European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 23 December 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for recombinant human monoclonal antibody to the p40 subunit of human interleukin-12 and human interleukin-23 of the IgG1-class (ABT-874) (EMEA-000552-PIP01-09) 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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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 Ltd. on 27 March 2009 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 13 November 2009, 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 an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan,

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

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[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 recombinant human monoclonal antibody to the p40 subunit of human interleukin-12 and human interleukin-23 of the IgG1-class (ABT-874), solution for injection, subcutaneous 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 recombinant human monoclonal antibody to the p40 subunit of human interleukin-12 and human interleukin-23 of the IgG1-class (ABT-874), solution for injection, subcutaneous 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

A waiver for recombinant human monoclonal antibody to the p40 subunit of human interleukin-12 and human interleukin-23 of the IgG1-class (ABT-874), solution for injection, subcutaneous 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 4

This decision is addressed to Abbott Laboratories Ltd., Queenborough, Kent, ME11 5EL, United Kingdom.

Done at London, 23 December 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/336512/2009
EMEA-000552-PIP01-09

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

Scope of the application

Active substance(s):
Recombinant human monoclonal antibody to the p40 subunit of human interleukin-12 and human interleukin-23 of the IgG1-class (ABT-874)

Condition(s):
Psoriasis vulgaris

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Subcutaneous use

Name/corporate name of the PIP applicant:
Abbott Laboratories Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories Ltd. submitted for agreement to the EMEA on 27 March 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 30 April 2009.

Supplementary information was provided by the applicant on 7 September 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,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, 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 member(s) agree(s) 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.

London, 13 November 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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Psoriasis vulgaris

B. WAIVER

- **Condition**

Psoriasis vulgaris

The waiver applies to:

- children from birth to less than 6 years;
- for solution for injection, for subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Psoriasis vulgaris

- **Proposed PIP indication**

Treatment of patients with severe chronic plaque-type psoriasis vulgaris who are candidates for systemic therapy.

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

From 6 years to less than 18 years.

- **Formulation(s)**

Solution for injection, for subcutaneous use

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	Peri- and postnatal toxicity study in cynomolgous monkeys.
Clinical	2	Open-label, multi-centre, multiple-dose study to evaluate the pharmacokinetics of ABT-874 in paediatric subjects from 6 years to less than 18 years of age with chronic moderate to severe chronic plaque-type psoriasis vulgaris. Multi-centre, randomized, double-blind study to evaluate ABT-874 compared to methotrexate in paediatric subjects from 6 years to less than 18 years of age with severe chronic plaque-type psoriasis vulgaris.

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 November 2016**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**