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Clinical Trial Affirms CoviDTH Diagnostic Approach to screen for T cell-mediated immune response to SARS-CoV-2 is safe and effective in humans

Yvelise Barrios, MD, PhD, Immunologist and leading expert in the clinical use of delayed type hypersensitivity ("DTH"), the mechanism behind CoviDTH, joins BioVaxys as scientific adviser

VANCOUVER, BC and SAN CRISTÓBAL DE LA LAGUNA, Spain, Aug. 3, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) **(**"BioVaxys" or "the Company") is pleased to announce that Immunologist Yvelise Barrios, MD, PhD, a specialist in Clinical Immunology at Hospital Universitario de Canarias, Tenerife, Spain, has joined BioVaxys as a Scientific Adviser to support development of CoviDTH, the Company's disposable point-of-care diagnostic tool that screens for a T cell response to SARS-CoV-2 in vaccinated patients or those exposed to SARS-CoV-2. Dr. Barrios is a leading expert in the clinical use of delayed type hypersensitivity ("DTH"), the mechanism behind CoviDTH, as an immuno-diagnostic tool.

In June, the medical research journals *Clinical Immunology* and *Vaccines* both published the results of two clinical studies [1,2] led by Dr. Barrios and her colleagues at Hospital Universitario de Canarias in Spain on use of the DTH reaction to measure cellular immune responses to SARS-CoV-2 in patients after infection and in individuals vaccinated with the Pfizer mRNA vaccine. These studies in human volunteers by Dr. Barrios and her colleagues are the first publications of the results obtained using the classical DTH response to the SARS-CoV-2 s-spike protein ("s protein") to assess T cell immune responses in vaccinated individuals, and proved that this affordable and simple test, which is substantially equivalent to CoviDTH, is effective and safe, and can answer basic immunogenicity questions in large-scale populations.

Dr. Barrios stated, "The use of this test will provide clinicians with a fundamental tool to answer immunogenicity questions basic to understanding how long T cell immune responses are detectable in exposed and vaccinated individuals. This simple method is also ideal for those groups of patients that do not have easy access to troublesome *in vitro* studies, such as the young and pediatric population, being extremely useful because it can be interpreted by any non-specialist medical doctor. The study of cellular immune responses in Covid-vaccinated individuals will also provide insight to optimize dosing and type of vaccines in different scenarios of selected groups of patients such as immunodeficient and transplant patients."

There is significant evidence that an antibody-mediated and T cell-mediated immune response is required for protection against SARS-CoV-2 [3,4] and also that T cell-mediated immunity is a more reliable correlate of vaccine protection than antibody titers in seniors [5], strongly supporting the need for a determination of T cell response in COVID-19 vaccine design and population screening.

Kenneth Kovan, President and Chief Operating Officer of BioVaxys, stated, "The results of Dr. Barrios' studies infer that our planned US Phase I/II study will likewise find CoviDTH to be effective and safe in humans. This is obviously extremely exciting news for us, as the clinical data from this study has shown that CoviDTH has the potential to answer basic SARS-CoV-2 immunogenicity questions in large-scale populations."

Dr. Barrios is a specialist in Clinical Immunology at Hospital Universitario de Canarias, with a clinical focus on histocompatibility, autoimmune diseases and allergy, and is senior Immunology consultant for primary immunodeficiency diseases. Her lab is the Reference Laboratory for kidney transplantation of the Canary Islands Province in Spain. Dr. Barrios received her medical degree at La Laguna University, Tenerife, Spain and conducted her Clinical Immunology Residency at Puerta de Hierro Hospital. She received her PhD on Active Immunotherapy in B-cell Tumors, from Universidad Autonoma, Madrid, and did her post-doctoral in phage display expression of antibody fragments in Immunotechnology at Lund University in Sweden.

Dr. Barrios and her colleagues will also be collaborating with BioVaxys on research that explores the use of the DTH reaction to measure cellular immune response in a population exposed to different variants of SARS-CoV-2, as well as evaluating the potential use of M and N proteins in CoviDTH.

References:

[1] The Beauty of Simplicity: Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Responses in RNA-SARS-Cov-2 Vaccinated Individuals. Barrios Y, Franco A, Sánchez-Machín I, Poza-Guedes P, González-Pérez R, Matheu V.Vaccines (Basel). 2021 Jun 1;9(6):575. doi: 10.3390/vaccines9060575.

[2] A Novel Application of Delayed-Type Hypersensitivity Reaction to Measure Cellular Immune Response in SARS-CoV-2 Exposed Individuals. Barrios Y, Franco A, Sanchez-Machin I, Poza-Guedes P, Gonzalez-Perez R, Matheu V.Clin Immunol. 2021 May;226:108730. doi: 10.1016/j.clim.2021.108730. Epub 2021 Apr 16.

[3] Sariol, A.; Perlman, S. Lessons for COVID-19 Immunity from Other Coronavirus Infections. J. Immun. 53, 248–263

[4] Tay, M.Z.; Poh, C.M.; Rénia, L.; Macary, P.A.; Ng, L.F.P. The trinity of COVID-19: Immunity, inflammation and intervention. Nat. Rev. Immunol. 2020,20, 363–374.

[5] Haq, K.; E McElhaney, J. Immunosenescence: Influenza vaccination and the elderly. Curr. Opin. Immunol. 29, 38–42

About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. (www.biovaxys.com) is a British Columbia-registered, early 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 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 trades on the Frankfurt Bourse (FRA: 5LB) and in the US (OTCQB: BVAXF).

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 BioVayxs' 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.

ON BEHALF OF THE BOARD

Signed "James Passin"
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