EMA/779382/2012

European Medicines Agency decision

P/0313/2012

of 21 December 2012

on the acceptance of a modification of an agreed paediatric investigation plan for fidaxomicin (Dificlir), (EMEA-000636-PIP01-09-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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on the acceptance of a modification of an agreed paediatric investigation plan for fidaxomicin (Dificlir), (EMEA-000636-PIP01-09-M01) 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 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/98/2010 issued on 4 June 2010,

Having regard to the application submitted by Astellas Pharma Europe B.V. on 13 September 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 7 December 2012, 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 fidaxomicin (Dificlir), tablet, powder for oral suspension, 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 Astellas Pharma Europe B.V., Elisabethhof 19, 2353 EW Leiderdorp, The Netherlands.

Done at London, 21 December 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/635324/2012

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

EMEA-000636-PIP01-09-M01

Scope of the application

Active substance(s):

Fidaxomicin

Invented name:

Dificlir

Condition(s):

Treatment of enterocolitis caused by Clostridium difficile

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Astellas Pharma Europe B.V.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Astellas Pharma Europe B.V. submitted to the European Medicines Agency on 13 September 2012 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/98/2010 issued on 4 June 2010.

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

The procedure started on 10 October 2012.

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 in the scope set out in the Annex I of this opinion.

   The Icelandic and the Norwegian Paediatric Committee members agree 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 annexes and appendix.

London, 7 December 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of enterocolitis caused by Clostridium difficile

2.1.1. Indication(s) targeted by the PIP

Treatment of Clostridium difficile infections (CDI) also known as Clostridium difficile associated diarrhoea (CDAD).

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)

Powder for oral suspension.

Tablet.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	**Study 1** Development of an age-appropriate oral suspension formulation for use in children from birth to less than 18 years.
Non-clinical	3	**Study 2** Pharmacokinetic evaluation of fidaxomicin oral suspension as compared to fidaxomicin oral tablets in adult beagle dogs. **Study 3** Dose range-finding study for the evaluation of toxicokinetics and tolerability of fidaxomicin oral suspension in young beagle dogs. **Study 4** Study for the evaluation of toxicity and toxicokinetics and effect on the developing gastrointestinal tract of fidaxomicin oral suspension in young beagle dogs.

Area	Number of studies	Description
Clinical	5	**Study 5** Multi-centre, open-label study to determine the safety and pharmacokinetics of fidaxomicin oral suspension and tablets taken for ten days in paediatric patients aged 6 months to less than 18 years with Clostridium difficile Associated Disease (CDAD). **Study 6** Multi-centre, open label, randomized, parallel-group study to compare the safety and efficacy of fidaxomicin oral suspension and tablets taken q12h, with vancomycin oral solution and capsules taken q6h, for ten days in paediatric patients aged 6 months to less than 18 years with Clostridium difficile Associated Disease (CDAD). **Study 7** (This study was deleted in EMEA-000636-PIP01-09-M01). **Study 8** Study to determine the role of Clostridium difficile in the pathogenesis of disease observed in neonates and to investigate the feasibility of a study to evaluate safety, efficacy and pharmacokinetics of fidaxomicin oral suspension in neonates with Clostridium difficile Associated Disease (CDAD). **Study 9** Study to evaluate safety, efficacy and pharmacokinetics of fidaxomicin oral suspension in paediatric patients of less than 6 months of age with Clostridium difficile Associated Disease (CDAD) .

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By February 2016
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Condition: Treatment of enterocolitis caused by Clostridium difficile

   Authorised indication:

   - Treatment of Clostridium difficile infections (CDI) also known as C. difficile associated diarrhoea (CDAD)

Authorised pharmaceutical formulation(s):

Film-coated tablet

Route(s) of administration:

Oral use