BIOVAXYS

FDA Provides Necessary Guidance For BioVaxys To Begin Preparation Of Ind For Phase I/II Clinical Trials Of CoviDTH

VANCOUVER, British Columbia, July 22, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA:5LB) (OTCQB: BVAXF) ("BioVaxys"), is pleased to announce today that the US Food and Drug Administration ("FDA") has provided its official Written Response to the Company's request for a Pre-IND Type B review of CoviDTH as a diagnostic for evaluating T-cell immune response to SARS-CoV-2.

The FDA found the Chemistry, Manufacturing and Controls, and other elements of the clinical development program proposed by BioVaxys to be acceptable and provided guidance and feedback supportive of BioVaxys' clinical development plans for CoviDTH. In addition, the FDA indicated that animal toxicity studies for CoviDTH were not required and that the Company could start its clinical development program with a combined Phase I/II study. Based on this feedback, BioVaxys will begin preparation of an IND application to support a Phase I/II safety, dosing, and efficacy study.

BioVaxys submitted a Pre-Investigational New Drug ("IND") meeting request and briefing package with the FDA's Center for Biologics Evaluation and Research (CBER) for CoviDTH earlier this year. The Pre-IND review is a critical step in the US regulatory approval process, as it affords an opportunity for study sponsor companies to seek clarification from the FDA on clinical trials design, clinical materials manufacturing, quality controls, etc.

"With the guidance we received from this FDA review, BioVaxys is now able to begin preparing its IND," stated BioVaxys President and Chief Operating Officer Ken Kovan. He adds "Although the FDA has indicated that our planned animal tox study is discretionary, we will likely continue with the animal tox study of CoviDTH as it does not interfere with the development time frame and may in fact provide useful data."

James Passin, BioVaxys CEO, stated, "We are pleased to advance CoviDTH towards clinical trials, as we believe that mass screening for T cell immunity to Covid-19 will represent a critical tool for public health authorities to address the continued pandemic, as Covid variants continue to circulate and major governments in the southern hemisphere enact new lockdown policies."

The Company is not making any express or implied claims that its product has the ability to eliminate, cure, or contain Covid-19 (SARS-CoV-2) at this time.

About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. is a British Columbia-registered, early 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 ovarian cancer. Also in development is 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 trades on the Frankfurt Bourse (FRA: 5LB) and in the US (OTCQB: BVAXF).

ON BEHALF OF THE BOARD

Signed "James Passin"

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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 Private Placement, the use of proceeds of the Private Placement and the overall development of BioVaxys' vaccines and diagnostic technologies. ***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 locating suitable purchasers for Private Placement and in developing and testing vaccines and diagnostic tools, 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 BioVaxys' vaccines and diagnostic tools 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.

ON BEHALF OF THE BOARD

Signed "James Passin"

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