EMA/532461/2021

European Medicines Agency decision

P/0424/2021

of 29 October 2021

on the acceptance of a modification of an agreed paediatric investigation plan for imatinib (as imatinib mesylate), (EMEA-002643-PIP01-19-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.

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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 European Medicines Agency's decision P/0171/2020 issued on 13 May 2020,

Having regard to the application submitted by Accord Healthcare S.L.U. on 3 June 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, 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 imatinib (as imatinib mesylate), powder for oral solution, oral use, nasogastric 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 Accord Healthcare S.L.U., 6a Planta, World Trade Center, Moll De Barcelona s/n, Edifici Est, 08039 – Barcelona, Spain.

EMA/PDCO/324292/2021 corr
Amsterdam, 10 September 2021

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

EMEA-002643-PIP01-19-M01

Scope of the application

Active substance(s):

Imatinib (as imatinib mesylate)

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 22 of Regulation (EC) No 1901/2006 as amended, Accord Healthcare S.L.U. submitted to the European Medicines Agency on 3 June 2021 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/0171/2020 issued on 13 May 2020.

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

The procedure started on 12 July 2021.

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

2. The measures and timelines of the 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