BioVaxys Announces Successful Test-Run Production of its Bi-Haptenized Ovarian Cancer Vaccine

VANCOUVER, BC, Dec. 1, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company") is pleased to announce the successful sterile and bacteria-free test-run production of BVX-0918, the Company's bi-haptenized autologous ovarian cancer vaccine.

The complete manufacturing of BVX-0918 from a cancer patient's ovarian tumor now validates the production protocols that had been in development over the past few months for the successful extraction of tumor cells, the cryo-packaging and cryo-preservation of tumor cells, identification of ovarian cancer cells as the components of the vaccine using specially developed monoclonal antibodies and flow cytometry, sterility processes, and development of the process for double haptenization of the ovarian tumor cells used in the vaccine.

The production protocols have reduced the time needed to haptenize the tumor cells by fifty percent having established a semi-automatic technique for mechanically extracting tumor cells from a tumor mass, resulting in a time savings for GMP manufacturing.

The next steps include further optimization of the vaccine production process, finalizing the protocol for GMP manufacturing of BVX-0918, followed by transfer of the production protocol to larger scale manufacturing and GMP validation for submission of a CTA to EU regulatory authorities. The CTA is the European equivalent of the FDA's Investigational New Drug application, or IND, which is filed to seek approval for a clinical study.

BioVaxys President and Chief Operating Officer Kenneth Kovan stated, "BioVaxys has successfully met a major manufacturing milestone by establishing the process to take surgically excise ovarian cancer cells from a cancer patient, conjugate two haptens, and manufacture a sterile and bacteria-free complete vaccine. The next steps now involve GMP product characterization and applying analytical methods to validate that each step of BVX-0918 production is under GMP conditions to the satisfaction of EU regulatory authorities. We have completed the clinical study protocol, and our EU clinical development and marketing partner, Procare Health Iberia, has selected a CRO and already begun meeting with prospective Spanish Phase I study investigators."

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

Signed "James Passin"

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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 animal model study, regulatory approval for a Phase I study of its BVX-1021 Vaccine Candidate in humans and the overall development of BioVaxys' vaccines, including any haptenized SARS-Cov-2 or SARS-CoV 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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