

May 15, 2020



# IMV Inc. Provides Clinical and Operational Update and Announces First Quarter 2020 Financial Results

- *Phase 2 SPiReL study of DPX-Survivac combination regimen with Keytruda® in r/r DLBCL successfully reached primary efficacy endpoint with 64% (7/11) of evaluable patients demonstrating a clinical response*
- *Translational and updated clinical response data from Phase 2 DeCidE1 study of DPX-Survivac in advanced ovarian cancer to be presented by Oliver Dorigo, MD, Ph.D., at the upcoming 2020 ASCO Virtual Scientific Program*
- *DPX-COVID-19, a vaccine candidate against COVID-19, on schedule to complete preclinical studies before the end of May and progressing towards initiation of Phase 1 study expected this summer*
- *Completed CAD \$25.1M private placement with new and existing institutional investors, extending cash runway well into 2021*
- *Management to host a conference call and webcast today 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 cancer immunotherapies and vaccines against infectious diseases, today announced financial results for the first quarter ended March 31, 2020 and provided an update on its clinical and operational progress.

"Despite the current pandemic, we have continued to validate our platform and advance our clinical pipeline targeting various cancers and other serious diseases, including COVID-19," said Frederic Ors, Chief Executive Officer at IMV. "Today, we are especially pleased to announce that SPiReL, a Phase 2 study of a DPX-Survivac combination regimen in patients with r/r DLBCL, has met its primary efficacy endpoint. This represents a significant milestone for DPX-Survivac, which has so far demonstrated the ability to shrink both solid and hematological tumors with long-lasting clinical responses and a differentiated safety profile. We believe these results in r/r DLBCL, taken together with emerging data from our DeCidE1 study in advanced ovarian cancer, support our plan to accelerate development in both of these indications."

Mr. Ors continued, "Our recent financing fortifies our corporate position, with cash to fund operations for more than 12 months and several milestones anticipated across our portfolio in the interim. We look forward to presenting translational and updated clinical response data from DeCidE1 at the ASCO20 Virtual Scientific Program, and to further updates from each of our Phase 2 studies of DPX-Survivac later this year. Additionally, we are preparing to advance a DPX-based vaccine candidate for COVID-19, which is on track to enter into clinical trials later this summer."

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

## **Phase 2 SPiReL Study in Recurrent / Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL)**

SPiReL is an investigator-initiated Phase 2 study evaluating DPX-Survivac/CPA in combination with Keytruda® (pembrolizumab) in r/r DLBCL. The study is led by Dr. Neil Berinstein, MD, FFCP®, ABIM, hematologist-oncologist at the Odette Cancer Centre at Sunnybrook Health Sciences Centre in Toronto, Ontario.

The study has met its primary efficacy endpoint with 64% (7/11) of evaluable patients demonstrating a clinical response so far. The study remains ongoing and the top line data are expected to be presented at a conference later in 2020.

In December 2019, updated clinical results were reported in a [poster presentation](#) at the American Society of Hematology (ASH) annual meeting in Orlando, FL. At the time of this presentation, 17 subjects were enrolled in the study, of which nine (9/17) were evaluable. At that time, three (3/9) complete responses (CR) and two partial responses (PR) had been observed, with an overall response rate (ORR) of 59% (5/9).

As of May 7, 2020, 20 patients have been enrolled across five different clinical sites in Canada.

## **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, IMV [reported interim data from this study](#), including:

- 15/19 (79%) evaluable subjects demonstrated disease control, including 10 tumor regressions (53%);
- 7/19 subjects (37%) achieved clinical benefit with partial response or stable disease 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 are available [here](#).

An abstract has been selected for a poster presentation at the upcoming American Society of Clinical Oncology (ASCO) [Virtual Scientific Program](#), which will be held May 29–31, 2020. The poster presentation by Oliver Dorigo, MD, Ph.D., Associate Professor of Obstetrics and Gynecology (Oncology), Stanford University Medical Center, Stanford, CA will provide translational data and an update on clinical responses and their duration.

