02 May 2022

Dr Harald Enzmann
Chair of the CHMP
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Withdrawal of Marketing Authorisation Application for:
Sitoiganap; Autologous glioma tumor cells, inactivated, Autologous glioma tumor cells lysates, inactivated Allogeneic glioma tumor cells, inactivated, Allogeneic glioma tumor cells lysates, inactivated

Dear Dr Enzmann

We write to inform you that, at this point in time, ERC Belgium SA, has taken the decision to withdraw the Application for Conditional Marketing Authorization for Sitoiganap, for the treatment of adult patients suffering from recurrent glioblastoma.

This withdrawal is based on feedback from the rapporteurs that efficacy data collected in our clinical trials to date, are not sufficient to convince them of the efficacy of the product even though the real world data was overwhelmingly positive. We will continue to collect clinical trial data and will return to the EMA in the future.

The withdrawal of this application has no impact on ongoing clinical trials with Sitoiganap.

We reserve the right to make additional applications at a future date for Sitoiganap or other therapies.

ERC would like to thank the CHMP Rapporteurs, CHMP Members, and the EMA for the effort invested to review our application, and the advice provided during the examination.

We agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,

[redacted]