

May 12, 2021



# IMV Inc. Announces First Quarter 2021 Financial and Operational Results and Expansion of its Clinical Pipeline

*Phase 2B study in r/r DLBCL to begin in Q2 of this year*

*New investigator-initiated study of maveropepimut-S in breast cancer to be initiated this summer*

*First in human dual-targeted immunotherapy (DPX-SurMAGE) study in bladder cancer later in the year*

*Two recognized senior leaders joined Board of Directors*

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 first quarter ended March 31, 2021.

"We remain focused on our commitment to provide effective and well-tolerated immunotherapies for patients with difficult-to-treat cancers. Clinical programs with our lead immunotherapy are progressing as expected, and we are pleased that maveropepimut-S will soon be evaluated in subjects with HR+/HER2- breast cancer, another unmet medical need," announced Fred Ors, Chief Executive Officer at IMV. "We are reaching another milestone as our second immunotherapy, DPX-SurMAGE, is entering into a clinical trial in patients with bladder cancer later this year with the support of a C\$1.8M grant. Also, we will now benefit from the expertise of two new board members who are recognized strategic thought leaders in immuno-oncology."

## **Clinical Programs**

### **Maveropepimut-S: Phase 2B Study in Relapsed/Refractory DLBCL ("r/r DLBCL")**

Following the results of the SPiReL study presented at *The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting* in November, the Company announced in April that it has entered into an agreement with Merck (NYSE: MRK) to initiate a Phase 2B clinical trial to evaluate its lead compound, maveropepimut-S in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy in r/r DLBCL. The study is expected to begin in Q2.

### **Maveropepimut-S: Phase 2 DeCidE1 Study in Advanced, Recurrent Ovarian Cancer**

IMV is currently analyzing translational data with the goal of identifying markers of activity to inform future development and to finalize the design of our Phase 2B trial.

## **Maveropepimut-S: Phase 2 Basket Trial in Multiple Advanced Metastatic Solid Tumors**

Enrollment continues for subjects with metastatic bladder cancer, liver cancer (hepatocellular carcinoma, HCC), and for the microsatellite instability high (MSI-H) tumors. IMV intends to provide a clinical update on the trial in the second half of this year.

## **Maveropepimut-S with Standard of Care, with/without Radiotherapy, or Cyclophosphamide in Breast Cancer**

This investigator-initiated clinical study will be conducted at the Providence Cancer Institute in Portland, Oregon. It is a three-arm Phase 1b trial designed to assess the combination of maveropepimut-S plus standard-of-care aromatase inhibitor with/without radiotherapy or CPA prior to surgery. Across the three arms of this study, IMV's lead compound will be evaluated in 18 subjects with resectable, non-metastatic HR+/HER2 high breast cancer.

The Hormone Receptive (HR+) and HER2 negative (HER2-) is the most common form of breast cancer representing more than 70% of all cases. Investigators at Providence have identified ki67 as a prognostic marker of resistance to treatment that is associated with the upregulation of survivin expression. Targeting survivin with maveropepimut-S T cell therapy in this population represents a promising approach that will be tested in the study.

This investigator-initiated clinical study is expected to begin during Q3 2021.

## **DPX-SurMAGE, a First-in-Human Dual T Cell Therapy for Bladder Cancer**

This IMV-sponsored trial will be led by [Yves Fradet, M.D.](#), professor of surgery and researcher in cancer immunotherapy at le *Centre de recherche du CHU de Québec-Université Laval* and his team, in collaboration with IMV's team.

Both survivin and MAGE-9 have been associated with a poorer prognosis in bladder cancer and represent promising therapeutic targets to improve outcomes. Dr. Fradet's team identified immunogenic peptides of the MAGE protein family member A9 (MAGE-A9), a protein which is frequently expressed in various human cancers including bladder, lung, and kidney. These peptides will then be combined with selected immunogenic peptides from the survivin protein. Researchers believe that the formulation of MAGE-A9 and survivin peptides with the DPX platform can generate a sustained, dual targeted T cell response that has the potential to destroy tumors with limited off-target events. Dr. Fradet and his team will evaluate DPX-SurMAGE in an initial clinical application in non-muscle invasive and muscle invasive bladder cancer.

