



## FluGen Initiates a Phase 1 Clinical Trial of the RedeeFlu™ Universal Influenza Vaccine in Healthy Subjects

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MADISON, WI, July 27, 2016 – FluGen Inc., a clinical-stage biopharmaceutical company focused on the discovery and development of more effective influenza vaccines, today announced the initiation of the first Phase 1 clinical trial of its RedeeFlu™ universal influenza vaccine. The trial is a randomized, blinded, dose-ranging Phase 1 study of the H3N2 RedeeFlu™ influenza vaccine in 96 healthy adult subjects between 18 and 49 years of age. In addition to the trial’s primary goal of evaluating the safety of the vaccine in this population, the study also will evaluate both antibody and T-cell responses induced by the vaccine.

“The initiation of this first in man study is an important milestone achieved through the research and development efforts of the FluGen team and our collaborators. We believe that RedeeFlu™ could be the first influenza vaccine to show robust protection from drifted or mismatched flu strains,” said Paul V. Radspinner, President & CEO.

During the 2014-15 flu season in the US, the chosen vaccine strain was different than the “drifted” circulating virus. As a result, the existing flu vaccines had dramatically reduced efficacy. During the 2015-16 flu season questions have been raised about the effectiveness of live attenuated influenza vaccines. The RedeeFlu™ vaccines are novel, M2-deleted single replication (M2SR) viruses that rapidly induce antibody and cellular immune responses similar to wild type influenza, but cannot produce infectious virus. In multiple preclinical models, RedeeFlu™ (M2SR) vaccines have demonstrated superior protection against both drifted and completely mismatched strains of influenza when compared to other live or inactivated influenza vaccine technologies. RedeeFlu™ vaccines also have protected against influenza in older animals and in the face of pre-existing immune responses.

“Most of the morbidity and mortality associated with influenza is experienced by young children and older adults,” said Dr. Dan Stinchcomb, Executive Chairman. “This trial is the first step in a clinical development plan designed to assess the safety of H3N2 RedeeFlu™ (M2SR) and to demonstrate the breadth of protection in multiple age groups. If our preclinical results are reproduced in human clinical studies, RedeeFlu™ (M2SR) could meet a significant global health need”.

Additional information regarding the Phase I clinical trial can be found under ClinicalTrials.gov identifier NCT02822105.

### **About Influenza**

Influenza (flu) is a contagious respiratory disease caused by influenza viruses. The influenza virus is transmitted

easily from person to person via droplets and small particles produced when infected people cough or sneeze. Influenza tends to spread rapidly in seasonal epidemics. Infection usually lasts for about a week, and is characterized by sudden onset of high fever, aching muscles, headache and severe malaise, non-productive cough, sore throat and rhinitis. Some people are at high risk for serious flu complications, including the elderly, young children, pregnant women, and people with certain health conditions such as asthma, chronic lung disease, diabetes, heart disease, blood, kidney or lung disorders, or weakened immune systems. Worldwide, it is estimated that 3 to 5 million cases of severe influenza and 250,000 to 500,000 influenza-related deaths occur every year.

### **About FluGen, Inc.**

FluGen, Inc. is a privately held biotechnology company founded in 2005 and based in Madison, WI. The company has been developing novel influenza vaccine technology first invented at the University of Wisconsin-Madison, in the laboratories of Dr. Yoshihiro Kawaoka and Dr. Gabriele Neumann, and exclusively licensed to FluGen by WARF. The RedeeFlu™ influenza vaccine contains mutations in the M2 gene of the virus. The mutated virus can infect cells, express the entire spectrum of influenza RNA and proteins, yet fails to produce any infectious virus particles. Thus, the vaccine does not shed infectious virus and does not cause any pathological signs of infection. In multiple animal models, RedeeFlu™ is safe yet induces robust innate, antibody and cellular immune responses that can protect against “drifted” or even mismatched influenza strains. The Company is developing RedeeFlu™ to address two unmet needs in the prevention of human influenza: better protection against influenza in the elderly and better protection against drifted influenza strains that can cause influenza epidemics. More information is available at [www.flugen.com](http://www.flugen.com).