## **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/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 May 7, 2020, a total of 92 patients out of the planned 184 patients were enrolled across all five indications at 19 clinical sites in Canada and the US.

The COVID-19 pandemic has impacted data collection and validation processes and IMV now anticipates reporting updated results from this study in the second half of 2020.

### **DPX-COVID-19 Vaccine Program Update**

In early March, IMV [announced plans](#) to develop a DPX-based vaccine candidate for COVID-19 in collaboration with experts in the field. IMV is on schedule to complete preclinical studies before the end of May and is on track to initiate a Phase 1 clinical study for DPX-COVID-19 this summer.

Since this update, IMV has met with Health Canada in preparation for its clinical trial application (CTA) and is in the process of finalizing its Phase 1 design. The randomized, placebo-controlled study will enroll approximately 84 healthy subjects in two age strata and will assess two different doses of DPX-COVID-19.

IMV has also submitted to relevant authorities' requests for grants for its DPX-COVID-19 program.

IMV will provide regular updates on the development of DPX-COVID-19 and more information can be found on the dedicated DPX-COVID-19 page on the Company's [website](#).

### **Update on Business and Clinical Operations in the Context of COVID-19 Pandemic**

IMV continues to closely monitor the COVID-19 pandemic and adapt its business operations while prioritizing the health and well-being of patients, clinical investigators, and personnel. In accordance with recommendations from health authorities, IMV has transitioned to a remote working arrangement to protect employees and the broader community while maintaining business continuity. All clinical trial sites remain open and active with a heightened focus on patient safety and data integrity. While the effects of the pandemic are expected to slow the pace of patient recruitment due to the diversion of healthcare resources to COVID-19 response activities, they have not had a material impact on the Company's financial condition, liquidity, or longer-term strategic development plans.

To date, the COVID-19 pandemic has impacted data collection and validation processes and as outlined above, this has delayed the planned readout from the Phase 2 basket study of DPX-Survivac/CPA in combination with Keytruda®. The Company continues to monitor this situation and will provide regular updates in the future.

### **Upcoming Milestones**

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

- Initiation of Phase 1 clinical trial for DPX-COVID-19 in the summer of 2020
- Top line Phase 2 clinical results update in the DLBCL combination trial in 2020

- Update on the Phase 2 clinical results in the ovarian monotherapy trial at ASCO 2020
- Updated Phase 2 clinical results for Basket trial in 2H 2020.

### **Overview of Q1 2020 Financial Results**

Research and development expenses increased by \$2,811,000 for the quarter ended March 31, 2020, compared to Q1 2019. These increases are mainly due to a spike in enrollment prior to the onset of the pandemic related to the ongoing basket trial and non-recurring purchases of GMP grade raw materials and contract manufacturing for DPX-Survivac. The purchases of GMP grade materials in 2019 and Q1 2020 covers all the needs of the Corporation for ongoing DPX-Survivac trials until mid-2021. The increase in research and development expenses is, to a lesser extent, also attributable to preclinical development of DPX-SurMAGE for bladder cancer and personnel costs due to an increase in headcount.

General and administrative expenses increased by \$1,073,000 for the quarter ended March 31, 2020 compared to Q1 2019. This increase is mainly due to non-cash DSU compensation caused by share price fluctuation, foreign exchange loss, and investor relations activities, including travel costs incurred prior to the start of the COVID-19 pandemic. The Company expects reduced comparative volatility in the DSU compensation expense from Q3 2020 onward as a result of electing to settle all future DSU redemptions in shares effective August 8, 2019.

The net loss and comprehensive loss of \$9,664,000 (\$0.19 per share) the quarter ended March 31, 2020 was \$3,721,000 higher than the net loss and comprehensive loss for the quarter ended March 31, 2019.

