

Press release

Konstantynów Łódzki, 18 January 2022

Mabion and Novavax expand scope of collaboration to include additional key elements of the COVID-19 vaccine manufacturing process

- Mabion has agreed two additional contract areas with its US partner, which broaden the scope of cooperation established in the agreements concluded with Novavax in October 2021 and March 2021.
- The work newly contracted to Mabion includes:
 - the service of producing, in a GMP environment, cell banks that will be used as the key biological material for the production of the vaccine antigen of the Nuvaxovid product at Mabion's facility, as well as at other facilities collaborating with Novavax; and
 - additional contract analytical services in the area of product quality control provided on a long-term basis during the term of the manufacturing agreement, i.e. in the years 2022-2025
- The additional scope of work in the area of product quality control is a critical area of the vaccine manufacturing process. Contracting these activities to Mabion confirms the company's very high expertise in the area of biological medicinal product analytics. Product samples produced by the Company under a manufacturing contract, as well as samples from other entities engaged in contract manufacturing for Novavax, will be eligible for quality control.
- The contract of 8 October last year, which Mabion began executing in Q4 2021 and under which it produced the first full commercial batch of the antigen, is being implemented according to a previously agreed schedule. Each party is fulfilling its obligations: Mabion is currently producing further batches, whose volumes will gradually increase in the coming months, and Novavax is meeting the payments agreed in the contract.
- Commissioning additional work to the Company (including work previously performed in other laboratories working for Novavax) will allow the process to become more efficient and reduce the time taken to manufacture individual batches.

Mabion will perform analytical testing of samples of the Nuvaxovid vaccine on COVID-19 throughout the term of the manufacturing agreement with Novavax. The samples that will be subject to quality control by Mabion in its laboratories will come from batches produced at Mabion's facility, and eventually the collaboration may also be extended to include analyses for other facilities involved in contract manufacturing for Novavax.

The cell bank manufacturing service ordered by Novavax to the Company will be performed in the first quarter of 2022 in accordance with the technical and quality requirements specified in the order and according to Good Manufacturing Practices (GMP) standards. These banks will be used as key biological material, which is the base for the production of antigen for Nuvaxovid vaccines at Mabion's facility and other Novavax partners.



- We are expanding our cooperation with Novavax into new areas, and once again this is a source of pride for us, as we prove how high and unique our competences we have built over the years of working on projects in the field of therapeutic recombinant proteins and what an efficient organisation we are. In doing so, we confirm and strengthen our competence as a CDMO, i.e. an entity that conducts a comprehensive range of contract development, manufacturing and analytics of medicinal products. The antigen we manufacture is consistently characterised by good quality parameters, in line with our partner's requirements and those indicated by regulators, as validated by a wide range of analytical methods in our laboratory and cross-validated by laboratories working for Novavax in the USA and Europe. With these achievements and the ability to implement and apply advanced analytical methods we have validated our additional competences and received orders from Novavax for further key services in the vaccine manufacturing process, characterised by very attractive margins, - says Adam Pietruszkiewicz, a member of the board of Mabion S.A. - Another contract is a proof that we work according to the highest standards in the Company. We have become a real partner that is involved not only in regional processes but much more broadly, also in global operations. Novavax appreciates the speed with which we have conducted processes so far, including technology transfer. Mabion was selected to manufacture cellular banks through an international competition in which our offer proved to be the most attractive while meeting all Novavax requirements. This confirms Mabion's great potential in the CDMO market, which we will certainly want to exploit in the future. We hope that additional orders may open the way to even broader cooperation with Novavax in the area of manufacturing biological medicinal products, - adds Dr Sławomir Jaros, Mabion S.A. board member for scientific and operational affairs.

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' expertise covers 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 characteristcs), clinical development, clinical analytics 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 in October 2021 for the commercial production of the vaccine for COVID-19, 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