# BiondVax Reports Positive Phase 2b Clinical Trial Results for its Universal Flu Vaccine

## European UNISEC Co-Sponsored Trial Meets Both Primary Endpoints

**Ness Ziona, Israel –** July 20, 2017 –

**BiondVax Pharmaceuticals Ltd.** (NASDAQ: BVXV, TASE: BVXV), and the UNISEC consortium today reported statistically significant positive results from the Phase 2b clinical trial of M-001, BiondVax's universal flu vaccine candidate.

The study had two primary endpoints: Safety and influenza-specific cellular immune responses. Both endpoints were achieved.

**Trial Design:** The randomized placebo-controlled double-blind trial consisted of 3 arms; The 219 participants, aged 18 to 60 years, twice received either 0.5mg M-001, 1.0mg M-001, or saline placebo. All participants were then immunized with a partial dose of avian H5N1 pandemic vaccine.
**Primary Safety Results:** The Company previously reported[1] and today confirms that M-001 has a good safety profile and is well-tolerated.
**Primary Cellular Results:** TH1 cytokines including Il-2, Interferon-gamma, and TNF-alpha are biological molecules with known anti-viral and anti-influenza virus activity. These cytokines are produced by CD4 immune system cells when activated as part of T-cell dependent immunity. In this trial, T-cell (also known as cellular) immunity was measured at baseline (prior to immunization), and after immunization with M-001. Compared to the placebo group, statistically significant elevated T-cell dependent immune responses were found in both dosage forms, more notably in the 1.0mg dose group.

The study's secondary endpoint evaluated antibody (HAI) response to avian H5N1 pandemic vaccination after M-001 or placebo administration. In one of the four H5N1 strains tested, a statistically significant HAI elevation was observed in participants who had received M-001.

Immunological assays and statistical analysis were performed by various UNISEC[2] consortium partners. **Dr. Ed Schmidt**, Executive Manager of the UNISEC consortium, commented, "*The development of universal influenza vaccines can be highly successful when public health institutes and companies work together, share expertise, technologies, and networks. In the UNISEC consortium, we are very pleased to have BiondVax with their M-001 vaccine as one of our partners. The cell mediated immunity observed in our Phase IIB clinical study with the M-001 vaccine is very impressive and of high scientific interest. We are certainly looking forward to continuing this collaboration with BiondVax.*"

In light of these encouraging clinical trial results that confirm previous study results, the recent €20 million EIB funding[3], the Israel Ministry of Economy grant approval[4], and following consultations with leading European and American regulatory experts, BiondVax is considering taking the opportunity to proceed directly to testing the clinical efficacy of vaccination with M-001 alone in a pivotal Phase 3

clinical trial. Clinical efficacy is planned to be assessed by measuring reduction of flu illness rate and severity.

**Dr. Tamar Ben-Yedidia**, BiondVax's Chief Science Officer (CSO), noted, "*These significant results confirm that the M-001 is a unique and innovative influenza vaccine that elicits strong T-cell responses and is expected to provide multi-strain and multi-season protection against influenza illness. Along with the substantial funding recently brought to BiondVax we can now concentrate on performing all activities needed to launch the pivotal Phase 3 clinical trial.*"

[1] http://www.biondvax.com/2016/11/biondvax-phase-2b-trial-preliminary-safety-results-the-universal-flu-vaccine-candidate-is-safe-and-well-tolerated/

[2] Research leading to these results received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n°602012.

[3] http://www.biondvax.com/2017/06/european-investment-bank-eib-supports-late-stage-development-and-production-of-biondvaxs-universal-flu-vaccine-candidate-under-horizon-2020-initiative/

[4] http://www.biondvax.com/2017/03/biondvax-approved-for-grant-from-israels-ministry-of-economy-and-industry-to-build-facility-for-commercial-scale-production-of-its-universal-flu-vaccine/

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**About BiondVax Pharmaceuticals Ltd**

BiondVax is a clinical phase biopharmaceutical company developing a universal flu vaccine. The vaccine is designed to provide multi-season protection against most seasonal and pandemic human influenza virus strains. BiondVax's proprietary technology utilizes a unique combination of conserved and common peptides from influenza virus proteins, activating both arms of the immune system for a cross-protecting and long-lasting effect. BiondVax is traded on NASDAQ: BVXV and TASE: BVXV. Please visit www.biondvax.com.

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**BiondVax Forward Looking Statements**

*This press release contains forward-looking statements within the meaning of the Private Litigation Reform Act of 1995. Words such as "expect," "believe," "intend," "plan," "continue," "may," "will," "anticipate," and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve certain risks and uncertainties reflect the management's current views with respect to certain current and future events and are subject to various risks, uncertainties and assumptions that could cause the results to differ materially from those expected by the management of BiondVax Pharmaceuticals Ltd. risks and uncertainties include, but are not limited to, uncertainties and risks in the clinical development process, including, among others, length, expense and the ability to enroll trial patients, reliance on third parties and that the results of earlier research and/or preclinical or clinical trial results may not be predictive of actual results, conclusions or interpretations of subsequent research or trials, the results of the Phase 2 & 3 trials, delays or obstacles in launching and/or successfully completing our clinical trials, the lengthy and unpredictable nature of the FDA's approval process, our ability to satisfy rigorous regulatory requirements, the impact of the global economic environment on the Company customer target base, the adequacy of available cash resource and the ability to raise capital when needed. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2016 filed with the U.S. Securities and Exchange Commission, or SEC, which is available on the SEC's website, www.sec.gov, and in the Company's periodic filings with the SEC and the Tel-Aviv Stock Exchange.*

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