BioVaxys announces completed synthesis of its Pan-Sarbecovirus Vaccine candidate and launch of in vivo animal study

VANCOUVER, BC, Sept. 6, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company") announced today that Millipore-Sigma, the contract manufacturer for its preclinical viral vaccine program, has completed the bioproduction and batch release endotoxin screening of BVX-1021, the Company's vaccine for SARS-CoV, which is being used in the collaboration with The Ohio State University ("OSU") to develop a pan-sarbecovirus vaccine. The next step is measuring neutralizing antibody development to sarbecoviruses following immunization of study animals with BVX-1021, followed by administration of a SARS-CoV-2 vaccine---in this case with BVX-0320, the Company's Covid-19 vaccine candidate.

In June, the Company disclosed that yields of recombinant SARS-1 protein obtained from a Chinese supplier for the bioproduction of BVX-1021 were determined to contain the presence of a natural protein aggregate byproduct in addition to the SARS-1 protein. Although not likely to have impacted the neutralizing antibody studies, the Company felt it prudent to synthesize BVX-1021 using a new batch of recombinant SARS-1 protein from the supplier that screened out the extraneous protein aggregate. A Covid-19 outbreak in August at a supplier of the reagents needed for the final QC/QA led to a short delay in final release of BVX-1021.

BVX-1021 is the subject of an ongoing research collaboration between OSU and BioVaxys that is evaluating the Company's novel approach for a "universal vaccine" that can treat a broad range of sarbecoviruses. These are a family of viruses that include SARS-CoV-2 and emerging variants, SARS-CoV-1, and a broad range of other potentially dangerous zoonotic viruses. The collaboration, which began earlier this year, is evaluating the combination of BioVaxys' BVX-0320 and BVX-1021 in a guinea pig model. The major endpoints of the study are the development of virus-neutralizing antibodies to live virus SARS-CoV-2 and other sarbecoviruses, including bat and pangolin SARS-related coronaviruses.

Bats are a major reservoir of many strains of SARS, with several strains have been identified in palm civets, which were likely ancestors of SARS-CoV-1 ("SARS-1") (Journal of Virology. 84 (6): 2808–19, 2010). The presence of neutralizing antibodies in the animal model would strongly suggest that BVX-1021 would confer an additional immune response across all sarbecoviruses in those people fully vaccinated for Covid-19 as well as those with natural immunity.

BioVaxys President and Chief Operating Officer Kenneth Kovan says, "Now that BVX-1021 has been synthesized using the purified SARS1 protein, OSU is now able to complete the neutralizing antibody studies. Barring any unforeseen circumstances, we anticipate data from the study in September."

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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