EMA/2921/2017

European Medicines Agency decision

P/0018/2017

of 30 January 2017

on the acceptance of a modification of an agreed paediatric investigation plan for idelalisib (Zydelig), (EMEA-001350-PIP02-13-M03) 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 European Medicines Agency's decision P/0278/2013 issued on 31 October 2013, and the decision P/0220/2014 issued on 3 September 2014,

Having regard to the application submitted by Gilead Sciences International Ltd on 26 September 2016 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 16 December 2016, 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 idelalisib (Zydelig), film-coated tablet, age-appropriate dispersible tablet, oral 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 Gilead Sciences International Ltd, Flowers Building, Granta Park, Abington, CB21 6GT – Cambridge, United Kingdom.

EMA/PDCO/649901/2016
London, 16 December 2016

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

EMEA-001350-PIP02-13-M03

Scope of the application

Active substance(s):

Idelalisib

Invented name:

Zydelig

Condition(s):

Treatment of mature B-cell neoplasm

Authorised indication(s):

See Annex II

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

Information about the authorised medicinal product:

See Annex II

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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 26 September 2016 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, and the decision P/0220/2014 issued on 3 September 2014.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral. The procedure started on 18 October 2016.

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 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 annexes 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

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.
Clinical	2	Study 4: Deleted in procedure EMEA-001350-PIP02-13-M03. 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. Study 6: Open-label, nonrandomised, multi-centre, multiple dose trial to

		evaluate pharmacokinetics, safety and tolerability of idelalisib in children from 1 to less than 18 years of age with a diffuse large B-cell lymphoma (DLBCL) or a mediastinal B-cell lymphoma (MBCL) as single-agent and as add-on to RICE chemotherapy.

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of mature B-cell neoplasm:

Authorised indication(s):

- Zydelig is indicated in combination with an anti-CD20 monoclonal antibody (rituximab or ofatumumab) for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
  - who have received at least one prior therapy (see section 4.4), or
  - as first line treatment in the presence of 17p deletion or TP53 mutation in patients who are not eligible for any other therapies (see section 4.4).
- Zydelig is indicated as monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment (see section 4.4).

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use