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Top-line Results of JTE-052 Ointment, JAK inhibitor, Phase 3 Clinical Study in Pediatric Patients with Atopic Dermatitis (Comparative Study) in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) today announce the top-line results of Phase 3 comparative study in pediatric patients with atopic dermatitis in Japan for JTE-052 (generic name: delgocitinib) ointment, a Janus kinase (JAK) inhibitor. Delgocitinib ointment was originated by JT and has been developed in Japan by JT and Torii under the terms of an agreement for co-development and marketing in Japan, signed on October 28, 2016.

This study is a double blind, randomized and parallel-group comparison study to evaluate the efficacy and safety of delgocitinib ointment in comparison to the vehicle over 4 weeks in pediatric patients with atopic dermatitis (aged 2 to <16), conducted in Japan. The top-line results show that the primary endpoint of efficacy, the percentage change of the mEASI score* from baseline, has met superiority to the vehicle. The favorable tolerability profile on safety was obtained within the treatment period.

* mEASI score (modified) is the score except for head and neck part from Eczema Area and Severity Index (EASI) score, a tool used to measure the extent area and severity of atopic dermatitis.

JT and Torii will aim to submit a marketing application for delgocitinib ointment in Japan, based on the results of this and other clinical studies. In addition, the new drug application in patients with atopic dermatitis (aged ≥ 16) was filed on January 31, 2019.

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).

tobacco vapor products under the Ploom brand and various e-cigarette products under the Logic brand. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit https://www.it.com/.

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