Current Report no 19/2020
Date of preparation: 2020-03-30
Abbreviated name of the Issuer: MABION S.A.
Subject matter: Information on the withdrawal of registration applications for MabionCD20 from the EMA
Legal basis: Article 17(1) MAR –confidential information.
Contents:

With reference to previous communication of Mabion S.A. ("Company") in relation to applying to the European Medicines Agency (EMA) for the marketing authorisation for the drug under the working name of MabionCD20 and to Current Report no. 15/2020 of 16 March 2020 on the change of the regulatory strategy for the drug as part of the registration procedure with the EMA, the Management Board of the Company hereby informs that on 30March 2020, the EMA's website published information confirming the withdrawal of the Company's registration applications submitted in June 2018 and May 2019.

The confirmation of the Company's withdrawal of the registration application concludes the existing registration procedure initially based on a two-step strategy (obtaining small-scale marketing authorisation, followed by a subsequent submission of a variation application relating toa large-scale manufacturing process). The Company managed to resolve the vast majority of all requests for additional information, however, in light of the Company's goal to register a product based on a commercially attractive large-scale quality process, the Company considering the pervious interactions with the Agency adjudged that such data be reviewed in a future application, and hence the application for the small-scale process was withdrawn.

The Company informed about its intention to withdraw the applications in the above-mentioned report no. 15/2020. Today the Agency published the "Questions and Answers" ("Q&A") document with a short summary of the process, however detailed information on the completed registration procedure (European public assessment report -EPAR), in accordance with EMA regulations will be published by the regulator in the months to come. The EPAR will be based on the latest approved by CHMP version of assessment report (Day 195) where there were more unresolved issues than at the moment of withdrawal so it will not be reflecting the most current status.

While the Company acknowledged all remaining questions as valid based on the available data at the time of the last approved version of the assessment report (Day 195), the Company has since made significant progress towards a new marketing authorization application based on the commercial-scale quality process.

Currently the Company is preparing such a new marketing authorization application aimed at obtaining marketing authorisation for MabionCD20 from EMA in due time. The scope and format of the new application will be reviewed with representatives of EMA as part of a scientific advice procedure, in order to verify that they meet all of the Agency's expectations.