Accord Healthcare receives positive CHMP opinion for IMULDOSA®, ustekinumab biosimilar to Stelara®

- Accord announces that the CHMP has issued a positive opinion for Imuldosa® (development code: DMB-3
- 115), a biosimilar to Stelara®, indicated for range of immunology conditions.
- The CHMP positive opinion is based on a comprehensive package of analytical, non-clinical, and clinical similarity data, including a multi-regional phase III clinical trial in patients with plaque psoriasis. The study confirmed therapeutic equivalence between DMB-3115 and Stelara®, alongside a comparable safety profile.
- The CHMP's positive opinion paves the way for the authorization of Imuldosa® in the EU ustekinumab market, valued at approximately €2.9 billion (US$3.18 billion) according to IQVIA MAT June 2024 data.
- Intas holds exclusive licensing rights to commercialize Imuldosa® worldwide, excluding Japan, Korea, and certain other Asian countries. Imuldosa® was already approved by the USFDA on October 10, 2024.

Accord Healthcare Limited (Accord) announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorisation for Imuldosa® (development code: DMB-3115), a biosimilar of Stelara® (ustekinumab), marketed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson. In July 2021, Dong-A ST and Meiji Seika Pharma entered into an exclusive global license agreement with Intas Pharmaceuticals, granting them worldwide commercialization rights for DMB-3115, excluding Korea, Japan, and certain Asian countries. Intas Pharmaceuticals plans to commercialize DMB-3115 through its global subsidiaries, Accord BioPharma in the US and Accord Healthcare in the EU, UK, and Canada.

Ustekinumab is a human monoclonal antibody that targets the cytokines interleukin-12 and interleukin-23 which may play an important role in inflammatory and immune responses. Stelara® is indicated for range of immunology indications and has recorded global sales of US$ 19 billion of which US$D 3.2 billion sales coming from Europe as per IQVIA MAT Jun'24 data.

"We are truly excited by this partnership which, besides strengthening our existing biosimilar portfolio, also reinforces our long-term commitment towards bettering access to world-class biosimilar drugs for patients globally," said Mr Binish Chudgar, Executive Chairman and Managing Director of Intas Pharmaceuticals Ltd.

Mr. Paul Tredwell, Executive Vice President of Accord Healthcare said, " We are delighted with the positive CHMP opinion for Imuldosa®, a biosimilar to Ustekinumab. This recommendation affirms the robust scientific approach behind our goal of broadening access to high-quality biologic therapies for patients in Europe and beyond. Upon approval by the European Commission, Imuldosa® will become Accord's fifth biosimilar in Europe. Building on this success, we remain committed to advancing our biosimilar pipeline and aim to launch 20 biosimilars by 2030."

A spokesperson for Dong-A ST & Meiji stated, "We will spare no effort to ensure DMB-3115 is supplied to the global market."

According to the EMA CHMP summary of positive opinion, DMB-3115 is highly similar to the reference product Stelara® (ustekinumab) and has demonstrated comparable quality, safety and efficacy to Stelara®. The MAA submission is based on results from the phase III multi-regional clinical trials in patients with plaque psoriasis (NCT04785326).

The approval of Imuldosa® (ustekinumab biosimilar) further enhances Accord Healthcare's biosimilar portfolio and strengthens Accord presence in Autoimmune therapy area.