

September 30, 2019



# Preliminary Results From IMV's Phase 2 Basket Trial Evaluating DPX-Survivac as a Combination Therapy in Patients With Advanced and Metastatic Solid Tumors to Be Presented at ESMO Congress 2019

*Tumor regressions and partial responses observed in subjects with ovarian, non-small cell lung and bladder cancer*

*Treatment well-tolerated, with no related Grade 3-4 or immune-related adverse events*

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical stage immuno-oncology company, today presented preliminary results from its ongoing Phase 2 basket trial, evaluating DPX-Survivac in combination with Merck's Keytruda® (pembrolizumab) and intermittent low dose cyclophosphamide (CPA) in patients with advanced and metastatic solid tumors. The data were presented during the Immunotherapy of Cancer poster session at the European Society for Medical Oncology (ESMO) 2019 Congress, being held September 27 – October 1, 2019, in Barcelona, Spain.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20190930005137/en/>

“We are encouraged by the initial response observed from these preliminary data, which feature a safety profile consistent with observations across other studies of DPX-Survivac as well as promising signs of clinical activity. Importantly, these results expand our clinical dataset into four additional hard-to-treat solid tumor indications, as we continue to explore the broad potential of our targeted T cell therapy in more than 20 solid and hematological tumor types that express survivin,” said Frederic Ors, IMV's Chief Executive Officer. “Later this year, we anticipate additional data from ongoing studies of DPX-Survivac in our lead indications – including topline results from DeCidE1, a Phase 2 study evaluating DPX-Survivac in ovarian cancer, and updated results from SPiRel, a Phase 2 study evaluating DPX-Survivac in combination with Keytruda in r/r DLBCL – both of which have demonstrated this program's potential to safely generate a durable clinical response.”

## **Preliminary Results from the Phase 2 Basket Trial**

At the time of cut-off, 23 patients were enrolled across all five patient cohorts. This includes 19 patients across all cohorts who received DPX-Survivac in combination with pembrolizumab with CPA, and four patients from the ovarian cancer cohort receiving DPX-Survivac with only pembrolizumab:

- Preliminary results from the first on-study scan showed tumor reduction in patients with

ovarian cancer (with and without CPA), non-small cell lung cancer (NSCLC) and bladder cancer;

- Partial responses observed at first scan in two subjects (bladder cancer, ovarian cancer); 19/23 subjects are still active on study treatment.
- T cell infiltration observed in biopsy samples from subjects who achieved tumor reduction on treatment;
- Eight ovarian cancer patients were enrolled in the study, randomized 1:1 to treatment with and without CPA. Tumor control and tumor reductions were observed in both groups; and
- Safety evaluation on all evaluable patients demonstrated that treatment was well-tolerated, with no related Grade 3-4 or immune-related adverse events (AEs) reported.

The poster is available on the Investors section of the company's website, under "Events, Webcasts & Presentations" at [www.imv-inc.com](http://www.imv-inc.com).

### **About the Phase 2 Basket Trial**

IMV's Phase 2 basket trial is an open label, multi-center study, evaluating DPX-Survivac across five cohorts of patients with bladder cancer, liver cancer (hepatocellular carcinoma), ovarian cancer (with and without CPA), NSCLC and tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker.

Subjects will receive DPX-Survivac (SC: 2 x 0.25 mL every three weeks, followed by up to 11 x 0.1 mL every nine weeks), in combination with pembrolizumab (IV: 200 mg every 3 weeks cycle) and CPA (oral: 50 mg BID on alternating weeks) across five cohorts of patients with bladder cancer, liver cancer (hepatocellular carcinoma), ovarian cancer, NSCLC and tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker. The study is designed to assess primary endpoints of safety and objective response rate (ORR), with multiple secondary and exploratory measures.

The study included a safety lead-in, which included 20 patients from all five cohorts. The five cohorts are now expanded to recruit additional subjects following a Simon two stage design. Enrollment in the ovarian cancer cohort will be randomized 1:1 into two arms with and without CPA. All other cohorts will utilize a single-arm design and administer treatment with the triple combination. As of Sept. 27<sup>th</sup>, 2019, 28 patients are enrolled (50 were screened). IMV expects to enroll 184 patients across clinical sites in the U.S. and Canada.

### **About DPX-Survivac**

DPX-Survivac is the lead candidate in IMV's new class of immunotherapies that programs targeted T cells in vivo. It has demonstrated the potential for industry-leading targeted, persistent, and durable T cell activation. IMV believes this mechanism of action (MOA) is key to generating durable solid tumor regressions. DPX-Survivac consists of survivin-based peptides formulated in IMV's proprietary DPX drug delivery platform. DPX-Survivac is designed to work by eliciting a cytotoxic T cell immune response against cancer cells presenting survivin peptides on their surface.

Survivin, recognized by the National Cancer Institute (NCI) as a promising tumor-associated antigen, is broadly over-expressed in most cancer types, and plays an essential role in antagonizing cell death, supporting tumor-associated angiogenesis, and promoting

resistance to chemotherapies. IMV has identified over 20 cancer indications in which survivin can be targeted by DPX-Survivac.

DPX-Survivac has received Fast Track designation from the U.S. Food and Drug Administration (FDA) as maintenance therapy in advanced ovarian cancer, as well as orphan drug designation status from the U.S. FDA and the European Medicines Agency (EMA) in the ovarian cancer indication.

## **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 with Merck. Connect at [www.imv-inc.com](http://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](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).*

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Source: IMV Inc.