EMA/468296/2014

European Medicines Agency decision

P/0220/2014

of 3 September 2014

on the acceptance of a modification of an agreed paediatric investigation plan for idelalisib (EMEA-001350-PIP02-13-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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on the acceptance of a modification of an agreed paediatric investigation plan for idelalisib (EMEA-001350-PIP02-13-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/0278/2013 issued on 31 October 2013,

Having regard to the application submitted by Gilead Sciences International Ltd on 28 April 2014 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 18 July 2014, 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 idelalisib, film-coated tablet, age-appropriate dispersible tablet, oral 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 Gilead Sciences International Ltd, Flowers Building, Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

Done at London, 3 September 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/271259/2014

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

EMEA-001350-PIP02-13-M01

Scope of the application

Active substance(s):

Idelalisib

Condition(s):

Treatment of mature B-cell neoplasm

Pharmaceutical form(s):

Film-coated tablet

Age-appropriate dispersible tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd submitted to the European Medicines Agency on 28 April 2014 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/0278/2013 issued on 31 October 2013.

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

The procedure started on 21 May 2014.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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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.

2. 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 annex and appendix.

London, 18 July 2014

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

1.1. Condition

Treatment of mature B-cell neoplasm

The request for the waiver applied to:

- all paediatric patients from birth to less than 1 year of age;
- film-coated tablet, age-appropriate dispersible tablet, oral 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 mature B-cell neoplasm

2.1.1. Indication(s) targeted by the PIP

Treatment of children from 1 year to less than 18 years of age with a relapsed or refractory diffuse large B-cell lymphoma (DLBCL), mediastinal B-cell lymphoma (MBCL) or Burkitt lymphoma.

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

From 1 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Film-coated tablet including 50 mg strength.

Age-appropriate dispersible tablet.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Study 1: Development of an age-appropriate dispersible tablet.
Non-clinical	2	Study 2: In-vitro activity study in paediatric lymphoma cells. Study 3: In-vitro study in primary patient samples.

Area	Number of measures	Description
Clinical	2	Study 4: Open-label, nonrandomised, multi-centre, multiple dose trial to evaluate pharmacokinetics and tolerability of idelalisib in children from 1 to less than 18 years of age with a relapsed or refractory mature B-cell neoplasm. Study 5: Randomised, multi-centre, placebo controlled trial to evaluate safety and efficacy of idelalisib in combination with standard of care multi-agent anti-tumour chemotherapy in children from 1 to less than 18 years of age with a relapsed or refractory mature B-cell neoplasm.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By July 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes