POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 6 / 2018
Prepared on: 2018-01-15

Abbreviated name of the issuer
MABION S.A.

Subject matter
Results of the clinical trial related to MabionCD20 NHL in relation to other pharmacokinetic endpoints

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

Content of the report:
With regard to Current Reports no. 2/2018 of 5 January 2018 and no. 3/2018 of 10 January 2018 concerning the results of clinical trials involving the MabionCD20 medicine carried out with participation of patients treated in the indication Non-Hodgkin lymphoma (NHL), the Management Board of Mabion S.A. ("Company", "Issuer") informs that on 15 January 2018 it received from an external company an initial data compilation in the scope of secondary pharmacokinetic entpoints as well as pharmacodynamics of MabionCD20 (secondary endpoints). In the assessment of the Management Board, the pharmacokinetic parameters obtained in groups treated with MabionCD20 and MabThera are equivalent. As regards pharmacodynamics, in both groups, triggering of B cell depletion (removal) was observed; the degree of repletion (reconstruction) of the lymphocytes in both groups was similar. 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 based on a simplified statistical approach. 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. Hereby, the Company has obtained data in the scope of nearly all trial endpoints. The Company does not plan to publish other results related to the long-term observation of patients by reason of their limited significance for the overall assessment of the implementation and schedule of the MabionCD20 project. The final version of trial reports shall be used in the market authorisation application (MAA) which the Company plans to submit to the EMA.