

March 30, 2020



# IMV Inc. Announces Fourth Quarter and Full Year 2019 Financial and Operational Results

- *Launched development program for a DPX-based vaccine candidate against COVID-19*
- *Reported updated Phase 2 data from DeCidE1 study in advanced ovarian cancer; These encouraging results support DPX-Survivac being amongst the first in vivo T cell therapy to demonstrate meaningful clinical activity in a hard-to-treat solid tumor with 37% (7/19) evaluable subjects achieving durable clinical benefit lasting  $\geq$  6 months*
- *Updated Phase 2 data from SPiReL study evaluating DPX-Survivac as a combination therapy in r/r DLBCL presented at ASH 2019, where 78% (7/9) evaluable subjects exhibited clinical benefit, including three complete responses and two partial responses.*

*One subject, who received three prior lines of systemic therapies and failed autologous stem cell transplant, reached a complete response at the first on-study scan following treatment with the DPX-Survivac combination regimen and remained free of disease recurrence after completing the study*

- *Demonstrated, through our trials, DPX-Survivac's ability to elicit sustained clinical activity in both solid and hematologic tumors with a favorable tolerability and safety profile*
- *Implemented, in the context of the COVID-19 pandemic, measures to ensure the continuity of its business and clinical activities*
- *Management to host conference call and webcast tomorrow at 8:00 a.m. ET*

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (the "Company" or "IMV") (TSX:IMV; NASDAQ:IMV), a clinical-stage biopharmaceutical company pioneering a novel class of immunotherapies, today announced its financial and operational results for the fourth quarter and full year ended December 31, 2019.

"We have made significant progress this past year at IMV, with multiple encouraging readouts from clinical and translational studies of our lead candidate, DPX-Survivac. Taken together, these data not only provide important validation of our platform's novel mechanism and survivin as a target antigen, but also demonstrate its ability to elicit sustained clinical activity in both solid and hematologic tumors," said Frederic Ors, Chief Executive Officer of IMV. "In particular, the recent results from DeCidE1, our ongoing Phase 2 study in advanced ovarian cancer, show DPX-Survivac's potential to deliver improved outcomes over standard-

of-care chemotherapy across key measures in a heavily pre-treated solid tumor population while also providing for excellent benefits and being well tolerated by patients during treatment.”

Mr. Ors continued, “More recently, the 2019 novel coronavirus (COVID-19) pandemic has significantly impacted businesses across all sectors and the healthcare industry is not spared. In this context, we implemented a continuity plan for our current business and clinical operations following the FDA guidance. Vaccines against infectious disease have been a core part of IMV’s heritage across the DPX platform technology, and we have decided to launch the development of a DPX-based vaccine against COVID-19.”

“Even in these challenging times, we expect to keep a forward momentum with planned updates from ongoing Phase 2 studies. Looking ahead, as we hope to accumulate proof-of-concept in multiple hard-to-treat indications, we plan to engage with the U.S. Food and Drug Administration (FDA) on the design of potential pivotal trials in support of an accelerated pathway for DPX-Survivac in advanced ovarian cancer and r/r DLBCL.”

### **Development of the DPX-COVID-19 vaccine candidate**

On Wednesday, March 18, 2020, IMV announced in a [press release](#) plans to develop of a DPX-based vaccine candidate for COVID-19 in collaboration with experts in the field. Earlier today, we announced an update on our progress:

- The Company has used sequences of the virus and immunoinformatics to predict and identify several hundred epitopes, of which 23 were selected for their biological relevance to the virus and potential to generate neutralizing antibodies against SARS-CoV-2;
- Based on this analysis, IMV has begun manufacturing peptide candidates targeting these epitopes as well as planning with IMV’s suppliers and contract manufacturers to prepare for the cGMP batch required to support a clinical study in humans;
- In collaboration with Gary Kobinger, Ph.D., Director of the Research Centre on Infectious Diseases at the University Laval in Quebec City, preclinical assays in animal models are also planned in April through May of this year to validate the safety and potency of the vaccine candidate before initiating the human clinical study;
- In collaboration with Joanne Langley, M.D. at the Canadian Center for Vaccinology (CCfV) and the Canadian Immunization Research Network (CIRN) the design of a Phase 1 clinical study in 48 healthy subjects has been completed and clinical sites identified in both Nova Scotia and Quebec;
- IMV has initiated discussions with Health Canada in preparation for a Clinical Trial Application (CTA). A meeting is being scheduled in the week of April 20, 2020 with the goal to initiate the clinical study in the summer of 2020; and
- The company has submitted several grant applications in Canada in an effort to help support its clinical program.

