POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 27 / 2019

Date: 2019-10-23

Abridged name of issuer

MABION S.A.

Subject

Appointment of BPD Type 3 meeting with the US Food and Drug Administration _FDA_ concerning registration and marketing authorisation for the drug MabionCD20 within the territory of the United States.

Legal grounds

MAR art. 17 section 1 – confidential information.

Contents of the report:

The Management Board of Mabion S.A. _"Company"_ hereby informs that it has been informed by the agent representing the Company before the US Food and Drug Administration _FDA_ of the Company being granted a BPD _Biosimilar Biological Product Development_ Type 3 meeting with the FDA and of the date of the meeting in question – 22 January of 2020.

The objective of the meeting is to obtain confirmation for the regulation strategy in scope of application for registering MabionCD20 within the territory of the United States of America.

The appointment of the Type 3 meeting constitutes the next stage in the activity aimed towards registration of MabionCD20 in the United States. It is the effect of FDA's evaluation of the documents submitted by the Company, which include complete reports from clinical tests on MabionCD20 involving the European reference listed drug in patients suffering from Rheumatoid arthritis _RA_ and non-Hodgkin's lymphoma _NHL_, results of analytical similarity tests between MabionCD20 _clinically tested drug series_ with the European reference _MabThera_ and the American reference _Rituxan_ with the clinical-bridging test report. Appointment of the meeting does not guarantee a positive effect of the aforementioned activity.

The Company also reserves the right of FDA to change the time of the meeting in question.