ENGLISH TRANSLATION

16 December 2019

Meiji Seika Pharma and Dong-A Socio Holdings Initiate Phase I Clinical Trial of DMB-3115, a Ustekinumab Biosimilar Candidate

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi, "Meiji") and Dong-A Socio Holdings Co., Ltd. (Headquarters: Seoul, Korea, CEO: Jong Hyun Han, "Dong-A") today announced the initiation of a Phase I clinical trial of DMB-3115.

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 under the name of Stelara®) in healthy volunteers at a single site in Europe. The dosing for subjects in the study was started on 13 December.

Meiji and Dong-A are developing DMB-3115 as a biosimilar candidate to ustekinumab, a recombinant immunoglobulin G1kappa monoclonal antibody targeting interleukin (IL)-12 and IL-23. The reference product has been approved in many regions for the treatment of patients with several inflammatory diseases such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

The investigational product of DMB-3115 for the Phase I study was manufactured by DM Bio Limited (Headquarters: Incheon, Korea, CEO: Byoung Jo Min), established as a joint venture company in Incheon Free Economic Zone, under the strategic collaboration partnership agreement on biosimilars between Meiji and Dong-A signed in September 2011.