EMA/242581/2020

European Medicines Agency decision

P/0171/2020

of 13 May 2020

on the agreement of a paediatric investigation plan for imatinib (EMEA-002643-PIP01-19) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 12 August 2019 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 27 March 2020, 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 imatinib, powder for oral solution, oral use, nasogastric 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/22293/2020
Amsterdam, 27 March 2020

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

EMEA-002643-PIP01-19

Scope of the application

Active substance(s):

Imatinib

Condition(s):

Treatment of chronic myeloid leukaemia

Treatment of acute lymphoblastic leukaemia

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Nasogastric use

Name/corporate name of the PIP applicant:

Accord Healthcare S.L.U.

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 12 August 2019 an application for a paediatric investigation plan for the above mentioned medicinal product, for which the applicant intends to submit an application for a paediatric use marketing authorisation.

The procedure started on 17 September 2019.

Supplementary information was provided by the applicant on 12 December 2019. 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 annex 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:

Treatment of chronic myeloid leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of Philadelphia chromosome-positive chronic myeloid leukaemia

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral solution

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1:** Development of a powder for oral solution
Non-clinical studies	0	Not applicable
Clinical studies	2	**Study 2:** Open-label, randomised, single dose, two-way crossover trial to evaluate comparative bioavailability of the imatinib powder for oral solution compared to imatinib tablets in healthy adult volunteers under fasting condition. **Study 3**: Open-label trial to evaluate acceptability and palatability of imatinib powder for oral solution in children with leukaemia for whom a treatment with imatinib is indicated.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of acute lymphoblastic leukaemia

2.2.1. Indication(s) targeted by the PIP

Treatment of Philadelphia chromosome-positive acute lymphoblastic leukaemia

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

From 1 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for oral solution

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** same as for condition 1
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2:** same as for condition 1 **Study 3**: same as for condition 1
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	By August 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No