POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 21/2019

Date of preparation: 2019-07-23

Abbreviated name of the issuer:

MABION S.A.

Subject:

Mabion S.A. obtains the GMP certificate for the complex in Konstantynów Łódzki for the production of the active substance

Legal basis

Article 17(1) of MAR – confidential information.

Report content:

The Management Board of Mabion S.A. ("Company") hereby informs that on 23 July 2019 it received information that as a result of an inspection carried out by the Chief Pharmaceutical Inspectorate ("CFI"), the Company obtained a GMP (Good Manufacturing Practice) certificate for the Mabion S.A. Scientific and Complex for Medical Biotechnology in Konstantynów Łódzki with respect to the production of the active substance (Rituximab).

The GIF inspection was commissioned by the European Medicines Agency (EMA) as part of the evaluation of the Company's marketing authorisation application related to MabionCD20. The GMP certificate confirms that the Company runs production processes in accordance with GMP principles for the production of the active substance (Rituximab) used to obtain the finished product. This is the first certificate in the above mentioned scope that the Company has obtained so far. The certificate is valid for 3 years from the date of the last inspection (i.e. 17 May 2019).

In accordance with the scope of the inspection, the Company is also awaiting a decision on certification for the manufacture of a medicinal product (finished product). The Company will inform about the above mentioned decision in a separate current report.

Obtaining both GMP certificates is necessary for the manufacture and commercialisation of MabionCD20 after it has been authorised by the EMA. The Company informs that obtaining the certificate referred to in this report does not guarantee the approval of the product by the EMA.