IDRI and Medicago announce authorization to initiate a Phase 1 clinical trial for an H5N1 vaccine

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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, and 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), announce that they have been cleared by the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial for an H5N1 Avian Influenza VLP vaccine candidate ("H5N1 vaccine"). This is an important step toward development of an influenza vaccine that could be rapidly and widely administered in case of a pandemic flu outbreak. The trial is focused on evaluating the safety and immunogenicity of the H5N1 vaccine, combined with IDRI's Glucopyranosyl Lipid A ("GLA") adjuvant, which will be administered intramuscularly or intradermally. Each study participant in the trial will receive two doses of a given formulation in order to collect and compare data.

The trial is believed to be the first human test of an intradermal adjuvant – a technology platform that could potentially benefit a number of worldwide vaccination programs – and could result in a vaccine that could be self-administered in case of a pandemic. "A massive flu outbreak would cause a strain on health care centers as people rush to get a vaccination," said Darrick Carter, Ph.D., Vice President of IDRI's

Adjuvant Technology program and co-principal investigator for the project. "Our idea is to ultimately produce a one-dose vaccine that you could give yourself – imagine a flu vaccine that you can easily administer using a simple, painless microneedle device arriving in your mailbox."

"This research collaboration may provide for expedited vaccination and greater ease of use in the event of an influenza pandemic," said Andy Sheldon, President and Chief Executive Officer of Medicago. "We view our collaboration with IDRI on this important initiative as a testament to the quality and efficacy of our H5N1 Influenza VLP vaccine. We look forward to now combining our vaccine candidate with IDRI's adjuvant and the microneedle technology. Together, these three technologies could enhance protection, reduce the amount of product required, and simplify vaccine distribution and administration."

According to the Centers for Disease Control and Prevention, the highly pathogenic avian influenza A (H5N1) virus is a deadly virus that occurs mainly in birds including domestic poultry. Though relatively rare, sporadic human infections with this virus have occurred and caused serious illness and death. Because of the unpredictability of pandemic flu, efforts are being made to create and stockpile a vaccine to combat H5N1 that reduces the amount of vaccine needed per person and can be easily administered.

"The predicted efficacy of a pandemic influenza vaccine is directly related to three key components: the nature of the vaccine, the way the vaccine is administered, and the presence or absence of a given adjuvant," said Steven Reed, Ph.D., IDRI's President, Founder and Chief Scientific Officer, and co-principal investigator for the project. "IDRI's adjuvants can be used to increase the number of available vaccine doses by reducing the amount of vaccine needed per individual – this is called 'dose sparing.' Combining our adjuvant technology with Medicago's

rapid VLP technology is key to the next generation of flu vaccines, as well as an innovative delivery method from NanoPass. This gives us a great platform to test."

The H5N1 vaccine candidate includes IDRI's GLA adjuvant and is produced in Medicago's plant-based expression system, which is speedier than the traditional route of producing flu vaccines in eggs. The adjuvant system has been successfully combined with Medicago's vaccine candidate and other recombinant protein antigens to elicit both humoral and cell-mediated immune responses associated with protection in pathogenic animal challenge models. In animal studies, GLA has also been shown to expand the cross reactivity of antibodies induced by the H5N1 vaccine to other potential pandemic influenza strains such as H2N2.

The Phase 1 clinical trial is expected to start in September 2012, and will enroll 100 healthy adult volunteers, ages 18-49 years, at three locations in the U.S., testing for safety and immune response. The trial is anticipated to take 15 months to complete, and initial safety and immunology data are expected in the first quarter of 2013. It 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 develop an influenza vaccine for pandemic flu.

While the trial will include testing of the traditional intramuscular route of delivery for comparison purposes, NanoPass' proprietary MicronJet600™ microneedle device will test the intradermal route that could further improve immunogenicity. "Intradermal injection may have advantages over the intramuscular route in that the injection is painless, needle-free, and potentially more immunogenic as it provides targeted delivery of the vaccine to specialized cells of the immune system," said Yotam Levin, M.D., Chief Executive Officer of NanoPass. "We have

demonstrated in a recent Phase 2 study that we actually improve the immune response of seasonal flu vaccines in the elderly, despite using only 20% of the dose. This is an enabling technology that allows reducing the dose of antigens and/or adjuvants, improving the vaccination effect and at the same time improving patient comfort and compliance, making it an attractive proposition for pandemic preparedness."

In June 2011, Medicago reported positive final results from its Phase 2 human clinical trial with its H5N1 vaccine with an alum adjuvant. Healthy volunteers in the Phase 2 trial received two doses 21 days apart, and data were analyzed 21 days after the last dose. The vaccine induced a solid immune response and was found to be safe and well-tolerated. The H5N1 vaccine has been tested in over 200 healthy volunteers to date, none of whom experienced any serious adverse reactions.

Provided by Infectious Disease Research Institute