

EMA/568187/2015

European Medicines Agency decision

P/0220/2015

of 2 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A) (EMA-001638-PIP01-14-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/0076/2015 issued on 1 April 2015,

Having regard to the application submitted by Roche Registration Ltd on 26 May 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 August 2015, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision on the granting of 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

Changes to the agreed paediatric investigation plan for anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A), 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

A deferral for anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A), solution for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Roche Registration Ltd, 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 2 October 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/368101/2015
London, 14 August 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001638-PIP01-14-M01

Scope of the application

Active substance(s):

Anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A)

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Roche Registration Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration Ltd submitted to the European Medicines Agency on 26 May 2015 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0076/2015 issued on 1 April 2015.

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

The procedure started on 16 June 2015.

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 in the scope set out in the Annex I of this opinion;
 - to grant a deferral, the details of which are 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(s)

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients from birth to less than 18 years old with a PD-L1 positive paediatric solid tumour as part of the first line treatment

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	1	Study 1: Non-clinical biomarker study in paediatric tumour tissue.
Clinical studies	2	Study 2 Open-label, multi-centre, multiple dose study to evaluate pharmacokinetics, pharmacodynamics, safety and anti-cancer activity of MPDL3280A in paediatric patients from birth to less than 18 years of age with a refractory or relapsed solid tumour known or expected to be PD-L1 positive for which no effective treatment is known, and with expansion cohorts in selected tumour types. Study 3 Randomized, controlled study to evaluate efficacy and safety of MPDL3280A in combination with standard of care in children from birth to less than 18 years of age with a PD-L1 positive paediatric solid tumour selected on the basis of the results of Study 1 and Study 2.

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

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 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes