



IMV Announces Clinical Update for DPX-Survivac Program in Ovarian Cancer Following Positive Feedback from U.S. FDA

- *DECIDE phase 2 clinical trial amendment successfully completed with multiple sites now open for enrollment*
- *FDA provided guidance for future registration trial design and for a potential shorter regulatory pathway for developing DPX-Survivac as a monotherapy in certain ovarian cancer patients*

DARTMOUTH, Nova Scotia, Jan. 29, 2019 (GLOBE NEWSWIRE) -- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical stage immuno-oncology corporation, today announced updates on its clinical program for its lead investigational treatment, DPX-Survivac, as a potential monotherapy in advanced recurrent ovarian cancer. In December 2018, IMV met with the U.S. Food and Drug Administration (FDA) in a Type B meeting to discuss the results-to-date of its DECIDE1 clinical trial and ongoing development plan, as well as to obtain agency guidance on a potential accelerated regulatory pathway for DPX-Survivac as a T cell immunotherapy for the treatment of advanced ovarian cancer in patients with progressing disease.

“This FDA meeting was an important milestone for the DPX-Survivac program, and we are very pleased to be aligned with the agency on key aspects of our clinical development plan,” said [Frederic Ors, Chief Executive Officer at IMV](#). “We believe that, with no currently approved immunotherapy options available, ovarian cancer remains a serious unmet medical need. We look forward to advancing our ongoing phase 2 DECIDE study in order to potentially expedite DPX-Survivac development as a possible first-in-class T cell immunotherapy treatment for patients with advanced ovarian cancer.”

FDA Meeting Highlights

The purpose of IMV’s Type B meeting with the FDA was to request feedback on the design of the clinical program for DPX-Survivac. This program includes the ongoing DECIDE phase 2 clinical study and a potential future registration trial for accelerated approval in a subset of ovarian cancer patients.

The FDA reviewed the Company’s proposed clinical development plan and acknowledged the potential for accelerated approvals in advanced ovarian cancer based on objective response rate (ORR) according to RECIST 1.1 criteria with reported median duration of response (DOR). In addition, the FDA provided important guidance on clinical design considerations for different lines of therapy and platinum-sensitive and -resistant patient

populations.

In addition, IMV submitted a protocol amendment for a predictive enrichment approach to the phase 2 DECIDE trial, and further discussed those details with the FDA during the Type B meeting. The phase 2 primary endpoint, based on objective response rate (ORR) per RECIST 1.1 criteria, is intended to confirm the high response rate and duration of clinical benefits observed [in previously announced results](#) in a patient population defined by a clinical biomarker based on baseline tumor burden (BTB).

Multiple clinical sites are now open for enrollment in the DECIDE phase 2 trial. Subject to phase 2 results, IMV plans to schedule a follow-up meeting with FDA to finalize the design of a potential pivotal trial based on ORR and DOR.

About the DECIDE Phase 2 Trial Cohort

The DECIDE (DPX-Survivac with low dose intermittent cyclophosphamide) phase 2 study is an open label safety and efficacy study for individuals with advanced platinum-sensitive and -resistant ovarian cancer with sum of base line target lesions per RECIST criteria less than 5 cm. Primary and secondary endpoints include:

- Safety profile,
- ORR and DOR using RECIST 1.1 criteria,
- Induction of systemic survivin-specific T cells in the blood, and
- Induction of T cell infiltration into tumors.

About IMV

IMV 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 other serious diseases. IMV is pioneering a new class of immunotherapies based on the Company's proprietary drug delivery platform. This patented technology leverages a novel mechanism of action that enables the programming of immune cells *in vivo*, which are aimed at generating powerful new synthetic therapeutic capabilities. IMV's lead candidate, DPX-Survivac, is a T cell-activating immunotherapy that combines the utility of the platform with a target: survivin. IMV is currently assessing DPX-Survivac as a monotherapy in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies in collaboration with Merck. Connect at www.imv-inc.com.

IMV 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. In the press release, such forward-looking statements include, but are not limited to, statements regarding the FDA potentially granting accelerated regulatory approval of DPX-Survivac. 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 design and completion of clinical trials and the receipt and timely receipt of all regulatory approvals. IMV Inc. assumes no

responsibility to update forward-looking statements in this press release except as required by law. These forward-looking statements involve known and unknown risks and uncertainties and those risks and uncertainties include, but are not limited to, our ability to access capital, the successful and timely completion of clinical trials, the receipt of all regulatory approvals and other risks detailed from time to time in our ongoing quarterly filings and annual information form. Investors are cautioned not to rely on these forward-looking statements and are encouraged to read IMV's continuous disclosure documents, including its current annual information form, as well as its audited annual consolidated financial statements which are available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

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