

# BioVaxys And BioElpida Sign Definitive Exclusive Agreement To Begin Ovarian Cancer Vaccine Bioproduction

VANCOUVER, BC, May 3, 2021 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (CSE: BIOV.CN) (FRA: 5LB) (OTC: BVAXF) ("BioVaxys" or "Company") announced today that it has signed the definitive exclusive bioproduction agreement ("Agreement") with BioElpida S.A.S. ("BioElpida") of Lyon, France, to begin the clinical-grade bioproduction and aseptic packaging for BXV-0918A, BioVaxys' vaccine candidate for Stage III/Stage IV ovarian cancer. BioVaxys and BioElpida executed a Term Sheet in February outlining the commercial relationship, with today's definitive Agreement focusing on the GMP facility build-out in Lyon, and technical aspects of the bioproduction protocol such as process design and validation, quality control and quality assurance steps, batch test runs, stability testing, and aseptic fill. BioVaxys expects to be able to prepare its regulatory submission for a EU Phase I study of BVX-0918A in Stage III/Stage IV ovarian cancer near the end of this year, with vaccine supply for the planned clinical study available early May 2022.

BioElpida is a biotechnology contract development and manufacturing company ("CDMO") which applies single-use bioprocessing for development and manufacturing of biological and cell-based products. BioElpida's expertise extends from R&D to pharmaceutical manufacturing and release of clinical batches, and intermediate steps such as process development, feasibility studies, analytical method validation, as well as aseptic fill & finish and other bioproduction services. BioElpida's facility is certified for clinical bioproduction by France's National Security Agency of Medicines and Health Products (ANSM).

"Early on we made the decision to seek a bioproduction partner with the ability to quickly move from smaller-yield GMP-grade clinical study supplies to large-scale manufacturing if our clinical trials prove successful and EU regulatory approval is granted," said Kenneth Kovan, Co-Founder, President and Chief Operating Officer of BioVaxys. "BioElpida's technical experience and previous work on early generations of our cancer vaccine platform will be a significant advantage in our efforts to provide hope to those suffering from advanced ovarian cancer."

BioVaxys is collaborating on the ovarian cancer vaccine clinical program with Spanish biopharma company ProCare Health Iberia S.A.S., which plans to submit a Clinical Trial Application ("CTA") for BVX-0918A to the European Medicines Agency ("EMA") later this year for a compassionate use approval in Stage III & Stage IV ovarian cancer. ProCare Health will have marketing rights to BVX-0918A in the EU and UK, whereas BioVaxys will market its ovarian cancer vaccine in North America and Rest of World.

Globally, there remain significant unmet therapeutic needs for ovarian cancer treatment. Worldwide, over 300,000 women are diagnosed with ovarian cancer each year (World Cancer Research Fund, 2020), with ovarian cancer the leading cause of death from gynecologic malignancy in the United States (American Cancer Society Facts & Figures 2020). An estimated 21,750 new cases of ovarian cancer were expected in the US in 2020 with 13,940 deaths (National Cancer Institute, Surveillance and Epidemiology Program, 2020). The majority of women with Stage III or Stage IV cancer will ultimately have recurrent disease resistant to chemotherapy. Patients who have relapsed after platinum-based chemotherapy have limited life expectancy even with multiple salvage regimens. This large group of non-responders to first line therapy, or those who relapse after first line therapy, are the initial target market for BioVaxys.

The global [ovarian cancer drugs market](http://www.medgadget.com/2020/11/ovarian-cancer-drugs-2020-global-market-to-reach-us-4-6-bn-and-growing-at-cagr-of-18-29-by-2026.html) was valued US\$1.2B in 2017 and is expected to reach US\$4.6B by 2026, at a CAGR of 18.29 % ([www.medgadget.com/2020/11/ovarian-cancer-drugs-2020-global-market-to-reach-us-4-6-bn-and-growing-at-cagr-of-18-29-by-2026.html](http://www.medgadget.com/2020/11/ovarian-cancer-drugs-2020-global-market-to-reach-us-4-6-bn-and-growing-at-cagr-of-18-29-by-2026.html)).

## About BioVaxys Technology Corp.

Based in Vancouver, [BioVaxys Technology Corp.](http://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 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 (OTC: BVAXF).

ON BEHALF OF THE BOARD

Signed "James Passin"

James Passin, CEO  
+1 646 452 7054

## Media Contacts BioVaxys Technology Corp.

Nikita Sachdev  
Luna PR  
[info@lunapr.io](mailto:info@lunapr.io)

## 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 to 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 BioVaxys' 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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