POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 54 / 2021

Date of preparation: 2021-10-14
Abbreviated name of the Issuer: MABION S.A.

Subject matter: Mabion obtains authorisation to conduct a bridging clinical trial of MabionCD20 in patients with rheumatoid arthritis in Georgia

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

Content of the Report:

The Management Board of Mabion S.A. ("Company") hereby informs that on 14 October 2021, it became aware of an authorisation ("Authorisation") issued by the Head of Regulation Agency for Medical and Pharmaceutical Activities in Georgia for the Company to conduct a clinical trial of MabionCD20 in patients with rheumatoid arthritis ("RA") in Georgia. The Company also holds an approval of the competent bioethics committee in this regard.

The Authorisation granted by the Agency makes it possible to extend the bridging clinical trial to the territory of Georgia. The Company currently holds an authorisation to conduct the trial in Poland and is awaiting relevant approvals in Belgium and Ukraine. Moreover, the Company does not exclude that the trial will be extended to other countries.

Detailed information on the parameters of the bridging clinical trial was provided in Current Report no. 53/2021 of 11 October 2021.