BioVaxys Executes Binding Term Sheet for the US Marketing & Distribution for Papilocare Gel and Oral Immunocaps

Agreement Includes Right of First Refusal in the US for Ovosicare and Libicare

VANCOUVER, BC, Oct. 6, 2022 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company") announced today that it has executed a binding Term Sheet ("Term Sheet" or "Agreement") with Procare Health Iberia, S.L. ("Procare Health"), of Barcelona, Spain ("Procare Health"), for exclusive marketing and distribution in the United States of Procare Health's leading patented product, Papilocare™, the world's first and only vaginal gel product with clinical evidences to prevent and treat HPV-dependent cervical lesions, and for Immunocaps®, **an oral over-the-counter nutritional supplement that supports immune function** and vaginal microbiota to help re-epithelialization of cervical lesions. As Immunocaps® is an OTC supplement, BioVaxys anticipates that regulatory approval is not required, allowing the rapid build out of sales channels and revenue generation from the product.

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In addition, the agreement gives BioVaxys right-of-refusal in the United States for Ovosicare® and Libicare®, Procare Health's over-the-counter supplements to support fertility enhancement for late maternity or IVF processes and Menopausal symptoms improvements which includes low libido among women suffering menopausal changes.

Financial terms include milestone payments and royalties on sales. The companies have agreed to complete an initial ten-year duration exclusive supply and distribution agreement ("Distribution Agreement") by December for Papilocare® Gel (packs of 7 and 21 5ml cannulas), 2x40ml and applicators, packs of 1x5ml samples, and 30 capsule packs of Immunocaps®. Manufacturing will remain in Spain under Procare Health.

Founded in 2012, Procare Health is a leading privately-held pharmaceuticals company in the women's health field based in Spain with several affiliates in Europe including France, Portugal and the UK, with marketed products including Papilocare®, Libicare®, Palomacare®, Idracare®, Pronolis HD® and Ovosicare®. Procare Health commercializes its products within more than 60 countries in the world via distribution agreements with well-known and established pharmaceuticals company within the Women's Health field.

The Agreement follows the Letter of Intent ("LOI") signed last year outlining several collaborations between the two companies, including Papilocare® and the clinical development of BioVaxys' BVX-

0918 for late-stage ovarian cancer. Whereas the LOI had originally granted BioVaxys right of first refusal for Papilocare®, today's agreement grants BioVaxys exclusive right to market and distribute the brand in the United States and establishes marketing support from Procare Health for Papilocare® and Immunocaps®.

Left untreated, HPV infection can lead up to cervical cancer (World Health Organization, *HPV and Cervical Cancer*, 11 November 2020). In Procare Health's PALOMA PhaseIIb clinical trial for Papilocare, which results were recently published into *the Journal of Lower Genital Tract Disease*, which is affiliated with the American Society of Cervical Pathologies (ASCCP), 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. A "CE mark" indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health, and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.

Under the Term Sheet, BioVaxys will have responsibility for US regulatory approval for Papilocare® and anticipates US registration as a Class II medical device.

James Passin, the CEO of BioVaxys, stated, "We are honored to expand the terms of our partnership with Procare Health, one of Europe's leading innovators in women's healthcare, further strengthening our women's healthcare product pipeline."

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. (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. ***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 and diagnostic tools, 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 and diagnostic tools 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.

Photo - https://mma.prnewswire.com/media/1915162/BioVaxys_Papilocare_Gel.jpg
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