EMA/245270/2021

European Medicines Agency decision

P/0206/2021

of 10 May 2021

on the agreement of a paediatric investigation plan for pegfilgrastim (Pelgraz), (EMEA-002671-PIP02-20) 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 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 Accord Healthcare S.L.U. on 4 July 2020 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 March 2021, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for pegfilgrastim (Pelgraz), solution for injection in pre-filled syringe, subcutaneous 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 2

This decision is addressed to Accord Healthcare S.L.U., World Trade Center, Moll De Barcelona s/n, Edifici Est, 6a Planta, 08039 – Barcelona, Spain.

EMA/PDCO/413194/2020
Amsterdam, 26 March 2021

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-002671-PIP02-20

Scope of the application

Active substance(s):

Pegfilgrastim

Invented name:

Pelgraz

Condition(s):

Prevention of chemotherapy-induced febrile neutropaenia

Treatment of chemotherapy-induced neutropaenia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection in pre-filled syringe

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Accord Healthcare S.L.U.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Accord Healthcare S.L.U. submitted for agreement to the European Medicines Agency on 4 July 2020 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 18 August 2020.

Supplementary information was provided by the applicant on 15 December 2020.

The applicant proposed modifications to the paediatric investigation plan.

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 17(1) of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Prevention of chemotherapy-induced febrile neutropenia

2.1.1. Indication(s) targeted by the PIP

Reduction in the duration of neutropaenia and the incidence of febrile neutropaenia in paediatric patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	Study 1 Development of an age-appropriate formulation for subcutaneous use.
Non-clinical studies	0	Not applicable.
Clinical studies	1	Study 2 Open-label, randomised, multiple dose, active controlled trial to evaluate pharmacokinetics, pharmacodynamics, safety, activity of pegfilgrastim compared to filgrastim in children from birth to 6 years of age with rhabdomayosarcoma or Wilms tumuor on myelosuppressive chemotherapy.
Extrapolation, modelling and simulation studies	0	Not applicable.

Other studies	3	Study 3 Systematic literature review ofall available literature on comparative evidence of pegfilgrastim against filgrastim and clinical use of pegfilgrastim in children. Study 4 Meta-analysis of published literature data identified in study 3 with the objective to compare the efficacy and safety of pegfilgrastim versus filgrastim in children. Study 5 Meta-analysis of published literature data from study 3, including results from study 2, with the objective to compare the efficacy and safety of pegfilgrastim versus placebo in children.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of chemotherapy-induced neutropaenia

2.2.1. Indication(s) targeted by the PIP

Reduction in the duration of neutropaenia and the incidence of febrile neutropaenia in paediatric patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection in pre-filled syringe

2.2.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	Study 1 Same as study 1 for condition prevention of chemotherapy-induced febrile neutropenia
Non-clinical studies	0	Not applicable.

Clinical studies	1	Study 2 Same as study 2 for condition prevention of chemotherapy-induced febrile neutropenia
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	3	Study 3 Same as study 3 for condition prevention of chemotherapy-induced febrile neutropenia Study 4 Same as study 4 for condition prevention of chemotherapy-induced febrile neutropenia Study 5 Same as study 5 for condition prevention of chemotherapy-induced febrile neutropenia
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of chemotherapy-induced febrile neutropaenia

Authorised indication(s):

- Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

2. Treatment of chemotherapy-induced neutropenia

Authorised indication(s):

- Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use