POLISH FINANCIAL SUPERVISION AUTHORITY

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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 Poland

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 11 October 2021, the Company became aware that on 6 October 2021, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issued an authorisation ("Authorisation") for the Company to conduct, in Poland, a clinical trial of MabionCD20 in patients with rheumatoid arthritis ("RA"), entitled "A double-blind, randomised parallel-group clinical trial to evaluate the pharmacokinetics and clinical similarity between MabionCD20 (manufactured on a commercial scale), and the European Union-approved MabThera® preparation and the United States-approved Rituxan® preparation in patients with moderate to severe rheumatoid arthritis". The Company also holds an approval of the competent bioethics committee in this regard.

The Authorisation enables the launch of the clinical trial necessary for the first marketing authorisation of MabionCD20 in the territory of the EU, the initiation of cooperation with clinical sties in Poland, and the recruitment of patients for the trial.

The clinical trial of MabionCD20 will be a three-arm bridging clinical trial in RA patients using MabionCD20 originating from the target manufacturing scale, with MabThera as the European reference and Rituxan as the US reference. According to the approved trial protocol, the bridging clinical trial will ultimately include 280 patients from not less than 35 clinical sites located in Poland, Belgium, Georgia, and Ukraine. The Company is currently awaiting approvals for clinical trials in the countries listed above, in addition to Poland. Moreover, the Company does not exclude that the trial will be extended to other countries. The primary endpoint of the trial will be the analysis of pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. The patient population assumed will also allow for the assessment of treatment efficacy, which is the secondary endpoint of the trial. The basic observation of patients will last for 6 months (the so-called primary endpoint). In addition, a long-term observation of safety and immunogenicity of the therapy will be carried out (follow-up period) up to 48 weeks from the first administration of the medicine.

The Company will inform in current reports on subsequent significant events concerning the above-mentioned clinical trial.