BioVaxys Enters Agreement With Inotiv To Conduct Preclinical Toxicity Studies For Its Covid-T™ Immunodiagnostic Program

VANCOUVER, BC, March 18, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTC: LMNGF) ("BioVaxys"), the world leader in haptenized protein vaccines for antiviral and cancer applications, announced today that it has entered into an agreement with Bioanalytical Systems, Inc. d/b/a Inotiv ("Inotiv"), a global Contract Research Organization ("CRO"), to conduct preclinical toxicology studies for its Covid-T™ immunodiagnostic. Headquartered in West Lafayette, IN, Inotiv, provides contract research services and monitoring instruments to emerging pharmaceutical companies and some of the world's leading drug development companies and medical research organizations.

Covid-T™ is a low-cost, easy-to-administer, and accurate tool to test for the presence of T cells against SARS-CoV-2, and to evaluate the effectiveness of *any* SARS-CoV-2 vaccine candidate in stimulating T cell immunity. Covid-T™ uses *Delayed-Type Hypersensitivity* ("DTH"), which is known to be a measure of T cell immunity and has been used for many years for other infectious diseases including tuberculosis, fungal diseases, and mumps. The test is performed by placing a small amount of synthesized test material, e.g., SARS-Cov-2 spike protein, intradermally and inspecting the site for mild localized reddening and hardening of the skin ~24 hours later.

Under the terms of the March 15th, 2021, agreement, Inotiv will evaluate the safety, tolerability, and toxicity of purified SARS-CoV-2 s-protein in an intradermal research model, which will include a battery of clinical pathology, immunology, and histopathology evaluations. The fully characterized, Good Laboratory Practice (GLP) grade SARS-CoV-2 s-protein will be synthesized by WuXi Biologics and is a core element of the Covid-T immunodiagnostic. BioVaxys anticipates that the preclinical toxicity study results will be available early summer, with the successful completion of the study a critical step towards the initiation of a pivotal human trial of Covid-T later this year, subject to FDA approval. BioVaxys intends to submit its pre-IND meeting request to the FDA for Covid-T early next month.

BioVaxys President and Chief Operating Officer Ken Kovan stated, "Based on previous preclinical studies conducted with BVX-0320, and the fact that our SARS-CoV-2 vaccine candidate likewise incorporates synthetic s-protein, we have high expectations that this detailed toxicology study of the s-protein with Inotiv will confirm the safety profile of the diagnostic and lead to our planned pivotal clinical study later this year."

James Passin, BioVaxys CEO, stated "We are delighted to work with Inotiv, a leading CRO, to complete a toxicity study, further advancing Covid-T, our novel low cost and scalable skin test for T cell immunity to SARS-CoV-2, the virus that causes Covid-19. We believe that Covid-T will help to solve the world's most pressing public health policy crisis by enabling the rational distribution and allocation of vaccine resources, while preventing unnecessary and wasteful vaccination of people with demonstrable T cell immunity to Covid-19."

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. 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 US OTC: LMNGF.

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 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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