Accord BioPharma, Inc. Announces U.S. FDA Acceptance of Biologics License Application for Proposed STELARA® Biosimilar DMB-3115

Biosimilar for STELARA® (Ustekinumab) *seeks to treat several autoimmune disorders caused by overactive immune response*

Accord BioPharma, Inc. the U.S. specialty division of Intas Pharmaceuticals Ltd. focused on development of oncology, immunology, and critical care therapies, announced today the U.S. Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) for DMB-3115. DMB-3115 is a proposed biosimilar to STELARA®, a blockbuster drug developed by Janssen Biotech Inc. and approved for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. In the U.S., STELARA® recorded $13.9 billion in sales (IQVIA Sales in 2022) and is one of the best-selling biologics.

"The ability of DMB-3115's reference product, STELARA®, to treat autoimmune diseases is well established and we're excited to take this important step toward providing patients a more accessible avenue to treatment for conditions that present such a significant disease burden," said Chrys Kokino, U.S. president of Accord. "Our mission to go beyond the biology of medicine includes seeking to ease the financial burden for patients and the U.S. healthcare system by providing medicines that may be more affordable, such as biosimilars."

Joint development for DMB-3115 was initiated in 2013 by Dong-A Socio Holdings and Meiji Seika Pharma, with exclusive commercialization rights granted to Intas Pharmaceuticals through a partnership announced in 2021. As a global subsidiary of Intas Pharmaceuticals, Accord BioPharma will be responsible for U.S. commercialization.

"Our partnership with Dong-A Socio Holdings and Meiji Seika Pharma reinforces our long-term commitment towards improving access to world-class biosimilar drugs for patients globally," said Mr. Binish Chudgar, vice chairman and managing director of Intas Pharmaceuticals.

The BLA submission for DMB-3115 is based on results from phase III multi-regional clinical trials in patients with plaque psoriasis, in which the primary endpoint was the rate of change in the Psoriasis Area and Severity Index (PASI) for skin symptoms. The clinical results demonstrated that DMB-3115 and its reference product, ustekinumab, are highly similar, and have no clinically meaningful differences in terms of quality, safety and efficacy.

In October of 2023, Accord BioPharma reached a settlement with Janssen Biotech Inc., a Johnson & Johnson company, under confidential terms that would allow Accord BioPharma to launch its proposed ustekinumab biosimilar no later than May 15, 2025, pending its approval by the U.S. FDA.

The announcement of DMB-3115's BLA acceptance comes as Accord BioPharma awaits a string of additional regulatory milestones. The company has submitted three separate Biologics License Applications to the FDA for biosimilar versions of trastuzumab, pegfilgrastim and filgrastim. Accord BioPharma is planning to introduce several additional biosimilars to the U.S. market during the next five years.

About Accord BioPharma

Accord BioPharma, the U.S. specialty division of Intas Pharmaceuticals, seeks to provide affordable, accessible, patient-centric therapies in oncology, immunology, and critical care. With a focus on improving the patient experience, Accord BioPharma goes beyond the biology of medicine to see disease from the patients' perspective and develop high-quality therapies that impact patients' lives. Accord BioPharma believes in the ability of biosimilars to increase access to a number of biologic medicines which in the past may not have been considered for patients due to their high cost. Accord's biosimilars not only provide treatment options for patients but also deliver considerable savings to the US healthcare system. Accord BioPharma looks forward to providing one of the deepest biosimilar portfolios in the industry in the near future. For more information, visit AccordBioPharma.com.

STELARA® is a registered trademark of Johnson & Johnson.