



European Medicines Agency

Doc. Ref.: EMEA/562638/2008
P/94/2008

EUROPEAN MEDICINES AGENCY DECISION

of 3 November 2008

**on the application for agreement of a Paediatric Investigation Plan for vandetanib,
EMEA-000052-PIP01-07 in accordance with Regulation (EC) No 1901/2006
of the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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**on the application for agreement of a Paediatric Investigation Plan for vandetanib,
EMEA-000052-PIP01-07 in accordance with Regulation (EC) No 1901/2006
of the European Parliament and of the Council as amended**

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 726/2004¹,

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 Agency²,

Having regard to the application submitted by AstraZeneca AB on 19 September 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 September 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation 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 a positive opinion,
- (2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision granting a waiver.
- (4) 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 vandetanib, tablet, 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 waiver for vandetanib, tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for vandetanib, tablet, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to AstraZeneca AB, Building 411A, Floor 4, 85 Sodertalje, SE-151 85, Sweden.

Done at London, 03 November 2008

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/562638/2008
EMEA-000052-PIP01-07

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A REQUEST FOR AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN FOR**

Scope of the application

Active substance:

Vandetanib

Condition(s):

Medullary thyroid carcinoma

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted for agreement to the EMA on 19 September 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 16 January 2008.

Supplementary information was provided by the applicant on 17 July 2008.

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 Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 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 Agency, together with its annex(es) and appendix(ces).

London, 19 September 2008

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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Medullary thyroid carcinoma

B. WAIVER

Medullary thyroid carcinoma

- **Condition**

The waiver applies to:

Children from birth to less than 5 years for tablet for oral use

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Medullary thyroid carcinoma

- **Proposed PIP indication**

Treatment of unresectable, recurrent or metastatic hereditary medullary thyroid carcinoma

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

From 5 years to less than 18 years

- **Formulation(s)**

Tablet for oral use

- **Studies**

Area	Number of studies	Description
Quality	-	Not applicable
Non-clinical	-	Not applicable
Clinical	1	Open-label study to evaluate pharmacokinetics, safety and activity of vandetanib in children from 5 years to less than 18 years of age

Measures to address long term follow-up of potential safety issues in relation to paediatric use:

Yes

Date of completion of the paediatric investigation plan:

By October 2011

Deferral for initiation of some or all studies contained in the paediatric investigation plan:

No

Deferral for completion of some or all studies contained in the paediatric investigation plan:

Yes