IMV will continue to provide updates on the development of DPX-COVID-19, and is working on a dedicated DPX-COVID-19 page on its [website](#).

### **DPX-Survivac Clinical Program Updates**

#### **Phase 2 DeCidE1 Study in Advanced Recurrent Ovarian Cancer**

DeCidE1 is a Phase 2 multicenter, randomized, open-label study to evaluate the safety and efficacy of DPX-Survivac with intermittent low dose cyclophosphamide (CPA). This phase 2 arm enrolled 22 patients with recurrent, advanced platinum-sensitive and/or resistant ovarian cancer.

In February 2020, IMV [reported interim data from this study](#), demonstrating amongst others:

- 15/19 (79%) evaluable subjects demonstrated disease control, including 10 tumor regressions (53%);
- 7/19 subjects (37%) achieved clinical benefit with partial/stable responses lasting > 6 months; and
- Treatment was well-tolerated with majority of adverse events being grade 1-2 reactions at the injection site.

At the time of the data cutoff, six (31%) patients remained on therapy. Five (26%) of these patients were still on treatment at > 6 months. Additional data available [here](#).

### **Phase 2 SPiReL Study in r/r DLBCL**

SPiReL is an investigator-initiated Phase 2 study evaluating DPX-Survivac and CPA in combination with Keytruda® (pembrolizumab) in r/r DLBCL.

In December 2019, updated clinical results were reported in a [poster presentation](#) at the American Society of Hematology (ASH) annual meeting in Orlando, FL. Highlights of the data included:

- 7/9 (77.8%) evaluable subjects exhibited clinical benefit, including three (33.3%) complete responses and two (22.2%) partial responses;
- Reproducible survivin-specific T cell responses observed in all subjects that achieved clinical responses on treatment;
- One subject, who received three prior lines of systemic therapies and failed autologous stem cell transplant, reached a complete response at the first on-study scan following treatment with the DPX-Survivac combination regimen and remained free of disease recurrence after completing the study; and
- Clinical benefits and favorable toxicity profile observed in a heterogenous population of r/r DLBCL patients, including patients of advanced age and/or with comorbidities, who are more susceptible to adverse effects and more difficult to treat.

The study remains ongoing, with preliminary topline results expected in 2020.

### **Phase 2 Basket Trial in Multiple Advanced Metastatic Solid Tumors**

The Basket Trial is an open label, multi-center Phase 2 study, evaluating the safety and efficacy of DPX-Survivac and CPA in combination with Keytruda® 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.

As of March 24, 2020, a total of 82 patients were enrolled across all five indications out of a maximum target number of 184 patients.

In the context of the COVID-19 pandemic, IMV expects to report preliminary topline clinical results on several of the solid tumor indications later in 2020.

## **Clinical Translational Studies**

In November 2019, IMV presented translational data from the DeCidE1 clinical study at the 34<sup>th</sup> Annual Meeting of the Society for the Immunotherapy of Cancer (SITC) in National Harbor, MD. The data validate DPX-Survivac's underlying mechanism of action and are available [here](#).

In February 2020, Dr. Oliver Dorigo, MD, Ph.D. presented, on behalf of IMV, translational data supporting DPX-Survivac's mechanism of action at the ASCO-SITC Clinical Immunology Symposium in Orlando, FL. The data included samples collected from three Phase 1 and/or Phase 2 studies evaluating DPX-Survivac alone or in a combination regimen in patients with advanced, platinum-sensitive or resistant ovarian cancer and are available [here](#).

