Naobios and Sumagen successfully optimize HIV vaccine candidate for industrial production

Key milestone reached within expected initial timelines with successful set up of cell growth and production of HIV-1 vaccine candidate at bench scale

Phase I/II trial to assess safety and efficacy expected to start after cGMP production end of 2025

Nantes, France October 29, 2024 – Naobios, a CDMO (Contract Development and Manufacturing Organization) providing bioprocess development and GMP production of clinical batches of virus-based products, and Sumagen Canada Inc (Sumagen), a Korean-Canadian biotechnology company developing an HIV-1 vaccine candidate, today announce the production of the HIV-1 vaccine candidate at bench scale.

This key milestone puts Naobios in a position to scale up the production of Sumagen's HIV-1 vaccine candidate following a partnership agreement signed in April 2024 to manage the manufacturing process. Naobios has achieved this within the initial schedule, bringing Sumagen closer to delivering its HIV vaccine candidate to the public. This was made possible through the Naobios' site, which has the required BSL3 production capabilities for highly pathogenic viruses.

"We are thrilled to have reached such a strategic industrial milestone within expected initial timelines, which is extremely significant due to the initial project delays resulting from the Covid-19 pandemic. This achievement solidifies our trust in Naobios to help our HIV-1 vaccine reach the crucial phase II trials, bringing us closer to delivering a vaccine to patients in need," said Dr Sangkyun Lee, president of Sumagen.

Sumagen's HIV vaccine candidate (SAV001) is a genetically modified, whole-killed HIV vaccine which represents the first of its kind in HIV vaccine trials. In the Phase I clinical trial, SAV001 demonstrated both tolerance and safety for human use. All subjects vaccinated with SAV001 produced broadly neutralizing antibodies.

Naobios and Sumagen will now focus on industrial scale-up activities up until mid-2025, followed by cGMP production to bring Sumagen's HIV-1 vaccine candidate into phase I/II clinical trials.

"To have reached the process development and optimization stage within the challenging initial planned timelines speaks volumes of our capabilities and decades of experience in viral process development. We are proud to be working with innovators like Sumagen who have the ability to significantly impact global human health," said Eric Le Forestier, general manager of Naobios.

At the end of 2022, the World Health Organization (WHO) reported that approximately 39 million people were living with HIV. The development of an HIV vaccine has been a huge challenge for the medical community. With Naobios' experience working with several dozen cell types and viral strains, the company is well-positioned to support Sumagen in its goal of delivering an HIV vaccine to patients with high unmet needs.

About Sumagen
Sumagen Co. Ltd is a biotech company focused on the research and development of pharmaceutical products, such as vaccines for various viruses based on recombinant genetic modified virus technology. Its major vaccine projects are an inactivated vaccine for HIV/AIDS and various infectious viral vaccine developments using a new highly attenuated rVSV viral vector platform technology. It was established in September 2000 in South Korea and extended its reach to North America, with Sumagen Canada Inc., in 2008. Sumagen Co. Ltd was acquired by its parent company, CreoSG Co., Ltd., in September 2024. Sumagen Research Institute opened in 2018, located at the International Vaccine Institute (IVI) in Seoul, to promote close cooperation in variant vaccine research. Sumagen has also varied the pipeline to antibiotics with its acquisition of Inferrex, a local Canadian company that focuses on antibiotics in super bacterial target research.
www.sumagen.com

About Naobios
Naobios is a Contract Development and Manufacturing Organization (CDMO) providing bioprocess development and offering GMP production of clinical batches of BSL2/BSL3 viral vaccines, oncolytic viruses, challenge agents, viral vectors and exosomes. Naobios joined the Clean Biologics group in 2019.
Having built up 20 years' experience in bioprocess development, Naobios helps its clients to bring their drug candidates to the clinical stage as rapidly as possible – at the highest level of quality – whilst building on its technical know-how in scalable and industrial processes. With its adaptability and range of skills, the company can lead a project from the initial stages through to completion, with a motivated and dedicated team. Its highly qualified staff have the experience to deal with a wide range of viruses, as well as multiple cell substrate lines.
Naobios is based near Nantes, in Western France. It currently has 40 staff.
www.naobios.com

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