ENGLISH TRANSLATION

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Promising results of Phase I Clinical Trial of DMB-3115, a Proposed Ustekinumab Biosimilar, and Initiation of Phase III Clinical Trial in Patients with Plaque Psoriasis

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") today announced that the bioequivalence of DMB-3115, a proposed ustekinumab biosimilar, has been demonstrated in phase I clinical trial compared to the reference products marketed in Europe and the United States. Meiji also announced the initiation of phase III multi-regional clinical trial in patients with plaque psoriasis. Those clinical trials are conducted in collaboration with Dong-A Socio Holdings (Headquarters: Seoul, Korea, CEO: JUNG Jae-Hun, "Dong-A").

DMB-3115 is a proposed biosimilar to ustekinumab, a recombinant monoclonal antibody for the treatment of patients with several inflammatory diseases such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. Meiji and Dong-A are co-developing DMB-3115 under the strategic collaboration partnership agreement on biosimilars signed in September 2011. DMB-3115 is produced by using Sp2/0 cells, the same as those used in reference products to achieve high similarity in quality aspects.

The Phase I clinical trial is a randomized double-blind, three-arm, single-dose study to compare pharmacokinetics, safety and tolerability of DMB-3115 with its reference products (US- and EU-marketed products) in 296 healthy volunteers at a single site in Europe. As a result, bioequivalence of DMB-3115 compared to reference products was demonstrated in terms of several pharmacokinetic parameters. A single subcutaneous injection of DMB3115 in healthy volunteers was well tolerated. The reported adverse events corresponded with the known safety profile of ustekinumab. There were no new unexpected adverse events.

The Phase III multi-regional clinical trials in patients with plaque psoriasis, with the target number of patient being 590, has been initiated in Europe and the United States. In this study, efficacy, safety, pharmacokinetics and immunogenicity of DMB-3115 and reference products (45 mg or 90mg subcutaneous injection, respectively) are being compared in randomized, double-blinded controlled trial.

Meiji aims to contribute to medical care and society by developing and launching biosimilars with high quality as well as biologics products.

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