BioFactura Announces Material Transfer Agreement with RANI Therapeutics

FREDERICK, MARYLAND, UNITED STATES, September 9, 2021 /EINPresswire.com/ -- BioFactura Inc. ("BioFactura"), a leading developer of high-value biosimilar and biodefense drugs using its patented StableFastTM platform, announces an agreement with Rani Therapeutics ("Rani") to assess its Ustekinumab Biosimilar (BFI-751) in combination with Rani's RaniPill™ platform.

BFI-751 is being developed by BioFactura Australia Pty Ltd, a subsidiary of BioFactura, as a biosimilar drug to Stelara® (Ustekinumab), a biologic medication used to treat people diagnosed with Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis. Stelara® is an immunosuppressant that reduces the effects of inflammatory proteins within the body. BFI-751 employs BioFactura's StableFastTM technology, a novel platform that allows for the faster generation of fingerprint-like copies of the targeted reference drug.

Under terms of the material transfer agreement, Rani has agreed to evaluate BFI-751 in its RaniPill™ capsule, a novel, proprietary and patented platform technology, intended to replace subcutaneous or IV injection of biologics with oral dosing. The RaniPill™ capsule is designed to be a pain-free alternative for delivering large molecule chronic disease treatments that are typically administered via injection. Rani will conduct preclinical studies to determine whether BFI-751 can successfully be delivered into the bloodstream, when administered orally via the RaniPill™ capsule.

Dr. Darryl Sampey, BioFactura's President and CEO, stated, "With the prevalence of autoimmune diseases across the globe, it is important to provide new options to treat patients in innovative ways. The combination of BFI-751 and Rani's delivery platform could provide an alternative treatment for debilitating disorders and improve patient compliance with an easy-to-swallow option."

Dr. Jeffrey Hausfeld, Chief Medical Officer and Chairman of the BioFactura Board of Directors commented, "It's very exciting being on the cutting edge of technology. Bringing together our Stelara® biosimilar with Rani's oral platform is a good example of BioFactura's mission to

continuously innovate, provide patients with high quality products, and offer improved value and accessibility.”

In April 2021, BioFactura Australia Pty Ltd initiated a Phase I double-blind trial comparing the pharmacokinetics of BFI-751 to US-Stelara® and EU-Stelara® following a single subcutaneous dose. The Phase I study, being conducted in Australia and New Zealand, is also assessing the safety and tolerability of BFI-751 in 210 healthy volunteers, as well as their immune response.

For further information, please contact:

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About BioFactura
BioFactura (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 10 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.

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