

Date of preparation: 2020-10-29

Issuers short name: MABION S.A.

Title of the report:

Conclusion of an agreement with Parexel to conduct the final clinical trial before submitting a marketing authorisation application for MabionCD20 to the European Medicines Agency (EMA)

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 29 October 2020, it entered into an agreement with Parexel International (IRL) Limited with its registered office in Ireland ("Parexel") to conduct a 3-arm, double-blind, randomized, clinical trial of MabionCD20 in parallel groups among patients with rheumatoid arthritis diagnosis (in moderate to severe condition). The aim of the trial is to determine the pharmacokinetic and clinical similarity between the commercially manufactured MabionCD20, MabThera registered in the EU and Rituxan authorised in the US ("Agreement").

Parexel is a leading global clinical research organization (CRO) that organizes and conducts clinical trials on behalf of other entities. The scope of activities commissioned to Parexel under the Agreement includes, among others, verification of the clinical trial protocol, submission of applications for permission to conduct the trial in individual countries, recruitment of clinical centres and patients, supervision over the course of the trial, regular reviews and analysis of data, preparation of documentation and reports related to the trial for the purposes of the registration procedure, including the final integrated clinical trial report.

The above trial is a bridging clinical trial (Phase I/II), of which the Company informed in its Current Report no. 29/2020 of 9 July 2020, performed to obtain data necessary to submit a new marketing authorisation application (MAA) for MabionCD20 manufactured on a large commercial scale to the European Medicines Agency (EMA). This approach and the scope of the data were consulted by the Company with the European Medicines Agency (EMA) as part of the Scientific Advice procedure in Q2 2020.

The data obtained for the purpose of the MMA, combined with the data obtained separately for the US market, will also be used by the Company in the application process before the US Food and Drug Administration (FDA). The Company is in the process of consulting the proposed approach with the US regulator.

The cost of conducting the trial in compliance with the Agreement shall be approx. EUR 5.4 million net, and its completion is planned in mid-2022. In the current report no. 29/2020 of July 9, 2020 the Company estimated that the works related to obtaining data necessary for the submission of a new Marketing Authorisation application, including the clinical trial, would be completed by or at the

beginning of 2022. The new timeline of conducting the clinical trial has been consulted with Parexel. The change takes into account a cautionary approach to conducting clinical trials in the current pandemic situation.

Any of the Parties may terminate the Agreement for reasons specified therein or without cause upon a written notice.

However, the Company would like to make a reservation that the above assumptions may change in the future due to the fact that they are based on many factors that may impact timeframes, including the factors independent of the Company, such as the rate of recruitment of clinical trials. Moreover, the Company stipulates that the assumptions made and actions performed do not guarantee product registration.