BioVaxys Files Patent Application for Novel COVID-19 Diagnostic for T-Cell Immunity

Vancouver, British Columbia--(Newsfile Corp. - November 2, 2020) - BioVaxys Technology Corp. (CSE: BIOV) ("BioVaxys" or "the Company"), a world leader in haptenized protein vaccine research and development, announced today that it has filed a Provisional Patent Application with the U.S. Patent and Trademark Office entitled METHOD AND KIT FOR DETECTION OF CELL MEDIATED IMMUNE RESPONSE related to the potential development of a diagnostic for evaluating the presence or absence of a T-cell immune response to SARS-CoV-2, the virus that causes COVID-19.

The BioVaxys method is based on measuring an immune response in a human showing no signs or symptoms of an active SARS-CoV-2 infection by administering a skin test of a subunit of the SARS-CoV-2 S-protein. Using Delayed Type Hypersensitivity[1] ("DTH"), a method which is known to demonstrate prior exposure and T cell immunity to tuberculosis[2], the immune system causes an inflammatory response that develops 24 to 72 hours after exposure. This type of immune response involves mainly T-cells rather than antibodies, which are made by B-cells.

If ultimately successful, the diagnostic is intended to provide a low-cost, easy-to-administer, and accurate way to test for the presence of T-cells against SARS-CoV-2. Currently, the available methods of measuring T-cell immunity require a blood draw from the test subject followed by the time-consuming and expensive analysis of the blood sample at specialized laboratories. BioVaxys' diagnostic includes a way to digitally measure T-cell presence via a smartphone (through the magnitude of the skin response which is a hallmark of DTH) so results can be sent immediately to healthcare providers. At this time, future studies and experiments are required to demonstrate that DTH from protein skin prick correlates to T-cell immunity in the blood against SARS-CoV-2. Now that the provisional patent application has been filed, BioVaxys intends to begin its studies, leveraging the planned work in Q1 2021 related to the manufacturing and clinical development of BVX-0320, BioVaxys's preclinical vaccine candidate for SARS-CoV-2, as it is anticipated that BioVaxys will initially investigate the use of the same GMP-compliant protein for the DTH diagnostic that is used in the manufacturing of BVX-0320.

David Berd, M.D., Chief Medical Officer at BioVaxys, who initially studied the potential use of DTH as a surrogate marker of T cell immunity in the context of clinical investigation of therapeutic autologous haptenized cancer vaccines[3], stated, "The availability of a low-cost and simple diagnostic for T-cell immunity would represent a critical tool for public health authorities to identify safe and at-risk populations and may contribute to worldwide efforts to combat COVID-19. BioVaxys believes that its novel T-cell diagnostic also provides an effective and low-cost tool to evaluate the effectiveness of any SARS-CoV-2 vaccine candidate in stimulating T cell immunity."[3]

Recent peer-reviewed studies, including one in *Nature*[4] and *Cell*[5], have highlighted the potential importance of T-cell, in addition to antibodies, when it comes to evaluating long-term immunity in patients who have recovered from COVID-19. While further evaluation is necessary, exploring this part of the immune system's response to prevent future infection will be necessary in the global fight against this disease.

BioVaxys' CEO, James Passin stated, "We are thrilled to further develop and move our novel diagnostic for SARS-CoV-2 T-cell immunity towards commercialization. The mass availability of our low cost and easy-to-administer T-cell immunity diagnostic could help to complement antibody testing and various public health risk mitigation strategies."

A provisional patent application offers a patent applicant an option of filing without including a formal patent claim. In BioVaxys's case, however, numerous patent claims have been included in the Provisional Application. The aim of a provisional patent application is to establish an early effective filing

date, in addition to allowing the patent applicant to ascribe the phrase "patent pending" to any commercial products, methods, or services contemplated by the subject matter claimed. BioVaxys also plans to pursue an international Patent Cooperation Treaty (PCT) application, from which national stage patent applications can be submitted in both industrial jurisdictions and developing countries around the world.

Additional Information:

- BioVaxys' patent application is for a diagnostic tool to test for SARS-COV-2, and not for a therapeutic treatment of SARS-COV-2. In addition, BioVaxys intends to seek future clearance from the U.S. Food & Drug Administration after sufficient clinical tests can be evaluated.
- BioVaxys makes no express or implied claims that it has developed a vaccine to treat COVID-19 (or SARS-2 Coronavirus) at this time.

David Berd, M.D. the Chief Medical Officer of BioVaxys, has reviewed and approved the scientific disclosure contained in this press release. Dr. Berd is a medical oncologist with a lifelong record of clinical research in medical oncology and cancer immunotherapy. Dr. Berd received his BS from Pennsylvania State University and his MD from Jefferson Medical College of Thomas Jefferson University.

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 for SARS-CoV-2 and various cancers. 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 therapy used in combination with anti-PD1 and anti-PDL-1 checkpoint inhibitors that will initially be developed for ovarian cancer. BioVaxys has two issued US patents and two patent applications related to its cancer vaccine, and a patent application for its SARS-CoV-2 (Covid-19) technology. BioVaxys common shares trade on the CSE under the stock symbol "BIOV" and are listed on the Frankfurt Bourse (FSE: 5LB).

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, the success and ultimate commercialization of its diagnostic test for T-cell immunity. ***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 commercializing its diagnostic test for T-cell immunity and the issuance of a patent for such technology, 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 such diagnostic testing 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 diagnostic tests for marketing approval and, if so, whether the technology 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 newintellectual 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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[1] Immunology and Allergy Clinics of North America; Volume 21, Issue 2, 1 May 2001, Pages 383-397

[2] M. tuberculosis-complex specific T-cell stimulation and DTH reactions induced with a peptide from the 38-kDa protein. H M Vordermeier 1, D P Harris, P K Mehrotra, E Roman, A Elsaghier, C Moreno, J Ivanyi. Scandavian Journal of Immunology 1992 Jun;35(6):711-8.

[3] BERD D, Sato T, Maguire HC Jr, Kairys J, Mastrangelo MJ: Immunopharmacological analysis of an autologous, hapten-modified human melanoma vaccine. J. Clin. Oncol., 22:403-415, 2004.

[4] Le Bert, N., Tan, A.T., Kunasegaran, K. et al. (2020). "SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls." Nature 584:457-462, 2020

[5] Sekine, T., et al. (2020). "Robust T cell immunity in convalescent individuals with asymptomatic or mild COVID-19." Cell 183: 158-163