IMV and the CHUQ have successfully completed preclinical evaluations which support the clinical development of DPX-SurMAGE in two distinct Phase 1 studies:

- DPX-SurMAGE with or without CPA prior to transurethral resection of recurrent low-grade or high-grade non-muscle invasive bladder cancer
- DPX-SurMAGE, CPA and anti-PD-1 for the treatment of muscle invasive bladder cancer prior and after cystectomy.

Based on the current timeline, IMV anticipates that the Phase 1 clinical study will be initiated in subjects with non-muscle invasive cancer in the second half of this year.

## **DPX-COVID-19: A DPX-Based Vaccine Candidate Against SARS-CoV-2**

Due to the evolution of the regulatory landscape and at the request of the Canadian regulatory authorities the Company is currently conducting complementary preclinical studies, including evaluating the impact of new variants, and will provide an update once these preclinical studies are completed.

### **Changes in Board of Directors and Management**

#### **Appointment of Mr. Kyle Kovalanka to the Board of Directors**

IMV recently announced the appointment of Mr. Kyle Kovalanka to the Board of Directors on April 1, 2021. Bringing over 20 years of experience as a senior leader in the biopharmaceutical industry, Mr. Kovalanka has a successful track record in forming and negotiating strategic collaborations, leading financings, facilitating strategy development, as well as building and directing business and finance functions. Currently, Mr. Kovalanka serves as Chief Financial Officer and Chief Operating Officer at Goldfinch Bio, a kidney precision medicines company.

#### **Appointment of Dr. Michael Kalos to the Board of Directors**

On May 11, 2021, IMV also announced the appointment of Michael Kalos, Ph.D. to its Board of Directors effective May 11, 2021. Dr. Kalos is an internationally recognized expert in T cell therapy and immunotherapy. He brings over 25 years of experience and expertise in cell therapy and immuno-oncology. In his career, Mr. Kalos served as Vice President of Immuno-oncology and Oncology Cell Therapies at Janssen and as Chief Scientific Officer of immuno-oncology at Eli Lilly.

Wayne Pisano, who has served on IMV's Board of Directors since October 2011, retired at the end of the quarter. James Hall will be retiring from the Board of Directors after the annual general meeting in June 2021. James served as a board member for more than 11 years. Andy Sheldon, Board Chairman of IMV, commented: "We are very grateful to Wayne and James for more than 10 years of dedicated service to IMV. On behalf of my fellow board members and IMV's management team, I would like to thank them for their long service and important contribution to the Company."

#### **Departure of Dr. Joanne Schindler**

Dr. Joanne Schindler gave her resignation as Chief Medical Officer (CMO) for personal reasons, effective June 11, 2021. Over the next weeks, Dr. Schindler will transition responsibilities while remaining fully empowered in her role as IMV's Chief Medical Officer. The Company is actively working with a recruitment firm to hire a new CMO who will drive maveropepimut-S towards registration. Fred Ors, CEO, commented: "We thank Joanne for her contribution during her tenure and wish her the best in the future."

### **Overview of First quarter 2021 Financial Results**

All dollar amounts noted herein are denominated in United States dollars (unless otherwise noted herein).

As of March 31, 2021, the Company had cash and cash equivalents of \$30.5 million and

working capital of \$31.6 million, compared with \$36.3 million and \$35.6 million, respectively as of December 31, 2020. Based on its current operating plan and not considering the \$47.7 million remaining under the \$50 million At-The-Market facility executed in October 2020, IMV expects its current cash position will be sufficient to fund operations until Q1 2022.

Research and development expenses were \$4.7 million for the three months ended March 31, 2021 compared with \$5.1 million for the three months ended March 31, 2020. This decrease of \$400,000 was mainly due to a decrease in expenses related to the ongoing basket trial and the timing of manufacturing activities for DPX-Survivac and DPX-SurMAGE, partly offset by an increase in personnel costs due to an increase in headcount, and pre-clinical development of DPX-COVID-19, which was offset by the increase in government assistance described below.

General and administrative expenses were \$3.2 million for the three months ended March 31, 2021 compared with \$2.3 million for the three months ended March 31, 2020. This increase of \$900,000 was mainly attributable to an increase in insurance premium following rate increases in mid-2020.

