Clinical Response and Translational Data from DeCidE1, a Phase 2 Study of DPX-Survivac Immunotherapy in Patients with Advanced Recurrent Ovarian Cancer

Survivin-targeted T cell therapy continues to show significant, durable anti-tumor activity and is well-tolerated in this hard-to-treat cancer patient population.

5/19 patients (26%) achieved a partial regression on target lesions.

Strong translational data link the observed clinical benefits with DPX-Survivac’s unique mechanism of action; 87% of subjects showing survivin-specific immune response.

Poster to be presented by Oliver Dorigo, MD, Ph.D. at the ASCO20 Virtual Scientific Program.

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)--IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical-stage biopharmaceutical company pioneering a novel class of targeted cancer immunotherapies and vaccines against infectious diseases, today reported updated clinical response and translational data from DeCidE1, its Phase 2 study evaluating the safety and efficacy of DPX-Survivac with intermittent low-dose cyclophosphamide (CPA) in patients with recurrent, advanced platinum-sensitive and -resistant ovarian cancer.

Results from the ongoing study showed prolonged durable clinical responses, alongside...
favorable tolerability, and strong translational data linking the observed clinical benefit with DPX-Survivac’s mechanism of action. Oliver Dorigo, M.D., Ph.D., Principal Investigator of the DeCidE1 study, is presenting these results in a poster presentation at the American Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program.

“IMV’s targeted T-cell therapy continues to elicit a rapid and robust immune response with survivin-specific T cells infiltrating tumors as soon as 56 days post-treatment. These results validate DPX-Survivac’s unique mechanism of action and support the hypothesis that survivin-specific T cells can translate into clinical benefits when sustained over an extended period of time,” said Dr. Dorigo associate professor and director of gynecologic oncology at Stanford University. “These results support DPX-Survivac as a new and much-needed treatment option, with potential to improve the quality of life in women with recurrent late-stage ovarian cancer, a hard-to-treat indication where other immunotherapies have so far had limited success.”

“With these results, DPX-Survivac continues to exhibit significant and durable anti-tumor activity, paving the way for targeted T cell therapies in advanced recurrent ovarian cancer and other solid tumors. In particular, we are quite pleased to observe an additional patient with stable disease (SD) convert to partial response (PR), implying the potential for responses to deepen over time with ongoing therapy. Additionally, DPX-Survivac continues to be well tolerated, which is especially meaningful compared to single-agent chemotherapy and other approaches in development,” said Joanne Schindler, M.D., D.V.M., Chief Medical Officer at IMV. “We believe these results highlight DPX-Survivac’s potential to alter the treatment landscape in advanced ovarian cancer and support its continued development. We look forward to providing updates from other studies evaluating DPX-Survivac, in multiple solid tumors and r/r DLBCL, later this year.”

**Updated Results from DeCidE1**

As of data cut-off date, May 2, 2020, 19 patients were evaluable for efficacy with four patients (21%) still receiving treatment. Notably, 18/19 evaluable patients had stage 3 or 4 disease at time of diagnosis, the majority of whom had received ≥3 lines of prior therapy and were platinum resistant. Key findings on the safety and efficacy of DPX-Survivac/CPA are outlined below:

- 5/19 patients (26%) achieved a PR with tumor regression >30% on target lesions
- 15/19 patients (79%) achieved disease control, defined as Stable Disease (SD) or Partial Response (PR) on target lesions
- Tumor shrinkage of target lesions was observed in 10 patients (53%)
- Overall, treatment was well-tolerated. The majority of treatment-related adverse events reported were Grade 1 events and related to reactions at the injection site.

Durable clinical benefits lasting ≥ 6 months were observed in seven patients (37%)

- 5/7 patients (71%) have now reached duration of clinical benefit > 10 months including three patients with PR and two patients with SD
- The two patients with SD are about to reach the 1-year mark

Translational analyses on longitudinally collected peripheral blood mononuclear cell (PBMC) and tumor tissue samples link observed clinical benefit and survivin-specific T cells,
supporting DPX-Survivac’s unique mechanism of action. Key translational findings are outlined below:

- Treatment generated a survivin-specific CD8+ T cell response in PBMC samples of 14/16 (87%) evaluable patients.
- Treatment induced infiltration of survivin-specific T cell clones into the tumors as early as day 56 following treatment, which was shown in an analysis of the TCRβ repertoires in five subjects who achieved stable disease.

These data are presented in a poster session (Abstract Number: 6075) at the ASCO20 Virtual Scientific Program, available on-demand to ASCO20 participants beginning at 8:00 am ET on Friday, May 29, 2020. A copy of the poster is available under “Scientific Posters” in the "Events, Webcasts & Presentations" section of IMV’s website.

About the DeCidE1 Study

“DeCidE1” is a Phase 2 multicenter, open-label study evaluating the safety and effectiveness of DPX-Survivac, with intermittent low-dose cyclophosphamide (CPA) used as an immunomodulator to increase the level of survivin-specific T cells. This Phase 2 arm enrolled 19 evaluable patients with recurrent, advanced platinum-sensitive and –resistant ovarian cancer. Except for one patient, all patients had stage 3 or 4 disease at time of diagnosis. 12 patients had received 3 or more lines of prior therapy.

Patients received 2 subcutaneous injections of DPX-Survivac three weeks apart and every eight weeks thereafter, and intermittent low dose CPA one week on and one week off for up to 1 year. Paired tumor biopsies were performed prior to treatment and on treatment.

Primary endpoints of this study are overall response rate, disease control rate and safety. Secondary endpoints include cell mediated immunity, immune cell infiltration in paired biopsy samples, duration of response, time to progression, overall survival and biomarker analyses.

About DPX-Survivac

DPX-Survivac is the lead candidate in IMV’s new class of targeted immunotherapies designed to elicit antigen-specific functional, robust and sustained de novo T cell response. IMV believes this mechanism of action is key to generating durable solid tumor regressions. DPX-Survivac consists of five unique HLA-restricted survivin peptides formulated in IMV’s proprietary DPX drug delivery platform and known to induce a cytotoxic CD8+ T cell response against survivin expressing cancer cells.

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 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 drug delivery platform. 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. IMV is also developing a DPX-based vaccine to fight against COVID-19. Visit 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 FDA potentially granting accelerated regulatory approval of DPX-Survivac 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 Corporation, including access to capital, the successful design and completion of clinical trials and the receipt and timely receipt of all regulatory approvals. 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, our ability to access capital, the successful and timely completion of clinical trials and studies, the receipt of all regulatory approvals and 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 and on EDGAR at www.sec.gov/edgar

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Investor Relations
Marc Jasmin, Senior Director, Investor Relations, IMV
O: (902) 492-1819 ext : 1042
M: (514) 617-9481 E: mjasmin@imv-inc.com

Josh Rappaport, Director, Stern IR
O: (212) 362-1200
E: josh.rappaport@sternir.com
Media
Delphine Davan, Director of Communications, IMV
O: (514) 968-1046
E: ddavan@imv-inc.com

Source: IMV Inc.