BLUE EARTH DIAGNOSTICS
A Bracco Company

11th February 2020

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

Withdrawal of Type II variation for Axumin® (fluciclovine (^{18}F)), 1600/3200 MBq/mL solution for injection

Extension of indication to include diagnosis and continuing assessment of glioma in adult patients.

Procedure number EMEA/H/C/004197/II/0011

Dear Dr Enzmann

I would like to inform you that, at this point in time, Blue Earth Diagnostics Ltd (BED) has taken the decision to withdraw the application for a new indication for Axumin (fluciclovine (^{18}F)) to include diagnosis and continuing assessment of glioma in adult patients.

On 26 November 2018, BED submitted a Type II variation based on 4 clinical studies. The EMA Committee for Orphan Medicinal Products had granted an orphan designation to BED for fluciclovine (^{18}F) for the diagnosis of glioma and these studies were conducted in a limited number of patients, due to the orphan nature of the disease.

Whilst the Applicant believes that the information included in the dossier is clinically meaningful, BED acknowledges the Committee's preliminary assessment of the application. This withdrawal is based on the current CHMP opinion that the data provided do not allow the committee to determine a positive benefit-risk balance for this indication.

This withdrawal does not have any impact on ongoing clinical trials with fluciclovine (^{18}F).

There are no consequences regarding the use of Axumin for its approved indication, as the benefit-risk ratio remains positive in this indication.

BED believes that Axumin is a valuable diagnostic agent and is further developing this product in other oncology areas. We reserve the right to make further submissions at a future date for this or other potential indication(s).

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BED would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

[redacted]

[redacted]

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