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# IMV Inc. Presents Positive Initial Results From The MVP-S Phase 2B VITALIZE Trial

*Early analysis reveals clinically meaningful activity in refractory DLBCL patients*

*Multiple confirmed complete responses observed in heavily pre-treated patients*

*No adverse safety and tolerability signal reported, consistent with previous clinical trials*

DARTMOUTH, Nova Scotia, & CAMBRIDGE, Mass.--(BUSINESS WIRE)-- IMV Inc. (Nasdaq: IMV; TSX: IMV) ("IMV" or the "Company"), a clinical-stage biopharmaceutical company developing a portfolio of immune-educating therapies based on its novel DPX<sup>®</sup> platform to treat solid and hematologic cancers, today announced positive preliminary data from the VITALIZE Phase 2B trial evaluating its lead DPX product, maveropepimut-S ("MVP-S"), in combination with pembrolizumab in patients with relapsed, refractory Diffuse Large B Cell Lymphoma ("r/r DLBCL").

Key initial findings from the ongoing VITALIZE trial:

- 8 Patients with an ECOG<sup>1</sup> score of 0-1 have been enrolled in arm 1 of the study. Of these, 6 have so far been evaluable for efficacy;
- Of these 6 evaluable patients, 3 patients showed confirmed complete responses, 1 patient was assessed with stable disease as best response and 2 patients were assessed with progressive disease as best response; and
- 2 patients with poor level of baseline functionality (ECOG  $\geq$  2) failed to stay on study through to the first scan and therefore could not be evaluated.

Overall Response Rate ("ORR") will be communicated when the totality of stage one data are available for definitive assessment.

"VITALIZE is our most advanced and rigorous trial to date, and we are encouraged by the way the data for MVP-S are trending. This is the most refractory population of patients we have treated so far, and to show complete, confirmed clinical responses is notable. These positive initial results, combined with the accelerating recruitment of the AVALON study in platinum resistant ovarian cancer add, we believe, to the growing industry enthusiasm about the potential for MVP-S in multiple tumor settings," said Andrew Hall, CEO of IMV.

## About the VITALIZE Study

The VITALIZE Phase 2B trial is a randomized, parallel group, Simon two-stage study designed to assess IMV's lead candidate, MVP-S, in combination with pembrolizumab with (arm 1) or without (arm 2) cyclophosphamide. Across the arms of this study, the combination will be evaluated in up to 30 patients in stage one (two arms of 15) with the option to expand to up to a total of 102 subjects in stage two with r/r DLBCL who have received at least two

prior lines of systemic therapy and who are ineligible or have failed autologous stem cell transplant (ASCT) or CAR-T therapy.

### **About the AVALON study**

The AVALON study is an open label, company-sponsored phase 2b, single arm trial evaluating the efficacy and safety of MVP-S and intermittent low-dose cyclophosphamide (CPA) in patients with platinum-resistant ovarian cancer. The study is a Simon two-stage design where up to 41 subjects will be evaluated in stage one, with the option to expand to up to a total of 73 patients in stage two. Patients participating in the trial will receive two doses of subcutaneous MVP-S once every three weeks, followed by an MVP-S dose once every eight weeks, plus low-dose oral CPA on a repeating cycle of one week on/one week off.

### **About IMV**

IMV Inc. is a clinical-stage immuno-oncology company advancing a portfolio of therapies based on the Company's immune-educating platform, DPX<sup>®</sup>. Through a differentiated mechanism of action, the DPX platform delivers instruction to the immune system to generate a specific, robust, and persistent immune response. IMV's lead candidate, maveropepimut-S (MVP-S), delivers antigenic peptides from survivin, a well-recognized cancer antigen commonly overexpressed in advanced cancers. MVP-S also delivers an innate immune activator and a universal CD4 T cell helper peptide. These elements foster maturation of antigen presenting cells as well as robust activation of CD8 T cell effector and memory function. MVP-S treatment 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. MVP-S is currently being evaluated in clinical trials for hematologic and solid cancers, including Diffuse Large B Cell Lymphoma (DLBCL) as well as ovarian, bladder and breast cancers. IMV is also developing a second immunotherapy leveraging the DPX immune delivery platform, DPX-SurMAGE. This dual-targeted immunotherapy combines antigenic peptides for both the survivin and MAGE-A9 cancer proteins to elicit immune responses to these two distinct cancer antigens simultaneously. A Phase 1 clinical trial in bladder cancer, using MVP-S or DPX-SurMAGE, was initiated in early 2022. For more information, visit [www.imv-inc.com](http://www.imv-inc.com) and connect with us on [Twitter](#) and [LinkedIn](#).

### **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 use such word as "will", "may", "potential", "believe", "expect", "continue", "anticipate" and other similar terminology. Forward-looking statements are based on the estimates and opinions of management on the date the statements are made. In this press release, such forward-looking statements include, but are not limited to, statements regarding the potential and efficacy of MVP-S, the potential impact of the VITALIZE study and timing of availability of the ORR from the remaining stage one patients from its Phase 2B trial, the Company's ability to advance its development strategy, and the prospects for its lead immunotherapy and its other pipeline of immunotherapy candidates. 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, those related to the detailed results when presented being at least consistent with the initial results from the VITALIZE Phase 2B trial, the Company's priorities with MVP-S and its DPX delivery platform, the potential for its delivery platform and the anticipated timing of enrollment and results for its clinical trial programs and studies as 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).

<sup>1</sup> ECOG is a measure of patient functionality and is measured according to a standardized measure ranging from 0-5. Oken et al., Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-655. PMID: 7165009

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