



FOR IMMEDIATE RELEASE

Tokyo, March 23, 2021

**JT Receives Approvals of
CORECTIM[®] Ointment 0.25% and CORECTIM[®] Ointment 0.5%
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 received manufacturing and marketing approval for CORECTIM[®] Ointment 0.25% (generic name: delgocitinib), a Janus kinase (JAK) inhibitor, for an indication of pediatric atopic dermatitis in Japan. In addition, JT has received approval for additional pediatric dosage and administration for CORECTIM[®] Ointment 0.5%.

CORECTIM[®] Ointment 0.25% and 0.5% are non-steroidal, JAK inhibitors that are expected to improve autoimmune and allergic diseases by inhibiting the action of JAKs, which play key roles in immune activation signalling in cells, by suppressing the overactivation of immune responses. In the Phase 3 comparative clinical study of CORECTIM[®] Ointment 0.25% 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* from baseline, has met superiority to the placebo. Safety of long-term administration of CORECTIM[®] Ointment 0.25% and 0.5% was also confirmed.

JT and Torii expect CORECTIM[®] Ointment 0.25% and 0.5% to be a new option for the treatment of pediatric patients with atopic dermatitis in Japan. Under the terms of the agreement between JT and Torii, CORECTIM[®] Ointment 0.25% 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. CORECTIM[®] Ointment 0.5%, the world's first topical JAK inhibitor as an indication of atopic dermatitis in adults, has been distributed in Japan by Torii since June 2020.

Separately, the Phase 3 clinical study in infant patients with atopic dermatitis (aged 6 to <24 months) for delgocitinib ointment is being conducted in Japan.

* 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.

Outline of approval

Product Name : CORECTIM® Ointment 0.25% and CORECTIM® Ointment 0.5%

Generic Name : Delgocitinib

Indications : Atopic Dermatitis

Dosage and Administration:

For adults, apply an appropriate amount of 0.5% formulation to the affected areas twice daily. The dose applied should not exceed 5 g per dosing.

For children, apply an appropriate amount of 0.25% formulation to the affected areas twice daily. 0.5% formulation can be applied twice daily depending on the symptoms.

The dose applied should not exceed 5 g per dosing, however, the body size should be taken into consideration.

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. The Group is also present in the pharmaceutical and processed food businesses. For more information, visit <https://www.jt.com/>.

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