

Meiji Seika Pharma Co., Ltd.

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Meiji Seika Pharma Presents Positive Findings from Phase II Study of ME3183, Novel Highly-Potent Selective PDE4 Inhibitor, in Patients With Plaque Psoriasis at EADV Congress 2023

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi) today announced that positive findings from the phase II clinical trial of ME3183, a novel highly-potent selective phosphodiesterase-4 (PDE4) inhibitor, in patients with plaque psoriasis conducted in the United States and Canada ([NCT05268016](#)) were presented on 12 October at the [European Association of Dermatology and Venereology \(EADV\) Congress 2023](#) held in Berlin.

The outline of the presentation is as follows:

Meiji Seika Pharma evaluated the efficacy and safety of ME3183, a novel oral, highly potent, selective phosphodiesterase-4 inhibitor, characterized by low blood-brain barrier transmission, over 16-week treatment period in adults with moderate to severe plaque psoriasis.

In total, 132 patients were randomly assigned to ME3183 (n=26, 26, 26, and 27, respectively) or placebo (n=27). Mean Psoriasis Area and Severity Index (PASI) score at baseline was 15.9–17.6 and 16.8 in the ME3183 and placebo groups, respectively. A significantly greater proportion of patients in the ME3183 5 mg BID, 7.5 mg BID, and 15 mg QD groups achieved ≥75% reduction from baseline PASI score (PASI-75) at Week 16 (primary endpoint) versus placebo (58.3%, 61.5%, and 52.0% vs 14.8%, $P < 0.001$; 10 mg QD group: 32.0%). A greater proportion of patients in the ME3183 groups versus placebo achieved PASI-90, PASI-100, and Static Physician's Global Assessment 0/1 combined with 2-point reduction (secondary endpoints). Early PASI improvement after administration was observed in the ME3183 groups. The most frequent treatment-emergent adverse events were diarrhea, nausea, and headache. In the ME3183 5 mg BID, 10 mg QD, 7.5 mg BID, 15 mg QD and placebo groups, 2, 2, 4, 3, and 1 patients, respectively, discontinued because of adverse events. ME3183 was well tolerated. No unexpected safety signals were observed.

In conclusion, ME3183 administered orally was effective in the treatment of plaque psoriasis and had an acceptable safety profile.

Meiji strives to provide efficacious and safe treatment for unmet medical needs, such as psoriasis and other autoimmune diseases.