



**Novavax COVID-19 vaccine receives positive recommendation
from European Medicines Agency and approval for use in European Union countries.
Mabion executes Novavax contract as planned and in full agreement with partner.**

Konstantynów Łódzki, 20 December 2021 - protein vaccine against SARS-CoV-2 virus by US company Novavax, under the name “Nuvaxovid”, has been positively recommended for use by the European Medicines Agency (EMA) and has received marketing authorisation in the European Union. The EMA recommendation underlines the importance of the agreement signed in October this year on long-term cooperation between Mabion and Novavax.

“The opinion of the European Medicines Agency and the decision of the European Commission to authorise the Novavax vaccine for marketing is a clear confirmation of its efficacy and good safety profile. Congratulations to our partner – the launch of the vaccine in the highly regulated EU market is a great success. We are glad that the antigen, the key component of the vaccine, is produced in our plant in Konstantynów Łódzki. We have already successfully produced several technical series on a commercial scale,” - emphasises Krzysztof Kaczmarczyk, President of the Management Board of Mabion S.A.

On 8 October this year, Mabion signed an agreement with Novavax for commercial-scale production of the protein antigen recombinant nanoparticle vaccine for COVID-19 (under the working name NVX-CoV2373). The agreement is concluded for the period 2022-2025 and is worth nearly PLN 1.5bn.

“Protein vaccines, such as the Novavax formulation, are a modern but also already proven technology which has been present in medicine for years. This is a significant step and another tool in the global fight against the pandemics. I hope that the registration of the Novavax vaccine will be a factor that will convince further groups of patients to embrace the opportunity to be vaccinated against coronavirus, precisely because of the long-standing and positively verified history of this class of preparations,” adds Dr Sławomir Jaros, Mabion S.A. board member for scientific and operational affairs.

At the beginning of August this year the European Commission approved a contract with Novavax for 200 million doses of COVID-19 vaccine. Under this agreement, EU member states will be able to purchase up to 100 million doses of Novavax vaccine, with an option for 100 million additional doses. Poland is a party to the agreement with the European Commission as part of the joint purchasing EU mechanism. According to the Ministry of Health, Poland is to receive 8 million doses of the Novavax vaccine.

The NVX-CoV2373 preparation was created on the basis of a combination of nanoparticle technology and antigen corresponding to protein S of coronavirus, as well as patented adjuvant Matrix-M™ based on saponin, which stimulates immune response and induces production of high level of antibodies. Clinical studies show that the Novavax vaccine is safe, well tolerated

and has a high efficacy of over 90% in protecting against COVID-19 symptoms. The largest Phase III clinical trial, whose results were recently published in the New England Journal of Medicine, showed 90.4% efficacy against COVID-19 infections of any severity and 100% protection against moderate to severe COVID-19. The efficacy against new strains of the virus was 92.6% and it did not differ from the overall results. Adverse reactions to the vaccine were mostly mild to moderate and lasted for an average of 1 day or less.

The protein antigen manufactured by Mabion is part of Novavax's global manufacturing chain. The Novavax vaccine has already been approved for use in Indonesia and the Philippines, and the World Health Organisation (WHO) has approved the Novavax vaccine, which is manufactured in partnership with the Serum Institute of India under the name Covovax, for emergency use. Applications have also been submitted

for registration in other countries, including Japan, Great Britain, Australia and the United Arab Emirates. According to the announcement, Novavax plans to submit an application to the FDA for registration of the vaccine in the US later this year.

Information on Mabion S.A.

Mabion S.A. (WSE: MAB) is a fully integrated Polish biopharmaceutical company established in 2007, whose core business is the design and development of the latest generation of medicines based on recombinant protein technology (e.g., monoclonal antibodies). Mabion's competencies cover both the drug design phase and the selection of protein expression technologies, their purification, production activities in the GMP standard (obtaining Active Substances "Drug Substance" and Finished Products "Drug Product"), the development of analytical tools (for structural, functional, physicochemical characteristics), clinical development, clinical analytics (PK, PD, NAB, ADA) and a full range of regulatory activities in the development and operational areas. The company's most advanced project is MabionCD20, a biosimilar to MabThera (Rituximab) with therapeutic indications for non-Hodgkin's lymphoma, leukaemia and rheumatoid arthritis (RA). In addition, since signing the contract with Novavax for commercial production of the vaccine on COVID-19 in October this year, Mabion has been developing and expanding its existing platform to include CDMO activities, i.e. contract development services, GMP manufacturing and GMP/GLP analytical services across the full range of the above capabilities. Mabion is a public company listed on the Warsaw Stock Exchange. More information about the Company is available at www.mabion.eu

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