

**The Management Board and the Supervisory Board of Mabion S.A.
in favour of share issue to support the next phase of work
in the registration of MabionCD20 in several regulated markets**

On May 19, 2020, the Management Board of Mabion S.A. decided to issue up to 1.91 million U series shares and at a maximum 16% of shares admitted to public trading. Shortly, a General Meeting of the Company's shareholders will be convened, during which a resolution on increasing the company's capital will be presented for vote. The Management Board's decision to issue shares is supported by the company's Supervisory Board.

It is the Management Board's intention that the issue of shares will be in the form of a private subscription by way of a public offering exempted from publishing a prospectus and excluding pre-emptive rights. The issue will be addressed to investors indicated by the Management Board and with a priority right for the widest possible group of investors, namely current shareholders of the Company. In the draft resolutions for the General Meeting, the minimum price of shares will be determined in accordance with market standards.

'Our top objective, on which we focus almost all of our activities and resources, is to achieve the successful registration of our biosimilar candidate, MabionCD20, in the European Union. From the planned share issue we seek additional funds to substantially accelerate the ongoing development of MabionCD20. Our goal is to register the commercial scale process of MabionCD20 with the European Medicines Agency (EMA) on the basis of compelling data we are currently generating, as well as to pursue registration of the product with US FDA. Mabion is a fully integrated developer of biosimilar drugs and is holding a current Good Manufacturing Practice (GMP) licence. The capital acquired will enable us to further speed up development and swiftly progress based on the experience, solid quality processes and the experienced and qualified workforce we are proud of supporting us in this endeavour' **says Dr. Dirk Kreder, President of the Management Board of Mabion S.A.**

As a result of past consultations with the regulators (the EMA), the Company's Management Board and Supervisory Board decided to adopt a streamlined registration strategy for MabionCD20. The Company withdrew the previous registration application for MabionCD20 formerly based on a small-scale manufacturing process and now intends to resubmit the registration application for the product from the final commercial scale process.

'We are of course aware we are operating in a highly competitive environment facing competition from others, including the world's largest pharmaceutical companies. I would like to emphasize that we are driven by two overriding principles, one, to offer another cost efficient option for the treatment of rituximab's clinical indications, and secondly to further the interest of the Company and its Shareholders, who believe in this product' **says Dr. Dirk Kreder, President of the Management Board of Mabion S.A.**

The biosimilar market is one of the most dynamically developing segments of the pharmaceutical market globally. The drivers for the market of biosimilar drugs are, amongst others: the increase in the



incidence of oncological and immunological diseases and the expiry of patents for blockbuster biological drugs. In 2018, the share of biosimilars in the biological drugs market in Europe rose to 29% (compared to just 9% in 2013). According to the report titled "Biosimilar Market in Europe: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024", the value of the market now reached USD 2.9 billion. By 2024, the market for biosimilar medicines in Europe is expected to reach USD 11.6 billion, with CAGR of 24.9% between 2019 and 2024. Due to its world-leading position in the regulation and approval of biosimilar products, the market for biosimilar medicines in Europe at current is the world's largest, representing about 60% of the global market for biosimilar products and growing steadily year over year.

A few weeks ago, the main (founding) shareholders of Mabion declared a capital injection of not less than PLN 15 million in 2020. According to the declarations received from the shareholders, the recapitalisation may take place by taking up new issue shares or using debt instruments. Mabion is also in talks with several financial institutions on additional loan facility for the company.

'We appreciate the support of the founding shareholders and their confidence in our ability to register and introduce the first Polish biosimilar drug to the European and the US markets. We want to address the new issue of shares primarily to the current shareholders, who will have priority in taking up shares. We are convinced that their support will be rewarded' says **Dr. Dirk Kreder, President of the Board of Mabion S.A.**

The Company is well advanced in its preparations for initiating the registration procedure for the commercial-scale MabionCD20 process.

'In the results of our analyses to date, we see that MabionCD20, the large-scale medicinal product, has a very attractive analytical profile compared to other biosimilar drugs. An important stage on the way to submitting the registration application is scientific advice, which we want to conduct soon with the regulator (the EMA). In this process, we will finally confirm with the regulator the required scope of data to submit a large-scale application. We will include validation, analytical biosimilarity and stability studies in the newly submitted application,' explains **Dr. Eng. Sławomir Jaros, Member of the Management Board and Chief Scientific Officer of Mabion S.A.** *'I would like to emphasize that we have proven the safety and efficacy of MabionCD20 in clinical trials involving oncological and RA patients, we have gained invaluable experience in preparing the dossier for drug registration. We have solved almost all issues raised by the regulator during the assessment of the first application, which is a good starting point in terms of application to the target process. Moreover, we meet all safety and quality standards confirmed by certificates (including GMP) in our factory, which is perfectly prepared for the production,'* adds **Sławomir Jaros.**

Currently, the validation of the MabionCD20 production process is almost completed. Then, the stability and analytical biosimilarity of the product will be tested. In the meantime, as part of scientific advice, the Company will also confirm with the EMA the scope of the required data and the format of the new applications and, according to the procedures, adapt them to the regulator's guidelines, which will streamline the large-scale target registration procedure. The EMA is scheduled to be consulted under the scientific advice procedure in June-July 2020.



Mabion cooperates with CC Group sp. z o.o., a company providing services in the field of investor relations and financial communication, with which it has additionally entered into an agreement on financial consulting in connection with the preparation and implementation of the share issue.

About Mabion:

Mabion is the first Polish biotech company whose primary objective is to develop, manufacture and market oncological medicines biosimilar to original biotech medicines (reference drugs) existing on the market.

The Company's priority project is to introduce MabionCD20 to as many markets globally as possible. The Company is carrying out the registration process as part of a central procedure for the European Union. The partner in this process is Mylan - one of the largest global pharmaceutical companies. Another main objective of the Company is to introduce MabionCD20 to the American market. The company is also implementing other projects, such as studies on MabionMS or MabionEGFR.

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

More information: www.mabion.eu

For further information please contact:

Michał Wierzchowski

cc group

phone: +48 531 613 067

e-mail: michal.wierzchowski@ccgroup.pl