POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 15 / 2020

Date of preparation: 2020-03-16
Abbreviated name of the Issuer:
MABION S.A.

Subject matter:
Change of regulatory strategy for the marketing authorisation of MabionCD20 in the EMA

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

Content of the report:

With reference to Current Report no. 13/2020 of February 26th, 2020 and earlier communication within the scope of marketing authorisation applications submitted by Mabion S.A. ("Company") to the European Medicines Agency (EMA) for a drug under the working name of MabionCD20, the Management Board of the Company hereby informs that on March 16th, 2020 it made a decision to modify the regulatory strategy for the authorisation of MabionCD20 in the EMA.

The change basically aims at obtaining the marketing authorisation for the drug in the EMA directly for a large commercial scale as opposed to the previously planned 2-step strategy, i.e. obtaining the marketing authorisation for small scale production – step 1, and then on the basis of a change application, the marketing authorisation for a large, commercial scale production – step 2. The Management Board of the Company made this decision on the basis of today's opinion of external consultants and recommendations of the Supervisory Board of the Company. The change of strategy involves the withdrawal of registration applications submitted on June 1st, 2018 and May 6th, 2019. The new application, in which the target production scale will be evaluated by the Agency, will be submitted shortly after the validation and biosimilarity data for the product coming from the full-scale production are obtained. The existing large-scale analytical data indicate a reproducible quality and high degree of biosimilarity, which, in the Company's opinion, translates into a high probability that additional, larger clinical trials will be unnecessary. For procedural and formal reasons, the Company could not proceed with its previously submitted and pending applications with additional large-scale data. At present, the Company has started the 3rd production validation batch in a large scale. In the opinion of the Company's Management Board, the change of strategy is currently the most optimal path in terms of both cost and time for the registration of the product coming from the large scale process which the Company plans to complete in June 2020, as well as the possibility of commercialising MabionCD20 in the European Union.

The scope and format of the new applications will first be consulted with representatives of the EMA as part of the scientific advice procedure planned for April/May this year in order to adapt them to the Agency's expectations, which will streamline the registration procedure for a large scale, targeted production.

At the same time, the Company informs that the decision to withdraw applications for registration of MabionCD20 in the EMA does not affect the adopted schedule of work in the field of large-scale production validation and the bridging test, as well as work aimed at registering MabionCD20 in the U.S. market.

The Company emphasises that the current work schedule may change as a result of guidelines obtained from the regulator.