Accord Healthcare

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Accord Healthcare is granted marketing authorisation for IMULDOSA®, ustekinumab biosimilar to Stelara®

London (ots/PRNewswire) -

- Accord announces that the European Commission (EC has granted marketing authorisation for Imuldosa® (development code: DMB-3115), a biosimilar to Stelara®, indicated for a range of immune medicated inflammatory diseases.
- The EC approval follows a positive opinion issued on 19 October 2024 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is applicable to all 27 European Union (EU) Member States plus Iceland, Norway and Liechtenstein.
- 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, in the primary outcome, between DMB-3115 and Stelara®, alongside a comparable safety profile.
- The marketing authorisation paves the way for the launch 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 commercialise 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 European Commission (EC) has granted marketing authorisation for Imuldosa® (development code: DMB-3115), a biosimilar of Stelara® (ustekinumab), marketed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson.

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 immune medicated inflammatory diseases 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.

Joe Dunford, VP of Speciality Brands stated, "Accord is committed to becoming a significant player in the autoimmune space, and we are delighted that the European Commission (EC) has granted marketing authorisation for our fifth biosimilar in Europe, Imuldosa®. This approval ensures that patients have access to high-quality therapies in Europe and beyond. We remain dedicated to advancing our biosimilar pipeline, with the goal of launching 20 biosimilars by 2030.

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