



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/415352/2020

European Medicines Agency decision P/0322/2020

of 10 August 2020

on the acceptance of a modification of an agreed paediatric investigation plan for iodine (^{131}I) murine IgG1 monoclonal antibody against B7-H3 (^{131}I -omburtamab) (EMEA-002101-PIP02-18-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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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/0405/2019 issued on 4 December 2019,

Having regard to the application submitted by Y-mAbs Therapeutics A/S on 15 April 2020 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 24 July 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 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 iodine (¹³¹I) murine IgG1 monoclonal antibody against B7-H3 (¹³¹I-omburtamab), solution for infusion, intracerebral 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 Y-mAbs Therapeutics A/S, Agern Alle 11, 2970 – Hoersholm, Denmark.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/248363/2020
Amsterdam, 24 July 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002101-PIP02-18-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Y-mAbs Therapeutics A/S submitted to the European Medicines Agency on 15 April 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0405/2019 issued on 4 December 2019.

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

The procedure started on 26 May 2020.

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 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 central nervous system (CNS)/ leptomeningeal (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 (Trial 03-133) 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, from birth to less than 18 years of age. Study 2 (Trial 101) Single-arm, open-label, non-randomized, uncontrolled, activity, safety, and dosimetry trial with ¹³¹ I-omburtamab in paediatric neuroblastoma patients with CNS/LM relapse, from birth to less than 18 years of age.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	1	Study 3 Interim Analysis of Study 101 (study 2) to evaluate dosimetry, pharmacokinetic (PK), safety and available activity/efficacy data of ¹³¹ I-omburtamab in paediatric neuroblastoma patients with CNS/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 June 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes