BioVaxys Vaccine Platform Stimulates Robust T-cell Response Against Viral Antigens

BVX-0320 ACTIVATES IMMUNE SYSTEM MEMORY 'HELPER ' CD4+ AND KILLER CD8+ T-CELLS AGAINST SARS-COV-2

POTENTIAL FOR LONGER-TERM VIRAL PROTECTION

VANCOUVER, British Columbia, Dec. 21, 2020 /CNW/ -- BioVaxys Technology Corp. (**CSE: BIOV, FRA:5LB, OTC:LMNGF) (**"BioVaxys") announced today that further analysis of the data from a preclinical animal study (also known as the "murine model study") of its haptenized viral protein vaccine technology show that BVX-0320, its COVID-19 vaccine candidate based on the Company's haptenized viral protein platform, elicits a robust T-cell response against SARS-CoV-2.

Using a technique called flow cytometry, the BioVaxys team 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.

BioVaxys Co-Founder, President and Chief Operating Officer Kenneth Kovan says, "This is an exciting development not only in the COVID-19 vaccine field, but potentially for other viral vaccines. Post-vaccination generation of antibodies is no doubt critical and garners much attention. However, antibody levels can quickly become undetectable after just a few months, leading to the conclusion that anti-viral immunity has waned." He goes on to say that "a robust CD4 and CD8 T-cell response, such as that we are seeing, has potential to confer much longer protection."

Recent data from the preclinical study, which began in September 2020 and was conducted by leading independent contract research organization ("CRO") Charles River Laboratories, Inc. under contract with BioVaxys, 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. Co-founder and Chief Medical Officer David Berd, MD, says that "Stimulating a 96.4% antibody response is an excellent development, but we believe that activation of T-cells is even more important. A post-SARS2 infection T cell response appears to be a defining characteristic following recovery in COVID-19 patients. Seeing activation of CD4 and CD8 T-cells differentiates our approach from some other COVID-19 vaccines." Dr. Berd adds that "a duration of immunity that cannot be guaranteed past a few months is really not useful protection. Activation of a T-cell response may be the critical determinant for effective long-term protection."

A separate study sponsored by BioVaxys is underway at The Ohio State University Wexner Medical Center, where the mouse sera (collected from the test animals) is being tested for the ability to inactivate live SARS-Cov-2 virus. Results are anticipated later this month.

James Passin, the CEO of BioVaxys, stated, "The outstanding results from the Murine Model Study of BVX-0320, including robust T cell and antibody results and an excellent safety and manufacturing profile, evidences the value of our haptenized viral protein vaccine technology platform and should support ongoing discussions with potential pharmaceutical partners. We are excited to continue to leverage this scientific momentum, as well as to continue advancing our novel COVID-19 T-cell diagnostic, a low cost and scalable tool which may assist public health authorities in the distribution of scarce vaccine resources, as it should not be a priority to immunize individuals presenting T cell immunity to SARS-CoV-2."

BioVaxys's product pipeline includes BVX-0918A, an IND-stage haptenized cancer cell vaccine for treating late-stage ovarian cancer. In Phase I and Phase II clinical studies previously conducted by BioVaxys, co-founder and Chief Medical Officer, Dr. David Berd, 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 has developed its vaccine technology platforms based on the established immunological concept that modifying proteins 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.

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.

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, <u>BioVaxys Technology Corp</u>. 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.

<u>Signed "James Passin"</u> James Passin, CEO +1 646 452 7054

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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 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.

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