POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 4/2020

Date of preparation: 2020-01-22

Abbreviated name of the issuer: MABION S.A.

Subject matter:

Information regarding a Type 3 BPD meeting with the Food and Drug Administration (FDA) on the registration and marketing authorisation of MabionCD20 in the USA

Legal basis: Article 17(1) MAR – confidential information.

Content of the report:

Referring to current report no. 27/2019 of October 23, 2019 on setting a date for the meeting with the U.S. Food and Drug Administration (FDA), the Management Board of Mabion S.A. (hereinafter "Company") informs that in accordance with the set date, the meeting on BPD (Biosimilar Biological Product Development) of Type 3 with the FDA took place on January 22, 2020.

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.

During the meeting, there was a productive discussion on the data needed to apply for registration in the USA for all indications of a reference drug. At this point, the Company is awaiting a summary of the meeting, the content of which will be finally determined after internal FDA discussion. The Company has been invited to contact the FDA on a regular basis in order to ensure smooth implementation of the application for registration of the medicine in the USA.

The Type 3 BPD meeting is the stage of implementation of activities aimed at obtaining registration of MabionCD20 in the USA. The Company stipulates that holding a Type 3 meeting does not guarantee a positive effect of these activities, the process of registration and approval of the medicine for marketing in the US is multi-stage, and it cannot be ruled out that there will be additional requirements related to the product approval by the FDA in the future.