

# Covid-T™ Clinical Development Program Initiated Regulatory Advisory Group Engaged

VANCOUVER, BC, Jan. 28, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTC: LMNGF) ("BioVaxys" or "Company") is pleased to announce that it has initiated the clinical development program for Covid-T™, the Company's novel diagnostic platform for detecting T-cell activity. The US Food and Drug Administration ("FDA") has tentatively agreed to permit that BioVaxys can file for a pre-Emergency Use Authorization ("EUA") for Covid-T™. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.

Covid-T™ addresses an unmet need for a low-cost, easy-to-administer, and accurate tool to test for the presence of T-cells which may offer lasting protection against SARS-CoV-2.

It is believed that detection of T-cells can potentially identify safe and/or at-risk populations. Covid-T™ also provides an ability to evaluate the effectiveness of any SARS-CoV-2 vaccine candidate in stimulating T-cell immunity. Mass availability of Covid-T™ would complement antibody testing and various public health risk mitigation strategies.

James Passin, CEO of BioVaxys, stated, "We believe that our low cost, scalable, easy-to-administer test for T cell immunity to SARS-CoV-2 may help solve the urgent global public health crisis of prioritizing the distribution of Covid-19 vaccines; we look forward to rapidly advancing Covid-T™ towards commercialization."

Current methods of measuring T-cell immunity require drawing blood from the test subject, followed by a time-consuming and expensive analysis of the blood sample at laboratories possessing specialized equipment.

Covid-T™ is based on the well-established concept of Delayed Type Hypersensitivity ("DTH"), the oldest and most reliable test of human T lymphocyte function. The process involves an intradermal "skin prick" of an immunogenic composition of the SARS-CoV-2 S-protein, where an inflammatory response develops 24-72 hours after skin exposure to the s-spike antigen.

BioVaxys anticipates that once clinical testing is complete, Covid-T™ would have the potential for detecting differences in T-cell responses between the original SARS-CoV-2 virus and the two new strains of SARS-CoV-2 that had originally been identified in the UK and South Africa--B.1.1.7 and 501Y.V2, respectively-- but which are spreading worldwide

"Although our vaccine programs are of major importance to us, Covid-T™ is a priority for BioVaxys, especially given the unmet need for such a simple, disposable, and accurate tool to test for the presence of T-cells against SARS-CoV-2," says BioVaxys President and Chief Operating Officer Ken Kovan.

BioVaxys has prepared the clinical development plan for Covid-T™, and engaged global regulatory advisory group Rio Pharmaceutical Services ("RPS") of Bridgewater, NJ, to provide strategic regulatory guidance, prepare an FDA pre-submission guidance package, recommend regulatory pathway, and support BioVaxys on the registration filing.

RPS has provided pharmaceutical and medical-device advisory services across the entire drug, biologic and device development and approval spectrum of the pharmaceutical industry since 2000. Collectively, the RPS team of pharmaceutical industry executives offers nearly 150 years of experience in providing advice and support services for medical, scientific, clinical-trial and regulatory issues to clients including a majority of Fortune 500 pharmaceutical companies.

Since Covid-T™ requires a biological substance to be placed intradermally, a nonclinical study will be needed to establish the risk profile prior to the start of clinical studies.

BioVaxys plans to shortly conduct a GLP animal toxicology study, is currently evaluating proposals from Contract Research Organizations (CROs), and is in the process of obtaining the appropriate cell lines, expression systems, and licenses so as to produce its own supply of SARS-CoV-2 s-spike protein.

The Company is not making any express or implied claims that its product line 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 trade on the Frankfurt Bourse (FRA: 5LB) and US OTC: LMNGF.

ON BEHALF OF THE BOARD

*Signed "James Passin"*

## 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.*

**Contact:**

James Passin  
CEO  
+1 646 452 7054

**Media Contacts**

Nikita Sashdev  
Luna PR  
[info@lunapr.io](mailto:info@lunapr.io)

View original content:

<http://www.prnewswire.com/news-releases/covid-t-clinical-development-program-initiated-regulatory-advisory-group-engaged-301217231.html>

SOURCE BioVaxys Technology Corp.

View original content: <http://www.newswire.ca/en/releases/archive/January2021/28/c4005.html>

%SEDAR: 00045617E

CO: BioVaxys Technology Corp.

CNW 08:00e 28-JAN-21