BioFactura and CuraTeQ Sign Exclusive License for BFI-751—A Biosimilar to Stelara

The CuraTeQ-BioFactura licensing deal allows the parties to improve outcomes, quality of life, and the patient experience with high quality biosimilars.

FREDERICK, MD, UNITED STATES, July 12, 2023 /EINPresswire.com/ -- BioFactura and CuraTeQ Sign Exclusive License for BFI-751—A Biosimilar to Stelara FREDERICK, MARYLAND, July 10, 2023: BioFactura, Inc. today announced that CuraTeQ Biologics Private Limited, a wholly owned subsidiary of Aurobindo Pharma Limited, has entered into an exclusive license to commercialize BFI-751, BioFactura's proposed biosimilar to Stelara (Ustekinumab). Ustekinumab is a recombinant monoclonal antibody that works by blocking both interleukins IL-12 and IL-23 and is used for treating Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis. (Benson, et.al., MAbs. 2011 Nov-Dec; 3(6): 535–545). The global drug sales of Ustekinumab stood at close to 10 billion in 2022 presenting a significant opportunity with a good number of indications and a wider use.

> We are proud to partner with CuraTeQ to bring BioFactura's high quality biosimilar of Ustekinumab to the global marketplace."
>
> *Jeffrey N Hausfeld, MD, MBA., Chairman of BioFactura*

Under the terms of the agreement, CuraTeQ has been granted exclusive license rights to commercialize BFI-751 in all major regulated markets including US, EU, UK, Canada, ANZ and certain other semi-regulated and emerging markets worldwide. Additionally, CuraTeQ will have the global manufacturing rights for this product, which will be produced at CuraTeQ facilities in Hyderabad, India. BioFactura plans to begin a global Phase 3 trial of the product as the next logical milestone in development. CuraTeQ intends to file this product in India and Emerging Markets as early as in 2024 and the regulated markets filing is expected to begin in 2026. BioFactura will receive license fees not exceeding $33.5 million spread across different milestones leading to commercialization and will obtain up to 43% profit sharing depending on the territory.

Commenting on the deal with BioFactura, Dr. Satakarni Makkapati, CEO - Biologics, Vaccines and Peptides, Aurobindo Pharma said, "BioFactura has demonstrated bio-equivalence of BFI-751 vs

US and EU registered originator product Stelara in a three-arm Phase 1 study conducted in 200 plus healthy subjects. (Hausfeld, J. et. al., pending publication July 2023, Clinical Pharmacology in Drug Development. Pharmacokinetic Profiles of a Proposed Biosimilar Ustekinumab (BFI□751): Results From a Randomized Phase 1 Trial). We are excited by the prospect of this Ustekinumab biosimilar advancing to Phase 3 clinical studies in the due course of time. Ustekinumab fits into our expanding immunology products portfolio very well and we will use our presence across key markets to commercialize this product."

Commenting on the deal with BioFactura, Mr. Nithyananda Reddy, MD and Vice Chairman, Aurobindo Pharma said, "This agreement underscores our investment intentions in biosimilars business. It is our commitment to improve lives of patients suffering from these debilitating immune and inflammatory diseases by delivering them access to cost-effective and high quality biosimilars such as Ustekinumab."

Commenting on the development, Darryl Sampey, Ph.D., President and CEO of BioFactura said, "The development of our BFI-751 biosimilar to Stelara has been an all-encompassing endeavor at BioFactura which led to the impressive clinical results of our pivotal bio-comparability trial. With CuraTeQ, we have found the optimal partner to successfully complete the journey and bring this important product to market."

Additionally, Jeffrey N Hausfeld, MD, MBA., Chairman and Chief Medical Officer of BioFactura, stated, "The purpose and regulatory framework of bringing biosimilars into the mainstream of healthcare systems worldwide should be focused on improving outcomes, quality of life, accessibility, and enhancing the patient experience, with medicines proven to be as potent, pure, safe, and effective as the branded drugs. We are proud to partner with CuraTeQ to bring BioFactura's high quality biosimilar of Ustekinumab to the global marketplace in order to fulfill these goals."

About BioFactura, Inc. BioFactura, Inc. (Frederick MD) develops and commercializes high-value biodefense medical countermeasures and biosimilars (i.e., follow-on biologics or generic biopharmaceuticals) using its patented StableFast™ Biomanufacturing Platform, the optimal system for bringing these drugs to market with faster, lower cost, superior-quality manufacture. For over 15 years, BioFactura has been advancing life-saving medicines from the research bench to the patient using its innovative drug development and manufacturing technologies. Current and past programs include biodefense drugs against smallpox and Ebola, novel medicines for cancer, and low-cost/high-quality biosimilars for autoimmune and infectious diseases. www.biofactura.com

About CuraTeQ Biologics Private Limited Curateq Biologics, a subsidiary of Aurobindo Pharma Ltd, is engaged in the research and development of recombinant biologics, especially in areas of biosimilars drug substance development and proteins formulations. Curateq Biologics is headquartered in Hyderabad, Telangana, India.
###

Jeffrey Hausfeld MD,MBA
BioFactura, Inc.
+1 301-792-8601
email us here
Visit us on social media:
LinkedIn
Other
