BioFactura's Biosimilar Ustekinumab, Demonstrates Pharmacokinetic (PK) Bioequivalence to Stelara® in Phase 1 Study

•Phase 1 clinical study demonstrated PK bioequivalence and comparable safety and immunogenicity profiles between BFI-751 and reference Stelara®.

FREDERICK, MARYLAND, UNITED STATES, October 13, 2022 /EINPresswire.com/ -- BioFactura Inc. has announced today the completion of the pivotal pharmacokinetic comparability clinical trial for its Ustekinumab Biosimilar (BFI-751). The clinical trial was conducted in two sites in Australia and one site in New Zealand. BioFactura developed BFI-751 using its proprietary NS0 host cell line-based StableFastTM Biomanufacturing Platform.

> meeting the primary endpoint of clinical bioequivalence in this trial, along with our bioanalytical comparative data, puts BFI-751 on the way to regulatory approval and commercial launch."
>
> *Jeffrey N. Hausfeld MD, MBA*

Ustekinumab is a targeted monoclonal antibody directed against the common p40 subunit of the naturally occurring proteins interleukin (IL)-12 and IL-23, which regulate the immune system. The reference product, Stelara ®, has been approved for the treatment of plaque psoriasis, active psoriatic arthritis, Crohn's disease, and ulcerative colitis and is projected to have global market sales at $10B in 2023 prior to patent expiry.

A total of 226 subjects were enrolled and randomly assigned 1:1:1 to receive BFI-751, EU-STELARA® and US-STELARA®. Pairwise comparisons between the three treatments all met the standard bioequivalence criteria that the 90% CI (Confidence Interval) of the geometric mean ratios of AUCinf, AUC0-tlast and Cmax of Ustekinumab lay completely within the acceptance interval of 80% - 125%. Clearance and elimination rates were shown to be comparable across the three treatment arms.

Secondary endpoints met included no marked differences in the safety and tolerability profile for subjects receiving BFI-751 as compared to EU- or US-STELARA®. Similar immunogenicity

profiles were seen with EU- and US-STELARA®. BFI-751 showed a lower immunogenicity rate at all time points in the assay compared with EU- and US-STELARA®.

BioFactura intends to conduct a confirmatory safety and efficacy study in patients to pave the way for global registration.

“Unlike novel drugs, a phase 1 trial for a biosimilar asset is called a pivotal pharmacokinetic study because it quantifies and compares how a biosimilar drug is absorbed and metabolized in relation to the innovator products. The establishment of meeting the primary endpoint of clinical bioequivalence in this trial, along with our fingerprint bioanalytical comparative data, puts BioFactura well on the way to regulatory approval and commercial launch of BFI-751. My gratitude goes out to all those who participated in the trial and supported the completion of this study, said Jeffrey N. Hausfeld MD, MBA, Chairman of the Board and Chief Medical Officer of BioFactura.”

Dr. Darryl Sampey, President and CEO, stated, “The successful completion of BioFactura’s first clinical study marks a capstone for the company. This product was conceived, created and manufactured entirely in-house by the most capable and hardworking team of people I have ever known. A sincere thanks to all who worked tirelessly over many years to bring us this remarkable outcome!”

About BioFactura, Inc.
BioFactura, Inc. (Frederick MD) develops and commercializes high-value 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 18 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
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