

POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 3 / 2018
Prepared on: 2018-01-10

Abbreviated name of the issuer
MABION S.A.

Subject matter

Results of the clinical trial related to MabionCD20 NHL in relation to certain secondary pharmacokinetic endpoints (treatment efficacy and general safety profile).

Legal basis

Article 17(1) of the Market Abuse Regulation – inside information.

Content of the report:

With regard to Current Report no. 2/2018 of 5 January 2018 concerning the positive initial results of the clinical trial involving the MabionCD20 medicine carried out with participation of patients treated in the indication Non-Hodgkin lymphoma (NHL) in the scope of primary pharmacokinetic endpoints, the Management Board of Mabion S.A. (“Company”, “Issuer”) informs that on 10 January 2018 it received from an external company an initial data compilation in the scope of the treatment efficacy and general safety profile of MabionCD20 (secondary endpoints). On the basis of treatment efficacy data, the Management Board assessed patients’ response to treatment in both groups (treated with MabionCD20 and MabThera) as comparable. In the opinion of the Company, MabionCD20 fulfils the general safety profile requirements. The Management Board stresses that due to a relatively small population of patients taking part in the trial when compared to MabionCD20 RZS, this assessment is not based on statistical inference. It was made on the basis of descriptive statistics. This means that the final assessment of the reported results will be carried out by the European Medicines Agency (EMA) and may differ from that of the Company. The final version of trial reports shall be used in the market authorisation application (MAA) which the Company plans to submit to the EMA.