

Naobios manufactures FluGen Inc's M2SR influenza vaccine candidate for upcoming clinical trials

Naobios' development work and GMP manufacturing of vaccine clinical batches will enable FluGen to prepare its 2022 clinical trials in the United States

Nantes, France, September 21, 2021 – Naobios, a CDMO (Contract Development and Manufacturing Organization) providing bioprocess development and GMP production of clinical batches of viral vaccines BSL2/BSL3, oncolytic viruses and viral vectors, today announces the next phase in its partnership with FluGen, Inc., a clinical-stage vaccine company transforming vaccine efficacy in infectious respiratory diseases. Naobios will initiate the GMP manufacturing of the clinical batches of FluGen's M2SR influenza vaccine-candidate, in preparation for their upcoming clinical trials - commencing in 2022 in the United States.

Since 2019 Naobios and FluGen have collaborated on the process development of a scalable platform for FluGen's M2SR vaccine. The company's lead candidate is a supra-seasonal, live, single-replication, intranasal flu vaccine. Unlike standard of care flu vaccines, M2SR stimulates mucosal, humoral and cellular immunity.

"Manufacturing is a critical component of clinical trial execution; the success of a study is often highly dependent on the standards to which comparative viruses are developed," said Paul Radspinner, president and CEO of FluGen, Inc. "We are pleased to continue our work with Naobios, a trusted partner that has consistently provided excellence in both standards and quality. We look forward to working with them throughout the execution of the clinical trials for our investigational intranasal M2SR influenza vaccine."

"Cell-based manufacturing of influenza vaccines has been a vexing challenge for our industry for a long time. We are really excited by the results obtained so far during the process development and we're looking forward to the manufacturing of this first GMP batch for FluGen's clinical trials," said Eric Le Forestier, general manager of Naobios. "This will take place as we continue with parallel scale-up for additional valences. We are very proud of our partnership with FluGen; supporting its mission to bring to market a flu vaccine with a broader, more effective protection for all age groups."

Influenza – at a glance

Influenza, also known as flu, is an acute viral infection characterized by the sudden onset of high fever, cough, headache, muscle and joint pain, malaise and a runny nose - it typically lasts two to seven days. In the northern hemisphere, annual influenza epidemics occur during autumn and winter, affecting approximately 5-15% of the population. The most effective way to prevent the disease or its severe outcomes is through [vaccination](#).

About Naobios

Naobios joined the Clean Biologics group in 2019. It is a CDMO (Contract Development and Manufacturing Organization) providing bioprocess development and offering GMP production of clinical batches of viral vaccines BSL2/BSL3, oncolytic viruses and viral vectors.

Boasting 15 years' experience in bioprocess development, Naobios helps its clients to bring their drug candidates to clinical stage as quickly as possible - with the highest quality level - whilst building on its technical know-how in scalable and industrial processes. With its adaptability and range of skills, and a motivated and dedicated team, the company can lead

a project from the initial stages through to completion. Its highly qualified staff have the experience to deal with a wide range of sensitive viruses such as measles, SARS-CoV-2, polio and vaccinia, as well as various cell substrate lines.

Naobios is based near Nantes, in Western France. It currently has 40 employees.

www.naobios.com

About FluGen

FluGen, Inc. is a clinical-stage vaccine company, transforming vaccine efficacy in respiratory diseases. The company's lead candidate is M2SR, a supra-seasonal, live, single-replication, intranasal flu vaccine. Unlike standard of care flu vaccines, M2SR stimulates mucosal, humoral and cellular immunity. In an unprecedented challenge trial, M2SR demonstrated protection against infection and illness across seven years of virus drift; M2SR induces a durable antibody response with potential to cover an entire flu season and beyond. M2SR has also shown activity as a vaccine vector for other respiratory vaccines and infectious diseases, including a COVID-19/flu combination.

FluGen is based in Madison (Wisconsin) in the United States.

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