At March 31, 2020, the Corporation had cash and cash equivalents of \$7,372,000 and working capital of \$4,553,000, compared with \$14,066,000 and \$13,199,000, respectively at December 31, 2019. This does not reflect the proceeds from the CDN \$25,100,000 private placement completed on May 7<sup>th</sup>, 2020 or utilization of the ATM Distribution subsequent to the period end date. Based on its current plan, IMV expects its current cash position will be sufficient to fund operations for more than 12 months.

For the quarter ended March 31, 2020, 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 \$8,646,000. IMV expects the cash burn for the remainder of 2020 to return to \$5-6,000,000 per quarter due to the impact of COVID-19 and the non-recurring expenditures incurred in Q1 2020.

As of May 14, 2020, the number of issued and outstanding common shares was 60,454,474 and a total of 5,079,375 stock options, deferred share units and warrants were outstanding.

The Company's unaudited interim condensed consolidated results of operations, financial condition and cash flows for the quarter ended March 31, 2020 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 today, May 15, 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# 8081886 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 cancer immunotherapies and vaccines against infectious diseases 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-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. Visit [www.imv-inc.com](http://www.imv-inc.com) and connect with us on [Twitter](#) and [LinkedIn](#).

## **Cautionary Language Regarding 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 progress in developing a DPX-based vaccine candidate against COVID-19, the Company's belief that the DPX-based platform creates the opportunity for production of a COVID-19 vaccine, the Company's belief in the potential efficacy of its DPX-based vaccine against COVID-19, the anticipated timing of the Company's preclinical assays, studies and clinical trials related to its DPX-based vaccine against COVID-19 and the expected impact of COVID-19 on the Company's other clinical studies and trials and its operations generally. 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 preclinical assays, studies and clinical trials, the receipt of all regulatory approvals by the Company to commence and then continue clinical studies and trials, and, if successful, the commercialization of its proposed vaccine candidate related to COVID-19, the Company's ability to raise sufficient capital, including potentially through grant awards available in Canada, to fund such clinical studies and trials 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, the ability for the Company to accurately assess and anticipate the impact of COVID-19 on the Company's other clinical studies and trials and operations generally 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.

Unaudited Interim Condensed Consolidated Statements of Loss and Comprehensive Loss

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

	Three months ended, March 31,	
	2020	2019
	\$	\$
<b>Revenue</b>		
Subcontract revenue	–	8
Interest Income	68	74
Total revenue	<u>68</u>	<u>82</u>
<b>Expenses</b>		
Research and development	6,824	4,013
General and administrative	3,033	1,960
Government assistance	(558)	(346)
Accreted interest	433	398
Total operating expenses	<u>9,732</u>	<u>6,025</u>
<b>Net loss and comprehensive loss</b>	<u>(9,664)</u>	<u>(5,943)</u>
<b>Basic and diluted loss per share</b>	<u>(0.19)</u>	<u>(0.13)</u>
Weighted-average shares outstanding	<u>50,719,488</u>	<u>46,712,436</u>

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Financial  
Position

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

	March 31, 2020	December 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 7,372	\$ 14,066
Accounts receivable	653	845
Prepaid expenses	2,676	3,032

Investment tax credits receivable	1,886	1,661
Total current assets	<u>12,587</u>	<u>19,604</u>
Property and equipment	2,742	2,830
Total assets	<u>\$ 15,329</u>	<u>\$ 22,434</u>

### **Liabilities and Equity**

#### Current liabilities

Accounts payable and accrued liabilities	\$ 7,525	\$ 6,157
Amounts due to directors	64	60
Current portion of long-term debt	342	88
Current portion of lease obligations	103	100
Total current liabilities	<u>8,034</u>	<u>6,405</u>
Lease obligation	1,181	1,208
Long-term debt	<u>8,529</u>	<u>8,373</u>
Total liabilities	<u>17,744</u>	<u>15,986</u>
Equity	<u>(2,415)</u>	<u>6,448</u>
Total liabilities and equity	<u>\$ 15,329</u>	<u>\$ 22,434</u>

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<https://www.businesswire.com/news/home/20200515005219/en/>

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