

EMA/738893/2013

European Medicines Agency decision

P/0019/2014

of 22 January 2014

on the acceptance of a modification of an agreed paediatric investigation plan for albiglutide (EMA-001175-PIP01-11-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.

European Medicines Agency decision

P/0019/2014

of 22 January 2014

on the acceptance of a modification of an agreed paediatric investigation plan for albiglutide (EMA-001175-PIP01-11-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 726/2004¹,

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 European Medicines Agency's decision P/0130/2012 issued on 4 July 2012,

Having regard to the application submitted by GlaxoSmithKline Trading Services Limited on 13 September 2013 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 6 December 2013, 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.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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 albiglutide, powder and solvent for solution for injection, subcutaneous use, 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 GlaxoSmithKline Trading Services Limited, 6900 Cork Airport Business Park, Kinsale Road, Cork, Ireland.

Done at London, 22 January 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/575476/2013

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

EMA-001175-PIP01-11-M01

Scope of the application

Active substance(s):

Albiglutide

Condition(s):

Treatment of Type 2 diabetes mellitus

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Subcutaneous use

Name / corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 13 September 2013 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/0130/2012 issued on 4 July 2012.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 10 October 2013.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 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 and appendix.

London, 6 December 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, 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

1.1. Condition: treatment of Type 2 diabetes mellitus

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age,
- for powder and solvent for solution for injection, subcutaneous 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).

2. Paediatric Investigation Plan

2.1. Condition: treatment of Type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of Type 2 diabetes mellitus

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

From 10 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder and solvent for solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	3	Study 1 Comparative mouse study (albiglutide compared to liraglutide and byetta) to determine the relative potency of albiglutide compared to liraglutide (long acting) and byetta (short acting) on calcitonin response in mice . Study 2 In vitro binding study evaluating GLP-1R distribution in thyroid from healthy, untreated rodents and monkeys compared to human. Study 3 Mouse juvenile toxicity study to determine if albiglutide has effects on sexual maturation and CNS/behaviour.

Area	Number of studies	Description
Clinical	1	Study 4 Randomised, double-blind, multicenter, placebo-controlled study. Part A: Evaluation of dose selection, safety/tolerability, Part B: Evaluation of efficacy and safety of albiglutide, in patients aged from 10 to less than 18 years with Type 2 Diabetes Mellitus (T2DM) inadequately controlled on diet and exercise or metformin monotherapy (above 1000mg/d or have a documented maximum tolerated dose (MTD) 1000mg/d and below).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By April 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes