POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 49 / 2021
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Abbreviated name of the Issuer: MABION S.A.

Subject matter: Adoption of a joint work programme for the marketing authorisation of MabionCD20 in the European and US markets and elaboration of the final data and clinical trial scope for the registration application on the European market

Legal basis: Article 17(1) of MAR – confidential information.

Content of the Report:

With reference to Current Reports no. 29/2020 of 9 July 2020, no. 32/2020 of 28 August 2020, and no. 41/2020 of 29 October 2020 on the registration strategy for the product under the working name of MabionCD20 in the European and US markets, the Management Board of Mabion S.A. ("Company") hereby informs that after a number of interactions with European regulatory agencies as part of the Scientific Advice procedure (two consultations with the European Medicines Agency, hereinafter "EMA" and two consultations with the Paul Ehrlich Institute, the German national regulator working closely with the EMA, hereinafter "PEI") and the US Food and Drug Administration ("FDA"), the Company has defined a strategy for the co-development of MabionCD20 for registration in the European and US markets.

The core elements of the Company's regulatory strategy have not been altered and include:

1. A three-arm bridging clinical bridging trial in patients with rheumatoid arthritis ("RA")
2. A three-arm bridging analytical trial
3. Implementation of the above tasks using MabionCD20 originating from the target, i.e. large, commercial production scale (for the product manufactured in 2,500-litre bioreactors)
4. To include in the registration procedure on the European market the results of already completed Phase III clinical trials with MabionCD20 originating from a small scale of production (250-litre bioreactors); the trials were carried out with 709 patients for the indication of RA and with 143 patients for the indication of NHL (non-Hodgkin's lymphoma)

At the same time, as a result of numerous interactions with regulators over the last several months, the Company has managed to reach an agreement and developed the final scope of data (including the scope of the bridging clinical trial) for the purpose of the application for registration and marketing authorization of MabionCD20 as part of the central procedure in the European market. Taking into account the outcome of the agreements with European regulators, the Management Board anticipates - in the baseline scenario - to maintain the assumed schedule, i.e. to complete the trials and submit the registration dossier to the EMA for the European market in the second half of 2022.

The three-armed clinical and analytical bridging trials referred to above include: (a) MabionCD20 originating from large scale manufacturing, (b) MabThera, which is the European reference, and (c) Rituxan, which is the US reference, which is the basic assumption of the co-development strategy for MabionCD20. The Company will further clarify with the FDA the scope of additional trials (which, as anticipated by the Company, may include a clinical trial in the oncological indication) required for the US market approval of MabionCD20, and will report on these arrangements in a separate Current Report.

The three-arm bridging clinical trial in patients with RA referred to in item 1 above is to include a population of 280 patients, which is in accordance with the Company's assumption that it is not necessary to run separate new Phase III clinical trials in order to register MabionCD20 on the European market. The primary endpoint of the trial is the analysis of pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. The population in consideration will also allow for the assessment of treatment efficacy, which is the secondary endpoint of the trial.

The Company would like to reiterate that, in order to run the clinical trial, it has entered into an agreement with Parexel International (CRO), qualified several dozen clinical sites, and completed the documentation necessary to commence the trial. In addition, the Company has started the process of submitting applications to local bioethics committees for approval necessary to conduct the clinical trial.

With reference to item 2, the Company has determined with the EMA and PEI the target quality profile of MabionCD20 based on data obtained from validation batches of MabionCD20 produced at the target manufacturing scale and has established the scope of analytical trials for the commercial-scale MabionCD20. The objective of the analytical trials is to confirm analytical similarity to reference medicines and comparability to MabionCD20 originating from small scale manufacturing as used in previously conducted clinical trials.

In the Company's opinion, the trials described above and the scope of data (items 1-4) arrived at in the course of negotiations with the EMA and PEI are sufficient to submit a registration application to the EMA. Taking into account the above arrangements and assumptions, the Management Board of the Company has estimated the budget of the project consisting in admitting MabionCD20 (the target product manufactured on a commercial scale) to the European market, including also the costs of the RA-indication trial arm for the needs of the American market and the costs accompanying it and, in accordance with its best knowledge, has specified the planned net expenditures at PLN 105–115 million over the period assumed (i.e. until the anticipated registration of the product on the European market). At the same time, the Company informs that the projected budget reflects the costs already incurred by the Company for the implementation of the project starting from the first quarter of 2020. The estimates cover expenditures necessary for the development of the drug, including the costs of the three-arm bridging clinical trial, the three-arm analytical trial, production costs, maintenance costs, costs of the regulatory process (EMA and FDA) and expenses on quality assurance and quality control. The above budget items relate to the approximate full costs incurred for authorising MabionCD20 in the European market, while for the US market they concern the project budget with the exception of the costs of an additional trial in the oncological indication (anticipated by the Company as a required element of the registration application in the US market). The estimates assumed above do not include the costs of the Company's current operations and capital expenses related to production capacity increases.

The Company would like to point out that the above assumptions may change in the future (as they are based on many factors which may affect the timeframe, including factors beyond the Company's control such as the rate of recruitment for clinical trials) and that the described assumptions and activities do not warrant the registration of the product. At the same time, the Company informs that in the process of planning the scope and schedule of the clinical trial, it has taken into account the foreseeable limitations resulting from the COVID-19 pandemic.

Furthermore, the Company informs that the activities related to the development of MabionCD20 do not interfere with other projects pursued by the Company, including in particular the cooperation programme with Novavax in the area of production of the active substance for a vaccine against COVID-19.