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USFDA approves Intas Pharma’s biosimilar to STELARA (ustekinumab), for treating chronic inflammatory conditions

14 October 2024 | News

US FDA approval of IMULDOSA was granted based on a comprehensive clinical development programme

Accord BioPharma, Inc., the US specialty division of Ahmedabad-based Intas Pharmaceuticals, has announced that the US 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 US 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 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 US FDA-approved from Accord BioPharma, arriving shortly after the approval of HERCESSI (trastuzumab-strf), a biosimilar to Herceptin, earlier this year.

US FDA approval of IMULDOSA was granted based on a comprehensive clinical development programme. 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 US FDA.

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

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