

## Medicago achieves milestone in VLP vaccine production

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**Singapore:** Medicago, a biopharmaceutical company focused on developing highly effective and competitive vaccines based on proprietary manufacturing technologies and virus-like particles (VLPs), has achieved successful completion of a key milestone under an agreement with the Defense Advanced Research Projects Agency (DARPA). The milestone was the production of at least 10 million doses of H1N1 VLP influenza vaccine candidate in one month. This rapid fire test was conducted at Medicago's facility in Durham, North Carolina.

As part of the rapid fire test, production of the H1N1 VLP influenza vaccine candidate began on March 25, 2012, and was completed in 30 days on April 24, 2012. The production lots were then tested by a third party laboratory to confirm both the immunogenicity of the vaccine candidate and the number of doses produced. Testing confirmed that a single dose of the H1N1 VLP influenza vaccine candidate induced protective levels of neutralizing antibodies in an animal model. Significantly more than 10 million doses, as defined by the testing conditions, were confirmed.

"The completion of the rapid fire test marks a substantial achievement in demonstrating our technology and the potential for Medicago to be the first responder in the event of a pandemic flu outbreak," said Andy Sheldon, chief executive officer, Medicago. "We look forward to continuing to move our company closer to commercial capability in the near future."

The rapid fire test is the fifth milestone under a Technology Investment Agreement with the DARPA to demonstrate the scalable manufacturing of Medicago's plant-expressed VLP vaccines in the US. To date, Medicago has received \$19.8 million in milestone payments from the DARPA for this project, and expects to receive the fifth milestone payment of \$1 million in the near future.

"All of the milestones in the DARPA agreement were rigorous and challenging. Production of significantly more than 10 million doses in 30 calendar days was the key milestone in terms of demonstrating Medicago's capability to meet critical unmet needs in the area of pandemic flu response. Reaching this goal is also a testament to our experienced and dedicated North American team," said Mike Wanner, Executive Vice President Operations. "Our outside partnerships were also

instrumental in helping meet this milestone, including Alexandria Real Estate and the State of North Carolina."

Medicago previously signed a \$21 million Technology Investment Agreement with the DARPA to develop a 97,000-square-foot vaccine facility in Research Triangle Park (RTP), North Carolina. This state of-the-art facility is a large, cost-effective and scaled-up facility for Medicago's VLP plant-based vaccine technology, ultimately for the delivery of current good manufacturing practice (cGMP)-grade vaccine. This DARPA project is part of the Blue Angel influenza vaccine rapid response demonstration program which seeks to identify new ways to produce large amounts of high quality vaccine grade protein in less than 3 months in response to emerging and novel biologic threats.

Medicago's pipeline includes the initiation of a US Phase IIa clinical trial for a quadrivalent seasonal flu vaccine with interim data expected in the first quarter of 2013. A phase I clinical trial for a one-dose H5N1 VLP vaccine with a new adjuvant is planned in partnership with the Infectious Disease Research Institute (IDRI), with interim data expected in the second half of this year. GMP process development and a GLP toxicology study for a rabies vaccine are ongoing. Medicago is also working with Mitsubishi Tanabe Pharma under a strategic alliance to develop a vaccine for rotavirus, and at least two additional vaccine candidates. In addition to vaccines, Medicago is conducting research and development in the area of biosimilar products.