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Tokyo, January 12, 2018

Top-line Results of the Topical JTE-052 JAK Inhibitor Phase 3 Clinical Study (Comparative Study) in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) have announced the top-line results of Phase 3 comparative study. This study is a part of the Phase 3 program for JTE-052, conducted in Japan, for the treatment of atopic dermatitis.

This study is a double blind, randomized and parallel-group comparison study to evaluate the efficacy and safety of JTE-052 ointment in comparison to placebo over 4 weeks in patients with atopic dermatitis. In the top-line results, the primary endpoint of efficacy, the change of the mEASI score* from baseline, has met superiority to placebo. Furthermore, there were no clinically significant findings on safety and tolerability of JTE-052 ointment within the treatment period.

* 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.

JT and Torii will aim to submit a marketing application for JTE-052 ointment in Japan, based on the results of comparative study and other Phase 3 studies currently being conducted.

JT and Torii made an exclusive licence agreement for co-development and commercialization of JTE-052 in October 2016, for the topical use in dermatological indication in Japan.

ABOUT Atopic Dermatitis

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to be developed by adding various irritation and allergic reaction into the patients who have physiological abnormality of the skin (dry skin and abnormal skin barrier function).

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