FOR IMMEDIATE RELEASE

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JT Files New Drug Application of JTE-052 Ointment, JAK inhibitor, for the Treatment of Pediatric Atopic Dermatitis in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced today that JT has filed a New Drug Application for JTE-052 (generic name: delgocitinib) ointment 0.25%, a Janus kinase (JAK) inhibitor, as an indication of pediatric atopic dermatitis (aged 2 to <16). In addition, JT has filed a supplemental New Drug Application for delgocitinib ointment 0.5% with the aim of an additional dosage and administration for the pediatric patients.

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.

Delgocitinib ointment is a non-steroidal, topical JAK inhibitor that is expected to improve autoimmune and allergic diseases by inhibiting the action of JAKs, which play key roles in immune activation signaling in cells, by suppressing the overactivation of immune responses.

In the Phase 3 comparative clinical study of delgoctinib ointment in pediatric patients with atopic dermatitis (aged 2 to <16), conducted in Japan, the primary endpoint of efficacy, the percentage change of the mEASI score[1] from baseline, has met superiority to the placebo, and safety of long-term administration was also confirmed. JT and Torii expect delgocitinib ointment to be a new option for the treatment of pediatric atopic dermatitis patients in Japan.

On January 23, 2020, JT received manufacturing and marketing approval for delgocitinib ointment 0.5% (CORECTIM® Ointment 0.5%, the world's first topical JAK inhibitor) as an indication of adult atopic dermatitis in Japan. Torii plans to launch the drug in Japan on June 24, 2020.

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[1]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.

ABOUT Atopic Dermatitis

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to develop through exposure to various irritants 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 with operations in more than 130 countries. With approximately 62,000 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 tobacco vapor products under its Ploom brand, and various e-cigarette products under its Logic brand. TheGroup is also present in the pharmaceutical and processed food businesses. For more information, visit https://www.jt.com/ .

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