

# Clinical Study Collaborator HCL Sends First Surgically Excised Ovarian Cancer Tumors to BioVaxys for BVX-0918 Vaccine Process Development

VANCOUVER, BC, June 15, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company"), announced today that its clinical study collaborator Hospices Civils de Lyon in France ("HCL") has surgically excised the first ovarian cancer tumors from cancer patients to be used by BioVaxys for process development and manufacturing "dry runs" of BVX-0918, a major step leading to the completion of Good Manufacturing Process ("GMP") production of the Company's ovarian cancer vaccine.

BioVaxys recently entered collaborations with HCL and 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 by BioVaxys' Lyon-based manufacturing partner, BioElpida ("BioElpida"), to validate the tumor collection protocol, cryopackaging, cryopreservation, and supply chain logistics for BVX-0918 bioproduction for prospective patients in the US and EU.

Donors of ovarian cancer tumors are required to sign a patient consent form, with the tumor extraction, storage, and shipping logistics following a strict protocol developed by BioVaxys, and subjected to institutional and regulatory approval.

BVX-0918 produced from the surgically removed tumor cells from HCL will be screened using the identity assays derived from the OVCAR-3 cell line recently completed by BioElpida. The identity assay will be performed on every batch of autologous ovarian cancer vaccine, and is mandatory for regulatory bodies in the EU and United States.

BioVaxys President and Chief Operating Officer Kenneth Kovan stated that, "The production of BVX-0918 is a process that built on the prior successful execution of sequential steps, such as the bioproduction technology transfer to BioElpida, development of validation procedures needed to support GMP manufacturing, sterility testing for transport, hapten fixation, cryopreservation methods, antibody generation, bioburden screening, endotoxin assays, and most recently, the development of the identity assays from the OVCAR-3 cell line. With the surgically excised tumors we can now begin the final stages of the vaccine production protocol and GMP validation."

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 haptentization "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. Haptentization 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, haptentized 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-haptentization"), which the Company believes will yield superior results.

## About BioVaxys Technology Corp.

Based in Vancouver, [BioVaxys Technology Corp.](http://www.biovaxys.com) ([www.biovaxys.com](http://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 haptentized viral protein technology, and is planning a clinical trial of its haptentized 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

Signed "James Passin"

James Passin, CEO  
+1 646 452 7054

## Government & Media Relations

JB&A, Inc.  
Davin Shinedling  
[davin@jennibyryne.com](mailto:davin@jennibyryne.com)  
1 (647) 991-6447

## 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 to 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 haptentized 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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