

## **Current report 2/2020**

In reference to the current report no. 38/2019 dated 16 December 2019 and previous communication concerning application for the marketing permit concerning the drug under the working name of MabionCD20 by Mabion S.A. (“Company”) to the European Medicines Agency, the Company’s management board hereby informs that – according to the telephone consultations held with EMA on 13 January 2020 – the Company is planning to submit responses to the list of inquiries discussed in the aforementioned report in January of this year. The aforementioned should allow the Company’s registration application to be processed further at the session of the Committee for Medicinal Products for Human Use (CHMP), which will most likely be held on 24-27 February of 2020. This date is subject to change. The Company will inform of the submission of responses to EMA in a separate current report.

Simultaneously, the Company wants to note that the regulator (EMA) holds extensive tools allowing it freedom of decision and the ability to adapt the solution on an individual basis to the requirements of the given registration procedure. The Company has no influence over the decision of EMA. There are numerous potential outcomes: release of a positive or negative decision, presentation of a list of additional questions (once or repeatedly), invitation to present verbal responses (once or repeatedly), the Company withdrawing the application and submitting it again in complete form, or other outcomes, which the Company is unable to foresee at this stage.