EMA/507355/2017

European Medicines Agency decision

P/0242/2017

of 4 September 2017

on the acceptance of a modification of an agreed paediatric investigation plan for tilmanocept (Lymphoseek), (EMEA-001255-PIP01-11-M02) 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.

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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 726/2004[1],

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 Agency[2],

Having regard to the European Medicines Agency's decision P/0303/2012 issued on 20 December 2012 and the decision P/0309/2015 issued on 21 December 2015,

Having regard to the application submitted by Norgine BV on 25 April 2017 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 21 July 2017, 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 tilmanocept (Lymphoseek), kit for radiopharmaceutical preparation, intradermal use, subcutaneous use, intratumoral use, peritumoural use, intralymphatic use, interstitial 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 Norgine BV, Hogehilweg 7, 1101 CA - Amsterdam, The Netherlands.

EMA/PDCO/288424/2017
London, 21 July 2017

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001255-PIP01-11-M02

Scope of the application

Active substance(s):

Tilmanocept

Invented name:

Lymphoseek

Condition(s):

Visualisation of lymphatic drainage of solid malignant tumours for diagnostic purposes

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Kit for radiopharmaceutical preparation

Route(s) of administration:

Intradermal use

Subcutaneous use

Intratumoral use

Peritumoural use

Intralymphatic use

Interstitial use

Name/corporate name of the PIP applicant:

Norgine BV

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Norgine BV submitted to the European Medicines Agency on 25 April 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0303/2012 issued on 20 December 2012 and the decision P/0309/2015 issued on 21 December 2015.

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

The procedure started on 24 May 2017.

Scope of the modification

Some 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

Visualisation of lymphatic drainage of solid malignant tumours for diagnostic purposes

2.1.1. Indication(s) targeted by the PIP

Visualisation of lymphatic drainage of rhabdomyosarcoma and melanoma for diagnostic purposes

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)

Kit for radiopharmaceutical preparation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 1** Open-Label, multi-centre, blinded pathology assessment, within-patient comparative study to evaluate the tolerability and the diagnostic utility of ^{99m}Technetium-labelled tilmanocept and of a vital blue dye in paediatric patients from birth to less than 18 years of age with a solid malignant tumour.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By January 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Visualisation of lymphatic drainage of solid malignant tumours for diagnostic purposes

Authorised indication(s):

- Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity. External imaging and intraoperative evaluation may be performed using a gamma detection device.

Authorised pharmaceutical form(s):

Kit for radiopharmaceutical preparation

Authorised route(s) of administration:

Intradermal use

Subcutaneous use

Intratumoral use

Peritumoral use