FDA Approves IMULDOSA® (ustekinumab-srlf), Accord BioPharma's Biosimilar to STELARA® (ustekinumab), for the Treatment of Chronic Inflammatory Conditions

With the approval of IMULDOSA, Accord BioPharma's (A division of Intas Pharmaceuticals) biosimilar portfolio continues to grow while expanding treatment options appropriate for patients

RALEIGH, N.C., [MONTH DAY, 2024 /PRNewswire/ -- **Accord BioPharma**, Inc., the U.S. specialty division of Intas Pharmaceuticals, Ltd., focused on the development of oncology, immunology, and critical care therapies, announced that the U.S. Food and Drug Administration (FDA) has approved IMULDOSA (ustekinumab-srlf), a biosimilar to STELARA® (ustekinumab), for the treatment of chronic inflammatory conditions, including psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. The FDA approved IMULDOSA for all indications of its reference medicine, STELARA. Accord anticipates a commercial launch of IMULDOSA in the first half of 2025.

"For Accord BioPharma, this is another step forward in our efforts to deliver affordable treatments and satisfy patient needs," said Chrys Kokino, U.S. president of Accord. "The approval of IMULDOSA, our second biosimilar, is evidence of our growing momentum in the industry and our leadership in supporting families with accessible options to address urgent and critical medical conditions."

For the millions of Americans living with chronic inflammatory conditions, which can be painful, and also can have a significant impact on quality of life, emotional well-being, and self-image, IMULDOSA has the potential to be an affordable treatment option that provides similar benefits to the current standard of care. It also marks the second biosimilar to be FDA-approved from Accord BioPharma, arriving shortly after the approval of HERCESSI™ (trastuzumab-strf), a biosimilar to Herceptin®, earlier this year.

FDA approval of IMULDOSA was granted based on a comprehensive clinical development program. The data showed that IMULDOSA is similar to its reference product STELARA in terms of pharmacokinetic characteristics, safety, tolerability, and efficacy, and that IMULDOSA adheres to current biosimilar guidance from the FDA.

"We're proud to add IMULDOSA to our U.S. biosimilar portfolio, which represents an affordable treatment option for patients living with painful inflammatory conditions. It is Accord BioPharma's goal to go beyond biology and continuously work to provide affordable world class treatments to the patients" said Binish Chudgar, Executive Chairman of the Board, Intas Pharmaceuticals. "As our presence in the biosimilar market continues to grow, so does our commitment to offering high quality, affordable and effective alternatives to reference drugs, to the patients in need"

IMULDOSA was initially developed as DMB-3115 in 2013 by Dong-A Socio Holdings and Meiji Seika Pharma. In 2021, Intas Pharmaceuticals acquired exclusive commercialization rights to DMB-3115 through a license agreement. As a global subsidiary of Intas Pharmaceuticals, Accord BioPharma will be responsible for U.S. commercialization of IMULDOSA

In addition to IMULDOSA and HERCESSI, Accord BioPharma is planning on introducing several additional biosimilars to the U.S. market during the next five years.