EMA/469210/2023

European Medicines Agency decision

P/0419/2023

of 25 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for peginterferon beta-1a (Plegridy), (EMEA-001129-PIP01-11-M06) 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.

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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 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/0182/2012 issued on 21 August 2012, the decision P/0040/2015 issued on 6 March 2015, the decision P/0127/2018 issued on 11 April 2018, the decision P/0067/2019 issued on 22 March 2019, the decision P/0371/2019 issued on 14 November 2019 and the decision P/0359/2022 issued on 22 August 2022.

Having regard to the application submitted by Biogen Idec Ltd on 25 May 2023 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 8 September 2023, 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, 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 peginterferon beta-1a (Plegridy), solution for injection, subcutaneous use, intramuscular 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 Biogen Idec Ltd, Innovation House, 70 Norden Road, SL6 4AY – Maidenhead, United Kingdom.

EMA/PDCO/264865/2023
Amsterdam, 8 September 2023

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

EMEA-001129-PIP01-11-M06

Scope of the application

Active substance(s):

Peginterferon beta-1a

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of multiple sclerosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Intramuscular use

Name/corporate name of the PIP applicant:

Biogen Idec Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Biogen Idec Ltd submitted to the European Medicines Agency on 25 May 2023 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/0182/2012 issued on 21 August 2012, the decision P/0040/2015 issued on 6 March 2015, the decision P/0127/2018 issued on 11 April 2018, the decision P/0067/2019 issued on 22 March 2019, the decision P/0371/2019 issued on 14 November 2019 and the decision P/0359/2022 issued on 22 August 2022.

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

The procedure started on 10 July 2023.

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 and to the deferral 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 multiple sclerosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- solution for injection, subcutaneous use, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of multiple sclerosis

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsing remitting forms of multiple sclerosis (RRMS)

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)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (105MS306, CHARGE)** Open-label, randomised, active controlled trial to evaluate safety and efficacy of pegylated human interferon beta-1a in children from 10 years to less than 18 years of age with relapsing remitting multiple sclerosis
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 April 2025
Deferral for one or more studies 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 multiple sclerosis

Authorised indication(s):

- Treatment of relapsing remitting multiple sclerosis in adult patients
  - Invented name(s): Plegridy
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Subcutaneous use, Intramuscular use
  - Authorised via centralised procedure