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BioVaxys DPX-Based Vaccines Exhibit Robust Efficacy Across Multiple Infectious Diseases

VANCOUVER, BC, Aug. 22, 2024 /CNW/ -- BioVaxys Technology Corp. (CSE: BIOV) (FRA: 5LB) (OTCQB: BVAXF) ("BioVaxys" or the "Company") highlights the potential of its novel lipid-in-oil delivery platform, DPX™, across multiple infectious disease studies and announces its plans for partnering and further development.

BioVaxys' DPX™ technology ("DPX") is a patented delivery platform that can incorporate a range of bioactive molecules to produce targeted, long-lasting immune responses enabled by various formulated components. The DPX platform facilitates antigen delivery to regional lymph nodes and has been demonstrated to induce robust and durable T cell and B cell responses in pre-clinical and clinical studies for both cancer and infectious disease.

Key findings demonstrated in completed infectious disease studies, which are discussed in more detail below include:

- In a phase 1 human study for respiratory syncytial virus (RSV), DPX-RSV demonstrated antigen-specific immune responses in 93% of subjects, with 100% of responders in the 25µg dose cohort maintaining antigen-specific immunity one year post vaccination.
- Animal challenge studies with DPX-Based Anthrax vaccine demonstrated 100% immunity following a single injection compared to current vaccines which require more than one dose.
- In a pre-clinical murine model, DPX-rHA for influenza achieves higher antibody levels than standard Alum rHA Vaccine and protects against multiple flu strains.

BioVaxys President and Chief Operating Officer Kenneth Kovan says "With data so compelling and supportive of the value of DPX-based vaccines for infectious diseases, we are seeking various off-balance sheet avenues to support development. The significant cargo capacity of DPX and the proven ability to package diverse antigens such as that shown with our DPX-SurMAGE multi-antigen cancer vaccine, could also greatly benefit potential partnerships for developing more effective viral vaccines, such as a multivalent mRNA DTP vaccine to address the recognized problem of immunity to the Bordetella pertussis waning over time, or for emerging global diseases such as MPox, where a DPX-mRNA formulation could have significant advantage. This fits well with our strategy of expanding development partnerships with DPX beyond oncology."

100% of Subjects in a Phase 1 Study Treated with a DPX-based RSV Vaccine Developed Antibodies with Persistent Immune Response

DPX™+RSV(A) "DPX-RSV" is BioVaxys' vaccine candidate targeting the respiratory syncytial virus (RSV) based on a DPX formulation of the SHe peptide of group A RSV. Results of a Phase 1 study showed that more than nine months after the last vaccination, 15 of 16 participants (93%) who received DPX-RSV demonstrated antigen-specific immune responses. This study evaluated the safety and immune response profile of two doses of DPX-RSV in 40 healthy older adult volunteers (aged 50-64 years) and was well tolerated amongst all study participants, with no SAEs reported. One of the two doses of DPX+RSV(A) was tested out to one year and 100% of older adults (7/7 immune responders) maintained antigen-specific immune responses one year after receiving a booster dose. After one year, their antibody levels measured were still at peak with no sign of decrease.

RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups. RSV circulation is seasonal, typically starting during the fall and peaking in the winter. In older adults, RSV is a common cause of lower respiratory tract disease (LRTD), which affects the lungs and can cause life-threatening pneumonia and bronchiolitis (swelling of the small airway passages in the lungs). According to the U.S. Centers for Disease Control and Prevention, each year in the U.S., RSV leads to approximately 60,000-120,000 hospitalizations and 6,000-10,000 deaths among adults 65 years of age and older.

Currently available RSV vaccines including GSK's Arexvy, Moderna's mResvia, and Pfizer's Abrysvo target either the F or G proteins of the virus and provide protection by neutralizing the RSV virus. Clinical measures of efficacy focus on the amount of neutralizing antibodies in the bloodstream. DPX-RSV works differently; it targets the SH viral ectodomain of the RSV virus and, instead of neutralizing the virus, it enables the immune system to recognize and destroy infected cells. BioVaxys has exclusive worldwide licenses on applications that target the SH ectodomain antigen in RSV.

The Company is exploring opportunities to out-license this product to potential partners.

Animal challenge studies with DPX-Based Anthrax Vaccine Demonstrated 100% Immunity from Single Injection

The promise and versatility of the DPX platform for infectious disease applications has been additionally supported by in vivo studies of a DPX formulation targeting anthrax, with a DPX Anthrax vaccine formulation exhibiting 100% immunity following a single injection.

