle over 12 weeks in patients with plaque psoriasis. The top-line results show that the PGA response¹ at week 12, the primary endpoint of efficacy, has achieved statistical significance in comparison 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 the study and other Phase 3 studies currently being conducted.

Separately, Phase 3 clinical studies in adult and adolescent patients with atopic dermatitis 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 is developed by Dermavant and was approved for the treatment of plaque psoriasis on May 23, 2022 in the U.S.

ABOUT Plaque Psoriasis

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

¹ Proportion of subjects which achieve a Physician Global Assessment (PGA) score of 0 (Clear) or 1 (Almost clear) with a minimum of 2-grade improvement from baseline. PGA score is a tool used to measure the extent area and severity of plaque psoriasis (IGA=0: Clear, 1: Almost clear, 2: Mild, 3: Moderate, 4: Severe).

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).

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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/>.

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