

EMA/436662/2019

European Medicines Agency decision

P/0285/2019

of 16 August 2019

on the acceptance of a modification of an agreed paediatric investigation plan for fluciclovine (18F) (Axumin), (EMEA-001644-PIP02-14-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

European Medicines Agency decision

P/0285/2019

of 16 August 2019

on the acceptance of a modification of an agreed paediatric investigation plan for fluciclovine (18F) (Axumin), (EMA-001644-PIP02-14-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0256/2015 issued on 30 October 2015,

Having regard to the application submitted by Blue Earth Diagnostics Ireland Ltd on 22 March 2019 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 June 2019, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for fluciclovine (18F)(Axumin), solution for injection, intravenous use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Blue Earth Diagnostics Ireland Ltd, 6th Floor, 2 Grand Canal Square, 2 – Dublin, Ireland.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/226832/2019
Amsterdam, 28 June 2019

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001644-PIP02-14-M01

Scope of the application

Active substance(s):

Fluciclovine (18F)

Invented name:

Axumin

Condition(s):

Diagnosis of amino acid metabolism in solid malignant tumours

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Blue Earth Diagnostics Ireland Ltd

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Blue Earth Diagnostics Ireland Ltd submitted to the European Medicines Agency on 22 March 2019 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0256/2015 issued on 30 October 2015.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 30 April 2019.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Diagnosis of amino acid metabolism in solid malignant tumours

2.1.1. Indication(s) targeted by the PIP

Diagnosis of primary and recurrent brain tumours

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Quality study to evaluate dilution of solution for injection, to introduce a dilution procedure for accurate dosing in younger children and to evaluate the effect of dilution on osmolality and pH
Non-clinical studies	0	Not applicable
Clinical studies	1	Study 2 Open-label two cohort trial to evaluate pharmacokinetics, safety and diagnostic performance of fluciclovine (18F) as add-on to MRI compared to MRI alone in children from birth to less than 18 years of age with suspected primary or recurrent malignant brain tumours
Extrapolation, modelling and simulation studies	1	Study 3 Analysis of existing in house and literature data on diagnostic performance of fluciclovine (18F) in children from birth to less than 18 years of age with malignant brain tumours
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Diagnosis of prostate cancer

Authorised indication(s):

- Axumin is indicated for Positron Emission Tomography (PET) imaging to detect recurrence of prostate cancer in adult men with a suspected recurrence based on elevated blood prostate specific antigen (PSA) levels after primary curative treatment

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intravenous use