## **Operational Highlights:**

- **Update on IMV's clinical operation following the COVID-19 pandemic:** It is anticipated that the COVID-19 pandemic crisis will impact ongoing trial activities across the industry due to the pressure placed on the healthcare system as well as governmental and institutional restrictions. IMV's clinical team is working closely with each clinical site and our CRO on a contingency plan to ensure that patient safety and the integrity of data is maintained. IMV is following the FDA guidance issued for the COVID-19 pandemic: "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards".

Additionally, the team continues to monitor updated institutional, regional and national guidance to fully comply with applicable guidelines as they are issued. It is noted that some clinical sites have paused or slowed enrollment in clinical trials, while other sites, less impacted, are continuing activities as planned. The overall enrollment rate may decrease, but clinical activities are continuing, and patients are encouraged to comply with directives from public health officials and, subject to such compliance, to attend visits as planned or to discuss alternatives with their physician.

The current activities performed at central labs to assess the eligibility of patients and the management of clinical samples is not impacted, and IMV is working with the vendors to ensure continuity of activities. Finally, drug supply is not expected to be impacted at this time. As added precaution, IMV is working on a contingency plan to ensure proper provisioning of drugs to all clinical sites in the event of future transportation or other constraints.

- **Appointment of Joanne Schindler, M.D., D.V.M. as Chief Medical Officer.** Dr. Schindler joined IMV in November 2019 and has over 15 years of experience in the biopharmaceutical industry, primarily in early-stage oncology drug development. Most recently, she served as Vice President, Clinical Development at H3 Biomedicine, and will oversee IMV's clinical development efforts.

- **Research collaboration with Navidea Biopharmaceuticals:** In November 2019, IMV entered into a preclinical research collaboration with Navidea to explore the potential combinatory effect of DPX-based immunotherapies with Navidea's activated macrophage-targeting therapeutics. IMV and Navidea will jointly conduct research throughout the duration of the study.

### **Upcoming Milestones:**

Over the course of upcoming quarters, the Company expects to deliver the following milestones:

- Top line Phase 2 clinical results update in the DLBCL combination trial in 2020
- Updated Phase 2 clinical results for Basket trial in 2Q20
- Potential initiation of Phase 1 clinical trial for DPX-COVID-19 during the summer of 2020

### **Overview of Year-End 2019 Financial Results**

Research and development expenses increased by \$6,044,000 for the year ended December 31, 2019, compared to 2018. These increases are mainly due to expenses related to the ongoing basket trial, pre-clinical development of DPX-SurMAGE for bladder cancer and personnel costs due to an increase in headcount. The increase is also attributable to manufacturing activities to support the increased clinical activity, which included purchasing raw materials and contract manufacturing organization costs.

General and administrative expenses increased by \$897,000 for the year ended December 31, 2019 compared to 2018. This increase is mainly due to personnel costs as a result of increased head count, investor relations activities, a full year of increased insurance premiums and regulatory fees following the Nasdaq listing in mid-2018, and a full year of increased rent, lease interest accretion, and utilities following the move to its new Dartmouth facility in mid-2018.

The net loss and comprehensive loss of \$27,365,000 (\$0.55 per share) the year ended December 31, 2019 was \$5,430,000 higher than the net loss and comprehensive loss for the year ended December 31, 2018.

At December 31, 2019, the Corporation had cash and cash equivalents of \$14,066,000 and working capital of \$13,199,000, compared with \$14,895,000 and \$12,247,000, respectively at December 31, 2018. For the year ended December 31, 2019, IMV's cash burn rate, defined as net loss for the period adjusted for operations not involving cash (interest on lease obligation, depreciation, accretion of long-term debt, stock-based compensation and DSU compensation), was \$25.5 million. IMV expects research and development expenditures to increase over time due to the continuing development of product candidates and other clinical, preclinical, and regulatory activities.

As of March 30, 2020, the number of issued and outstanding common shares was 51,028,180 and a total of 1,959,452 stock options and deferred share units were outstanding.

The Corporation's audited annual consolidated results of operations, financial condition and

cash flows for the year ended December 31, 2019 and the related management's discussion and analysis (MD&A) 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).

