

POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 11/2020

Date of preparation: 2020-02-12

Abbreviated name of issuer

MABION S.A.

Legal basis

Article 17(1) MAR - confidential information.

Subject matter:

MABION S.A. (11/2020) Receipt of the list of issues to be presented at the meeting of the Committee for Medicinal Products for Human Use to be held on 24-27 February 2020

Content of the report:

With reference to Current Report no. 7/2020 of 28 January 2020 and earlier communication related to the application by Mabion S.A. ("Company") for the marketing authorization of a drug under the working name of MabionCD20 by the European Medicines Agency (EMA), the Management Board of the Company hereby informs that on 13 February 2020 it received from the EMA a list of issues to be presented at the meeting of the Committee for Medicinal Products for Human Use (CHMP), which will be held on 24-27 February 2020.

The invitation to an oral hearing does not guarantee product approval. The company emphasizes that the regulator (EMA) has a number of tools at its disposal to ensure its discretion and the possibility of individually adjusting the solution applied to the needs of a given registration procedure. The Company has no influence on the assessment of the EMA, and there are a number of possible events – issuing a positive or negative decision, obtaining a list of additional questions (once or more), invitation to a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after additions, or other events not expected at this stage by the Company, which may arise.

The Company will keep you informed on a regular basis of any further formally binding and significant events within the EMA registration procedure for MabionCD20.