

JT to market CORECTIM in Japan to treat atopic dermatitis

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Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd. (Torii) have announced that JT has 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.