



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/111608/2015

European Medicines Agency decision

P/0076/2015

of 1 April 2015

on the agreement of a paediatric investigation plan for anti programmed death-ligand 1 (PD-L1) monoclonal antibody (MPDL3280A) (EMA-001638-PIP01-14) 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 application submitted by Roche Registration Ltd on 9 May 2014 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 February 2015, in accordance with Article 18 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 agreement of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan 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 of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

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

Done at London, 1 April 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/341706/2014

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

EMA-001638-PIP01-14

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 16(1) of Regulation (EC) No 1901/2006 as amended, Roche Registration Ltd submitted for agreement to the European Medicines Agency on 9 May 2014 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 July 2014.

Supplementary information was provided by the applicant on 21 November 2014. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a deferral and for a waiver.

A meeting with the Paediatric Committee took place on 11 February 2015

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 18 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.

London, 13 February 2015

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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.

Area	Number of measures	Description
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:	No