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Further Study in humans shows that the DTH response, the basis for CoviDTH, is highly durable and persists for at least one year after COVID-19 exposure or vaccine administration

VANCOUVER, BC and SAN CRISTÓBAL DE LA LAGUNA, Spain, Sept. 7, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "the Company") is pleased to announce that the Scientific Advisor for its CoviDTH program, Yvelise Barrios, MD, PhD, and Clinical Immunologist at Hospital Universitario de Canarias, Tenerife, Spain, has been invited to present her new clinical study entitled LONG TERM FOLLOW-UP OF IN VIVO CELLULAR IMMUNE RESPONSE TO SARS-CoV-2 USING DELAYED-TYPE HYPERSENSITIVITY CUTANEOUS TEST [1] at the 6th European Congress of Immunology ("ECI") held September 1-4, 2021. ECI is one of the most highly-regarded international conferences in the field of basic and clinical immunology.

Dr. Barrios is a leading expert in the clinical use of delayed type hypersensitivity ("DTH"), the mechanism behind 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. Her collaborators were Inmaculada Sanchez Machín MD, PhD, and Victor Matheu, MD, PhD, Allergology Department and Grupo de Expertos Inmunodeficiencias, Hospital Universitario de Canarias, Tenerife.

Their study shows that the DTH response, which is the basis for CoviDTH, in individuals who had recovered from COVID-19 is highly durable, persisting for at least one year after viral exposure in these preliminary data. They conclude that the DTH test can be used as a routine diagnostic method to monitor the T cell-mediated response to SARS-CoV-2.

Two recovered patients were tested for DTH at 6 and 12 months after infection. The DTH responses were as follows: Subject A: 6 months=41mm, 12 months=35mm; Subject B: 6 months=14mm, 12 months=30mm. These are considered very large responses, compared, for example, to the DTH responses of people with a history of tuberculosis. These results pointed out that natural, acquired immunity in these two patients is still very clearly present after one year of follow-up and that the DTH is a very simple and easy to interpret test to answer questions about durability of cellular immune responses in COVID-19.

In June 2021, Dr Barrios and her colleagues had previous human studies of DTH published in the medical research journals *Vaccines*[2] and *Clinical Immunology*[3], which validated the use of the CoviDTH approach of a delayed type hypersensitivity (DTH) cutaneous test as a feasible and safe *in vivo* method to assess cellular immune responses in both natural and vaccinated SARS-CoV-2 exposed individuals.

There is significant evidence that an antibody-mediated and T cell-mediated immune response is required for protection against SARS-CoV-2[4,5] and that T cell-mediated immunity is a more reliable correlate of vaccine protection than antibody titers in seniors[6], 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, "These human studies conducted by Dr. Barrios give us significant confidence in CoviDTH, especially as we now are preparing our IND for the planned US combined Phase I/II study."

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.

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]Long term follow-up of in vivo cellular immune response to SARS-CoV-2 using delayed-type hypersensitivity cutaneous test. Barrios Y, Sánchez-Machín I, Matheu V. Eur J Immunol 2021 51,S1, 338. Abstract P-0814 doi: 10.1002/eji.202170200

[2]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.

[3]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.

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

[5]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.

[6]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, 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"
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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 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.

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