

## FINANCIAL SUPERVISION AUTHORITY

Current report No. 13/2019

Date prepared: 2019-05-06

Abbreviated name of the issuer: MABION S.A.

Subject: The submission of the second registration application concerning MabionCD20 drug to the European Medicines Agency

Legal basis: Art.17 par. 1 MAR - confidential information

### Content of the report:

With reference to the current report No. 56/2018 dated on August 6, 2018 concerning granting an approval from the European Medicines Agency ('EMA') for submitting the second registration application ("Duplicate Application") for the drug under a working name MabionCD20, of Management Board Mabion S.A. ("the Company") hereby informs that on May 6, 2019 it received from its partner the confirmation of a correct submission in EMA the above-mentioned second registration application.

The submission of the second registration application, in case of positive completion of the registration procedure, will enable the Company obtaining the additional commercial name of the drug, for which the indication list for the product will be limited and it will not involve rheumatoid arthritis (RA). In the Company's judgment, this activity may accelerate the commercialization of the drug with the working name MabionCD20 in markets where RA is still covered by the patent protection for MabThera.

Currently, the Company is awaiting information on the results of the validation of the subject application.

The positive test results, which the Company has reported so far in the current and periodic reports and the consent of EMA to submit a second registration application do not guarantee product approval by the European Medicines Agency.