EMA/694485/2020

European Medicines Agency decision

P/0013/2021

of 28 January 2021

on the acceptance of a modification of an agreed paediatric investigation plan for brentuximab vedotin (Adcetris), (EMEA-000980-PIP01-10-M07) 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/59/2011 issued on 21 February 2011, the decision P/0278/2012 issued on 21 November 2012, the decision P/0263/2014 issued on 3 October 2014, the decision P/0211/2016 issued on 12 August 2016, the decision P/0232/2017 issued on 11 August 2017 and the decision P/0243/2020 issued on 22 June 2020,

Having regard to the application submitted by Takeda Pharma A/S on 11 September 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2020, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 brentuximab vedotin (Adcetris), powder for concentrate for solution for infusion, intravenous use, 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 Takeda Pharma A/S, Delta park 45, 2665 - Vallensbaek Strand, Denmark.

EMA/PDCO/495301/2020
Amsterdam, 11 December 2020

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

EMEA-000980-PIP01-10-M07

Scope of the application

Active substance(s):

Brentuximab vedotin

Invented name:

Adcetris

Condition(s):

Treatment of Hodgkin lymphoma

Treatment of anaplastic large cell lymphoma

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Takeda Pharma A/S

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Pharma A/S submitted to the European Medicines Agency on 11 September 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/59/2011 issued on 21 February 2011, the decision P/0278/2012 issued on 21 November 2012, the decision P/0263/2014 issued on 3 October 2014, the decision P/0211/2016 issued on 12 August 2016, the decision P/0232/2017 issued on 11 August 2017 and the decision P/0243/2020 issued on 22 June 2020.

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

The procedure started on 13 October 2020.

Scope of the modification

Some measures 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 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.

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

1.1. Condition

Treatment of Hodgkin lymphoma

The waiver applies to:

- the paediatric population from birth to less than 5 years of age;
- powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition

Treatment of anaplastic large cell lymphoma

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- powder for concentrate for solution for infusion, intravenous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition

Treatment of Hodgkin lymphoma

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with newly diagnosed, relapsed or refractory Hodgkin lymphoma

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

From 5 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	0	Not applicable

Non-clinical studies	0	Not applicable
Clinical studies	2	*Study 1* *Deleted in procedure EMEA-000980-PIP01-10-M01* **Study 2** Open-label, single-arm, dose-escalating, multi-centre trial with extension cohort to evaluate pharmacokinetics, safety, tolerability and activity of brentuximab vedotin in children from 2 years to less than 18 years of age with relapsed or recurrent anaplastic large cell lymphoma or relapsed or recurrent Hodgkin lymphoma **Study 3 (C25004)** Open-label, multi-centre, non-controlled trial to evaluate pharmacokinetics, safety and activity of brentuximab vedotin (A) in combination with AVD chemotherapy in paediatric patients from 5 to less than 18 years (and young adults) with a newly-diagnosed advanced stage Hodgkin lymphoma (HL)
Other measures	1	**Study 4** Meta-analysis of clinical trials of brentuximab vedotin with paediatric patients with a Hodgkin lymphoma

2.2. Condition

Treatment of anaplastic large cell lymphoma

2.2.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with first and subsequent relapse or refractory systemic anaplastic large cell lymphoma

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

From 2 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Same as for condition treatment of Hodgkin lymphoma

2.2.4. Measures

Area	Number of studies	Description
Quality	0	Not applicable

Non-clinical	0	Not applicable
Clinical	1	**Study 2** Same as for condition treatment of Hodgkin lymphoma

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 2020
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. Treatment of Hodgkin lymphoma

Authorised indication(s):

- Adcetris is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):
  - following autologous stem cell transplant (ASCT) or
  - following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option
- Adcetris is indicated for the treatment of adult patients with CD30+ HL at increased risk of relapse or progression following ASCT.
- ADCETRIS is indicated for adult patients with previously untreated CD30+ Stage IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD)
- ADCETRIS is indicated for the treatment of adult patients with CD30+ cutaneous T cell lymphoma (CTCL) after at least 1 prior systemic therapy.

2. Treatment of anaplastic large cell lymphoma

Authorised indication(s):

- Adcetris is indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL)
- ADCETRIS in combination with cyclophosphamide, doxorubicin and prednisone (CHP) is indicated for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL)

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use