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# IMV Announces Company-Sponsored Clinical Trial in Patients with r/rDLBCL in Collaboration with Merck Following Feedback from FDA

*The two companies agreed on final design of the new Phase 2B study*

*Patient population and clinical endpoints aligned with FDA guidance for potential path to accelerated approval*

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (Nasdaq: IMV; TSX: IMV) (“IMV” or the “Company”), a clinical-stage biopharmaceutical company pioneering a novel class of cancer immunotherapies, today announced that, following feedback from the U.S. Food & Drug Administration (FDA), the company has entered into an agreement with Merck to initiate a Phase 2B clinical trial to evaluate its lead compound, maveropepimut-S (DPX-Survivac) in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy, in patients with recurrent/refractory diffuse large B cell lymphoma (r/rDLBCL). The contribution of low dose cyclophosphamide (CPA) as an activator of immune response will also be evaluated in this trial.

“We are proud to continue working with Merck to deepen the relationship that was built during our basket trial and the prior “SPiReL” study in r/rDLBCL,” said Andrew Hall, Chief Business Officer at IMV. “This new agreement continues to leverage our common vision to save and improve lives by delivering better treatments to patients with unmet medical needs. In this collaboration we look forward to collaborating with Merck, beyond the provision of Keytruda, to ensure clinical and regulatory alignment, thus optimizing our probability of success.”

In a [press release](#) issued on March 17, 2021, the Company announced that the FDA provided valuable feedback on the clinical trial design and the study is expected to begin in Q2 2021.

Frederic Ors, Chief Executive Officer at IMV stated “The guidance from the FDA is an important milestone for the Company and we believe it provides us regulatory clarity and confidence to advance our development strategy for our lead immunotherapy in this difficult-to-treat patient population. We intend to initiate this trial rapidly and will seek to confirm the promising results obtained in the SPiReL study.”

The three-arm Phase 2B trial is a randomized, parallel group, Simon two-stage study designed to assess the combination of maveropepimut-S and KEYTRUDA® with or without CPA. A third arm will evaluate maveropepimut-S as a single agent. Across the three arms of this study, IMV’s lead compound will be evaluated in up to 150 subjects 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.

The primary endpoint is Objective Response Rate (ORR), centrally evaluated per Lugano (2014) and measured by the number of subjects per arm achieving a best response of Partial or Complete Response (PR+CR) during the 2-year treatment period. All subjects will be evaluated for their baseline PD-L1 expression with the goal to validate the SPiReL data that highlighted PD-L1 as a possible predictive biomarker for the combination therapy.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

### **About Maveropepimut-S**

Maveropepimut-S is the lead candidate in IMV's new class of immunotherapy that generates targeted and sustained cancer cell killing capabilities *in vivo*. Treatments with Maveropepimut-S in association with CPA have demonstrated a favorable safety profile across all clinical studies.

Maveropepimut-S, consists of survivin-based peptides formulated in IMV's proprietary delivery platform (DPX) which is designed to generate a sustained cytotoxic T cell 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 maveropepimut-S.

Maveropepimut-S has received Fast Track designation from the FDA as maintenance therapy in advanced ovarian cancer, as well as Orphan Drug designation status from the 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 cancer-targeted immunotherapies and vaccines based on the Company's proprietary delivery platform (DPX). This patented technology leverages a novel mechanism of action that enables the activation of immune cells *in vivo*, which are aimed at generating powerful new synthetic therapeutic capabilities. IMV's lead candidate, maveropepimut-S (DPX-Survivac), is a T cell-activating immunotherapy that combines the utility of the platform with a novel cancer target: survivin. IMV is currently assessing maveropepimut-S in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies with Merck's Keytruda®. IMV is also developing a DPX-based vaccine to fight against COVID-19. 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 the press release, such forward-looking statements include, but are not limited to, statements regarding the Company’s ability to advance its development strategy for its lead immunotherapy, the timing for enrollment of subjects in, and results related to, our clinical trial programs and studies. 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 Company, including access to capital, the successful design and completion of clinical trials and the timely receipt of all regulatory approvals to commence, and then continue, clinical studies and trials and the receipt of all regulatory approvals to commercialize its products. 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, the ability to access capital, the successful and, generally, the timely completion of clinical trials and studies and the receipt of all regulatory approvals as well 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)*

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