Konstantynów Łódzki, January 27, 2023

Press Release

Mabion has secured approval from the FDA to designate MabionCD20 as an orphan drug for the indication of membranous nephropathy

- **Membranous nephropathy is a rare autoimmune disease that leads to kidney failure**
- **Orphan drug status is granted by the FDA to therapies designed to treat rare conditions - provides biotech companies with a range of incentives to support the development of rare disease diagnostics and therapies**
- **Having orphan drug status allows for the exemption of a portion of fees to the FDA, including fees related to the registration of the drug, and guarantees 7 years of market exclusivity once registration is obtained**
- **The company will make a decision in 1H 2023 after completing strategic analyses on the further development of MabionCD20, including the possible determination of the pathways and timetables for the studies needed to register the drug**
- **MabionCD20 is a monoclonal antibody, a biosimilar drug to MabThera/Rituxan (rituximab). The mechanism of action of rituximab makes it used in many therapeutic indications, including numerous rare and autoimmune diseases, which at the same time increases the attractiveness of this drug for pharmaceutical companies**

"The FDA's announcement granting Orphan Drug Designation (ODD) status to MabionCD20 means that the Agency, on the basis of the data presented by Mabion on the MabionCD20 molecule, as well as the clinical literature, has deemed it reasonable to proceed with the project already in the orphan drug designation. This provides the Company with both cost benefits, in the form of fee waivers to the FDA, including fees related to the registration of the drug and annual fees related to the consultation of the project under development, as well as potentially tax benefits, and possible business benefits should Mabion undertake further development of the project. Should a decision be made to move forward with the project, we will be in dialogue with the FDA as to the determination of a further development path. Membranous nephropathy is one of several orphan indications that we are potentially considering and in which MabionCD20 may have a therapeutic application," **explains Slawomir Jaros, Mabion S.A. Board Member for Operations and Scientific Affairs.**

Orphan drug status is granted by the FDA to therapies designed to treat rare conditions. In the case of nephropathy in the U.S., this is about 1 case of disease per hundred thousand population per year. Obtaining ODD status means, among other things, market exclusivity for up to 7 years, following potential FDA registration of the drug, which in the case of MabionCD20 involves decisions on further development of this project, including possible initiation of clinical trials in this indication, necessary to obtain registration. Details in this regard will be provided once the necessary arrangements are completed, along with the announcement of the Company's long-term strategy, which is being advanced.

"Development opportunities for MabionCD20, including its potential in rare disease therapies, were indicated by the Company as early as 2020. Regardless of further decisions regarding the Company's long-term strategy, for today we are focused on building the value of our ongoing projects, including applications of rituximab in rare diseases. One of them is membranous nephropathy," **Slawomir Jaros added.**

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Information about Mabion S.A.

Mabion S.A. (WSE: MAB) is a fully integrated Polish biopharmaceutical company founded in 2007, whose main focus is the design and development of the latest generation of drugs based on recombinant protein technology (e.g. monoclonal antibodies). Mabion's competencies include the drug design phase, as well as the selection of protein expression technologies, their purification, GMP-standard manufacturing activities (obtaining Active Substances "Drug Substance" and Finished Products "Drug Product"), development of analytical tools (for structural, functional, physicochemical characterization), 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 drug to MabThera (rituximab) with therapeutic indications for non-Hodgkin's lymphoma, leukemia and rheumatoid arthritis (RA). In addition, since signing a contract with Novavax in October 2021 for commercial manufacturing 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.

For more information about the Company, visit www.mabion.eu

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