

September 27, 2018



IMV Provides Update on Progress of its DPX-RSV Program

New Proof of Concept Animal Health Data Validate RSV Vaccine Candidate's Novel Mechanism of Action and Its Potential to Impact RSV Pathology

DARTMOUTH, Nova Scotia, Sept. 27, 2018 (GLOBE NEWSWIRE) -- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical stage immuno-oncology corporation, today announced results of ongoing research to further explore the novel mechanism of action (MOA) of its DPX-RSV vaccine candidate for respiratory syncytial virus (RSV).

New data from a preclinical study highlighted the effects of two potential approaches to preventing RSV, comparing a single dose bovine version of DPX-RSV to a two-dose conventional investigational bovine RSV vaccine. Researchers found that IMV's vaccine candidate yielded strong antigen-specific immune responses and a protective effect on disease pathology. The degree of protection was comparable between the two vaccine candidates.

"While we remain focused on advancing our immuno-oncology clinical program, it is our intention to partner our DPX technology in other applications, including infectious diseases," said [Frederic Ors, Chief Executive Officer, IMV Inc](#) "We are pleased to see additional single-dose data supporting our differentiated approach to addressing RSV, and we believe that demonstrations of this unique MOA will further bolster our business development efforts to progress this asset."

Conventional RSV vaccine candidates target either the F or G proteins of the virus, providing protection by neutralizing the RSV virus. Clinical measures of efficacy focus on the amount of neutralizing antibodies in the bloodstream.^{i,[ii]} DPX-RSV works differently; it targets the SH viral ectodomain of the RSV virus, and, instead of neutralizing the virus, it enables the immune system to recognize and destroy infected cells. Because there are no neutralizing antibodies resulting from the DPX-RSV MOA, a different clinical assessment is required to determine the vaccine candidate's protective effect.

In this study, researchers compared the effects of both the IMV and conventional RSV vaccine approaches among bovines with known RSV infections (The bovine animal model is considered an optimal model of RSV infection.)^{iii,[iv]} Researchers administered one dose of DPX-bRSV to one cohort; the second received two doses of a subunit RSV bovine vaccine. Researchers measured immune response with an antibody titer test, and assessed disease pathology with a lung lesion score and other clinical parameters (such as body temperature changes).

They found SH antibodies in 14 of the 15 subjects that received DPX-bRSV, and the

improvements observed in disease pathology were comparable between the two cohorts. These were the first bovine animal health data to directly correlate the vaccine-induced immune response against IMV's novel RSV target - the SH viral protein— with measures of disease protection.

“We engaged in these studies to demonstrate that the unique immune response induced by DPX-RSV could provide protection against RSV infections,” said [Marianne Stanford, PhD, Vice President, Research, IMV Inc.](#) “We believe that the key takeaway is that these results underscore the viability of a novel MOA in providing benefit compared to traditional approaches. Our earlier Phase 1 clinical study of DPX-RSV provided impressive immunogenicity results and a tolerable safety profile. These additional data help to connect the dots of that immune response to its impact on disease pathology.”

IMV is also collaborating on additional studies to further demonstrate the validity of DPX-RSV's novel MOA. These include an academic collaboration to assess the levels of SH-specific antibodies present in the elderly population following RSV infections, and an ongoing collaboration with an undisclosed partner on the development of a SHe human monoclonal antibody.

IMV and its research partners plan to present complete data for these ongoing studies at an upcoming scientific conference or publish the results in a peer-reviewed scientific journal.

About RSV

Respiratory syncytial virus (RSV) is a common virus that infects the lungs and breathing passages. While it usually leads to mild, cold-like symptoms, it can be severe in elderly adults, infants, and individual with compromised immune systems. It is second only to influenza as the most commonly identified cause of viral pneumonia in older persons. Globally, it is estimated that [64 million cases of RSV infection occur annually](#) in all age groups, with 160,000 deaths. There is no vaccine currently available to prevent RSV.

About DPX-RSV

DPX-RSV is IMV's prophylactic, small B-cell epitope peptide vaccine candidate designed specifically to address the unmet medical needs in respiratory syncytial virus (RSV). DPX-RSV targets the SH antigen of RSV, which may provide additional immunogenic benefit over traditional approaches for high-risk populations, including infants and the elderly.^v Scientists from VIB and Ghent University (Belgium) demonstrated the protective potential of the ectodomain of the small hydrophobic (SH) protein of RSV as a vaccine antigen.^{vi} In addition, the concentrated dosage enabled by the DPX delivery system may help mitigate injection site point-of-pain, which has been a limitation for other potential treatments. [IMV reported Phase 1 data for DPX-RSV at the 12-month time point](#), in which 100 percent of healthy older adult volunteers who responded to vaccine achieved a sustained antigen-specific immune response that remained at peak one year post-vaccination. IMV holds exclusive worldwide license on applications that target the SH ectodomain antigen in RSV from VIB and Ghent University.

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.

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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ⁱ RSV Vaccine and mAb Snapshot. (2018, September) Retrieved from URL: <https://www.path.org/resources/rsv-vaccine-and-mab-snapshot>

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v Schepens, Bert, Michael Schotsaert, and Xavier Saelens. “Small Hydrophobic Protein of Respiratory Syncytial Virus as a Novel Vaccine Antigen.” *Immunotherapy* 7.3 (2015): 203-06. DOI: 10.2217/IMT.15.11

vi MS. Schepens et al, *EMBO Mol Med* 2014 6:1436-1454



Source: IMV Inc.