BIOVAXYS

BioVaxys Bioproduction Partner WuXi Biologics Completes Synthesis Of Recombinant SARS-CoV-2 s-proteins for BVX-0320 and CoviDTH Programs

VANCOUVER, BC, Sept. 14, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys"), announced today that global CDMO partner WuXi Biologics, has completed the synthesis of recombinant SARS-CoV-2 s-protein for BVX-0320, the company's COVID-19 vaccine candidate, and CoviDTH, its immunodiagnostic product. Both are headed for clinical trials, with BioVaxys having begun preparing an IND submission to the US Food and Drug Administration ("FDA") for a combined Phase I/II clinical study of CoviDTH as a diagnostic for evaluating T-cell immune response to SARS-CoV-2.

Under the terms of the March 11th, 2021 agreement, WuXi Biologics synthesized high yields of fully characterized, SARS-CoV-2 s-protein for BioVaxys' Good Laboratory Practice (GLP) preclinical safety study of its CoviDTH which will begin this month. In its official Written Response in July to the Company's request for a Pre-IND Type B review of CoviDTH, the FDA has indicated that BioVaxys' planned animal toxicity study is discretionary and not required for IND submission. However, the Company is continuing with this study of CoviDTH as it does not interfere with the IND submission and may in fact provide useful data.

BioVaxys President & Chief Operating Officer Kenneth Kovan commented that "The production of the recombinant s-protein using WuXi Biologics' proprietary cell expression system is a significant milestone for Biovaxys, as we not only have a high production yield of protein, but also now have the ability and know-how to produce protein in large scale with the level of purity, consistency and protein characterization required by the FDA for our clinical studies and commercial-scale yields."

For greater certainty, BioVaxys is not making any express or implied claims that it has the ability to treat the SAR-CoV-2 virus at this time.

About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. (www.biovaxys.com) is a British Columbia-registered, clinical stage biotechnology company that is developing viral and oncology vaccine platforms, as well as immuno-diagnostics. The Company is advancing a SARS-CoV-2 vaccine based on its haptenized viral protein technology, and is planning a clinical trial of its haptenized autologous cell vaccine used in combination with anti-PD1 and anti-PDL-1 checkpoint inhibitors that will initially be developed for Stage III/Stage IV ovarian cancer. Also in development is CoviDTH®, a diagnostic for evaluating the presence or absence of a T cell immune response to SARS-CoV-2, the virus that causes COVID-19. BioVaxys has two issued US patents and two patent applications related to its cancer vaccine, and pending patent applications for its SARS-CoV-2 (Covid-19) vaccine and diagnostic technologies. BioVaxys common shares are listed on the CSE under the stock symbol "BIOV" and trade on the Frankfurt Bourse (FRA: 5LB) and in the US (OTCQB: BVAXF).

ON BEHALF OF THE BOARD

Signed "James Passin"

Cautionary Statements Regarding Forward Looking Information

This press release includes certain "forward-looking information" and "forward-looking statements" (collectively "forward-looking statements") within the meaning of applicable Canadian and United States securities legislation including the United States Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, included herein, without limitation, statements relating the future operating or financial performance of the Company, are forward looking statements. Forward-looking statements are frequently, but not always, identified by words such as "expects", "anticipates", "believes", "intends", "estimates", "potential", "possible", and similar expressions, or statements that events, conditions, or results "will", "may", "could", or "should" occur or be achieved. Forward-looking statements in this news release relate to, among other things, completion of the murine model study, regulatory approval for a Phase I study of its BVX-0320 Vaccine Candidate in humans and the overall development of BioVaxys' vaccines, including any haptenized SARS-Cov-2 protein vaccine. ***There can be no assurance that such statements will prove to be accurate, and actual results and future events could differ materially from those expressed or implied in such forward-looking statements.***

These forward-looking statements reflect the beliefs, opinions and projections on the date the statements are made and are based upon a number of assumptions and estimates, primarily the assumption that BioVaxys will be successful in developing and testing vaccines, that, while considered reasonable by the Company, are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies including, primarily but without limitation, the risk that BioVayxs' vaccines will not prove to be effective and/ or will not receive the required regulatory approvals. With regards to BioVaxys' business, there are a number of risks that could affect the development of its biotechnology products, including, without limitation, the need for additional capital to fund clinical trials, its lack of operating history, uncertainty about whether its products will complete the long, complex and expensive clinical trial and regulatory approval process for approval of new drugs necessary for marketing approval, uncertainty about whether its autologous cell vaccine immunotherapy can be developed to produce safe and effective products and, if so, whether its vaccine products will be commercially accepted and profitable, the expenses, delays and uncertainties and complications typically encountered by development stage biopharmaceutical businesses, financial and development obligations under license arrangements in order to protect its rights to its products and technologies, obtaining and protecting new intellectual property rights and avoiding infringement to third parties and their dependence on manufacturing by third parties.

The Company does not assume any obligation to update the forward-looking statements of beliefs, opinions, projections, or other factors, should they change, except as required by law.

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