Government assistance totaled \$1.2 million for the three months ended March 31, 2021 compared with \$415,000 in Q1 2020. This increase is mainly explained by various government grants for the development of DPX-COVID-19, reimbursed for eligible development expenditures incurred to date.

The net loss and comprehensive loss of \$7.0 million (\$0.10 per share) for the three months ended March 31, 2021 was \$200,000 lower than the net loss and comprehensive loss of \$7.2 million (\$0.14 per share) for the three months ended March 31, 2020.

As of May 11, 2021, the number of issued and outstanding common shares was 67,795,933 and a total of 5,072,928 stock options, warrants 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, 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) as well as the Company's website at <https://www.imv-inc.com/investors/financial-information/financial-results>.

## **Selected Upcoming Milestones**

### **Maveropepimut-S**

- Q2 2021: Beginning of Phase 2B DLBCL trial
- Q2 2021: Translational and biomarker clinical update for ovarian cancer
- Q3 2021: Initiation of investigator-led study in breast cancer
- H2 2021: Meeting with FDA and final design for next clinical study in ovarian cancer
- H2 2021: Clinical update basket trial
- H1 2022: Clinical update Phase 2B DLBCL trial

### **DPX-SurMAGE**

- H2 2021: Initiation of a Phase 1 clinical study in bladder cancer

## Conference Call and Webcast Information

Management will host a conference call and webcast today May 12, 2021 at 8:00 a.m. ET. Investment professionals 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# 9284231

Other interested parties can 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 based on the Company's proprietary delivery platform (DPX). This patented technology leverages a differentiated mechanism of action that generates a targeted and durable immune activation with limited side effects. IMV's lead candidate, Maveropepimut-S, 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, breast cancer, as well as a combination therapy in multiple clinical studies with Merck. IMV is also evaluating DPX-SurMAGE, a dual targeted immunotherapy, in bladder cancer and 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 anticipated timing, enrollment of subjects and results from the Company's clinical studies and trials for its various drugs and therapies, the anticipated timing of meetings and submissions with the FDA for the Company's various drugs and therapies and the potential for synergistic action and results from the use of combined immunotherapies by the Company for various diseases. 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)

IMV INC.

**Consolidated Statements of Loss and Comprehensive Loss**

(In thousands of United States dollars, except for share and per share amounts)

	Three Months ended, March 31,	
	2021	2020
	\$	\$
<b>Revenue</b>		
Interest Income	69	51
Total revenue	<u>69</u>	<u>51</u>
<b>Expenses</b>		
Research and development	4,744	5,079
General and administrative	3,161	2,257
Government assistance	(1,234)	(415)
Accreted interest and valuation adjustments	355	322
Total operating expenses	<u>7,026</u>	<u>7,243</u>
<b>Net loss</b>	<u>(6,957)</u>	<u>(7,192)</u>
Currency translation adjustment	-	(47)
<b>Total comprehensive loss</b>	<u>(6,957)</u>	<u>(7,239)</u>
<b>Basic and diluted loss per share</b>	<u>(0.10)</u>	<u>(0.14)</u>
Weighted-average shares outstanding	<u>67,475,149</u>	<u>50,719,488</u>

IMV INC.

**Consolidated Statements of Financial Position**

(In thousands of United States dollars, except for share and per share amounts)

	March 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 30,453	\$ 36,268
Accounts receivable	967	1,574

Prepaid expenses	4,493	4,416
Investment tax credits receivable	1,250	1,519
Total current assets	<u>37,163</u>	<u>43,777</u>
Property and equipment	2,229	2,221
Total assets	<u>\$ 39,392</u>	<u>\$ 45,998</u>

### Liabilities and Equity

#### Current liabilities

Accounts payable, accrued and other liabilities	\$ 4,606	\$ 7,228
Current portion of long-term debt	868	856
Current portion of lease obligations	<u>113</u>	<u>109</u>
Total current liabilities	5,587	8,193
Lease obligation	936	953
Long-term debt	<u>6,271</u>	<u>6,050</u>
Total liabilities	<u>12,794</u>	<u>15,196</u>
Equity	<u>26,598</u>	<u>30,802</u>
Total liabilities and equity	<u>\$ 39,392</u>	<u>\$ 45,998</u>

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<https://www.businesswire.com/news/home/20210512005286/en/>

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