

## **Mabion is on the home stretch in the process of registering MabionCD20 in the European Union**

**Mabion S.A., a biotechnology company involved in the manufacture of oncological biosimilars, announced on 10 November that it had submitted answers to the second round of questions by the European Medicines Agency (EMA), received as part of the Day 180 stage of the registration procedure for MabionCD20. Mabion expects the EMA to evaluate the application for registration of MabionCD20 still in 2019.**

*'We sent the answers to the second round of EMA's questions on schedule, which brings us very close to an opinion on the registration of our drug, MabionCD20, in the EU. We have worked very hard to develop the answers and have devoted a lot of time to ensuring that their quality, level of detail and data meet the EMA's expectations. The timetable for the whole procedure is that we should receive feedback from the EMA later this year. After submitting the answers, we are at the stage of the so-called Day 181,' says Sławomir Jaros, PhD, Member of the Management Board of Mabion S.A.*

This year, the Company expects to receive an opinion of the Committee for Medicinal Products for Human Use (CHMP), a body of the European Medicines Agency. Such an opinion forms the basis for the issuance of a marketing authorisation for a medicine by the European Commission.

On 11 November, Mabion also informed that it had submitted answers to the EMA under the registration procedure for the "Duplicate application" for MabionCD20. The EMA's assessment of the second registration application is as important as the first one, as it will accelerate the commercialisation of the medicine in markets where rheumatoid arthritis (RA) is still protected by a patent for rituximab (a medicine registered under the trade name MabThera by Roche).

MabionCD20 is a biosimilar of the Roche-based medicine MabThera/Rituxan (rituximab), with a global market value of USD 6.9 billion in 2018. Mabion's clinical trial for MabionCD20 included patients with rheumatoid arthritis (RA) and non-Hodgkin's lymphoma (NHL). Mabion's partner in the research and commercialization of MabionCD20 is Mylan, one of the largest pharmaceutical companies in the world, which has exclusive rights to sell the drug in the European Union and the Balkan countries under an agreement with the company concluded in 2016.

Mabion may be the first Polish biotechnology company to introduce a biological medicine in all EU countries under the centralised procedure. In the process of introducing the drug to the market, Mabion is supported by the European and Polish financial institutions. The company's shareholders include, among others, the European Bank for Reconstruction and Development (EBRD) and the Polish Development Fund (PFR), which purchased the company's shares as part of the latest issue. The company also received a loan of EUR 30 million from the European Investment Bank (EIB), which will be utilised for research and production of innovative medicines used to treat cancer and autoimmune diseases, as well as to increase the company's production capacity.

In addition to MabionCD20, which is the company's most advanced project, two more medicines are under development: MabionMS (a drug developed for multiple sclerosis) and MabionEGFR (for colorectal, head and neck cancer). Additionally, the company has started work on new projects concerning oncological, metabolic and autoimmune indications.



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**About us:**

Mabion is the first Polish biotechnology company whose primary objective is to develop, manufacture and market biosimilars to the existing original biotech drugs (reference drugs) for oncological indications.

The Company's priority project is currently the introduction of MabionCD20 to the largest number of global markets possible. The Company conducts the process of registration as part of the centralised procedure throughout the European Union. The partner in this process is Mylan – one of the largest pharmaceutical companies in the world. Another main objective of the Company is to launch MabionCD20 on the American market. The company also conducts other projects, such as research on MabionMS or MabionEGFR.

Since 2013, Mabion has been listed on the WSE's main market as part of the mWIG40 index.

More information: [www.mabion.eu](http://www.mabion.eu)

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