BIOVAXYS

BioVaxys Prepares for Groundbreaking Study on reduced ACE2 binding capabilities of Hapten-modified SARS-CoV-2 proteins

- Potential for superior tolerability to mRNA and Adenovirus Vector vaccines

- Production Agreement signed with Millipore-Sigma for SARS-CoV-2 Vaccine Supply

VANCOUVER, BC, Sept. 23, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company"), announced today that it has initiated what could be a scientifically groundbreaking study on the reduced ACE2 binding capabilities of the hapten-modified spike protein that is the foundation of BVX-0320, the Company's SARS-CoV-2 vaccine.

Many SARS-CoV-2-infected patients develop pneumonia that may lead to acute respiratory distress, with some patients developing cardiac symptoms and cardiovascular injury.

In their peer-reviewed research paper, "SARS-CoV-2 binds platelet ACE2 to enhance thrombosis in COVID-19," published in the Journal of Hematological Oncology, S. Zhang *et.al*.[1] conclude that the Receptor Binding Domain (RBD) of the SARS-CoV-2 spike protein binds to the ACE2 receptor and that this binding of SARS-CoV-2 to ACE2 prevents the enzyme from converting angiotensin II, potentiating pulmonary and cardiovascular issues. Currently available vaccines, whether comprised of recombinant full-length or partial spike protein can result in rare, but life-threatening side effects, such as abnormal blood clotting or myocarditis. These toxicities may be caused by unwanted binding of the vaccine spike protein to ACE2 receptors in the heart or platelet factor 4. The Biovaxys vaccine for COVID-19, BVX-0320, comprises a portion of the spike protein that is modified by the hapten, dinitrophenyl (DNP). Biovaxys believes that the haptenized spike protein has much diminished ability to bind to ACE2, which would result in much diminished vaccine toxicity.

David Berd, MD, Chief Medical Officer of Biovaxys, explained that "Biovaxys will compare the binding of haptenized spike protein with the non-haptenized. The results could provide evidence that our vaccine has lowered potential for some of the observed serious vaccine side effects."

James Passin, BioVaxys CEO, stated, "Haptenization, as a method to inhibit the ACE2-binding ability of the spike protein, while increasing its immunogenicity, may prove to play a critical role in global COVID-19 vaccine development and deployment strategies, as public health authorities consider options for repeated seasonal vaccine boosters in the context of reported, albeit rare, adverse effects and apparent waning immunity."

This week BioVaxys entered into an agreement with Millipore-Sigma ("Millipore") a global Contract Development and Manufacturing Research Organization ("CDMO"), to manufacture a supply of GLP-grade BVX-0320, the Company's SARS-CoV-2 vaccine candidate for the study. Millipore produced similar yields of BVX-0320 last summer for the Company's animal immune response studies, but will now be incorporating in manufacturing the recently produced purified recombinant s-protein produced by BioVaxys bioproduction partner, WuXi Biologics. Millipore is a subsidiary of Merck KGaA (Deutsche Bourse: MRCG), one of the largest pharmaceutical companies in the world, with a market capitalization of US$102 billion.

BioVaxys is currently finalizing arrangements with a major US academic research institution who will be collaborating with the Company on the study.

For greater certainty, BioVaxys is not making any express or implied claims that it has the ability to treat the SAR-CoV-2 virus at this time.

[1]J Hematol Oncol 2020 Sep 4;13(1):120

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 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"

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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