

# Immunovaccine Announces Positive Interim Clinical Data from Ovarian Cancer Study of DPX-Survivac in Combination with Epacadostat

**Preliminary Analysis Supports the Ability of Immunovaccine's Lead Candidate to Induce T-Cell Infiltration**

**Early Data Reflect Tolerability and Clinical Potential of the Triple Combination Immunotherapy in Recurrent Ovarian Cancer**

**Halifax, Nova Scotia; March 29, 2017** – Immunovaccine Inc. (“Immunovaccine” or the “Company”) (TSX: IMV; OTCQX: IMMVF), a clinical stage vaccine and immunotherapy company, today announced the first interim data analysis from its **ongoing Phase 1b clinical study** of its novel T-cell activating immuno-oncology candidate, DPX-Survivac, in combination with epacadostat and low-dose cyclophosphamide. The analysis included the results of blood tests, tumor biopsies and CT scans to assess safety, disease progression and T-cell response for the first four evaluable patients in the trial.

All patients enrolled in the trial have recurrent ovarian cancer with evidence of progressive disease. Based on the interim analysis, the combination therapy appears to have an acceptable safety profile, with a single grade 3 and single grade 4 event reported and no serious adverse events (SAEs) reported.

At the time of the interim analysis, three of four patients exhibited stable disease, while a fourth patient continued to progress and discontinued the trial. In addition, researchers observed:

- Signs of increased T cell activity in tumors in three of the four patients based on RNA sequencing
- Stable disease with signs of tumor shrinkage in the patient who has been in trial for the longest duration thus far (based on CT scan at day 140)

“We are very encouraged by these early data, which are tremendously important to Immunovaccine, as they help to validate the underlying clinical potential of DPX-Survivac,” said **Frederic Ors, Immunovaccine's Chief Executive Officer**. “Research is consistently demonstrating that activating T cells is a crucial mechanism to improving tumor response rates.(i) This desired mechanism of action is exactly what we have developed DPX-Survivac to address, and this data set has provided an encouraging first clinical demonstration of this effect.”

Immunovaccine is developing DPX-Survivac as a combination therapy that can significantly expand the range of cancers successfully treatable by novel immunotherapeutic agents. Emerging data from other studies have shown limited clinical efficacy of checkpoint inhibitor monotherapy in ovarian cancer, with response rates ranging from 10-15 percent.(ii)

**Phase 1b Trial and Early Data**

The Phase 1b company-sponsored clinical trial is a single-arm, open-label study of patients who have been diagnosed with platinum-resistant and sensitive ovarian cancer, and who have completed first-line treatment with measurable disease. Investigators plan to enroll up to 40 participants at up to ten sites in the U.S. and Canada. The study's primary objective is to assess the safety and immunogenicity of the treatment, and to determine changes in the immune cell infiltration into tumors. Secondary objectives include objective response rate, duration of response, and time to progression.

Investigators are evaluating patients over a 12-month treatment schedule, collecting biopsy and blood samples before and after treatment. In addition, investigators are performing CT scans at the outset for each patient, repeating the scans every two months to evaluate status of the disease and to assess potential clinical benefit.

In addition to the early findings related to disease progression and the presence of survivin-antigen specific CD8+ T cells in the blood, analysis of the tumor revealed increases in multiple T cell markers, including cytotoxic markers and checkpoint inhibitor molecules.

"This readout, while from a limited number of patients, is important as it marks the first time DPX-Survivac has been tested in active progressive disease, where we can formally look at its impact on tumor progression and the tumor microenvironment, as well as assess potential clinical benefit," said **Marianne Stanford, PhD, Vice President, Research, at Immunovaccine**. "The data set thus far has provided a preliminary indication of DPX-Survivac's ability to induce T-cell infiltration in the tumor micro-environment. We are very encouraged by this information, and we look forward to the next opportunity to analyze the data and their related implications for this clinical program." Immunovaccine expects to complete enrollment and issue topline data by the end of 2017. Patients interested in enrolling in this trial can find more information via [clinicaltrials.gov](http://clinicaltrials.gov).

This triple combination study is the result of a **collaboration** between Immunovaccine and Incyte Corporation to assess the safety and effectiveness of DPX-Survivac, along with epacadostat, an investigational oral indoleamine 2,3-dioxygenase 1 (IDO1) enzyme inhibitor, and low-dose cyclophosphamide in patients with recurrent ovarian cancer who have measurable disease.

### **About Ovarian Cancer**

According to the American Cancer Society (ACS),<sup>(iii)</sup> ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. Often diagnosed in its advanced stages, about 21,290 women received a new diagnosis of ovarian cancer in 2015; approximately 14,180 women would die from the disease, according to ACS estimates.

