

## **Mabion initiated the national and regional PCT phases of the patent application for the use of MabionCD20 in the treatment of Multiple Sclerosis (MS) patients**

Mabion submitted an international patent application to selected patent offices, which triggered a national and regional phase to obtain patent protection in nearly 50 countries for its drug candidate, MabionCD20 (rituximab) - developed for a number of clinical uses, including multiple sclerosis therapy. As an innovative therapy for the treatment of multiple sclerosis patients, it is intended to combine MabionCD20 with other active substances (the "MabionMS project"). To date, rituximab has not yet been registered for the treatment of multiple sclerosis.

Based on the multiple sclerosis (MS) incidence statistics in individual regions as well as the potential of individual markets, Mabion has submitted patent applications to selected patent offices covering countries such as the USA, Canada, the UK, EU and EFTA countries, Australia, New Zealand, Israel, Turkey, Russia, and several others.

The start of the national and regional patent application phase in each country is the next step to obtain legal protection for Mabion's innovative multiple sclerosis therapy. Previously, Mabion filed patent applications with the Polish Patent Office and the European Patent Office in the Hague, which now allows patents to be obtained in countries that are party to the agreement (PCT) in a simplified process based on a single patent application (the so-called international application).

'The launch of the patent applications in each of the selected countries is intended to secure the intellectual property of our first innovative product (MabionMS). Based on several published studies we believe that MabionMS has significant potential for the treatment of multiple sclerosis. From a regulatory perspective, this is a new therapy, and a new clinical use of rituximab. A superior safety profile can also be expected for MabionCD20, and will be established in clinical studies. Importantly, as rituximab is now off-patent as a molecule in its label indications, and the manufacturing process is well established, this could also be a cost-effective treatment option' says Dr. Dirk Kreder, President of the Management Board of Mabion S.A. Our goal is to develop MabionMS together with a partner experienced in this therapy area. We believe that our production technology provides us a competitive advantage and we are actively inviting interested parties to discussions on licence arrangements for this asset,' adds Dr. Dirk Kreder.

According to the report "Multiple Sclerosis Drugs Market," published in May 2019 by Fortune Business Insights, the multiple sclerosis market will have a CAGR of 6.7% and will be worth USD 39 billion by 2026. This is due to the large and growing demand for therapies in this indication. According to research carried out by the Multiple Sclerosis Foundation, about 2.3 million people around the world live with multiple sclerosis today.



In 2019, Mabion prepared a synopsis of the clinical trial and the briefing package for consultations with Health Authorities. External experts in clinical trials for multiple sclerosis therapy were consulted on content and regulatory strategy. Subsequently, the Company submitted these documents to the European Medicines Agency (EMA) in August 2019, and received a written response confirming several of its assumptions. The Company is also consulting with the US FDA on the most appropriate regulatory pathway for MabionMS.

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**About the Company:**

Mabion is the first Polish biotechnology company whose primary objective is to develop, manufacture and market biosimilar drugs for several regulated markets.

The Company's lead project is MabionCD20. The Company is pursuing registration under the centralized procedure for all European markets in a partnership with Mylan - one of the largest pharmaceutical companies in the world. Another medium-term goal of the Company is to introduce MabionCD20 to the American market. In addition, the Company pursues MabionMS (MabionCD20 for the treatment of multiple sclerosis) and MabionEGFR.

Since 2013, Mabion has been listed on the WSE's main market. The company is included in the mWIG40 index.

Find more information at: [www.mabion.eu](http://www.mabion.eu).

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