

Naobios and Sumagen sign exclusive partnership to develop HIV vaccine

Naobios will manage process development and initiate launch of cGMP manufacturing for phase II clinical trials

Nantes, France, April 15, 2024 – Naobios, a CDMO (Contract Development and Manufacturing Organization) providing bioprocess development and GMP production of clinical batches of virus-based products, today announces the signing of a partnership with Sumagen, a Korean-Canadian biotechnology company developing an HIV-1 vaccine candidate, to manage the manufacturing process during its phase II clinical trials. Financial terms were not disclosed.

At the end of 2022, the [World Health Organization \(WHO\)](#) reported that approximately 39 million people were living with HIV. Developing an HIV vaccine has been one of the most difficult challenges in medical research, as it requires blocking a huge number of genetically variable forms of HIV. Naobios will manage the manufacturing process of Sumagen's whole-inactivated HIV vaccine candidate to confirm its safety and efficacy in a Phase I clinical trial and perform further process development to prepare the HIV-1 vaccine for phase II clinical trials.

With its BioSafety Level 3 (BSL3) production site, Naobios has the capability to support the development and production of vaccines for highly pathogenic viruses, like HIV, where no vaccine has yet been identified. It will manage process development and optimization activities for one year, after which it will support the launch of cGMP manufacturing for phase II clinical trials.

"We are very happy that Sumagen's HIV vaccine project, which had been delayed due to the COVID-19 pandemic, has resumed. As this is the long-awaited resumption of production, we will make every effort to initiate phase II clinical trials as soon as possible," said Jung-Gee Cho, CEO of Sumagen.

"As Sumagen's AIDS vaccine requires very sophisticated technology and a high biosafety level facility, it was very difficult to find a company that could produce it," said Dr. Sangkyun Lee, in charge of research and development at Sumagen. "With Sumagen's know-how and Naobios' experience, I am confident that we will be successful in clinical sample production. I am highly encouraged by the resumption of the project and the partnership with Naobios."

"We are honored that Sumagen trusts us to develop and manufacture its HIV vaccine candidate, which has the potential to be the first HIV-1 vaccine to achieve market authorization," said Eric Le Forestier, general manager of Naobios. "With our years of expertise in the development and production of viral vaccines, we are confident that we can support Sumagen through the next stages of its clinical development."

About Sumagen

Sumagen 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 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, viral vectors and challenge agents. Naobios joined the Clean Biologics group in 2019.

Having built up 15 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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