

BioVaxys Receives Positive FDA Response For Pre-IND Review For Covid19 Clinical Development

VANCOUVER, British Columbia, June 14, 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 reviewed its Pre-IND request for a Type B review of its Covid19 program and has determined that a Written Response is sufficient to address the Company's questions regarding bioproduction and clinical development plans for its planned pivotal Phase III study for its T-cell immune response diagnostic for SARS-CoV-2. The FDA has stated that the Written Response will be available by July 23, 2021.

BioVaxys submitted a Pre-IND meeting request and briefing package with the FDA's Center for Biologics Evaluation and Research (CBER) for Covid19 in March of this year. The Pre-IND review request 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.

The FDA has the option to not grant a Pre-IND review for substantive reasons such as it being premature for the stage of product development or not providing an adequate basis for the review.

Kenneth Kovan, President and Chief Operating Officer of BioVaxys, stated "We are pleased that our Pre-IND submission package was successful in presenting the rationale for Covid19 and our development plans. The FDA review and response to our questions will dovetail with the *in vivo* animal safety study of Covid19 that we are starting in July and ensure that we have the necessary information to file our IND."

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"

James Passin, CEO

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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 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 BioVaxys' 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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