EMA/501874/2008

European Medicines Agency decision

P/243/2010

of 26 November 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for [(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875), (EMEA-000734-PIP01-09) 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 8670
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 application submitted by Takeda Global Research and Development Centre (Europe) Ltd. on 16 October 2009 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 October 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation, and Article 13 of said Regulation,

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 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 [(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875), film-coated 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

A deferral for [(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875), film-coated 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 granted.

Article 3

A waiver for [(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875), film-coated 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 granted.

Article 4

This decision is addressed to Takeda Global Research and Development Centre (Europe) Ltd., 61 Aldwych, London, WC2B 4AE, United Kingdom.

Done at London, 26 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/607094/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000734-PIP01-09

Scope of the application

Active substance(s):

[(3S)-6-({2',6'-Dimethyl-4'-[3-(methylsulfonyl) propoxy] biphenyl-3-yl}methoxy)-2,3-dihydro-1-benzofuran-3-yl]acetic acid hydrate (TAK-875)

Condition(s):

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Takeda Global Research and Development Centre (Europe) Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Takeda Global Research and Development Centre (Europe) Ltd. submitted for agreement to the European Medicines Agency on 16 October 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 19 November 2009.

Supplementary information was provided by the applicant on 2 August 2010.

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

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

   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 European Medicines Agency, together with its annex and appendix.

London, 8 October 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. Condition(s)

Treatment of type 2 diabetes mellitus

2. Waiver

2.1. Condition:

Treatment of type 2 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 10 years,
- for film-coated tablets, oral use,
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

3. Paediatric Investigation Plan

3.1. Condition:

Treatment of type 2 diabetes mellitus

3.1.1. Indication(s) targeted by the PIP

Treatment of type 2 diabetes mellitus in children and adolescents aged 10 to less than 18 years of age as an add-on to metformin therapy when metformin and diet and exercise do not provide adequate glycaemic control.

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

From 10 years to less than 18 years of age.

3.1.3. Pharmaceutical form(s)

Film-coated tablet

3.1.4. Studies

Area	Number of studies	Description
Quality		Not applicable
Non-clinical	2	1) Range-finding study in juvenile rats. 2) Toxicity study in juvenile rats.

Clinical	2	3) Multicentre, randomised, open-label, parallel group study to evaluate the pharmacokinetics, pharmacodynamics, and safety of single doses of TAK-875 in subjects with type 2 diabetes mellitus (T2DM) aged 10 to less than 18 years. 4) Multi-centre, double-blind, randomized, parallel-group study to evaluate the efficacy and safety of TAK-875 compared to placebo as add-on therapy in children and adolescents from 10 to less than 18 years of age with type 2 diabetes mellitus inadequately controlled with metformin.

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By January 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes