

BioVaxys Announces Phase 1 Clinical Study Results Advancing DPX(TM)-Formulated Products in Patients with Non-Muscle Invasive Bladder Cancer

Vancouver, British Columbia--(Newsfile Corp. - January 8, 2026) - BioVaxys Technology Corp. (CSE: BIOV) (FSE: 5LB0) (OTCQB: BVAXF) ("BioVaxys" or the "Company"), a clinical stage biotechnology company focused on developing advanced treatments in oncology, infectious disease, allergy, and other immune diseases based on its DPX™ antigen delivery and immune-educating technology platform, is pleased to announce highly promising results from a two-arm phase 1 clinical study of the safety and immunogenicity of both its maveropepimut-S (MVP-S) and DPX-SurMAGE cancer vaccines in patients with non-muscle invasive bladder cancer (NMIBC). Treatment with either MVP-S or DPX-SurMAGE was shown to be well tolerated, with both products inducing significant systemic antigen-specific T cell responses, which is a critical goal in cancer immunotherapy.

MVP-S is a novel DPX-based formulation that delivers antigenic peptides from the survivin family, a set of well-recognized cancer antigens commonly overexpressed in advanced cancers such as bladder tumors, and also delivers an innate immune activator and a universal CD4⁺ T cell helper peptide. In previous human studies, MVP-S has been shown to be well tolerated and has demonstrated activation of a targeted and sustained, survivin-specific anti-tumor immune response in multiple cancer indications, such as in BioVaxys' recent phase 1 study of MVP-S with neoadjuvant hormone therapy in HR(+) / HER2(-) stage II-III breast cancer.

DPX-SurMAGE is a dual-targeted immunotherapy combining antigenic peptides for both survivin as well as MAGE-A9, both of which are tumor-associated antigens expressed by NMIBC, to elicit immune responses to these two distinct cancer antigens simultaneously.

Led by Dr Yves Fradet, MD (Professor of Urology/Surgery, Université Laval and Researcher at the Centre de Recherche du CHU de Québec-Université Laval, Québec, Canada), the phase 1 study compared three 3 subcutaneous injections, prior to transurethral resection, of the two DPX-based products from BioVaxys, MVP-S and DPX™-SurMAGE, with or without intermittent low-dose cyclophosphamide, as treatment for patients with recurrent low-grade or high-grade recurrent NMIBC who have failed intravesical therapy.

The primary objectives were to assess tolerability in humans and to evaluate clinical induction of systemic antigen-specific T-cell responses. Study arms were testing either MVP-S alone (targeting survivin-only in Study Arm A), or DPX-SurMAGE (targeting both survivin plus MAGE-A9 in Study Arm B). In total, 12 patients were evaluated, 9 in Arm A and 3 in Arm B. Both MVP-S and DPX-SurMAGE were shown to be well tolerated, with strong antigen-specific T cell responses at Day 0, 28, 49 and 109 determined using INF- γ ELISPOT analyses, a highly sensitive technique to count individual immune cells (typically T cells) that are actively secreting [Interferon-gamma](#) (IFN-γ) in response to a specific antigen to reveal the strength of response to a tumor antigen. Of note, 55% of participants receiving MVP-S showed significant responses that peaked at Day 28, and 33% in the DPX-SurMAGE Study Arm showed a significant response that was stronger at Day 49. "Despite the small number of patients tested, we were very impressed by the strength and duration of the T cell responses to a combination of immunogenic peptides against two molecules with very distinct biological activity: Survivin with anti-apoptotic activity and MAGE-A9, a typical cancer antigen known to stimulate T cells," noted Dr Yves Fradet.

The BioVaxys DPX platform is a major innovation in vaccine development that offers a solution to limitations faced by vaccines using other antigen delivery methods. The DPX™ platform presents

antigens to the immune system using a novel non-systemic mechanism of action that does not release active ingredients at the site of the injection, but rather forces an active uptake of immune cells and delivery into the lymphatic nodes. The programming of immune cells happens in vivo and offers a more efficient approach that mimics the natural function of the immune system. This "no release" mechanism allows for an active uptake of antigens into immune cells and lymph nodes for a sustained activation of the immune system in which the T cell flow is sustained over a longer duration than traditional vaccines on the market.

Dr Fradet added: "The patients enrolled in this phase I trial had multiple previous recurrences of high grade NMIBC. After an average two years of follow-up, many of these patients were free of recurrence, suggesting that this simple and well-tolerated vaccination could represent an attractive new treatment for NMIBC patients who failed BCG. It may be a valuable alternative to the many intravesical and systemic treatments currently being developed that warrants further investigation in a phase II trial."

The global bladder cancer market is projected to grow from \$3 billion in 2023 to \$16 billion in 2033, at a compound annual growth rate (CAGR) of 18% (GlobalData 2025), with the NMIBC market expected to be driven by therapies for patients who are unresponsive to BCG.

Kenneth Kovan, President and Chief Operating Officer at BioVaxys says that "We are very encouraged by the findings as both MVP-S and DPX-SurMAGE exhibit significant clinical proof-of-product and are now candidates for further clinical study in NMIBC. A major objective that was accomplished is the demonstration in humans that with DPX-SurMAGE we can package and deliver multiple dissimilar antigens which further builds our foundation for developing new multivalent infectious disease and cancer vaccines based on the DPX platform."

About BioVaxys Technology Corp.

BioVaxys Technology Corp. (www.biovaxys.com), a biopharmaceuticals company registered in British Columbia, Canada, is a clinical-stage biopharmaceutical company dedicated to improving patient lives with novel immunotherapies based on the DPX™ immune-educating technology platform and its HapTenix© tumor cell construct platform, for treating cancers, infectious disease, antigen desensitization for food allergy, and other immunological diseases. Through a differentiated mechanism of action, the DPX™ platform delivers instruction to the immune system to generate a specific, robust, and persistent immune response. The Company's clinical stage pipeline includes maveropepimut-S (MVP-S), based on the DPX™ platform, in phase IIB clinical development for advanced Relapsed-Refractory Diffuse Large B Cell Lymphoma (DLBCL) and platinum resistant Ovarian Cancer. MVP-S delivers antigenic peptides from the survivin family, a set of well-recognized cancer antigens commonly overexpressed in advanced cancers and also delivers an innate immune activator and a universal CD4⁺ T cell helper peptide. MVP-S has been well tolerated and has demonstrated defined clinical benefit in multiple cancer indications as well as the activation of a targeted and sustained, survivin-specific anti-tumor immune response. BioVaxys is also developing DPX™+SurMAGE, a dual-targeted immunotherapy combining antigenic peptides for both the survivin and MAGE-A9 cancer proteins to elicit immune responses to these two distinct cancer antigens simultaneously, DPX™-RSV for Respiratory Syncytial Virus, DPX+rPA for peanut allergy prophylaxis, and BVX-0918, a personalized immunotherapeutic vaccine using its proprietary HapTenix© 'neoantigen' tumor cell construct platform for refractive late-stage ovarian cancer.

BioVaxys common shares are listed on the CSE under the stock symbol "BIOV" and trade on the Frankfurt Bourse (FSE: 5LB0) and in the U.S. on the OTC Markets (OTCQB: BVAXF). For more information, visit www.biovaxys.com and connect with us on X and LinkedIn.

ON BEHALF OF THE BIOVAXYS BOARD

Signed "James Passin"

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This news release includes certain "forward-looking information" and "forward-looking statements" (collectively "forward-looking statements") within the meaning of applicable securities legislation. 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. 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.

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 BioVaxys, 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 DPX platform 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.

Many factors, both known and unknown, could cause actual results, performance or achievements to be materially different from the results, performance or achievements that are or may be expressed or implied by such forward-looking statements and the parties have made assumptions and estimates based on or related to many of these factors. BioVaxys 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 applicable securities laws.

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