Naobios and European Vaccine Initiative partner up to manufacture Respiratory Syncytial Virus (RSV) challenge agent

Collaboration will support Controlled Human Infection Model (CHIM) studies to accelerate development of effective and affordable RSV vaccines

Nantes, France and Heidelberg, Germany, October 8, 2024 – Naobios, a Contract Development and Manufacturing Organization (CDMO) providing bioprocess development and GMP production of clinical batches of virus-based products, and the European Vaccine Initiative (EVI), a leading European non-profit Product Development Partnership (PDP), today announce their collaboration in the manufacturing of an RSV challenge agent. This is part of the Inno4Vac project, funded by the Innovative Health Initiative. The financial terms of the agreement were not disclosed.

Naobios has already successfully completed the development, manufacturing and filling of several Human Viral Challenge Agents (HVCA) for study use on the global market. HVCA are used in strictly controlled clinical trials (or CHIM) where volunteers are intentionally given a carefully considered dose of a pathogen to test a prophylactic vaccine or curative treatment. Naobios has a proven track record in HVCA, having successfully produced 15 GMP batches for various viral strains - including SARS-CoV-2, RSV and hMPV - and leveraging this innovative approach to accelerate the vaccine development process.

"*Our state-of-the-art facilities and deep expertise in challenge agent manufacturing enable us to meet the critical needs of clients worldwide, advancing research and therapeutic development in virology,"* said Eric Le Forestier, general manager of Naobios. "*This partnership with EVI marks a significant milestone in our mission to leverage HVCA to accelerate the production of effective and accessible vaccines in regions that struggle with the prevention of virus outbreaks.*"

Once the HVCA, manufactured to cGMP standards, is developed, it will play a crucial role in CHIM studies. These studies – which are used in several countries including the US, the UK, the Netherlands and Belgium – will allow for an early and cost-efficient evaluation of the effectiveness of RSV vaccines to prevent infection; in turn, this contributes to the accelerated development of effective and affordable vaccines against RSV.

In a 2019 study, the World Health Organization (WHO) found that RSV, an acute respiratory viral infection, was a leading cause of severe respiratory illness. According to the study, each year RSV is responsible for an estimated 33 million cases of acute lower respiratory infections globally, leading to more than 3.2 million hospitalizations and up to 149,400 deaths annually, primarily among young infants. Low- and middle-income countries with a high RSV burden, notably those in Sub-Saharan Africa, would benefit most from future intervention and easily accessible vaccines.

"*CHIM studies are a powerful methodology that can shortcut the traditional development process and generate early evidence for the effectiveness of new vaccines,"* said Ole Olesen, executive director of EVI. "*CHIM studies for RSV require high-quality HVCA; our collaboration with Naobios is therefore of crucial importance for the success of our endeavours."*

About the European Vaccine Initiative and Inno4Vac

The European Vaccine Initiative (EVI) is building a vaccine portfolio that proactively addresses critical challenges and opportunities and is promoting innovative solutions in vaccine research and development (R&D). It supports global efforts to develop safe, effective and affordable vaccines against diseases that disproportionately affect low- and middle-income countries; through constructive collaboration and exchange with academia, pharmaceutical and biotechnology companies, policy makers, donors and other Product Development Partnerships (PDPs). EVI helps them to advance and accelerate their vaccine candidates by openly providing its expertise and supporting vaccine R&D.

Inno4Vac is an EVI-led public-private partnership aiming to address scientific bottlenecks in vaccine development including Controlled Human Infection Models (CHIM).

Inno4Vac has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 101007799 (Inno4Vac). This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and from EFPIA.

www.euvaccine.eu - www.inno4vac.eu

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.

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