## Conference Call and Webcast Information

Management will host conference call and webcast tomorrow, March 31, 2020 at 8:00 a.m. ET. Financial analysts are invited to join the conference call by dialing (866) 211-3204 (U.S. and Canada) or (647) 689-6600 (international) using the conference ID# 7482187 Other interested parties will be able to access the live audio webcast at this link: <https://ir.imv-inc.com/events-and-presentations>.

## 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 and vaccines based on the Company's proprietary drug delivery platform (DPX). 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-targeted immunotherapy that combines the utility of the platform with a target: survivin. IMV is currently assessing DPX-Survivac targeted therapy 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 Company's intention to develop a DPX-based vaccine candidate against COVID-19, the Company's belief that the DPX-based platform creates the opportunity for accelerated development and rapid, large-scale production of a COVID-19 vaccine, the Company's belief in the potential efficacy of its DPX-based vaccine against COVID-19, the Company's belief in the benefits of the third-party research and studies in related coronavirus and SARS studies and third-party sequencing data and their applicability to the Company's DPX platform and a DPX platform related vaccine, the expected milestone completion dates and the Company's anticipated results and expected timing of such results from its DPX cancer and infectious disease studies. Such statements 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 and uncertainties affecting the Company and its products. The Company 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 Company's ability to develop a DPX-based vaccine candidate against the COVID-19 through the successful and timely completion of clinical trials and studies, the receipt of all regulatory approvals by the Company to commence and then continue clinical studies, and, if successful, the commercialization of its proposed vaccine candidate related to COVID-19,*



*the Company's ability to raise sufficient capital to fund such clinical trials and studies and the production of any COVID-19 vaccine, the ultimate applicability of any third-party research and studies in related coronavirus and SARS studies and sequencing, the Company's ability to enter into agreements with the proposed lead investigators to assist in the clinical development on its vaccine candidate related to COVID-19, the Company's ability to collaborate with governmental authorities with respect to such clinical development, the coverage and applicability of the Company's intellectual property rights to any vaccine candidate related to COVID-19, the ability of the Company to manufacture any vaccine candidate related to COVID-19 rapidly and at scale and other risks detailed from time to time in the Company's ongoing filings and in its annual information form filed with the Canadian regulatory authorities on SEDAR as [www.sedar.com](http://www.sedar.com) and with the United States Securities and Exchange Commission on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar). Investors are cautioned not to rely on these forward-looking statements and are encouraged to read the Company's continuous disclosure documents which are available on SEDAR and on EDGAR.*

IMV INC.

Consolidated Statements of Loss and Comprehensive Loss

(In thousands of Canadian dollars, except shares and per share amounts)

	Years ended December 31,	
	2019	2018
	\$	\$
<b>Revenue</b>		
Subcontract revenue	59	82
Interest Income	509	401
Total revenue	568	483
<b>Expenses</b>		
Research and development	18,986	12,852
General and administrative	10,140	9,243
Government assistance	(2,432)	(1,062)
Accreted interest	1,239	1,385
Total operating expenses	27,933	22,418
<b>Net loss and comprehensive loss</b>	(27,365)	(21,935)
<b>Basic and diluted loss per share</b>	(0.55)	(0.50)
Weighted-average shares outstanding	49,653,578	43,766,951

IMV INC.

Consolidated Statements of Financial Position

(In thousands of Canadian dollars, except shares and per share amounts)

	December 31,		December 31,	
	2019		2018	
<b>Assets</b>				
Current assets				
Cash and cash equivalents	\$	14,066	\$	14,895
Accounts receivable		845		1,337

Prepaid expenses	3,032	2,699
Investment tax credits receivable	1,661	1,111
Total current assets	19,604	20,042
Property and equipment	2,830	2,883
Total assets	\$ 22,434	\$ 22,925

### Liabilities and Equity

#### Current liabilities

Accounts payable and accrued liabilities	\$ 6,157	\$ 7,575
Amounts due to directors	60	49
Current portion of long-term debt	88	81
Current portion of lease obligations	100	90
Total current liabilities	6,405	7,795
Lease obligation	1,208	1,308
Deferred share units	–	1,436
Long-term debt	8,373	8,069
Total liabilities	15,986	18,608
Equity	6,448	4,317
Total liabilities and equity	\$ 22,434	\$ 22,925

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