European Medicines Agency

Doc. Ref. EMEA/388509/2009
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**EUROPEAN MEDICINES AGENCY DECISION**

**of 15 July 2009**

**on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea (ABT-869) (EMEA-000389-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

*DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.*

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**EUROPEAN MEDICINES AGENCY DECISION**

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Abbott Laboratories on 15 September 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 September 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a 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*

A 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, 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*

A deferral 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, 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 granted.

*Article 3*

This decision is addressed to Abbott Laboratories, Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berks, SL6 4XE, United Kingdom.

Done at London, 15 July 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
*Pre-authorisation Evaluation of Medicines for Human Use*

Doc. Ref. EMEA/PDCO/284414/2009
EMEA-000389-PIP01-08

# OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

## 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 16(1) of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories submitted for agreement to the EMEA on 15 September 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 16 October 2008.

Supplementary information was provided by the applicant on 19 March 2009.

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**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,

- to grant a deferral in accordance with Article 21 of said Regulation

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 agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 29 May 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

**ANNEX I**

**THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN**

**A. CONDITION(S)**

Solid malignant tumours

**B. WAIVER**

Not applicable

## C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Solid malignant tumours

- **Proposed PIP indication**

Treatment of solid malignant tumours (refractory to standard therapy)

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years

- **Formulation**(s)

age appropriate solid formulation, oral use
liquid formulation, oral use

- **Studies / Measures**

| Area | Number | Description |
|---|---|---|
| **Quality** | 2 | – Development of age-appropriate solid formulation for oral use<br>– Compatibility study of the dosing formulations with feeding tube materials and with other dosing apparati. |
| **Non-clinical** | 1 | – Study of uptake and efflux mechanisms of N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea |
| **Clinical** | 2 | – 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.<br>– 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 |

| | |
|---|---|
| **Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:** | **Yes** |
| **Date of completion of the paediatric investigation plan:** | **By June 2017** |
| **Deferral for some or all studies contained in the paediatric investigation plan:** | **Yes** |