EMA/34936/2017

European Medicines Agency decision

P/0017/2017

of 31 January 2017

on the acceptance of a modification of an agreed paediatric investigation plan for paclitaxel (Abraxane), (EMEA-001308-PIP01-12-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.

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on the acceptance of a modification of an agreed paediatric investigation plan for paclitaxel (Abraxane), (EMEA-001308-PIP01-12-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 726/2004[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/0116/2013 issued on 26 April 2013,

Having regard to the application submitted by Celgene Europe Limited on 23 September 2016 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 16 December 2016, 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 paclitaxel (Abraxane), powder for suspension for infusion, 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 Celgene Europe Limited, 1 Longwalk Road, Stockely Park, UB11 1DB – Uxbridge, United Kingdom.

EMA/PDCO/653971/2016
London, 16 December 2016

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

EMEA-001308-PIP01-12-M01

Scope of the application

Active substance(s):

Paclitaxel

Invented name:

Abraxane

Condition(s):

Treatment of solid malignant tumours

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for suspension for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Celgene Europe Limited

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, Celgene Europe Limited submitted to the European Medicines Agency on 23 September 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0116/2013 issued on 26 April 2013.

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

The procedure started on 18 October 2016.

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

Treatment of solid malignant tumours

2.1.1. Indication(s) targeted by the PIP

Treatment of a paediatric solid malignant tumour

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)

Powder for suspension for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a vial with age-appropriate dose content
Non-clinical studies	3	**Study 2** *In vivo* pharmacodynamic study of paclitaxel (formulated as albumin-bound nanoparticles) against Ewing sarcoma, rhabdomyosarcoma, osteosarcoma and neuroblastoma xenografts **Study 3** *In vivo* pharmacodynamic study of paclitaxel (formulated as albumin-bound nanoparticles) against paediatric bone sarcoma xenografts **Measure 4** *In vitro* and *in vivo* pharmacodynamic study of paclitaxel (formulated as albumin-bound nanoparticles) in neuroblastoma and sarcoma models
Clinical studies	3	**Study 5** Open-label, non-controlled, multi-centre trial to evaluate pharmacokinetics, pharmacodynamics, tolerability and safety of paclitaxel (formulated as albumin-bound nanoparticles) in children from 6 months to less than 18 years of age (and adults) with a solid malignant tumour

Area	Number of measures	Description
		Study 6 Open-label, randomised, controlled, multi-centre trial with lead-in to evaluate the pharmacokinetics, tolerability, safety and activity of paclitaxel (formulated as albumin-bound nanoparticles) as add-on to best standard of anti-cancer therapy in children from 6 months to less than 18 years of age (and adults) with a recurrent or refractory neuroblastoma or a recurrent or refractory rhabdomyosarcoma **Study 7** Open-label, randomised, controlled, multi-centre trial to evaluate the safety and efficacy of paclitaxel (formulated as albumin-bound nanoparticles) as add-on to best standard of anti-cancer therapy in children from birth to less than 18 years of age (and adults) with a first relapse or high-risk newly-diagnosed neuroblastoma or rhabdomyosarcoma

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2024
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. Treatment of solid malignant tumours

   Authorised indication(s):

   - Abraxane monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated
   - Abraxane in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.
   - Abraxane in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.

Authorised pharmaceutical form(s):

Powder for suspension for infusion

Authorised route(s) of administration:

Intravenous use