Medicago and IDRI Reports Positive Results for its Phase I Clinical Trial for an H5N1 Vaccine

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QUEBEC CITY, and SEATTLE, WA, April 17, 2013 /PRNewswire/ - Medicago Inc. (TSX: MDG; OTCQX: MDCGF), a biopharmaceutical company focused on developing highly effective and competitive vaccines based on proprietary manufacturing technologies and Virus-Like Particles (VLPs) and The Infectious Disease Research Institute (IDRI), a Seattle-based non-profit research organization that is a leading developer of adjuvants used in vaccines combating infectious disease, today reported positive interim results from a Phase I clinical trial for an H5N1 Avian Influenza VLP vaccine candidate ("H5N1 vaccine"). The results were announced at the World Vaccine Congress in Washington, DC. The H5N1 vaccine was found to be safe and well-tolerated and induced a solid immune response exceeding the three CHMP (Committee for Medicinal Products for Human Use) immunogenicity criteria for licensure of influenza vaccines. The vaccine was tested in three different configurations: using IDRI's Glucopyranosyl Lipid A ("GLA") formulated adjuvant, given both intramuscularly and intradermally, and using alum intramuscularly. All three configurations exceeded the CHMP criteria.

"These positive U.S. clinical trial results confirm that our H5N1 vaccine candidate is the best in class in our opinion, positioning Medicago as a significant player in the global pandemic market. The robustness of our H5N1 vaccine coupled with our rapid speed of production, offers a vastly improved solution in preparing for and managing potential pandemics. We also believe that our H5N1 vaccine with alum is the only alum-adjuvanted pandemic vaccine to achieve the three CHMP immunogenicity criteria," said Andy Sheldon, President and CEO of Medicago. "Moreover, the combination of our vaccine candidate with IDRI's adjuvant generated a robust immune response. In the case of a pandemic, governments will require the rapid development of an effective vaccine within their borders to conquer the spread of the virus, with our cost-effective and capital inexpensive system we are perfectly poised to obtain this objective. In summary, all three configurations tested of the H5N1 vaccine meet the CHMP criteria for licensure, placing us in a strong position with multiple product options. We will further investigate the use of alum and formulated GLA in a Phase II trial to be initiated in May 2013 with results expected in Q3 2013."

The trial results also underscore IDRI's leadership position in the field of adjuvants, with a focus on developing products that will reduce the burden of global infectious disease. "This study design and results demonstrate the potential for significant 'dose-sparing' -- increasing the number of available doses by reducing the amount of vaccine needed per individual, in a simple to administer format" said Dr. Steven Reed, IDRI Founder, President and Chief Scientific Officer, who presented the trial results at the World Vaccine Congress, along with Dr. Brian Ward, Professor of Medicine & Microbiology, McGill University, member of Medicago's scientific advisory committee and Medical Officer. "This H5N1 vaccine candidate represents the next generation of flu vaccines, combining our adjuvant technology with Medicago's rapid VLP technology and the intradermal delivery device from NanoPass."

Study Design
The Phase I clinical trial, which commenced in September 2012, enrolled 100 healthy adult volunteers, aged 18-49 years, at three locations in the U.S., testing for safety and immune response. The vaccine was also tested in comparison to Medicago’s H5N1 vaccine with alum. The trial is funded by a multi-million dollar grant IDRI received from the Defense Advanced Research Projects Agency (DARPA), a division of the United States Department of Defense, to investigate the safety and immunogenicity of a novel adjuvant with a Nicotiana benthamiana produced vaccine candidate. Each study participant in the trial received two doses of a given formulation in order to collect and compare data.

The trial focused on evaluating the safety and immunogenicity of the H5N1 vaccine, combined with IDRI's GLA adjuvant, which has been exclusively licensed to Immune Design Corp for certain fields, including influenza. The vaccine was administered intramuscularly or intradermally. The intradermal route of administration was also tested in comparison with intramuscular delivery, using an FDA licensed device (MicronJet600®, NanoPass Technologies) as the micro-needle device was previously shown in seasonal and pandemic flu tests to allow significant dose sparing. This study is among the first to test intradermal adjuvants and is the first time GLA has been tested intradermally.

Safety and Immunogenicity Results

The H5N1 vaccine candidate has been tested in over 300 healthy volunteers to date, none of which have experienced any serious adverse reactions. The H5N1 vaccine candidate was found to be safe and well tolerated. As planned in the clinical design, monitoring of adverse events will continue for one year.

All three configurations of adjuvant and route of administration for 20ug of the H5N1 vaccine candidate induced a solid immune response against the H5N1 viral strain that exceeded the CHMP immunogenicity criteria for licensure of influenza vaccines which are 40% seroconversion, 70% seroprotection and 2.5x geometric mean increase (GMI). For a 20ug dose of the H5N1 vaccine plus; 2.5ug GLA-AF administered intradermally (ID), 2.5ug GLA-AF delivered Intramuscularly (IM) and 0.5ug alum formulation administered IM, a four-fold increase in HI titers (seroconversion) was observed in 65.0%, 80.0% and 83.3% of subjects, respectively. The seroprotection rate was 70.0%, 85.0% and 89.9%, respectively. The GMI was 10.3x, 8.7x, and 11.4x, respectively.