BIOVAXYS files FDA pre-IND meeting request and briefing package for COVID-T

VANCOUVER, BC, March 31, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA:5LB) (OTC:LMNGF) **(**"BioVaxys"), the world leader in haptenized antigen vaccines for antiviral and cancer applications, announced today that it is has filed a pre-IND (Investigational New Drug) meeting request and submitted a briefing package with the US Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) for Covid-T, its T-cell immune response diagnostic for SARS-CoV-2. The pre-IND meeting 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, and quality control. BioVaxys anticipates a written response to its pre-IND briefing package later this month.

BIOVAXYS

Covid-T™ uses *Delayed-Type Hypersensitivi*ty (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 induration 24 hours later. *In vivo* skin test antigens are considered biological products and are regulated by CBER's Office of Vaccine Research and Review (OVRR).

In January, the FDA instructed BioVaxys that it can file for a pre-Emergency Use Authorization ("EUA") for Covid-T™. An EUA can be issued after several statutory requirements are met. Among these is a determination by the FDA that the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases when certain criteria are met, outweigh the known and potential risks of the product. In the case of biologics being developed for the diagnosis, treatment or prevention of COVID-19, this assessment is made on a case-by-case basis depending on the characteristics of the product, the totality of the available scientific evidence relevant to the product, and the preclinical and human clinical study data on the product.

Pending completion of clinical product development, BioVaxys is not making any express or implied claims that it has sufficient data to file for an EUA to test for T-cell immunity to the SAR–CoV-2 virus.

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

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.

ON BEHALF OF THE BOARD

Signed "James Passin"

James Passin, CEO
+1 646 452 7054

Media Contacts BioVaxys Technology Corp.
Nikita Sachdev
Luna PR
info@lunapr.io

View original content:
http://www.prnewswire.com/news-releases/biovaxys-files-fda-pre-ind-meeting-request-and-briefing-package-for-covid-t-301259252.html

SOURCE BioVaxys Technology Corp.

View original content: http://www.newswire.ca/en/releases/archive/March2021/31/c1251.html

%SEDAR: 00045617E

CO: BioVaxys Technology Corp.

CNW 08:00e 31-MAR-21