MABION S.A. (12/2020) Receipt of a summary of a BPD Type 3 meeting with the Food and Drug Administration (FDA) on the registration and marketing authorisation of MabionCD20 in the USA

14/02/2020

Profile: MABION

Current Report no. 12/2020

With reference to Current Report no. 4/2020 of 22 January 2020 concerning the BPD (Biosimilar Biological Product Development) Type 3 meeting with the US Food and Drug Administration (FDA), the Management Board of Mabion S.A. (the "Company") hereby informs that on 14 February 2020, it received from the FDA a summary of the BPD meeting held. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the United States of America.

Currently, the Company will proceed to the analysis of the document received and the conclusions and guidelines contained therein, as well as the assessment of their impact on the actions planned by the Company so far to register and get marketing authorisation for the drug in the USA.

The Company stipulates that the process of registration and approval of the drug for marketing in the United States is a multi-stage process and it cannot be ruled out that additional requirements related to product approval by the FDA may arise in the future.