EMA/920517/2011

European Medicines Agency decision

P/290/2011

of 2 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea (ABT-869) (EMEA-000389-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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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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/135/2009 issued on 15 July 2009,

Having regard to the application submitted by Abbott Laboratories on 26 August 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 October 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.

(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 N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea (ABT-869), liquid formulation, age-appropriate oral formulation, 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 Abbott Laboratories, Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berks SL6 4XE, United Kingdom.

Done at London, 2 December 2011

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

EMA/PDCO/815595/2011

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

EMEA-000389-PIP01-08-M01

Scope of the application

Active substance(s):

N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea (ABT-869)

Condition(s):

Solid malignant tumours

Pharmaceutical form(s):

Liquid formulation

Age-appropriate oral formulation

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 26 August 2011 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/135/2009 issued on 15 July 2009.

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

The procedure started on 14 September 2011.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scope of the modification

Some measures and/or 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.

   The Icelandic and the Norwegian Paediatric Committee members agree 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(es) and appendix.

London, 14 October 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of solid malignant tumours

2.1.1. Indication(s) targeted by the PIP

Treatment of solid malignant tumours (refractory to standard therapy).

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

From birth to less than 18 years.

2.1.3. Pharmaceutical form(s)

Liquid formulation

Age-appropriate oral formulation

2.1.4. Studies/Measures

Area	Number of studies/measures	Description
Quality	2	**Measure1** Development of an age-appropriate solid formulation for oral use. **Study 1** Compatibility study of the dosing formulations with feeding tube materials and with other dosing apparati.
Non-clinical	1	**Study 2** Study of uptake and efflux mechanisms of N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea.
Clinical	2	**Study 3** Open label, dose escalation trial to evaluate the pharmacokinetics and safety of N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea in paediatric patients with refractory or relapsed solid malignant tumours. **Study 4** Randomised, controlled, double-blind, clinical trial of N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea in patients from 0 to less than 18 years with relapsed or refractory solid tumours.

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 June 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes