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Meiji Seika Pharma Co., Ltd.

October 11, 2024

U.S. FDA Approves IMULDOSA™ (ustekinumab-srlf), a Biosimilar Referencing STELARA®

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced that the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for IMULDOSA™ (ustekinumab-srlf; development code: DMB-3115), a biosimilar referencing STELARA® (ustekinumab) which is marketed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson.

IMULDOSA™ was developed in collaboration with Dong-A ST Co., Ltd. (Headquarters: Seoul, South Korea, President and CEO: Jaehun Jung). The BLA was submitted by Accord BioPharma, Inc., the U.S. specialty division of Intas Pharmaceuticals Ltd. (Headquarters: Ahmedabad, India, Vice Chairman & Managing Director: Binish Chudgar), to which IMULDOSA™ has been licensed. IMULDOSA™ will be marketed in the United States by Accord BioPharma, Inc.

IMULDOSA™ is a recombinant monoclonal antibody approved for the treatment of patients with several autoimmune diseases such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. Meiji Seika Pharma is positioning IMULDOSA™ as a global strategic product and is promoting global development jointly with Dong-A ST. The worldwide distribution rights, excluding Japan, South Korea, and certain Asian regions, were licensed to Intas Pharmaceuticals in July 2021.

Meiji Seika Pharma strives to promote the spread of biopharmaceuticals and contribute to medical care and public health, through the development and commercial supply of high-quality biosimilars with low economic burden.