

Meiji Seika Pharma Co., Ltd.

9 August 2023

Meiji Seika Pharma Announces Positive Results in Phase II Study of ME3183, a Novel Highly-Potent Selective PDE4 Inhibitor, in Patients With Moderate-to-Severe Plaque Psoriasis in the United States and Canada

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi) today announced that ME3183, a novel highly-potent selective phosphodiesterase-4 (PDE4) inhibitor, met the primary endpoint based on “PASI-75”, defined as the proportion of subjects achieving 75% improvement in Psoriasis Area Severity Index (PASI), in phase II clinical trial in patients with moderate-to-severe plaque psoriasis conducted in the United States and Canada.

The phase II clinical trial ([NCT05268016](https://clinicaltrials.gov/ct2/show/study/NCT05268016))* was conducted to evaluate the efficacy, safety and tolerability of ME3183 after administered once or twice daily for 16 weeks in patients with moderate-to-severe plaque psoriasis. One-hundred and thirty-two patients were enrolled in the United States and Canada. The primary endpoint was defined as the proportion of subjects achieving 75% improvement (“PASI-75”) in Psoriasis Area Severity Index (PASI) Score at Week 16 from baseline. As a result, significantly greater proportion of PASI-75 achievement were observed in ME3183 treatment groups compared to the placebo group, which met the primary endpoint. In addition, early PASI improvement after administration was observed in ME3183 groups. ME3183 was shown to be safe and well tolerated. Details of the study will be presented at an upcoming medical meeting.

ME3183 is an orally-available and selective PDE4 inhibitor discovered by Meiji Seika Pharma. In non-clinical studies, it showed greater anti-inflammatory effect and approximately 30-fold greater inhibitory effect on TNF- α production than the existing orally-available PDE4 inhibitor for psoriasis. At the same time, the distribution of ME3183 in the brain was sufficiently low.

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

*: Meiji Pharma USA Inc. (Teaneck, NJ, President: Yasushi Miyazawa), a wholly owned subsidiary of Meiji, is in charge of the Phase II clinical trial.