Alphalyse and Bavarian Nordic A/S significantly shorten the time necessary to document HCP impurities in COVID-19 vaccine candidate for Phase 3 clinical trial – through world's first MS-based HCP analysis under GMP conditions

ODENSE, Denmark, November 3, 2022 – Alphalyse has performed the world's first GMP-certified mass spectrometry (MS)-based Host Cell Protein (HCP) analysis for product release testing for Phase 3 clinical trial, after being certified by the Danish Health and Medicines Authority to perform quality control of biological API using MS-based HCP analysis under GMP.

On September 2, 2022, Bavarian Nordic A/S announced the start of Phase 3 clinical trial of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 booster vaccine candidate. ABNCoV2 is being developed as a universal booster to any other type of COVID-19 vaccine and has shown potential to boost neutralizing antibodies against SARS-CoV-2, including variants of concern, to levels associated with a high degree of protection. The goal is to create a longer-lasting vaccine protection with broader efficacy that obviates the need for continuously adapting to new variants of the SARS-CoV-2 virus. The development of ABNCoV2 is being funded through an agreement with the Danish State, and the Danish Ministry of Health has committed DKK 800M to support the ongoing Phase 3 clinical trial. Prior to the Phase 3 clinical trial, Bavarian Nordic contracted Alphalyse to perform product release testing under GMP conditions, thereby becoming the first pharmaceutical company in the world to use MS-based HCP analysis for Phase 3 clinical trial documentation.

One of the biggest challenges in developing vaccines is ensuring and documenting that the downstream process consistently produces a safe product with low HCPs levels. Alphalyse offers a unique LC-MS-based HCP analysis, used for more than 300 biotherapeutic projects, which is significantly faster than traditional methods for product impurity documentation and enables pharmaceutical companies to identify and eliminate specific process-related impurities, thereby further increasing the quality, safety, and efficacy of their product. This makes the Alphalyse method particularly useful for developing vaccines during a global pandemic when the time to create a process-specific ELISA is limited.

The unique Alphalyse method has the potential to significantly reduce the time required to document new vaccines, from the current industry standard of 12-18 months to as little as 4 months, while being as safe or safer than older methods.

Thomas Kofoed, co-founder and Chief Executive Officer of Alphalyse, says: "This is a major milestone, not only for Alphalyse, but for the many companies struggling with the limitations of ELISA. With the potential for using mass spectrometry as a release assay, we can assist developers with short time frames, such as those producing vaccines during a pandemic, and very complex products, such as cell and gene therapies, in getting their HCP release assay in place for Phase 3 clinical trial and for marketed products."

About Alphalyse

Alphalyse is a specialist contract research organization that supports biopharmaceutical companies in developing and manufacturing patient-safe products, such as mAbs, vaccines, recombinant proteins, and cell and gene therapies. Alphalyse has offices in Denmark and the USA, supporting clients with the analysis of protein-related impurities and protein characterization, and has completed more than 10,000 customer projects since 2002.

About ABNCoV2
ABNCoV2 is a next-generation COVID-19 vaccine candidate, initially developed by AdaptVac, Denmark using their proprietary capsid virus-like particle (cVLP) technology. Virus-like particles (VLPs) represent a significant advance in the development of subunit vaccines, combining high safety and efficacy. Their particulate nature and dense repetitive subunit organization make them ideal scaffolds for display of vaccine antigens. Bavarian Nordic has licensed the global commercialization rights to ABNCoV2 and has assumed the responsibility for further clinical development towards licensure.

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacturing, and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. Government of a non-replicating smallpox vaccine, which has been approved by the FDA, also for the protection against monkeypox. The vaccine is also approved in Europe and Canada. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, which is licensed to the Janssen Pharmaceutical Companies of Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine. For more information visit www.bavarian-nordic.com.

Forward-looking statements
This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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