BIOVAXYS

BioVaxys and Procare Health Announce Broad Co-Development, Joint Commercialization and Marketing Collaboration for Cancer and Viral Vaccines

- USD$900,000 In-Kind Investment by Procare Health into Phase I Clinical Study for BVX-0918A in the EU

- Co-Development of Vaccines for Cervical Cancer and HPV

- Right of First Refusal for US Marketing of Papilocare™

VANCOUVER, BC and BARCELONA, Spain, Feb. 10, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTC:L MNGF) ("BioVaxys"), the world leader in haptenized protein vaccines for antiviral and cancer applications, and Procare Health Iberia, S.L., of Barcelona, Spain ("Procare Health"), a leading privately-held European pharmaceutical company, announced today that they have entered into a broad collaboration for the co-development, joint commercialization, and marketing of BioVaxys vaccines for ovarian cancer, cervical cancer, and human papilloma virus ("HPV"), and the right of first refusal for marketing by BioVaxys in the United States of Procare Health's vaginal gel product, Papilocare™, the world's first and only product to prevent and treat HPV-dependent cervical lesions. Left untreated, HPV infection generally leads to cervical cancer (World Health Organization, *HPV and Cervical Cancer,* 11 November 2020). Formed in 2012 as a spin-out from Procter & Gamble Pharmaceuticals, Procare Health is a market leader in the women's health field in the European Union ("EU"), with marketed products including Papilocare™, Libicare™, Palomacare™, Idracare™, Pronolis HD™ and Ovosicare™.

Under the terms of the agreement, which was executed on February 9th, 2021, the companies will jointly conduct a Phase I Clinical Study of BVX-0918A in Spain, BioVaxys' autologous haptenized protein vaccine for late-stage ovarian cancer. BioVaxys will be responsible for the core technology and vaccine production, with Procare Health overseeing and making an in-kind investment in the clinical program and regulatory planning, CRO management, patient/clinical center recruitment, marketing, and opinion leader management. Both companies have agreed to equally share costs associated with engaging a European clinical research organization ("CRO") to conduct the study. In return, Procare Health will have exclusive rights to market and distribute BVX-0918A in the European Union ("EU"), and the United Kingdom. Clinical data from the Spanish Phase I study will be used by BioVaxys to support its planned IND for BVX-0918A in the US next year, as well as for all other global markets. The two companies will be working out any remaining details by end of 2Q21.

BioVaxys President and Chief Operating Officer Ken Kovan said "This co-development gives BioVaxys access to Procare Health's clinical development and regulatory expertise in the EU, and to its marketing & sales presence in Europe." Kovan added that "Procare Health has an established portfolio of marketed brands that is focused heavily on the women's health and gynecological oncology markets. As we anticipate that these will be the primary users of our ovarian cancer vaccine, the relationship with Procare Health will give access to key gynecological oncology opinion leaders for patient access, clinical trial recruitment, and a relationship that post-approval will drive vaccine sales. Having a strong EU opinion leader network will also be invaluable for our planned US launch of the vaccine."

The collaboration with BioVaxys will help Procare Health fuel its product offerings in the gynecological oncology field. Yann Gaslain, CEO of Procare Health stated, "We are thrilled to start working the collaboration with BioVaxys as it brings a new hope in the field of gynecological cancer. We have been working for 8 years in the area of cervical cancer and HPV, investigating to understand how the immune response of the host could be stimulated to help defend versus HPV infection and persistency, and we believe that the new haptenized cell platform technology can bring a valid answer to this unmet therapeutical need, mainly when high grade lesions of the cervix or even cervical carcinoma have been characterized. The promising vaccine technology platform of BioVaxys will likely help bringing response in ovarian and cervical cancer¨

In Phase I and Phase II clinical studies previously conducted by BioVaxys, co-founder and Chief Medical Officer, Dr. David Berd, using an earlier generation of the BioVaxys cancer vaccine on nearly 500 patients with melanoma or ovarian cancer, the haptenized cell platform showed significant clinical promise. BioVaxys has developed its vaccine technology platforms based on the established immunological concept that modifying proteins with simple chemicals called haptens makes them more visible to the immune system. The process of haptenization "teaches" a patient's immune system to recognize and make target proteins more 'visible' as foreign, thereby stimulating an immune response.

