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Meiji Seika Pharma Co., Ltd.

NEWS RELEASE

March 12, 2026

Meiji Seika Pharma initiates Phase I clinical trial in Australia evaluating ME3241, an anti-PD-1 agonist antibody discovered through collaborative research with FBRI

Meiji Seika Pharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Japan; President and Representative Director: Toshiaki Nagasato) announced today that it has initiated a Phase I clinical trial of ME3241 (development code), an anti-PD-1 agonist monoclonal antibody discovered through collaborative research with the Foundation for Biomedical Research and Innovation at Kobe (Headquarters: Kobe, Japan; President: Shuh Narumiya; hereinafter "FBRI"). The Phase I clinical trial is designed as a randomized, placebo-controlled, double-blind study, with the objective of evaluating the safety and tolerability of ME3241 following single and multiple dosing, as well as its pharmacokinetics and pharmacodynamics (ClinicalTrials.gov: NCT07422207).

ME3241 was discovered through a collaborative research program led by Program Director Tasuku Honjo, a professor emeritus at Kyoto University. PD-1 is a molecule expressed on activated T cells and other lymphocytes that suppresses immune responses. Through this research, Meiji Seika Pharma and FBRI identified the conditions required to induce immunosuppression by stimulating PD-1 with antibodies, and these findings were published in Science Immunology on January 13, 2023. ME3241 is a unique anti-PD-1 agonist antibody with enhanced PD-1 agonist activity and has the potential to advance clinical development as a therapeutic agent for inflammatory diseases, including autoimmune diseases caused by excessive immune responses.

Meiji Seika Pharma and FBRI will continue to collaborate to advance the development of ME3241 and strive to provide meaningful benefits to patients with autoimmune diseases at the earliest opportunity.

Message from Tasuku Honjo, Program Director, Honorary President, Foundation for Biomedical Research and Innovation at Kobe (FBRI)

The initiation of the Phase I clinical trial of an autoimmune disease therapy by a PD-1 agonist antibody is highly significant, as our finding marks a major milestone in taking a step toward potential therapeutic application for human disease.

This therapeutic approach, which is completely opposite of the widely used cancer therapy employing a PD-1 antagonist antibody, originated from basic research initiated shortly after my appointment as director. After achieving robust results in animal models, we have now reached this

clinical stage.

Should safety be confirmed in Phase I, there is strong expectation that the program will progress to Phase II to evaluate efficacy, and subsequently to Phase III with the aim of practical implementation. I am truly delighted by this advancement toward the practical realization of the vision of Kobe Biomedical Innovation Cluster.

Message from Takeshi Naruse, Senior Managing Executive Officer and Head of Research & Development, Meiji Seika Pharma

We have been advancing collaborative research with Professor Tasuku Honjo to discover and develop new drug candidates for inflammatory diseases, an area closely related to Meiji Seika Pharma's focus on infectious diseases. We are pleased to begin a Phase I clinical trial of ME3241, a unique PD-1 agonist antibody established based on robust foundational research with Professor Honjo and his colleagues. We will expedite the development of ME3241 and strive to deliver it to patients with autoimmune diseases as soon as possible.

Contacts:

Meiji Seika Pharma Co., Ltd.:
Public Relations, Public & External Affairs Dept.
Email: pr-pharma (Please add "@meiji.com" to the end)

Foundation for Biomedical Research and Innovation at Kobe:
Public relations and Strategic planning group
Email: kbic-pr (Please add "@fbri-kobe.org" to the end)