Current Report no 29/2020

Date of preparation: 2020-07-09

Abbreviated name of the Issuer: MABION S.A

Subject matter: Information on initial assumptions regarding the renewed Marketing Authorization Application to be filed for MabionCD20

Legal basis Article 17(1) MAR - confidential information.

Content of the report:

Referring to Current Reports No. 15/2020 of 16 March 2020 and No. 28/2020 of 1 July 2020 on a change in the regulatory strategy for the product under the working name MabionCD20 (including the submission of a new Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) and the receipt of a reply by EMA to the request of the Company for Scientific Advice, the Management Board of the Company hereby informs, that after internal analyses, consultations with external experts, and aligned with the Company's Supervisory Board, a framework for the scope and schedule of work necessary to submit a MAA for the product have been adopted.

At the date of publication of this current report, the validation of the MabionCD20 large-scale manufacturing process based on three validation batches has been completed. Preliminary analytical studies show, that the batches produced so far, comply with all quality attributes. In addition, the Company has already initiated stability studies and will shortly commence similarity and comparability studies. In order to extend the analytical data available for the registration application, the Company is considering the production of additional batches, so that the MAA will be based on the full data set of at least four to five large-scale batches. In the Company's assessment, the presentation of a broad set of analytical data will allow to significantly reduce the residual regulatory risk of new Phase III clinical trials required for product registration. In addition to generating the analytical data package, it is the Company's intention to conduct a smaller bridging study (Phase I/II trial) for the registration dossier, which, in the Company's opinion, is required to demonstrate comparability while at the same time reducing the aforementioned residual risk and thereby reducing the cost and duration of the phase before registration. The Company has developed a draft protocol for the bridging study (3-arm clinical trial, scope of study: safety and pharmacokinetics, indication: rheumatoid arthritis, scale: estimated <80 patients per arm), which will be aimed at confirming the biosimilarity between MabionCD20 and MabThera (EU reference product) and Rituxan (US reference product).

Based on the above assumptions, the Company estimates that the work to obtain the data necessary to submit the new MAA including the bridging study will be completed by or before early 2022.. According to the Company's best estimates, the planned activities involve a net expenditure of about PLN 75-85 million until completed, of which about 70% will be R&D costs (estimates include the bridging clinical trial). The remainder of the estimated expenditure are production and maintenance costs (additional product batches), costs for regulatory filing (including fees due to EMA) as well as expenditures for quality assurance and control. The assumed estimates do not take into account the costs of current operations and investments in further increased production capacity.

The Company does not exclude the possibility that the above-mentioned assumptions may be modified in case of any circumstances that would require it. The Company's objective is to respond quickly and decisively on any need arising from the registration process with the goal of minimizing the regulatory risk while keeping costs at a level that can be financed by the Company and with adherence to the shortest timelines possible.

At the same time, the Company stipulates that the assumptions above may be subject to changes in the future due to the fact that a large number of factors have the potential to impact timelines, including factors not controllable by the Company (such as recruitment rates in clinical trials). Moreover, the Company stipulates that the assumptions used and the activities performed do not guarantee registration.

On 10 July 2020, the Company will organize a webinar for market participants to discuss the current status and plans for the MabionCD20 project with additional information on the Company’s website.