In a preclinical study led by the National Institutes of Health, a single intramuscular injection of recombinant *B. anthracis*-protective antigen (rPA) formulated in the Company's DPX platform ("DPX-rPA") was compared in animal models to rPA in alum, and to Biothrax® (anthrax vaccine adsorbed (AVA)), a US Food and Drug Administration approved vaccine that requires five administrations over 12 months with annual boosting to maintain pre-exposure prophylaxis. Serological analysis of anti-rPA immunoglobulin G and toxin neutralization activity demonstrated higher responses induced by DPX-rPA when compared to rPA in alum. In rabbit and non-human primate ("NHP") studies, the DPX-rPA formulation generated an immune response in as little as 14 days after a single immunization, whereas AVA required two immunizations. In the rabbit study, a single injection of DPX-rPA or two injections of AVA conferred 100% protection from a lethal anthrax challenge. Furthermore, in the NHP study, single-dose DPX-rPA was 100% protective against challenge, whereas one primate in the two-dose AVA group and all saline-administered animals succumbed to infection.

Anthrax, caused by exposure to aerosolized spores of *Bacillus anthracis*, remains a very serious biological threat, and is categorized by the Centers for Disease Control and Prevention (CDC) as a Category A biothreat agent, along with botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers posing the greatest risk to national security. At-risk populations for non-weaponized occupational exposure include those working with infected animals, contaminated animal products or environments such as farmers, veterinarians, livestock handlers, diagnostic laboratory workers, agriculture and wildlife workers, and workers who butcher animals or process meat, hides, hair and wool. The ideal anthrax vaccine would provide rapid protection with a single dose, generate a durable immune response, and have enhanced stability for stockpiling purposes. An anthrax vaccine formulated in DPX™ is expected to provide these characteristics.

There are currently no approved anthrax vaccines that can provide single dose, rapid protection. Currently approved anthrax vaccines include Biothrax, which requires multiple doses over the span of a year, and more recently, Cyfendus, which is intended for people with suspected or confirmed inhalational exposure to anthrax and is given in two intramuscular doses over two weeks and must be given together with antibiotics.

As the efficacy of Cyfendus for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax, BioVaxys is exploring potential advancement of DPX-rPA with its current preclinical data with the US Dept of Defense, Battelle and other organizations.

DPX-rHA for Influenza Achieves Higher Antibody Levels than Alum rHA Vaccine and Protects Against Multiple Flu Strains

Most recently, in preclinical influenza studies in a murine model, a single dose of DPX formulated with recombinant hemagglutinin (rHA) was shown to exhibit higher and more durable levels of HA antibodies than Alum+rHA. Alum is the market-standard adjuvant that can increase the immunogenicity of recombinant hemagglutinin (rHA) in influenza vaccines. When combined with rHA, alum can generate anti-HA titers that are 10 times higher than without the alum adjuvant.

Additional *in vivo* studies compared two different strains (Puerto Rico H1N1 and Hong Kong H3N2) of heat inactivated whole influenza virus packaged in DPX (DPX+FLU) compared to Alum + heat inactivated whole influenza virus (Alum+FLU). One month post vaccination the mice were challenged with both live influenza strains, with the animals that received DPX+FLU having an almost 100% survival 10 days post challenge to both the Puerto Rico H1N1 and Hong Kong H3N2 strains, compared to ~70% survival for mice challenged with Puerto Rico H1N1and receiving Alum+FLU, and <20% survival for mice challenged with Hong Kong H3N2 strain and receiving Alum+FLU.

BioVaxys is planning further preclinical studies to evaluate a quadrivalent (four flu strains) DPX formulation.

BioVaxys Technology Corp. (www.biovaxys.com), registered in British Columbia, Canada, is a clinical-stage biopharmaceutical company dedicated to improving patient lives with novel immunotherapies based on its DPX™ immune-educating technology platform and its HapTenix© "neoantigen" tumor cell construct platform, for treating cancers, infectious disease, antigen desensitization, 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, and is in Phase II clinical development for advanced Relapsed-Refractory Diffuse Large B Cell Lymphoma (DLBCL) and platinum resistant Ovarian Cancer. MVP-S delivers antigenic peptides from survivin, a well-recognized cancer antigen 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, and BVX-0918, a personalized immunotherapeutic vaccine using it 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 (FRA: 5LB) and in the US (OTCQB: BVAXF). For more information, visit www.biovaxys.com and connect with us on X and LinkedIn.

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, 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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