EMA/899035/2022

European Medicines Agency decision

P/0478/2022

of 2 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for saxagliptin (Onglyza), (EMEA-000200-PIP01-08-M10) 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/0478/2022

of 2 December 2022

on the acceptance of a modification of an agreed paediatric investigation plan for saxagliptin (Onglyza), (EMEA-000200-PIP01-08-M10) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/176/2009 issued on 7 September 2009, the decision P/16/2010 issued on 4 February 2010, the decision P/69/2011 issued on 15 March 2011, the decision P/97/2011 issued on 8 April 2011, the decision P/0061/2013 issued on 26 March 2013, the decision P/0059/2016 issued on 18 March 2016, the decision P/0051/2017 issued on 17 March 2017, the decision P/0277/2019 issued on 16 August 2019 and the decision P/0106/2022 issued on 13 April 2022,

Having regard to the application submitted by AstraZeneca AB on 1 July 2022 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 14 October 2022, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for saxagliptin (Onglyza), film-coated tablet, oral 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 AstraZeneca AB, S-151 85 – Södertälje, Sweden.

EMA/PDCO/651763/2022
Amsterdam, 14 October 2022

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

EMEA-000200-PIP01-08-M10

Scope of the application

Active substance(s):

Saxagliptin

Invented name and authorisation status:

See Annex II

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:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 1 July 2022 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/176/2009 issued on 7 September 2009, the decision P/16/2010 issued on 4 February 2010, the decision P/69/2011 issued on 15 March 2011, the decision P/97/2011 issued on 8 April 2011, the decision P/0061/2013 issued on 26 March 2013, the decision P/0059/2016 issued on 18 March 2016, the decision P/0051/2017 issued on 17 March 2017, the decision P/0277/2019 issued on 16 August 2019 and the decision P/0106/2022 issued on 13 April 2022.

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

The procedure started on 16 August 2022.

Scope of the modification

Some measures 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 Paediatric Committee member of Norway agrees 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 annexes and appendix.

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 (PIP)

1. Waiver

1.1. Condition

Treatment of type 2 diabetes mellitus

The waiver applies to:

- children from birth to less than 10 years of age;
- 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.

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 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablets

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** 26-week randomised, placebo-controlled, double-blind, parallel group study with a 26-week placebo-controlled safety extension period to evaluate the efficacy and safety of saxagliptin 2.5 and 5 mg in paediatric subjects with type 2 diabetes mellitus (T2DM) who are on diet and exercise with metformin immediate release (IR) or extended release (XR), insulin, or metformin IR or XR plus insulin (CV181375, D1680C00019).
Extrapolation, modelling and simulation studies	Not applicable

Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of type 2 diabetes mellitus

Authorised indication(s):

Onglyza is indicated in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- as monotherapy when metformin is inappropriate due to intolerance or contraindications
- in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations).

Authorised pharmaceutical form(s)

Film-coated tablet (tablet)

Authorised route(s) of administration

Oral use