Ovarian cancer has a significant impact globally as well. The World Cancer Research Fund<sup>(iv)</sup> reports that ovarian cancer is the seventh most common cancer in women worldwide (18 most common cancer overall), with 239,000 new cases diagnosed in 2012.

### **About DPX-Survivac**

DPX-Survivac consists of survivin-based peptide antigens formulated in the DepoVax™ platform, which is a patented formulation that provides controlled and prolonged exposure of antigens to the immune system, resulting in a strong, specific and sustained immune response. The National Cancer Institute (NCI) has recognized survivin as a promising tumor-associated antigen (TAA) because of its therapeutic potential and its cancer specificity. Survivin is broadly over-expressed in multiple cancer types in addition to ovarian cancer, including breast, colon and lung cancers. Survivin plays an essential role in antagonizing cell death, supporting tumor-associated

angiogenesis, and promoting resistance to anti-cancer therapies. Survivin is also a prognostic factor for many cancers and it is found in a higher percentage of tumors than other TAA's.

The DPX-Survivac vaccine is thought to work by eliciting a cytotoxic T-cell immune response against cells presenting survivin peptides. This targeted therapy attempts to use the immune system to search actively and specifically for tumor cells and destroy them. Survivin-specific T-cells have been shown to target and kill survivin-expressing cancer cells while sparing normal cells.

DPX-Survivac has been granted Fast Track designation by the U.S. FDA as maintenance therapy in individuals with advanced ovarian, fallopian tube, and peritoneal cancer who have no measurable disease following surgery and front-line platinum/taxane chemotherapy to improve their progression-free survival.

### **About Epacadostat (INCB24360)**

Indoleamine 2,3-dioxygenase 1 (IDO1) is a key immunosuppressive enzyme that modulates the anti-tumor immune response by promoting regulatory T-cell generation and blocking effector T-cell activation, thereby facilitating tumor growth by allowing cancer cells to avoid immune surveillance. Epacadostat is a first-in-class, highly potent and selective oral inhibitor of the IDO1 enzyme that reverses tumor-associated immune suppression and restores effective anti-tumor immune responses. In single-arm studies, the combination of epacadostat and immune checkpoint inhibitors has shown proof-of-concept in patients with unresectable or metastatic melanoma. In these studies, epacadostat combined with the CTLA-4 inhibitor ipilimumab or the PD-1 inhibitor pembrolizumab improved response rates compared with studies of the immune checkpoint inhibitors alone. A Phase 3 study, ECHO-301, evaluating the combination of epacadostat with the anti-PD-1 antibody pembrolizumab for the first-line treatment of patients with advanced or metastatic melanoma is underway. Ongoing Phase 1 and Phase 2 studies are also investigating epacadostat in combination with PD-1 and PD-L1 inhibitors in a variety of other cancer histologies.

### **About Immunovaccine**

Immunovaccine Inc. is a clinical-stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer and infectious diseases. Immunovaccine develops T-cell activating cancer immunotherapies and infectious disease vaccines based on DepoVax™, the Corporation's patented platform that provides controlled and prolonged exposure of antigens and adjuvant to the immune system. Immunovaccine has advanced two T-cell activation therapies for cancer through Phase 1 human clinical trials and is currently conducting a Phase 1b study with Incyte Corporation assessing its lead cancer therapy, DPX-Survivac, as a combination therapy in ovarian cancer. An investigator-sponsored Phase 2 study will assess the safety and efficacy of DPX-Survivac and low dose cyclophosphamide combined with an approved anti-PD-1 drug in advanced ovarian cancer. The Corporation is also exploring additional applications of DepoVax™, including DPX-RSV, an innovative vaccine candidate for respiratory syncytial virus (RSV), which has recently completed a Phase 1 clinical trial. Immunovaccine also has ongoing clinical projects to assess the potential of DepoVax™ to address malaria and the Zika virus. Connect at [www.imvaccine.com](http://www.imvaccine.com).

### **Immunovaccine Forward-Looking Statements**

*This press release contains forward-looking information under applicable securities law. All information that addresses activities or developments that we expect to occur in the future is forward-looking information. Forward-looking statements are based on the estimates and opinions of management on the date the statements are made. However, they should not be regarded as a representation that any of the plans will be achieved. Actual results may differ materially from those set forth in this press release due to risks affecting the Corporation, including access to capital, the successful completion of clinical trials and receipt of all regulatory approvals and the matters discussed under "Risk Factors and Uncertainties" in Immunovaccine's Annual Information Form filed*

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