EMA/30702/2011

European Medicines Agency decision

P/25/2011

of 26 January 2011

on the acceptance of a modification of an agreed paediatric investigation plan for briakinumab (EMEA-000552-PIP01-09-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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on the acceptance of a modification of an agreed paediatric investigation plan for briakinumab (EMEA-000552-PIP01-09-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/266/2009 issued on 23 December 2009,

Having regard to the application submitted by Abbott Laboratories Ltd. on 4 October 2010 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 10 December 2010, 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 briakinumab, solution for injection, subcutaneous 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 Limited, Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead SL6 4XE, United Kingdom.

Done at London, 26 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

(Signature on file)

EMA/PDCO/713713/2010

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

EMEA-000552-PIP01-09-M01

Scope of the application

Active substance(s):

Briakinumab

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 22 of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories Ltd. submitted to the European Medicines Agency on 4 October 2010 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/266/2009 issued on 23 December 2010.
The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 13 October 2010.

Scope of the modification

Some timelines of the original paediatric investigation plan have been modified.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 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 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(es) and appendix.

London, 10 December 2010

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

Psoriasis vulgaris

1.1. Condition: Treatment of Psoriasis vulgaris

The waiver applies to:

- The paediatric population from birth to less than 6 years of age;
- 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.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Psoriasis vulgaris

2.1.1. Indication(s) targeted by the PIP

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

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

From 6 years to less than 18 years.

2.1.3. Pharmaceutical form(s)

Solution for injection, for subcutaneous use

2.1.4. 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.

3. Follow-up, completion and deferral of PIP

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 December 2019
Deferral for some or all studies contained in the paediatric investigation plan:	Yes