FLUGEN COMPLETES DOSING OF PHASE 2 STUDY TO ASSESS EFFECTIVENESS OF NOVEL INFLUENZA VACCINE DESIGNED TO PROTECT AGAINST MISMATCHED STRAINS

—Influenza challenge virus genetically drifted by six years from vaccine strain —
MADISON, Wis., October 15, 2018—FluGen, Inc. announced today that all subjects have completed dosing in a first-of-its-kind clinical study which challenged subjects with an influenza virus that was intentionally mismatched by six years from the influenza strain utilized in FluGen's M2SR vaccine.

The primary endpoint of the study is influenza infectivity in the placebo group compared to the group vaccinated with FluGen's novel intranasal M2SR vaccine. Safety and immunogenicity data also will be evaluated for all subjects.

"Since 2004, there have been at least five influenza seasons where the recommended influenza vaccine has not matched one of the common circulating strains in the U.S., which has resulted in lower vaccine efficacy with a result of significant breakthrough illnesses and mortality. Imagine if a vaccine could protect people from the flu, even when such a mismatch occurs. The implications for improvement of influenza vaccine efficacy are significant," said Robert Belshe, M.D., chair of the FluGen clinical advisory board and the Diana and J. Joseph Adorjan Endowed Professor of Infectious Diseases and Immunology, Emeritus, at Saint Louis University.

The FluGen vaccine utilizes a proprietary M2 deleted, single replication (M2SR) influenza virus. The M2 gene is essential for the influenza virus to spread in the patient and the deletion of the M2 gene restricts the virus to a single replication cycle in the host. The body recognizes M2SR as an influenza infection and activates its robust immune response, but, because the virus can only replicate once, it cannot spread to other cells and cause symptoms of a real-world infection.

Patients naturally infected with wild type influenza often are protected from future influenza illness for many years. By convincing the body it has been infected with influenza, the M2SR vaccine is designed to activate this broad and durable wild type immune response, without causing influenza disease.

"This is a bold study which, if successful, would significantly advance our progress towards developing a flu vaccine which could provide broader protection against influenza," said Paul Radspinner, chief executive officer of FluGen.

Study Design
In the study, being conducted by SGS in Belgium, more than 100 subjects were randomized 1:1 to receive either intranasal placebo, or a single intranasal dose of M2SR vaccine, manufactured with the A/Brisbane/10/2007, H3N2 strain of influenza, which was utilized in marketed influenza vaccines during the 2008-2010 influenza seasons.

Subjects were then challenged intranasally with the A/Belgium/4217/2015, H3N2 influenza virus, which is a genetically drifted virus that caused outbreaks of influenza in 2015. Following influenza challenge, subjects were assessed for safety, infection with the challenge strain and clinical signs and symptoms. Subjects are being followed on an ongoing basis for four months.

The study is supported by a $14.4 million grant from the Department of Defense. The U.S. Army Medical Research Acquisition Activity is the awarding and administering acquisition office and this work was supported by the Office of the Assistant Secretary of Defense for Health Affairs through the Peer Reviewed Medical Research Program under Award No. W81XWH-17-1-0430.

A prior Phase 1a study of FluGen's M2SR vaccine in 96 subjects showed the vaccine to be generally safe and well tolerated, and to generate a robust immune response.