

Bio-Manufacturing Partner BioElpida Completes Next Phase of BVX-0918 GMP Production for EU Clinical Study

VANCOUVER, BC, June 8, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company"), announced today that its Lyon, France-based bioproduction partner, BioElpida ("BioElpida"), has completed the creation of multiple OVCAR-3 cell banks as the next step in the GMP manufacturing process development for BVX-0918, BioVaxys' vaccine for treatment of platinum-resistant ovarian cancer.

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The OVCAR-3 cell line is mandatory for creating the identity assays that will have to be performed on every batch of ovarian cancer vaccine. This assay is required by regulatory bodies in the EU and United States. The cell line is derived from a human ovarian adenocarcinoma, established from a patient refractory to cisplatin, a chemotherapeutic agent used in late-stage ovarian cancer. Patients whose tumors are innately cisplatin-resistant at the time of initial treatment generally have poor prognosis, which is the patient population target for BVX-0918.

BioVaxys President and Chief Operating Officer Kenneth Kovan stated that "Completion of OVCAR-3 cell banks is another step towards our ability to produce GMP yields of BVX-0918, and brings us closer to our Phase I study in the EU planned for later this year."

BioVaxys recently entered collaborations with Hospices Civils de Lyon in France 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 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.

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 haptization "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. Haptization 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, haptized 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-haptization"), 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) 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 haptized viral protein technology, and is planning a clinical trial of its haptized 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](http://www.biovaxys.com)).

ON BEHALF OF THE BOARD

Signed "James Passin"
James Passin, CEO
+1 646 452 7054

Government & Media Relations

JB&A, Inc.
Davin Shinedling
davin@jennibyrne.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 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 haptized 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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