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BioVaxys Begins Toxicity Study Ahead of CoviDTH IND Submission

VANCOUVER, BC, Sept. 28, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) (**"**BioVaxys" or "Company"), announced today that it has started its planned *in vivo* animal toxicology study of CoviDTH in parallel with the preparation of an IND submission. Under the terms of a March 2021 agreement, global contract research organization ("CRO") Inotiv, Inc. ("Inotiv") is evaluating the safety, tolerability, and toxicity of the purified recombinant SARS-CoV-2 s-protein that is a principal constituent of CoviDTH in an intradermal research model, which will include a battery of clinical pathology, immunology, and histopathology evaluations. The Inotiv study will be utilizing purified recombinant SARS-CoV-2 s-protein recently produced by BioVaxys bioproduction partner, WuXi Biologics.

Headquartered in West Lafayette, Indiana, Inotiv (NASDAQ: NOTV); (market capitalization: $795M) provides contract research services to emerging pharmaceutical companies and some of the world's leading drug development companies and medical research organizations.

In its July 2021 Written Response to BioVaxys on 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 US Food and Drug Administration ("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. Although the animal tox study is discretionary, it will not interfere with the IND timing and BioVaxys believes it may provide useful data when the study is completed next month.

CoviDTH™ is the world's first and only low cost, disposable, point-of-care diagnostic tool that screens for a T-cell response to SARS-CoV-2 in vaccinated patients, or those exposed to SARS-CoV-2. Recent published clinical studies[1,2] have validated the use of the delayed type hypersensitivity (DTH) cutaneous test behind CoviDTH as a feasible and safe *in viv*o method to assess cellular immune responses in both natural and vaccinated SARS-CoV-2 exposed individuals and also that the DTH response is highly durable and persists for at least one year after COVID-19 exposure or vaccine administration.[3]

BioVaxys President and Chief Operating Officer Ken Kovan stated, "Based on the millions of people who have received COVID-19 vaccines that are based on *in vivo* cellular expression of SARS-CoV-2 s-spike protein, as well as the human DTH studies, we are confident that the toxicology study with Inotiv of the s-protein will likewise confirm the safety profile of CoviDTH."

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.

[1]The Beauty of Simplicity: Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Responses in RNA-SARS-Cov-2 Vaccinated Individuals. Barrios Y, Franco A, Sánchez-Machín I, Poza-Guedes P, González-Pérez R, Matheu V.Vaccines (Basel). 2021 Jun 1;9(6):575. doi: 10.3390/vaccines9060575.

[2]A Novel Application of Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Response in SARS-CoV-2 Exposed Individuals. Barrios Y, Franco A, Sanchez-Machin I, Poza-Guedes P, Gonzalez-Perez R, Matheu V.Clin Immunol. 2021 May;226:108730. doi: 10.1016/j.clim.2021.108730. Epub 2021 Apr 16.

[3]Long term follow-up of in vivo cellular immune response to SARS-CoV-2 using delayed-type hypersensitivity cutaneous test. Barrios Y, Sánchez-Machín I, Matheu V. Eur J Immunol 2021 51,S1, 338. Abstract P-0814 doi: 10.1002/eji.202170200

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

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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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