BioVaxys Cancer Vaccine Manufacturing Partner Bio Elpida Reaches Bioproduction Milestone

VANCOUVER, British Columbia, Sept. 17, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys"), announced today that cancer vaccine manufacturing partner Bio Elpida in Lyon, France, has reached major milestones in the development of the bioproduction process for BVX-0918A, BioVaxys' ovarian cancer vaccine and is beginning the next phase of manufacturing process development.

Bio Elpida has completed the technology process transfer with BioVaxys and started the development phase using a Quality by Design ("QbD") approach which includes establishing the control methods and manufacturing process development. In parallel, as Bio Elpida further prepares for GMP manufacturing of BVX-0918A, the preparation of the new manufacturing facility is ongoing and on schedule. The next step is the vaccine process validation using donated tumor samples obtained following surgical excision from ovarian cancer patients.

Bio Elpida President Gilles Devillers says that "This major step is essentially a 'dry-run' for manufacturing the vaccine and preparation for GMP production. Although there is significant know-how required to produce a GLP process that has been contributed by both BioVaxys and Bio Elpida, production of GMP-grade vaccine is about validation, proving sterility, quality control, etc., which must all be extremely well documented for regulatory authorities."

BVX-0918A is headed for a planned Phase I clinical trial in Spain early next year with BioVaxys' EU commercial partner Procare Health Iberia.

BioVaxys President and Chief Operating Officer Ken Kovan stated, "Today's news represents a significant manufacturing milestone for BioVaxys and follows on the back of the news earlier this week that our CDMO partner WuXi Biologics has completed the synthesis of recombinant SARS-CoV-2 sprotein for our BVX-0320 and CoviDTH programs, further demonstrating the outstanding strength of our bioproduction partners while serving as a testimony to the operational and executional capacity of BioVaxys."

About BioVaxys Technology Corp.

Based in Vancouver, <u>BioVaxys Technology Corp</u>. (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 a SARS-CoV-2 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 two patent applications related to its cancer vaccine, and pending patent applications for its SARS-CoV-2 (Covid-19) vaccine 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

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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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