THE COMMISSION OF FINANCIAL SUPERVISION

Current report nb. 32/100

Date of preparation: 2020-08-28

Issuers short name: MABION S.A.

Title of the report:
Information regarding a meeting with the US Food and Drug Administration (FDA) concerning registration and marketing authorization for MabionCD20 drug on the territory of the USA.

Content of the report:

The Management Board of Mabion S.A. ("the Company") informs about receipt by the Company a summary from the US Food and Drug Administration (" FDA", "Agency") after the BPD (Biosimilar Biological Product Development) Type 2 meeting.

The goal of the meeting was to review details of the Company's plans for the clinical development of MabionCD20 for the US market.

According to the content of the received summary the Company reached concurrence with the Agency on numerous parameters of the clinical program, including the possibility of using significant data packages generated for the clearance of MabionCD20 under EU jurisdiction.

This confirms previous advice where the Agency indicated the lack of necessity to conduct a completely separate development program for US market clearance.

In addition, the Company began exploring with FDA the possibility of applying an innovative regulatory strategy enabling earlier submission of the initial marketing application than previously envisioned. The Company accepted the Agency's suggestion to clarify the details of this approach in a separate to be scheduled meeting. The current arrangements are not binding for the Agency.

The Company informs that the registration and marketing authorization of MabionCD20 drug for the territory of the USA is a multi-stage process and it is possible that additional requirements concerning FDA's approval of the product may appear in the future.