POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 57 / 2021

Date of preparation: 2021-10-22
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 Belgium

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 22 October 2021, the Company became aware that the Federal Agency for Medicines and Health Products in Belgium has issued an authorisation ("Authorisation") for the Company to conduct a clinical trial of MabionCD20 in patients with rheumatoid arthritis ("RA") in Belgium. 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 Belgium. The Company currently holds an authorization to conduct the trial in Poland and Georgia, and is awaiting the relevant approval in 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.