BioFactura Awarded $67.4 Million Advanced Development Contract for its Smallpox Biodefense Therapeutic

*Contract awarded by Biomedical Advanced Research and Development Authority (BARDA).*

FREDERICK, Md. (PRWEB) September 27, 2019 -- BioFactura, Inc. today announced a contract awarded by the Biomedical Advanced Research and Development Authority (BARDA) valued at up to $67.4 million for the advanced development of its Smallpox Biodefense Therapeutic as a potential medical countermeasure (MCM) for the treatment of smallpox. This product has the potential to fulfill an unmet need in preparedness for a second anti-viral therapeutic with a different mechanism of action to the current stockpile to guard against potential host resistance.

This contract for the development of the Smallpox Biodefense Therapeutic consists of a base phase, valued at approximately $9.5 million, and three option phases over a total of 5 years. Under the base period-of-performance, work will focus on the development of manufacturing processes for the drug components, final product formulation, analytical method development, stability studies and regulatory activities to support formal engagement with the FDA. In addition to the base, the contract also includes U.S. Government options that may be activated to support process optimization and clinical manufacturing, additional non-clinical development studies to support an Investigational New Drug filing, and a first-in-humans Phase 1 clinical study.

While smallpox was declared eradicated in 1980 by the World Health Organization after an extensive vaccination campaign, the threat of bioterrorism and/or inadvertent release remains. Although TPOXX® (Tecovirimat, SIGA Technologies, Inc.) received FDA approval for smallpox treatment in 2018, Variola Virus (VARV), the causative agent for smallpox infections in humans, can become resistant to treatment suggesting that the best medical countermeasure approach would utilize complementary therapeutics. To fill the need for additional treatment options, BioFactura, in partnership with BARDA, is advancing the development of its monoclonal antibody-based Smallpox Biodefense Therapeutic in a stepwise approach building upon years of early product research and development and a strong foundation of cell line, process, analytical and manufacturing development experience and expertise.

Dr. Darryl Sampey, President and CEO of BioFactura, stated, “This advanced research and development contract award marks the culmination of decades of discovery and development work performed by our team, our partners at the National Institutes of Health and our principal government collaborator Dr. Jay Hooper at the U.S. Army Research Institute of Infectious Diseases. We look forward to working with BARDA in this new chapter of product development as we bring an important defense to our citizens.”

“This government contract for the development of a novel smallpox therapeutic countermeasure is the result of years of cutting edge biotechnology research, the perseverance of forward-thinking scientific entrepreneurs, the risk appetite of loyal investors, and the dedication of the Department of HHS/BARDA to maintain the safety and security of the United States population,” stated Dr. Jeffrey Hausfeld, BioFactura’s Chief Medical Officer and Chairman. “It is truly an evolving American success story and one which as a physician and Chairman of the Board of BioFactura, I am proud to be a part of.”

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Development Authority, under Contract No. 75A50119C00054.

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
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