

Meiji Seika Pharma Co., Ltd.

7 April 2022

## First Patient Dosed in Phase II study of ME3183, a selective PDE4 inhibitor, in patients with plaque psoriasis in the United States and Canada

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi, hereinafter “Meiji”) today announced that the first patient was dosed in Phase II clinical trial of ME3183, a selective phosphodiesterase-4 (PDE4) inhibitor, in patients with plaque psoriasis in the United States and Canada.

ME3183 is an orally-available and selective PDE4 inhibitor discovered by Meiji. In non-clinical studies, ME3183 showed greater anti-inflammatory effect and its inhibitory effect on TNF- $\alpha$  production was approximately 30-fold greater than the existing orally-available PDE4 inhibitor for psoriasis. The distribution of ME3183 in the brain was sufficiently low. The Phase I single and multiple dose clinical trials were conducted in healthy volunteers in the United States. ME3183 has been shown to be safe and well-tolerated across the doses which exceeded the effective exposures anticipated from the non-clinical data (EADV Congress 2021, P1340). The results suggest that ME3183 can exert higher clinical efficacy than the existing PDE4 inhibitors at the higher dose settings.

The Phase II clinical trial is a randomized, double-blind, placebo-controlled study 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 twenty-five patients are planned to be enrolled at approximately 30 facilities in the United States and Canada (NCT05268016). Meiji Pharma USA Inc. (Teaneck, NJ, President: Yasushi Miyazawa), a wholly owned subsidiary of Meiji, is in charge of the Phase II clinical trial.

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