Javier Cortés, MD, Specialist in Gynecology and Cytology for the international Academy of Cytology (Chicago, USA), member of the Spanish association against Cancer (AECC) and of the European Cervical Cancer Association (ECCA) stated, "I believe that the planned clinical trial in Phase I is of a very high interest based on my experience in oncology for more than 30 years. The immunotherapy is a line of treatment with very active investigation and promising early results in some cancers (lungs, melanoma and ovarian). That is why, every single line of investigation well based and with consistent criteria of quality in the design of the investigation should be very well received and encouraged."

Leveraging the recent proven ability of its haptenized viral antigen vaccine platform in stimulating both a 96.4% positive immune response and powerful 'memory' T-cell activation against SARS-CoV-2, BioVaxys will use the platform's flexibility to swap in viral antigens for Human Papilloma Virus ("HPV"), with the intent to develop a treatment for adults who are already infected with HPV. There are vaccines to protect against getting HPV, but none to treat someone who already has HPV. BioVaxys and Procare Health will split costs for feasibility, proof-of-concept, and preclinical development for a HPV viral vaccine, as well as a cervical cancer vaccine based on the BioVaxys cancer vaccine platform. In return, Procare Health will have an exclusive right in the EU and UK for a HPV and/or cervical cancer vaccine, with BioVaxys retaining rights to North America and Rest of World. Development milestones, go/no-go decisions, and other details will be finalized in 2Q2021.

In a major step toward transitioning to a revenue-generating company, BioVaxys has agreed to have a right of first refusal to market and distribute Papilocare™ in the US.

In Procare Health's PALOMA Phase IIb clinical trial, Papilocare™ showed consistent and significant efficacy in normalizing cervical cytology at 3 months and at 6 months in the total study population with 50% to 70% of High-Risk HPV clearance at 6 months in six different international studies and more than 600 patients. HPV infection causes 528,000 cases of cervical cancer and 266,000 cervical cancer deaths each year.[1] Papilocare™ has a CE mark valid for the entire EU, and is currently marketed as a Class IIa medical device in Spain, France, Portugal, Italy, Belgium, Luxembourg, Lithuania, Latvia, Poland, Czech Republic, Hungary, Bulgaria, and Romania. Once the FDA regulatory pathway has been determined for the US, BioVaxys will have a detailed plan in place by 3Q21 to build an appropriate capability to market and support the brand in the US, with BioVaxys providing the funding for such efforts.

James Passin, CEO of BioVaxys, stated, "We are honored to partner with Procare Health, a market leader in gynecological oncology and women's health in the EU; this transformative collaboration leverages all of the innovative work of Dr. David Berd in the field in oncology and novel vaccine development, as well as our recent success with the preclinical development of a viable haptenized viral protein vaccine for Covid-19. We look forward to using our proprietary haptenized vaccine technology to address urgent and large market deficiencies in the area of women's health and to potentially generate a new and material revenue stream for our company."

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. *WHO. https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)*

About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. 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 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 US OTC: LMNGF.

About Procare Health

Procare Health is a multi-national EU biotechnology company based in Barcelona (Spain) founded in 2012 as a result of the spin-off of executives and employees of Procter & Gamble Pharmaceuticals that is focused primarily to bring innovative solutions in women´s health, with a special interest into unmet therapeutical needs. Procare Health invests every year circa 25% of its investments budget into R&D, fundamental research on Cervix ("cervix on a chip" research project) and clinical trials in order bring clinical evidence of its main products in the market. Procare Health develops, investigates and commercializes its own products into more than 50 countries in the world with main focus in EU and in women´s genital tract diseases (HPV, cervical lesions, vaginal infections, vaginal dryness, and fertility). Procare Health vision is to become a women´s health leader in Europe.

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

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