

December 6, 2020



# Durable Clinical Benefits Induced by IMV's T Cell Therapy in Combination With Merck's Keytruda in Subjects With PD-L1 Positive r/r DLBCL Presented at ASH Annual Meeting

*Company's next milestone is to meet with FDA in Q1 2021 to design next clinical trial in collaboration with Merck*

*PD-L1 positive subjects demonstrated Objective Response Rate (ORR) of 86 % associated with long duration of clinical benefits*

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 and vaccines against infectious diseases, today announces that durable clinical benefits induced by combination treatment of IMV's T cell therapy with Merck's Keytruda<sup>®</sup> (pembrolizumab) in subjects with PD-L1 positive recurrent/refractory Diffuse Large B Cell Lymphoma (r/r DLBCL) have been presented at the [American Society of Hematology \(ASH\) Annual Meeting](#).

"Compared to currently approved therapies, this combination has demonstrated a promising duration of response with limited adverse events in this difficult-to-treat patient population," said Dr. Neil Berinstein, principal investigator of the SPiReL study and hematologist at Sunnybrook Health Sciences Center. "The improved clinical response in this subset of patients with PD-L1 expression is an exciting scientific finding. The baseline PD-L1 expression is a potential predictor of response to this treatment combination which may not be attributed to the activity of pembrolizumab alone<sup>1</sup> and is more likely caused by the complementary mechanisms of action of these two immunotherapies."

"These are exciting early data and the potential synergistic action of these two immunotherapies paves the way for a new treatment paradigm with combination therapeutics," said Dr. Joanne Schindler, Chief Medical Officer at IMV. "We are also evaluating this combination therapy with Merck in other solid tumor indications and we look forward to exploring further the potential of what we have seen in the SPiReL study."

In his presentation during the annual ASH meeting, Dr. Neil Berinstein describes the results from the SPiReL study:

- In the PD-L1+ population (n=7), subjects
  - Have significantly higher median Progression Free Survival (PFS) of 230 days, compared to the PD-L1 negative subjects (70 days) with a p-value of 0.007,

- suggestive of a strong predictive biomarker for this treatment combination,
- Demonstrated an objective response in six subjects, including three subjects who have completed one-year of study treatment,
- Demonstrated an ORR and a DCR at both 85.7%.
- Peripheral blood was assessed for survivin-specific ELISpot responses in 15 subjects with available samples. All 3 subjects with a CR, and 3 of 4 subjects with a PR had positive ELISpot responses while only 1 subject with SD and 1 subject with PD demonstrated survivin-specific ELISpot response, suggestive of an association between the clinical responses with the mechanism of action of DPX-Survivac.
- Treatment was well tolerated. The majority of treatment-related adverse events were grade 1 and 2 severity. A majority of these were injection site reactions associated with the subcutaneous administration of DPX-Survivac.

The poster presentation by Dr. Berinstein is available under the [Scientific Publications & Posters](#) section on IMV's website and is also available on the ASH meeting platform.

Biomarkers associated with clinical response were also discussed in a poster presentation at the [Society for Immunotherapy of Cancer \(SITC\) 35th Anniversary Annual Meeting](#) and during a [webcast](#) hosted by IMV on November 12, 2020.

### **About DPX-Survivac**

DPX-Survivac is the lead candidate in IMV's new class of immunotherapy that generates targeted and sustained cancer cell killing capabilities *in vivo*. Treatments with the DPX-Survivac T cell therapy have demonstrated a favorable safety profile across all clinical studies.

IMV's T cell therapy, DPX-Survivac, consists of survivin-based peptides formulated in IMV's proprietary delivery platform (DPX). IMV's lead compound 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 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 the SPiReL Study**

"SPiReL" is a Phase 2 non-randomized, open label, efficacy, and safety study of a novel immunotherapy combination with DPX-Survivac and pembrolizumab. Intermittent low dose cyclophosphamide is given as an immune modulator. Subjects with r/r incurable DLBCL and survivin expression are eligible for participation. The primary outcome is to document the objective response rate using modified Cheson criteria for the combination treatment.

Secondary objectives include safety, duration of response and time to next treatment. Exploratory endpoints include T cell response, tumor immune cell infiltration, and biomarker analysis. To date, 24 subjects have been enrolled.

## **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, 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 DPX-Survivac in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies with Merck. 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 FDA potentially granting accelerated regulatory approval of DPX-Survivac, the potential for synergistic action and results from the use of combined immunotherapies by the Company, the Company's ability to reach agreement with its collaboration partners and the timing of expected results from other DPX-Survivac's studies with other tumor types. 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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<sup>1</sup>Checkpoint inhibitors such as Keytruda<sup>®</sup> and Opdivo<sup>®</sup> are not approved in DLBCL and have demonstrated limited activity including in PD-L1 positive patients: Xu-Monette, Zijun Y et al. "PD-1 expression and clinical PD-1 blockade in B-cell lymphomas" Blood vol. 131,1 (2018): 68-83. doi:10.1182/blood-2017-07-740993; Suzuki Y, Kohno K, Matsue K, et al. PD-L1 (SP142) expression in neoplastic cells predicts a poor prognosis for patients with intravascular large B-cell lymphoma treated with rituximab-based multi-agent chemotherapy. Cancer Med. 2020;9(13):4768-4776. doi:10.1002/cam4.3104

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Source: IMV Inc.