Current Report No. 28/2020

Date of preparation: 2020-07-01

Abbreviated name of the issuer: MABION S.A.

Subject:
Receipt of a written response from the European Medicines Agency as a part of the 'Scientific Advice' regarding the assumptions for the new registration process for MabionCD20

Legal basis Article 17 para. 1 MAR - confidential information.

Report content:

In reference to the current report No. 15/2020 of March 16, 2020 regarding the change of the drug regulatory strategy for the product with the working name MabionCD20 (submission of a new application to the European Medicines Agency -EMA, for a marketing authorization based on a larger scale of manufacturing), the Management Board of Mabion SA (The "Company") informs that on the 1st July 2020, it has received a written response from EMA as part of "Scientific Advice" (i.e. scientific consultations with representatives of EMA).

The document obtained as part of "Scientific Advice" contains the Agency's response to individual assumptions made by the Company regarding the new registration process of the MabionCD20 product. In particular, the scope of data to be included in a new registration application as well as the activities required to generate such data, were proposed by and responded to by the Agency.

Currently, the Company is proceeding with the analysis of the documents received from EMA with the help of external experts in regulations. Subsequently, the Company will establish work schedules in order to execute on the advice received.

In the opinion of the Company, the consultation with EMA is allowing for a significant reduction of uncertainties and regulatory risk, as well as for an optimization of the time and effort required for the compilation of the Marketing Authorization Application (MAA) and its regulatory review. The Company cautions, however, that due to the specific responsibilities of the regulators, the content of the document is subject to interpretation, creating a certain risk of discrepant interpretations.

In the coming days, the Company will organize a webinar for the market to discuss the current status and plans for the MabionCD20 project, which will be announced on the Company's website.