28 February 2020
EMA/88420/2020
EMEA/H/C/004197/II/0011

# Withdrawal of application to change the marketing authorisation for Axumin (fluciclovine ($^{18}$F))

Blue Earth Diagnostics Ireland Ltd withdrew its application for the use of Axumin in the diagnosis of glioma (a type of brain tumour) and the continuing assessment of the disease.

The company withdrew the application on 11 February 2020.

## What is Axumin and what is it used for?

Axumin is a diagnostic medicine used with a body scan to check whether prostate cancer has returned.

It is used specifically with the body scan known as positron-emission tomography (PET) in men whose blood test for prostate-specific antigen (PSA) indicates that the cancer may have returned.

Axumin is a 'radiopharmaceutical'. It contains the active substance fluciclovine ($^{18}$F), which releases a small amount of radiation. It is available as a solution for injection.

Axumin has been authorised in the EU since 21 May 2017.

Further information on Axumin's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/axumin

## What change had the company applied for?

The company applied to extend the use of Axumin to include the detection and monitoring of glioma in adults using a PET scan.

Axumin was designated an 'orphan medicine' (a medicine used in rare diseases) on 24 April 2015 for the diagnosis of glioma. Further information on the orphan designation can be found on the Agency's website: ema.europa.eu/medicines/human/orphan-designations/eu3151472.

## How does Axumin work?

The active substance in Axumin, fluciclovine ($^{18}$F), works by entering cancer cells through structures (LAT-1 and ASCT2) that are present in high numbers on cancer cells. In this way fluciclovine ($^{18}$F)

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builds up inside the cancer cells, and the radiation it releases is detected on the PET scan, enabling doctors to detect the cancer and see where it is.

In the diagnosis of gliomas, Axumin is expected to work in the same way as it does in prostate cancer.

## What did the company present to support its application?

The company presented the results from 2 main trials and other studies in a total of around 100 adults. The studies looked at Axumin's use to detect the presence of primary glioma or glioma that has returned. The presence of glioma was confirmed following tissue collection and analysis.

## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

## What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Axumin could not have been authorised for the diagnosis of glioma.

The Agency considered that the results provided did not allow it to conclude that Axumin is effective in detecting glioma. In addition, there were not enough data to show that Axumin can differentiate cancerous (malignant) gliomas from non-cancerous brain tumours or other types of brain problems, such as inflammatory brain damage. The recommended dose of the medicine was based on data from Japanese patients and it was not clear that the data could be applied to European patients.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of using Axumin to detect and monitor glioma did not outweigh its risks.

## What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it withdrew its application because the Agency considered that the data provided did not allow it to determine that the medicine's benefit outweighs its risk when used for detecting glioma.

## Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Axumin.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

## What is happening with Axumin for the diagnosis of prostate cancer?

There are no consequences on the use of Axumin in the diagnosis of prostate cancer.