BioVaxys Announces Initiation of Cancer Vaccine EU Clinical Program, Completion of BVX-0320 Preclinical Program

VANCOUVER, BC, Jan. 25, 2021 /CNW/ --

- **Features Observation Of Neutralizing Antibodies To SARS-CoV-2**
- **Advancement Of Viral Vaccine Platform And T-cell Diagnostic To Address Emerging SARS-CoV-2 Strains**

BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTC: LMNGF) (**"**BioVaxys" or "Company") is pleased to provide a corporate update on recent advancements of its vaccine platforms, and viral diagnostic and corporate objectives for 2021. BioVaxys is pleased to announce that it has commenced the clinical development program for BVX-0918A, its haptenized tumor antigen vaccine for ovarian cancer. The Company plans to seek a compassionate use approval in the European Union ("EU") for Stage III & Stage IV ovarian cancer, followed by submitting an IND in the US. BioVaxys is in discussions with its designated Contract Manufacturing Organization ("CMO") and anticipates the execution of a manufacturing contract in 1Q21. The Company plans to submit its Clinical Trial Application ("CTA") for BVX-0918A with the European Medicines Agency ("EMEA") later this year.

There are significant unmet therapeutic needs for ovarian cancer treatment. Over 240,000 women are currently diagnosed with ovarian cancer worldwide, and over 140,200 succumbed to the disease. Ovarian cancer is the leading cause of death from gynecologic malignancy in the United States. An estimated 21,750 new cases of ovarian cancer are expected in the United States in 2020 with 13,940 deaths. The case-to-fatality ratio is nearly three times that of breast cancer and makes ovarian cancer the deadliest gynecologic malignancy in developed countries. Like other cancers, the stage of disease is inversely proportional to survival. The 5-year relative survival rate in all stages of the disease is approximately 45%. However, ovarian cancer is usually asymptomatic in the early stages (Stage I and Stage II), and therefore about 80% of patients are diagnosed with advanced stage disease (stages III and IV). The 5-year survival rate for stage III and IV patients is approximately 29%.[1]

BioVaxys has developed its vaccine technology platforms based on the established immunological concept that modifying tumor or viral antigens with simple chemicals called haptens makes them more visible to the immune system. The process of haptenization "teaches" a patient's immune system to recognize and make target proteins more 'visible' as foreign, thereby stimulating an immune response. In Phase I and Phase II clinical studies previously conducted by BioVaxys, co-founder and Chief Medical Officer, David Berd MD, using an earlier generation of the BioVaxys cancer vaccine on nearly 500 patients with melanoma or ovarian cancer, the haptenized cell platform showed significant clinical promise. BioVaxys Founder, President & Chief Operating Officer Ken Kovan says: "The autologous approach may have advantages over other approaches, such as those involving a search for specific antigens. Because autologous tumor cells by definition have the patient's unique set of antigens already on them, the challenge is to increase the immune system's ability to recognize the ovarian tumor cells as foreign, breaking the "self-tolerance". A way to achieve this is by the use of a hapten, which is the foundation for the BioVaxys' haptenized protein vaccine platform."

BioVaxys intends to develop its vaccine together with a "checkpoint inhibitor" that reduces or decreases the cellular function of an immune checkpoint gene or gene product. Checkpoint inhibitors are a type of drug that blocks proteins called 'checkpoints' that are made by some types of immune system cells, such as T cells and some cancer cells. These checkpoints help keep immune responses from being too strong, but also can sometimes keep T cells from killing cancer cells. When these checkpoints are blocked, T cells can more effectively kill cancer cells. BioVaxys' focus is on combinations of immune checkpoint inhibitors with its haptenized tumor antigen vaccine---primarily anti-CTLA4, anti-PD1, or PDL1 checkpoint antibodies---for treatment of ovarian cancer and other solid tumors. BioVaxys' rationale is that there is (1) a persistent unmet clinical need because the majority of ovarian cancer patients do not benefit from anti-checkpoint monotherapy; (2) evidence that not all patients make immune responses to their tumors; (3) evidence that immune responses to autologous tumor antigens can be induced by patient-specific vaccines; and (4) clinical evidence from the pre-checkpoint era that suggests survival can be positively impacted by such patient-specific vaccines.

BioVaxys also recently completed its preclinical program for its SARS-CoV-2 vaccine candidate, BVX-0320, which included those studies suggested by the U.S. Department of Health and Human Services, Food and Drug Administration ("FDA") Center for Biologics Evaluation and Research "(CBER") in their published guidance on *Development and Licensure of Vaccines to Prevent COVID-19*.

