FOR IMMEDIATE RELEASE

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JT Files New Drug Application of JTE-052 Ointment, JAK inhibitor, for the Treatment of 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, a Janus kinase (JAK) inhibitor, for atopic dermatitis as an indication on 31st January.

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. Under this agreement, JT grants Torii the exclusive rights to market delgocitinib ointment in Japan, subsequent to JT's obtaining manufacturing and marketing approval.

Delgocitinib ointment is the world's first 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 in patients with atopic dermatitis (aged ≥ 16) for delgocitinib ointment, conducted in Japan, the primary endpoint of efficacy, the percentage change of the mEASI score[1] from baseline, has met superiority to the placebo. Furthermore, delgocitinib ointment demonstrated a favorable safety profile in long-term treatment. JT and Torii expect delgocitinib ointment to be a new option for the treatment of atopic dermatitis patients in Japan.
Also, the Phase 3 clinical study in pediatric patients with atopic dermatitis (aged ≥ 2) for delgocitinib ointment has been conducted in Japan.

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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[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.

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Japan Tobacco Inc. is a leading international tobacco company with operations in more than 130 countries. With close to 60,000 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 Ploom TECH, its tobacco vapor product, 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.jt.com/.

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