



FOR IMMEDIATE RELEASE

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**JT Receives Manufacturing and Marketing Approval of
CORECTIM[®] Ointment 0.5%
for the Treatment of Atopic Dermatitis in Japan**

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that JT has today received manufacturing and marketing approval for CORECTIM[®] Ointment 0.5% (generic name: delgocitinib), a Janus kinase (JAK) inhibitor, for an indication of atopic dermatitis in Japan. JT filed a New Drug Application (NDA) for the drug on January 31, 2019.

CORECTIM[®] Ointment 0.5% is a non-steroidal topical product and the world's first topical JAK inhibitor that improves atopic dermatitis by inhibiting the action of JAKs, which play a key role 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 CORECTIM[®] Ointment 0.5%, conducted in Japan, the primary endpoint of efficacy, the percentage change of the mEASI score* from baseline, has met superiority to the placebo. Furthermore, CORECTIM[®] Ointment 0.5% demonstrated a favorable safety profile in long-term treatment.

JT and Torii expect CORECTIM[®] Ointment 0.5% to be a new option for the treatment of atopic dermatitis patients in Japan. Under the terms of the agreement on October 2016 between JT and Torii, the drugs will be sold exclusively by Torii in Japan, following its inclusion in the National Health Insurance (NHI) price list. The drugs' launch date will be announced as soon as a decision is made.

Also, the Phase 3 clinical study in pediatric patients with atopic dermatitis (aged 2 to <16) for delgocitinib is being conducted in Japan.

Outline of approval

Product Name: CORECTIM[®] Ointment 0.5%
Generic Name: Delgocitinib
Indications: Atopic Dermatitis

* 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.

Dosage and Administration: For adults, apply an appropriate amount of ointment to the affected areas twice daily. The dose applied should not exceed 5 g per dosing.

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 over 63,000 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 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.jt.com/>.

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