Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Notification of Withdrawal of the Aliqopa EU Marketing Authorization Application

20 Dec 2021

Bayer AG

INN: **Copanlisib**
Procedure No.: **EMEA/H/C/004334**

Dear Dr. Enzmann,

We would like to inform you about our decision to withdraw the marketing authorization application for Aliqopa in previously treated marginal zone lymphoma in monotherapy and in combination therapy with rituximab (EMEA/H/C/004334).

This decision was based on the need to await further analyses/data to appropriately support the benefit/risk assessment of the combination treatment and the timing needed to acquire these data. Bayer will consider re-applying for marketing authorization when additional analyses/data become available.

Please note that the decision to withdraw the marketing authorization application does not impact any completed or ongoing clinical trials involving copanlisib.

We recognize the Agency's time and effort in reviewing our application to date and for this we are greatly appreciative. This was a very recent decision made after much consideration by the Sponsor. We are at your disposal for a discussion should further context be warranted.

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

Yours sincerely,

Bayer AG