

BioFactura Announces Activation of a \$15.9M Contract Option for its Smallpox Biodefense Therapeutic

BioFactura today announced its second contract option activation of \$15.9 million from the Biomedical Advanced Research and Development Authority (BARDA)



FREDERICK, MARYLAND, UNITED STATES OF AMERICA, July 18, 2022

/EINPresswire.com/ -- BioFactura today announced its second contract option activation of \$15.9 million from the Biomedical Advanced Research and Development Authority (BARDA) to advance development of an antibody cocktail therapeutic for the treatment of smallpox.

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BioFactura is proud to be part of this collaborative partnership with BARDA in order to further align the mission and goals of governmental agencies and private biotechnology firms.”

Jeffrey N. Hausfeld MD, MBA

This funding is part of BioFactura’s prime contract valued at up to \$68.2 million for the advanced development of its smallpox biodefense therapeutic. This contract option will provide an accelerated path for product development leading to the filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration for first-in-human studies.

Prior to award of this prime contract, BioFactura’s product demonstrated strong efficacy in non-human primates lethally infected with monkeypox, a surrogate for smallpox in humans. Under this new option, the company will

conduct further testing of the antibody therapeutic in this pivotal animal model. Following a successful IND, BioFactura will initiate a Phase I trial that will compare the pharmacokinetics and pharmacodynamics to animal study data in order to gauge the efficacy of the product in humans.

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 two small molecule drugs have received FDA approval for a smallpox indication, Variola

Virus (VARV), the causative agent for smallpox infections in humans, can become resistant to antivirals. This phenomenon suggests that the best medical countermeasure approach would utilize complementary therapeutics that mitigate resistance such as BioFactura's monoclonal antibody-based smallpox biodefense therapeutic.

Dr. Darryl Sampey, President and Chief Executive Officer of BioFactura, stated, "This funding confirms BARDA's continued commitment to support development of this important product. We look forward to our close collaboration with BARDA's program and technical groups as we move into clinical manufacture and testing."

Dr. Kimberly Clark, BioFactura's Senior Program Manager, affirmed, "BARDA has been an excellent partner in this journey. We have worked with them in a collaborative and scientific manner that is moving the program to the Investigational New Drug Application (IND) stage as quickly as possible."

Dr. Jeffrey Hausfeld, BioFactura's Chairman of the Board and Chief Medical Officer, added, "BioFactura is proud to be part of this collaborative partnership with BARDA in order to further align the mission and goals of governmental agencies and private biotechnology firms for the benefit, welfare, and security of our population."

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50119C00054.

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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