Source*: (1) American Cancer Society, Cancer facts and figures; (2) Cannistra SA. Cancer of the Ovary. N Engl J Med 2004 Dec 9;351(24):2519-29; and (3) McGuire WP, Hoskins WJ, Brady MF, Kucera PR, Partridge EE, Look KY, et al. Cyclophosphamide and cisplatin compared with paclitaxel and cisplatin in patients with stage III and stage IV ovarian cancer. N Engl J Med 1996;334(1):1-6.*

The FDA's non-binding *Guidance* is intended to assist in the clinical development and licensure of vaccines for the prevention of COVID-19, and reflect the Agency's current thinking on the issue. Conducted by Charles River Laboratories, Inc. under contract with BioVaxys, the preclinical program which began in September 2020 evaluated the anti-virus immune response elicited by BVX-0320 in a controlled murine model by measuring the development of antibodies to the protein that binds the virus to human cells. Following two injections of BVX-0320 together with the immunological adjuvant, QS21, to 28 mice at four dosage levels, 96.4% developed positive antibody responses detected at week 6. The BioVaxys team also found that its haptenized SARS-CoV-2 s-spike vaccine activated CD4+ helper T-cells and CD8+ killer T-cells that express the activation markers, CD69 and CD25. This result indicates that immunization with BVX-0320 at two different dose levels of 3µg or 10µg stimulated immune system memory 'helper' T-cells as well as killer T-cells. $CD4^+$ T-cells are crucial in achieving a regulated effective immune response to viral pathogens, and are central to adaptive immune responses. Generated following an immune response, memory 'helper' CD4+ T-cells retain information about the virus, which enables them to respond rapidly after viral exposure. CD8+ T-cells have the capacity to kill cells infected by the virus, thereby stopping viral replication in those cells.

Under a BioVaxys-sponsored research collaboration with The Ohio State University ("OSU") Wexner School of Medicine, the OSU researchers used the available remaining mouse sera from the immune response assay to conduct a Plaque Reduction Neutralization Test, where the endpoint is reduction of plaques by 50%, where it was observed in a pooled sample that BVX-0320 elicited the production of neutralizing antibodies to SARS-CoV-2. Plaques are produced by infection of cultured human cells by a live SARS-CoV-2 virus. OSU is one of the few institutions that has the laboratory capability to study live SARS-CoV-2 virus.

Recently, two new strains of SARS-Cov-2 have been identified in the UK and South Africa – B.1.1.7 and 501Y.V2, respectively. Both strains exhibit a number of mutations, some of them in the spike protein. The mutation of most concern, found in both new strains, is the one in spike protein position 501, one of the key contact points in the receptor binding domain. Experimental data suggest that this mutation, called 501Y, can increase binding of the virus to human cells through the ACE2 receptor. This change could result in more rapid transmission of the virus between individuals and thus more rapid spread of Covid-19. There is also concern that the recent approved vaccines may not be completely effective against these new strains.

The BioVaxys haptenization strategy constitutes a platform technology in that it is adaptable to almost any virus-derived protein. The haptenization of viral proteins imparts BioVaxys with the flexibility of a 'cassette-type' approach not possible with other vaccines, where they can "swap in" the appropriate viral antigen(s) for haptenization and the creation of a new vaccine, potentially allowing for faster development timelines relative to other vaccine approaches.

BioVaxys proposes to respond to these potentially dangerous events by modifying its Covid-19 vaccine, BVX-0320. The original version contained the S1 subunit of the spike protein that was dominant in viral isolates at the beginning of the pandemic. A new SARS-CoV-2 vaccine candidate, BVX-0121, is under internal evaluation which would include modifications to address the emerging strains. This would a bivalent or trivalent vaccine containing the original S1 plus the S1 from one or both of the UK and South African strains. The manufacturing process would be similar to that of BVX-0320. BioVaxys plans to collaborate with a pharma partner and jointly seek government funding for the Phase II program.

BioVaxys' Covid-19 diagnostic, Covid-T™, has the potential of detecting differences in T cells responses between the original virus and the two new strains. Current methods of measuring T cell immunity require the drawing of blood from the test subject and a time-consuming and expensive analysis of the blood

sample at laboratories possessing specialized equipment. What is needed is a simple, low-cost, easy-to-administer, and accurate tool to test for the presence of T cells against SARS-CoV-2 to identify safe and at-risk populations. Covid-T™ provides 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. Mass availability of this low cost and easy-to-administer T cell immunity diagnostic would complement antibody testing and various public health risk mitigation strategies.

Subjects would be simultaneously tested for delayed-type hypersensitivity to all three S1 variants. The size of the DTH reactions is compared for each subject. The Company has engaged a global regulatory advisory group, is contracting with an FDA-approved Contract Development and Manufacturing Organization (CDMO) for a cell line, expression system and cloning expertise to source GMP-grade s-1 protein, and is preparing an FDA pre-submission guidance package with delivery to the FDA anticipated shortly. A non-GMP animal toxicity study is scheduled for this March, followed by the proposed Phase I study this summer.

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 trade on the Frankfurt Bourse (FRA: 5LB) and US OTC: LMNGF.

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 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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