

# BioVaxys and Procure Health Execute US Distribution Agreement for Papilocare Gel and Oral Immunocaps

VANCOUVER, British Columbia and BARCELONA, Spain, Dec. 19, 2022 /CNW/ - BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or "Company") and Procure Health Iberia, of Barcelona, Spain ("Procure Health") announced today that they have finalized and executed the United States Distribution Agreement ("Distribution Agreement") for Papilocare® and Oral Immunocaps®. Following the binding Term Sheet executed by the two companies in early October 2022, the Distribution Agreement finalized all remaining aspects of the transaction.

Developed by Procure Health, Papilocare® is the world's first and only patented vaginal gel product with clinical evidence to prevent and treat HPV-dependent cervical lesions. Immunocaps®, which can be used on its own or together with Papilocare®, is an oral over-the-counter nutritional supplement that supports immune function and vaginal microbiota to help re-epithelialization of cervical lesions.

Yann Gaslain, Founder and CEO of Procure Health Iberia commented: "We are delighted with this agreement, and if Papilocare® is approved by the FDA, to be able to provide access to millions of American women to a new treatment for cervical lesions caused by HPV. Papilocare is already approved in Europe and is available in 46 countries worldwide. In several clinical trials involving more than 600 patients, Papilocare® showed consistent and significant efficacy in normalizing cervical cytology at three months and at six months in the total study population with 50% to 70% of High-Risk HPV clearance at six months."

BioVaxys will immediately begin pursuit of regulatory approval for Papilocare® with the US Food and Drug Administration ("FDA") and anticipates US registration as a Class II medical device. As Immunocaps® is an OTC supplement, BioVaxys anticipates that regulatory approval will not be required, allowing the rapid build out of sales channels and revenue generation from the product. BioVaxys plans to begin stocking and distributing Immunocaps® in early 2023.

As per the Term Sheet executed in October, BioVaxys and Procure Health will begin discussions on the Company's right-of-refusal in the United States for Ovosicare® and Libicare®, Procure 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.

Kenneth Kovan, President & Chief Operating Officer at BioVaxys said "We are delighted to have been selected by Procure Health to market Papilocare® and Immunocaps® in the US, and together with Procure Health we look forward to playing a major role in the treatment of cervical lesions caused by HPV and what we hope is an accompanying reduction in cases of cervical cancer."

Founded in 2012, Procure 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, and marketed products including Papilocare®, Libicare®, Palomacare®, Idracare®, Pronolis HD® and Ovosicare®. Procure 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.

Left untreated, HPV infection can lead up to cervical cancer (World Health Organization, *HPV and Cervical Cancer*, 11 November 2020). In Procure Health's PALOMA Phase IIb clinical trial for Papilocare, which results were recently published into *the Journal of Lower Genital Tract Disease*, 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.<sup>1</sup> 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, the UK, Germany, Belgium, Luxembourg, Lithuania, Latvia, Poland, Czech Republic, Hungary, Bulgaria, Romania, Greece, Balkans, Ukraine, Mexico, Colombia, Vietnam, and Kenya.

A "CE mark" indicates that a product and the manufacturer has been assessed by a Notify Body (as a delegation of the European Health Agency) under the new MDR EU regulation and deemed to meet EU efficacy and safety, health, and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU. Additionally, Procure Health has been granted the ISO 13485 Medical device certification and the MDSAP certification which recognizes the company as a validated worldwide manufacturer.

## About BioVaxys Technology Corp.

Based in Vancouver, BioVaxys Technology Corp. ([www.biovaxys.com](http://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 also trade on the Frankfurt Bourse (FRA: 5LB) and in the US (OTCQB: BVAXF).

ON BEHALF OF THE BOARD

Signed "James Passin"

James Passin, CEO

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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.*

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