EMA/607428/2019

European Medicines Agency decision

P/0405/2019

of 4 December 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I-omburtamab) (EMEA-002101-PIP02-18) 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 application submitted by Y-mAbs Therapeutics A/S on 23 March 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a 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

A paediatric investigation plan for iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I-omburtamab), solution for infusion, intracerebral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I-omburtamab), solution for infusion, intracerebral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Y-mAbs Therapeutics A/S, Agern Alle 11, 2970 – Hoersholm, Denmark.

EMA/PDCO/457858/2019
Amsterdam, 18 October 2019

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-002101-PIP02-18

Scope of the application

Active substance(s):

Iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I-omburtamab)

Condition(s):

Treatment of neuroblastoma

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intracerebral use

Name/corporate name of the PIP applicant:

Y-mAbs Therapeutics A/S

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Y-mAbs Therapeutics A/S submitted for agreement to the European Medicines Agency on 23 March 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 2 May 2018.

Supplementary information was provided by the applicant on 10 July 2019.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed 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 annex 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 neuroblastoma

2.1.1. Indication(s) targeted by the PIP

Treatment of neuroblastoma patients with CNS/LM metastases

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 infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** Single-arm, open-label, non-randomized, uncontrolled, dose escalation study in paediatric neuroblastoma patients with histologically confirmed diagnosis of a malignancy with ^{131}I-omburtamab reactivity with CNS/leptomeningeal disease, aged from birth to less than 18 years. The primary objective is to evaluate the overall survival rate at 3 years (Trial 03-133). **Study 2** Single-arm, open-label, non-randomized, uncontrolled, activity, safety, and dosimetry trial with ^{131}I-omburtamab in paediatric neuroblastoma patients with Central Nervous System(CNS)/Leptomeningeal (LM) relapse, aged from birth to less than 18 years. The primary efficacy objective is to describe the overall survival rate at 3 years (Trial 101).

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	1	Study 3 Interim Analysis of Study 101 (PIP Study 2) to evaluate dosimetry, pharmacokinetic (PK), safety and available activity/efficacy data of ^{131}I-omburtamab in paediatric neuroblastoma patients with Central Nervous System(CNS)/Leptomeningeal (LM) relapse.

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 January 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes