



FOR IMMEDIATE RELEASE

Tokyo, March 1, 2019

A Presentation on the Phase 3 Clinical Study (Comparative Study) of JTE-052 Ointment, JAK Inhibitor, at the 2019 AAD annual meeting

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) today announce that JT presents the results of a Phase 3 comparative study of JTE-052 (generic name: delgocitinib) ointment, a Janus kinase (JAK) inhibitor in Japanese adult patients with atopic dermatitis, at the 2019 American Academy of Dermatology (AAD) annual meeting, held in Washington D.C. in the US, March 1-5, 2019. Delgocitinib ointment has been co-developed by JT and Torii since 2016 in Japan.

Summary of the presentation

- ✓ Presentation Number:
8214
- ✓ Title:
Efficacy and Safety of Topical Delgocitinib (JTE-052), a Janus Kinase Inhibitor, in Japanese Adult Patients with Moderate-to-Severe Atopic Dermatitis: A Phase III, Randomized, Double-Blind, Vehicle-Controlled Study
- ✓ Result:
This study is a double blind, randomized and parallel-group comparison study to evaluate the efficacy and safety of delgocitinib ointment 0.5% in comparison to the placebo over 4 weeks in Japanese patients with atopic dermatitis (aged ≥ 16).
The primary endpoint of efficacy, the percentage change from baseline in the modified Eczema Area and Severity Index (mEASI¹) score at the end of treatment (EOT), in the delgocitinib group has met superiority to that in the vehicle group.
At EOT, the least-squares mean percentage changes from baseline in the mEASI score were -44.29% in the delgocitinib group and 1.74% in the vehicle group. The mEASI score in the delgocitinib group was significantly reduced compared with that in the vehicle group ($P < .001$).
On the following efficacy evaluations, it was improved in the delgocitinib group compared with the vehicle group;

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.

- Proportion of patients achieving $\geq 50\%$ or 75% improvement in the mEASI score at EOT
- Proportion of patients achieving an Investigator's Global Assessment (IGA²) score of 0 or 1 with ≥ 2 -point improvement from baseline at EOT
- Proportion of patients achieving a face/neck IGA score of 0 or 1 with ≥ 2 -point improvement from baseline at EOT
- Weekly change from baseline in pruritus numeric rating scale (NRS³) score over time for daytime and nighttime score
- Daily change from baseline in pruritus NRS score over the first week of treatment

The favorable tolerability profile was obtained, and no serious adverse events (AEs) including death, severe AEs, or AEs leading to study discontinuation were reported in either of the treatment groups. No clinically relevant changes in vital signs or laboratory parameters over time were found in either of the treatment groups.

The other presentation

JT also presents the results of a Phase 2 study of delgocitinib ointment in Japanese pediatric patients (aged 2 to <16 years) with atopic dermatitis at the 2019 AAD annual meeting.

✓ Presentation Number:

8216

✓ Title:

Efficacy and Safety of Topical Delgocitinib (JTE-052), a Janus Kinase Inhibitor, in Japanese Pediatric Patients with Atopic Dermatitis: A Phase II, Randomized, Double-Blind, Vehicle-Controlled Study

ABOUT Atopic Dermatitis

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to develop through exposure to various irritation or allergens for patients with a physiological abnormality of the skin (dry skin and abnormal skin barrier function).

² IGA score is the evaluation for the eczema with inflammation over the entire body on a 6-grade rating scale.

³ NRS score is the evaluation for the mean level of pruritus on an 11-grade rating scale.

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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 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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