IMV Inc. Presents Updated Positive Data From Phase 1b/2 Combination Clinical Trial in Advanced Ovarian Cancer at 2018 ESMO Immuno-Oncology Congress

73% of tumor regressions and 80% of clinical responses were observed in a subpopulation defined by a clinical biomarker based on Baseline Tumor Burden

All durable clinical responses continued beyond the one year of treatment, surpassing the progression-free interval from patients’ previous chemotherapy treatment

New data supports the correlation between DPX-Survivac’s novel T-cell activating mechanism of action and tumor regressions

IMV to hold investor call on Thursday, December 13, 2018 at 8:30 am ET to discuss data presented at the ESMO-IO meeting

DARTMOUTH, Nova Scotia, Dec. 13, 2018 (GLOBE NEWSWIRE) -- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical stage immuno-oncology corporation, today announced that investigators shared new positive data from the company’s ongoing DeCidE1 (DPX-Survivac with low dose Cyclophosphamide and Epacadostat) clinical trial at the 2018 ESMO Immuno-Oncology Congress. The phase 1b/2 study is evaluating the safety and efficacy of the combination of IMV’s lead candidate DPX-Survivac, low dose cyclophosphamide, and 100 mg or 300 mg of Incyte’s IDO1 enzyme inhibitor epacadostat in patients with advanced recurrent ovarian cancer.

In a poster presentation, Oliver Dorigo, M.D., Ph.D., Associate Professor of Obstetrics and Gynecology (Oncology), Stanford University Medical Center, who served as the trial’s lead investigator and author on the poster, shared topline safety results from 53 enrolled patients and efficacy data from the 32 participants evaluable for immune-related and clinical responses, as well as blood sample and tumor biopsy analyses.

Key findings include:

• Evidence of a clinical marker based on Baseline Tumor Burden (BTB), a measure of tumor size predictive of patient response to DPX-Survivac.
  ◦ 37.5% (12/32) of evaluable study subjects began treatment with a non-bulky disease defined as BTB < 5 cm.
  ◦ 73% (8/11) of tumor regressions and 80% of clinical responses (4/5) observed in subset of patients with BTB < 5 cm.
• Responders thus far showing prolonged duration of clinical benefits reaching up to more than two years, surpassing the progression-free interval from their previous
chemotherapy treatment.

- Robust systemic survivin-specific T cell responses and evidence of survivin-specific T cells tumor infiltration correlated with clinical benefits.
  - 100% of durable clinical responses correlated with T cell infiltration.
- Epacadostat triggered inhibition of the conversion of tryptophan into kynurenine that was dose dependent.
- Cohort demographics were balanced and the combination yielded a tolerable safety profile.

“This data set provided meaningful information on how the potential benefits of DPX-Survivac may best be translated to patients, including the connection between tumor regressions and T cell infiltration in the tumor microenvironment,” said Frederic Ors, Chief Executive Officer at IMV. “We believe that DPX-Survivac is the first targeted T cell therapy to induce significant tumor regressions in challenging tumors such as those seen in ovarian cancer. We remain committed to developing DPX-Survivac for patients with significant unmet medical needs, and look forward to our upcoming discussions with regulatory authorities in the USA, Canada and Europe.”

**Updated Clinical Response and Safety Data for DeCidE1**

At the time of data cut-off, 53 patients were enrolled in the phase 1b clinical trial, including 14 from the 100 mg epacadostat dosing cohort and 39 from 300 mg epacadostat cohort. Based on 300 mg cohort results, IMV and Incyte agreed to stop dosing patients with epacadostat before completion of the study. Patients who completed at least one CT scan, as required per the trial protocol, were evaluable for response analysis.

71% of patients were evaluable for responses in the 100 mg cohort and 56% in the 300 mg dose cohort. At time of data cut-off, 8 participants remained on treatment and were being evaluated for clinical responses.

<table>
<thead>
<tr>
<th>Efficacy Parameter</th>
<th>Total target lesion size &lt; 5 cm</th>
<th>Total target lesion size &gt; 5 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 mg (N=5)</td>
<td>300 mg (N=7)</td>
</tr>
<tr>
<td>Regression</td>
<td>Regression (N=5)</td>
<td>Regression (N=7)</td>
</tr>
<tr>
<td>PR(1)</td>
<td>5 (100)</td>
<td>3 (42.9)</td>
</tr>
<tr>
<td>PR(2)</td>
<td>3 (60.0)</td>
<td>1 (14.3)</td>
</tr>
<tr>
<td>SD(2)</td>
<td>2 (40.0)</td>
<td>4 (57.1)</td>
</tr>
<tr>
<td>DCR(3)</td>
<td>5 (100)</td>
<td>5 (71.4)</td>
</tr>
</tbody>
</table>

(1) Partial Response (PR) is defined as ≥30% decrease in sum of target lesions.
(2) Stable Disease (SD) is defined as < 30% decrease and ≤20% increase in sum of target tumor lesions.
(3) Disease Control Rate (DCR) refers to the total number of patients achieving complete response, partial response, and stable disease.

“Recurrent ovarian cancer treatment remains a significant unmet need and represents a
challenge for immunotherapy,” said Gabriela Nicola Rosu, M.D., Chief Medical Officer at IMV Inc. “What we have showed here is that the dynamic interaction between the survivin specific T cells induced by DPX-Survivac and the tumor size and its growth kinetics can be a determinant of clinical responses. We believe that this information is significant for the future development of DPX-Survivac and may indicate a pathway to more efficacious immunotherapeutic treatments for patients.”

Poster Session Details

Session: Poster Display Session
Title: Poster Display Session
Location: Foyer, Geneva Palexpo
Poster ID: 87P; Abstract ID 262
Abstract Title: “New clinical data from the DeCidE1 trial: Results on DPX-Survivac, low dose cyclophosphamide (CPA), and epacadostat (INCB024360) in subjects with advanced recurrent epithelial ovarian cancer”
Date: December 14 - 15, 2018
Time: 12:30 p.m. - 13:00 p.m. (local time)
Presenter: Dr. Oliver Dorigo, DeCidE1 Clinical Investigator and Lead Author

Investor Call Information

IMV will host a webcast and conference call on Thursday, December 13 at 8:30 a.m. ET to provide an overview of its ESMO-IO presentation.

- Dial-in: (844) 461-9932 (U.S. and Canada) or (636) 812-6632 (International)
- Conference ID#: 6192578
- A live audio webcast and presentation will be available via this link, or by pasting this URL in an internet browser: https://edge.media-server.com/m6/p/5uokxhky

About the DeCidE1 Phase 1b/2 Trial

The phase 1b/2 trial is an open label, uncontrolled, safety and efficacy study for individuals with advanced, platinum-sensitive and resistant ovarian cancer. The phase 1b portion has two dosing cohorts:

- 100 mg of epacadostat twice daily (BID), with DPX-Survivac and low dose cyclophosphamide, and
- 300 mg of epacadostat BID in combination with DPX-Survivac and low dose cyclophosphamide.

The primary endpoints are to determine:

- The safety profile of the combination regimen,
- Induction of systemic survivin-specific T cells in the blood, and
- Induction of T cell infiltration into tumors.

Secondary endpoints include objective response rate (ORR) using modified RECIST v1.1
criteria; duration of response based on modified RECIST criteria; time to progression (TTP); and overall survival (OS).

IMV conducted the phase 1b/2 study in collaboration with Incyte Corporation. IMV recently announced that, based on the 300 mg cohort results, **IMV and Incyte have agreed to stop dosing patients in this trial with epacadostat**. IMV is continuing the phase 2 portion of the trial as a monotherapy study evaluating DPX-Survivac in the advanced and recurrent ovarian cancer subpopulation with BTB < 5 cm.

IMV intends to report updated results from the phase 1b when data from at least 16 evaluable participants in the second dosing cohort are available. Investigators plan to submit final results for publication in a peer-reviewed journal.

**About Ovarian Cancer**

According to the American Cancer Society (ACS), ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. Often diagnosed in its advanced stages, about 21,290 women received a new diagnosis of ovarian cancer in 2015; approximately 14,180 women would die from the disease, according to ACS estimates.

Ovarian cancer has a significant impact globally as well. The World Cancer Research Fund reports that ovarian cancer is the seventh most common cancer in women worldwide (18 most common cancer overall), with 239,000 new cases diagnosed in 2012.

**About IMV**

IMV Inc., formerly Immunovaccine 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 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 combination therapy in multiple clinical studies with Incyte and 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. 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 completion of clinical trials and 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, 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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