Konstantynów Łódzki, February 08, 2023

Press Release

Mabion has received ODD status from the FDA for the drug MabionCD20 in the indication of autoimmune hemolytic anemia

- **Orphan drug status is granted by the FDA to drugs intended to prevent as well as treat diseases rare, provides biotechnology companies with a range of incentives to support the development of diagnostics and therapeutics**
- **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, guarantees 7 years of market exclusivity once registration is obtained, and entitles you to tax credits for conducting the clinical trial phase**
- **Obtaining Orphan Drug Designation (ODD) statuses, or orphan drug designation altogether in just 2 indications effectively builds the value of the MabionCD20 project**
- **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 schedules of the studies necessary for registration of the drug**
- **MabionCD20 is the second compound in the history of rituximab to achieve ODD status in the indication of autoimmune hemolytic anemia (AIHA)**
- **Autoimmune hemolytic anemia (AIHA) leads to a shortened life span of blood cells from about 120 to - in the most severe cases - just a few days**
- **MabionCD20 is a monoclonal antibody, a biosimilar drug to MabThera/Rituxan (rituximab), and its mechanism of action 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**

"After achieving ODD status for MabionCD20 in the indication of membranous nephropathy in January this year, we announce another positive decision for the company by the FDA, granting us ODD status in the indication of autoimmune hemolytic anemia. I note that MabionCD20 is historically only the second rituximab compound to be granted this status in the indication of AIHA. The possible proceeding of the project in this indication in the mode reserved for orphan drugs is associated with the possibility of obtaining a number of advantages at the cost and business level. These are primarily exemptions from a portion of fees to the FDA, including fees associated with registering the drug and eligibility for tax credits for conducting the clinical trial phase in the US. We will make a decision on the further development of MabionCD20 in 1H 2023, and the next potential development paths of this project will depend on it," - **explains Sławomir Jaros, Mabion S.A. Board Member for Operations and Scientific Affairs.**

The so-called Orphan Drug Designation (ODD) procedure was established by the FDA to support the development of drugs and therapies to prevent and treat rare diseases. For autoimmune hemolytic anemia (AIHA), the annual incidence is estimated at 0.8 to 2.4 cases per 100,000 population, with an estimated 60,000 people in the United States suffering from the disease. With the granting of orphan drug status, companies can receive several benefits, among the most significant are tax credits for conducting the clinical trial phase, a waiver of FDA consultation fees, and seven years of market exclusivity when the drug is approved by the FDA. Granting ODD status to Mabion could potentially accelerate the development of MabionCD20 as a biologic drug for autoimmune hemolytic disease.

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"The orphan drug status obtained by MabionCD20 already in two indications increases the attractiveness of the project according to several scenarios we are analyzing. When the work on the Company's long-term development strategy is closed, we will be able to define more precisely the possible paths for the MabionCD20 project," - **Adds Adam Pietruszkiewicz, Mabion S.A. Board Member for Sales.**

Autoimmune hemolytic anemia (AIHA) is a severe autoimmune disorder in which a patient's antibodies attack his or her own erythrocytes (red blood cells), causing them to break down and ultimately reducing the blood's ability to transport oxygen. The life span of the blood cells, which normally is about 120 days, can be shortened in the most severe cases to just a few days. Typical symptoms of the disease include fever, pallor, fatigue, muscle weakness, elevated heart rate and shortness of breath. AIHA can even cause life-threatening conditions such as venous thrombosis and acute renal failure. Recent studies indicate that rituximab is highly effective in treating AIHA. That's why it has recently been recommended by medical associations as a second-line therapy, to be used when standard immunosuppressants are ineffective or severe side effects appear. For the treatment of AIHA, specifically in - cold agglutinin disease one of the two main varieties of AIHA, only one drug has been registered so far. In 2022. FDA approved sutimlimab, a monoclonal antibody for which the cost of annual therapy is estimated to be as high as $280,000. Sutimlimab can only be used in a small population of AIHA patients (10-15%) and features a different mechanism of action than rituximab.

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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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