BioVaxys Expands Cancer Vaccine Platform

BVX-0922 to Target Colorectal Cancer Under Investigator-Sponsored IND

VANCOUVER, BC, March 30, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV), (FRA: 5LB), (OTCQB: BVAXF) **(**"BioVaxys" or "Company"), announced today the expansion of its cancer vaccine platform with BVX-0922, its autologous haptenized tumor vaccine for colorectal cancer ("CRC"). BioVaxys plans to advance an Investigator-Sponsored Clinical Trial Application ("CTA") in the EU with the European Medicines Agency ("EMEA") this year for BVX-0922. An Investigator Sponsored CTA is submitted to regulatory authorities by a clinical investigator who both initiates and conducts an initial clinical study of a new drug or procedure, and under whose immediate direction the investigational drug is administered.

CRC is the third most common malignancy and the second most deadly cancer world-wide, with an estimated 1.9 million new CRC cases diagnosed and 0.9 million deaths globally in 2020. The incidence of CRC is higher in highly developed countries, with global new CRC cases predicted to reach 3.2 million in 2040. When diagnosed early, the five-year relative survival rate for stage I and stage II colon cancer is 90%; however, CRC patients often experience no signs or symptoms associated with the disease. The 5-year survival rate for patients diagnosed at Stage IV is only 14% (Journal of Translational Oncology, Global Colorectal Cancer Burden in 2020 And Projections to 2040, Vol 14, Issue 10, October 2021).

A major benefit of the Company's autologous haptenized tumor vaccine technology platform is the rapid scalability into a range of tumor types, especially those where the standard of care for these cancer patients typically involves surgical excision of tumor tissue. Access to these tumor cells is necessary for BioVaxys to manufacture autologous haptenized tumor cell vaccines, such as BVX-0918 for late-stage ovarian cancer or BVX-0922 for CRC.

The BioVaxys vaccine platform is based on the established immunological concept that modifying surface proteins---whether they are viral or tumor---with haptens makes them more visible to the immune system. This process of haptenization "teaches" a patient's immune system to recognize and make target proteins more "visible" as foreign, thereby stimulating a T-cell mediated immune response. BioVaxys' cancer vaccines are created by extracting a patient's own (i.e., autologous) cancer cells, chemically linking with a hapten, and re-injecting them into the patient to induce an immune response to proteins which are otherwise not immunogenic.

Haptenization is a well-known and well-studied immunotherapeutic approach in cancer treatment, and has been evaluated in both regional and disseminated metastatic tumors. BioVaxys has a significant advantage over many other companies looking at cancer therapies in that it already has extensive promising clinical data for its cancer vaccines.

First-generation single-hapten vaccines invented by BioVaxys Co-Founder and Chief Medical Officer David Berd, MD, achieved positive immunological and clinical results in his previous FDA-approved Phase I and Phase II human trials in over 600 patients with different tumor types, as well as having no observed toxicity in years of clinical study.

For example, two studies of patients with metastatic melanoma were completed and published. The first trial tested the activity of the autologous, DNP-modified vaccine in 83 evaluable patients with incurable, metastatic melanoma (Berd et al, Int J Cancer 2001; 94: 531-539). Following vaccine administration there were 11 responses—2 complete, 4 partial, and 5 mixed; 2 patients were judged to have stable disease. Both complete responses and two of the four partial responses occurred in patients with lung metastases. Response durations were as follows: partial responses— 5, 6, 8, and

47+ months; complete responses—12, 29 months. In a second trial 214 patients with advanced stage III melanoma (lymph node metastases) underwent excision of large lymph node masses and then were administered the haptenized vaccine. With a median follow-up time of 5.1 years the 5-year overall survival rate was 46%, which is considerably higher than survival times reported with surgery alone (Berd et al, J. Clin. Oncology, 1997, 15:2359)

A first generation autologous, haptenized vaccine was also tested in two clinical trials conducted by Dr. Berd in women with advanced ovarian cancer who had ceased to respond to conventional chemotherapy. In the first trial 13 evaluable patients with bulky, chemotherapy-refractory disease were treated. The patients exhibited complete regression of a residual peritoneal mass by computed tomography (CT) and a concomitant fall in serum CA-125 (an ovarian cancer serum marker) from 65 to 6. Both the CT and CA-125 responses were maintained for 6 months.

In a second study (Taha et al, Gynecol Oncol 2014; 134, Abstract 25: 428-437), 26 subjects with recurrent platinum resistant ovarian cancer were enrolled. Vaccine was prepared for, but not administered to, 25 additional subjects. In six vaccinated subjects, CA125 levels became normal following surgery plus vaccine and remained normal throughout the 9-month duration of the protocol. Median overall survival by Kaplan–Meier method after surgery in the vaccinated group was 25.4 months compared to 6.5 months in the vaccine prepared but not administered group.

Finally, preliminary studies of a first generation, autologous, single-hapten vaccine have been performed in kidney cancer, non-small cell lung cancer, breast cancer, and acute myelogenous leukemia. The results indicated that preparation and administration of vaccine was feasible.

BioVaxys has enhanced the first-generation approach in these previous studies of using a single-hapten to now utilizing two haptens ("bi-haptenization"), which the Company believes will yield superior results. The global colorectal cancer therapeutics market is projected to reach $16.5 billion by 2026 (fortunebusinessinsights.com).

About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. (www.biovaxys.com) is a British Columbia-registered, clinical stage biotechnology company that is developing viral and oncology vaccine platforms, as well as immuno-diagnostics. The Company is advancing vaccines for SARS-CoV-2, SARS-CoV-1, and a pan-sarbecovirus 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 Stage III/Stage IV ovarian cancer. Also in development is CoviDTH®, 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 multiple US and international patent applications related to its cancer vaccines, antiviral vaccines, 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 in the US (OTCQB: BVAXF).

ON BEHALF OF THE BOARD

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Cautionary Statements Rearding 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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