EMA/398448/2011

European Medicines Agency decision

P/135/2011

of 10 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl] (ABT-263) (EMEA-000478-PIP01-08-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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European Medicines Agency decision

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of 10 June 2011

on the acceptance of a modification of an agreed paediatric investigation plan for benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl] (ABT-263) (EMEA-000478-PIP01-08-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/249/2009 issued on 14 December 2009,

Having regard to the application submitted by Abbott Laboratories on 3 February 2011 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 20 April 2011, 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 benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl] (ABT-263), powder for solution (age-appropriate liquid formulation), capsule, soft, 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 Abbott Laboratories, Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE, Maidenhead, Berks, United Kingdom.

Done at London, 10 June 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/253097/2011

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

EMEA-000478-PIP01-08-M01

Scope of the application

Active substance(s):

Benzamide, 4-[4-[[2-(4-chlorophenyl)-5,5-dimethyl-1-cyclohexen-1-yl]methyl]-1-piperazinyl]-N-[[4-[[(1R)-3-(4-morpholinyl)-1-[(phenylthio)methyl] propyl]amino]-3-[(trifluoromethyl)sulfonyl]phenyl] sulfonyl] (ABT-263)

Condition(s):

Treatment of non-Hodgkin lymphoma
Treatment of acute lymphoblastic leukaemia

Pharmaceutical form(s):

Powder for solution (age-appropriate liquid formulation)

Capsule, soft

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abbott Laboratories

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories submitted to the European Medicines Agency on 3 February 2011 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/249/2009 issued on 14 December 2009.

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

The procedure started on 23 February 2011.

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Scope of the modification

Timelines of the measures were modified and pharmaceutical forms were added.

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 and to refuse the changes to the waiver 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, 20 April 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

1. Waiver

1.1. Conditions: Treatment of acute lymphoblastic leukaemia and treatment of non-Hodgkin lymphoma

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days),
- for powder for solution (age-appropriate liquid formulation); capsule, soft; and tablet; oral use,
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Conditions: Treatment of acute lymphoblastic leukaemia and treatment of non-Hodgkin lymphoma

2.1.1. Indication(s) targeted by the PIP

Treatment of acute lymphoblastic leukaemia

Treatment of non-Hodgkin lymphoma

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

From 28 days to less than 18 years

2.1.3. Pharmaceutical form(s)

Powder for solution for oral use (age-appropriate liquid formulation)

Capsule, soft

Tablet

2.1.4. Studies

Area	Number of studies or measures	Description
Quality	1	Study 1: Development of an age-appropriate formulation for the use in paediatric patients from 28 days to less than 18 years of age.
Non-clinical	1	Study 2: In vitro study in paediatric tumour lines. Study 3: Oral toxicity study in juvenile rats.
Clinical	2	Study 4: Open-label, safety and pharmacokinetic study of ABT-263 single agent and combination therapy in paediatric patients from 28 days to less than 18 years of age with relapsed/refractory lymphoblastic leukaemia or lymphoblastic lymphoma. Study 5: Randomized, controlled, safety and activity study of ABT-263 in combination with a chemotherapeutic backbone in patients with relapsed/refractory lymphoblastic leukaemia or lymphoblastic lymphoma.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes