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BioVaxys enters bioproduction agreement with Wuxi Biologics for COVID-19 vaccine

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GearsÃ?Â up to synthesize proteins for its SARS-CoV-2 vaccine and COVID-TÃ¢â??Â¢ immunodiagnostic programsÃ?Â



British Columbia-registered BioVaxys Technology Corp., the world leader in haptenized protein vaccines for antiviral and cancer applications, has announced that it has entered into a major bioproduction agreement with WuXi Biologics Limited, a leading global Contract Development and Research Organization ("CDMO") and business unit of Shanghai-based Wuxi AppTec, to produce SARS-CoV-2 s-proteins required by BioVaxys for BVX-0320, its COVID-19 vaccine candidate, and for its Covid-T™ immunodiagnostic program.

Under the terms of the March 11th, 2021 agreement, WuXi will synthesize high yields of fully characterized, Good Laboratory Practice (GLP) grade SARS-CoV-2 s-protein for BioVaxys' preclinical safety study of its COVID-T™ diagnostic this spring. The recombinant s-protein will be constructed and expressed using WuXi Biologics' proprietary vector, with high yield protein production in a pilot plant bioreactor. By establishing its own source of s-protein, rather than depending upon a bulk commercial supplier, BioVaxys will be able to secure the level of purity, consistency and protein characterization required by the U.S Food and Drug Administration, as well as the economics of sourcing its own protein supply, facilitating the future production of GMP-grade s-protein for human trials and future commercial-scale production.

Synthesized GMP-grade s-protein is used in both BioVaxys's Covid-T™ immunodiagnostic as well as in BVX-0320, the company's SARS-CoV-2 candidate vaccine which is also being prepared for a clinical study this year. BioVaxys will submit its pre-IND meeting request to the FDA for Covid-T early next month.

BioVaxys President and Chief Operating Officer Ken Kovan stated that "Establishing a bioproduction method for a steady supply of purified and fully characterized s-protein from a validated process will enable us to quickly transition from having the GLP material for the upcoming Covid-T™ animal toxicity study to having a steady source the GMP-grade s-protein for clinical trials later this year. Now that we know the gene sequences, a further major benefit of our relationship with WuXi will be our ability to quickly source the s-protein of newly emerging SARS-CoV-2 variants for use in a planned multi-valent version of BVX-0320 and line extensions of Covid-T™."