POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 37 / 2019

Date: 2019-12-12

Abridged name of issuer

MABION S.A.

Subject

Update of information concerning the registration of drug MabionCD20 for marketing authorisation and disclosure of delayed confidential information

Legal grounds

MAR art. 17 section 1 – confidential information.

Contents of the report:

The management board of Mabion S.A. _"Company", "Issuer"_ hereby informs that the session of the Committee for Medicinal Products for Human Use (CHMP), which processes the applications filed by the Company concerning the registration of the drug under the working name of MabionCD20 for marketing authorisation was closed on 12 December 2019. According to the session agenda, which is available on the website of the European Medicines Agency _EMA_, the application filed by the Company was processed in scope of the list of outstanding issues, which means that it will continue to be processed as neither a positive nor a negative opinion was released.

In light of the closed CHMP session, the Company hereby informs that it received a draft report from the reporters concerning further processing of the Company's applications on the date of 29 November 2019. For purposes of protection of the Issuer's legitimate interests, pursuant to art. 17 sections 1 and 4 of Regulation (EU) no. 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse [...], the Company has decided to delay disclosure of this information to the public. Prompt publication of said information could have adverse effects on the legitimate interests of the Company due to CHMP potentially seeing publication of the internal information by the Company prior to CHMP's final decision concerning further processing of the applications during the session dated 9-12 December 2019, i.e. in accordance with effective registration procedures, in a negative light. If the Company were to publish the information prior to the closing of the CHMP session, it would breach the confidentiality standards of the registration procedure, thus potentially disrupt the process, and influence the final decisions of CHMP in a negative manner.

According to the obtained information, the Company was not able to specify the course of action in examination of the Company's applications during the CHMP session or the result of said session. According to the Company, the draft report received from the reporters covered matters, which were not touched upon in the previous questions of EMA. These questions are associated with increasing the production scale of MabionCD20 to 2x2500l of the culture volume in the bioreactor and the quality of the drug obtained under the new larger scale. This would be a new approach for the regulator, which would eliminate the procedural stage associated with evaluation of the post-registration application in scope of the aforementioned increase of the scale with simultaneous inclusion of said data into the main application. However, the Company reserves that the aforementioned information constitutes only the Company's initial assessment based on the information obtained from reporters, which constituted only internal draft documents before the CHMP session. Due to the above, these documents may be considerably different from the documents ultimately adopted at the

Committee session.

At present time, the Company does not have any information concerning the final arrangements made at the CHMP session. The Company is awaiting information on the applications from the Committee session. When said information is received and analysed, the Company will reveal the details in form of a current report.

In order to ensure equal access to the information concerning the registration procedure at the current stage, the Company informs that a teleconference with the Company's Management and Supervisory Boards has been appointed for tomorrow, i.e. 13 December 2019 at 8:15 AM. The relevant details will be published on the Company's website at www.mabion.eu.