Mabion S.A.
Langiewicza 60
95-050 Konstantynów Łódzki
Polska / Poland
tel.+48 42 207 78 90
fax.+48 42 203 27 03

Mabion S.A.
R&D Center
Fabryczna 17
90-344 Łódź
Polska/ Poland
tel.+48 42 290 82 10
fax. +48 42 355 12 11

European Medicines Agency **1083 HS Amsterdam** **The Netherlands**	[redacted]
CHMP Chair: Prof. Dr. Harald Enzmann	[redacted]

Request for withdrawal of the marketing authorization application

Applicant/MAH Name	Mabion S.A.
INN/Active Substance	Rituximab
Strength and pharmaceutical form	500 mg, solution for infusion
Product Name of centrally authorised medicinal product(s)	[redacted]
Procedure reference	H0004807/H0005387

March 16, 2020

Dear Dr. Harald Enzmann,

In accordance with the pending centralized procedure, as referred above, Mabion S.A. (“**the Applicant**”) – I would like to inform you that, at this point of time, **the Applicant has taken the decision to withdraw the currently pending application for Marketing Authorisation of** [redacted] (also referred MabionCD20 biosimilar product), rituximab, 500 mg, solution for infusion, which was intended to be used for Non-Hodgkin’s lymphoma (NHL), Chronic lymphocytic leukaemia (CLL) and Rheumatoid arthritis.

This withdrawal is based on the following reasons:

Current MAA procedure pertains only to the initial scale of the manufacturing process, while the Applicant decided to prepare and commence a new centralized procedure for the final process instead of the current MAA.

Mabion S.A.
Langiewicza 60
95-050 Konstantynów Łódzki
Polska / Poland
tel.+48 42 207 78 90
fax.+48 42 203 27 03

Mabion S.A.
R&D Center
Fabryczna 17
90-344 Łódź
Polska/ Poland
tel.+48 42 290 82 10
fax. +48 42 355 12 11

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Therefore, we petition as first above written.

[redacted]