BIOVAXYS

BioVaxys Confirms First Clinical Site and Principal Investigators for Ovarian Cancer Vaccine Trial and Enters into Second Tumor Cell Supply Agreement

VANCOUVER, BC, May 18, 2022 /CNW/ -- BioVaxys Technology Corp. (**CSE: BIOV; FRA: 5LB; OTCQB: BVAXF**) ("BioVaxys" or "Company"), announced today that Hospices Civils de Lyon, France ("HCL") has agreed to serve as a clinical study site for the Phase I study of BVX-0918, the Company's autologous haptenized tumor cell vaccine for late-stage ovarian cancer. HCL has further agreed to supply BioVaxys with surgically debulked tumors from Stage III/Stage IV ovarian cancer patients undergoing treatment at the hospital to permit the Company to perform manufacturing tests. BioVaxys, together with its EU partner, ProCare Health of Barcelona, Spain, is preparing for a Phase I clinical study with BVX-0918 later this year.

HCL is a public hospital and France's second University Hospital Center, and a premier site for clinical studies in the EU. Hospices Civils de Lyon is at the heart of the healthcare ecosystem of Greater Lyon, one of the major biotechnology and healthcare markets in Europe.

BioVaxys and Procare personnel will collaborate with Dr Pierre Adrien Bolze, MD, PhD, and Pr. Benoît You, MD, PhD, of HCL who are planned Clinical Investigators for the Phase I study of BVX-0918.

BioVaxys is preparing to file a Clinical Trial Application ("CTA") with the European Medicines Agency ("EMA") later in 2022. Access to surgically removed ovarian cancer tumor cells is a critical step enabling BioVaxys to validate the manufacturing process for BVX-0918. BioVaxys recently entered a similar collaboration with Deaconess Research Institute in the United States to provide the Company with surgically debulked tumors from Stage III/Stage IV ovarian cancer patients. Tumor samples from both hospitals are being used to validate the tumor collection protocol, cryopackaging, cryopreservation, and supply chain logistics for BVX-0918 bioproduction for prospective patients in the US and EU. Tumor samples from HCL will also be used for process testing and manufacturing "dry runs" of BVX-0918, a major step leading to the completion of Good Manufacturing Process ("GMP") production, a requirement for the planned CTA with the EMA.

HCL has pre-screened the first patient for tumor collection, with patient enrollment for surgical debulking planned for next week.

Dr. You stated, "There is an unmet medical need for innovative approaches, based on vaccines and immunotherapies drugs, in ovarian cancer, as a way of improving the prognosis of patients. It has been defined as a priority for our institution. This collaboration with BioVaxys is a great opportunity for developing a vaccine that would then be assessed in a first-in-human trial in our early phase trial unit." Professor You is a medical oncologist and head of the Phase 1 trial unit oncology group (Centre d'Investigation des Thérapeutiques en Oncologie et Hématologie de Lyon), certified by French National Cancer Institute.

"We are very happy to partner with BioVaxys to contribute to the development of innovative therapeutic strategies for our ovarian cancer patients," stated Pierre Adrien Bolze, MD, PhD, Professor of Gynecological Obstetrics at HCL. "Our department is certified by the European Society of Gynaecological Oncology for ovarian cancer surgery, and has an extensive track record in gynecology oncology studies."

"BioVaxys is honored to be working with Dr Bolze and Dr You on the Phase I study of BVX-0918. They are leaders in gynecological oncology, and have led an extensive range of clinical studies," says Kenneth Kovan, President and Chief Operating Officer of BioVaxys. Ovarian cancer ranks fifth for cancer-related death in women. About 75% of ovarian cancers are diagnosed at late stage of the disease, when the peritoneum is involved (stage III) or disease has spread to other organs (stage IV). The standard of care for late-stage ovarian cancer relies on a medical-and-surgical treatment associating a platinum-based chemotherapy and a surgical debulking of the tumor mass meant to be complete with no post-operative residual lesion.

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 (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 to cancer immunotherapy and has been clinically evaluated in both regional and disseminated metastatic tumors.

A first generation single-hapten vaccine invented by BioVaxys Co-Founder and Chief Medical Officer David Berd, MD, achieved positive immunological and clinical results in 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. These studies were conducted under an FDA-reviewed IND. A first generation autologous, haptenized vaccine was also tested by Dr. Berd in women with advanced ovarian cancer who had ceased to respond to conventional chemotherapy. The results were encouraging: In 24 patients, the median overall survival was 25.4 months with a range of 4.5-57.4 months; 8 patients survived for more than 2 years. BioVaxys has enhanced the first-generation approach by utilizing two haptens ("bi-haptenization"), which the Company believes will yield superior results.

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-PDL1 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 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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