EMA/650005/2010

European Medicines Agency decision

P/200/2010

of 27 October 2010

on the acceptance of a modification of an agreed paediatric investigation plan for Sodium-X-5-Hydroxy-X-6,10-dioxo-3,4,5,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572), (EMEA-000409-PIP01-08-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 Sodium-X-5-Hydroxy-X-6,10-dioxo-3,4,5,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572), (EMEA-000409-PIP01-08-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/178/2009 issued on 7 September 2009,

Having regard to the application submitted by ViiV Healthcare UK Ltd. on 28 June 2010 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 10 September 2010, 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 Sodium-X-5-Hydroxy-X-6,10-dioxo-3,4,5,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572), tablet, 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 ViiV Healthcare UK Ltd., 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

Done at London, 27 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/513245/2010

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

EMEA-000409-PIP01-08-M01

Scope of the application

Active substance(s):

Sodium-X-5-Hydroxy-X-6,10-dioxo-3,4,5,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-X-benzylamide (GSK1349572)

Condition(s):

Treatment of human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ViiV Healthcare UK Ltd.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ViiV Healthcare UK Ltd. submitted to the European Medicines Agency on 28 June 2010 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/178/2009 issued on 7 September 2009.
The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 15 July 2010.

Scope of the modification

Some measures and timelines of the original Opinion have been modified.

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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 member(s) agree(s) 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(es) and appendix.

London, 10 September 2010

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 human immunodeficiency virus (HIV-1) infection

2.1.1. Indication(s) targeted by the PIP

Treatment of human immunodeficiency virus 1 infection

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)

1) 1 mg, 10 mg, 25 mg and 50 mg tablet for oral use

2) An age appropriate formulation for oral use for the age group less than 6 years of age

2.1.4. Studies

Area	Number of studies	Description
Quality		A formulation age appropriate for paediatric patients less than 6 years of age such as a powder for reconstitution, and oral solution, oral granules, dispersible tablets or mini-tablets
Non-clinical	2	Juvenile Toxicicty Study in rats Pre and Postnatal Toxicity Study in rats
Clinical	2	Study 1) Multicentre, open-label, non-comparative study to evaluate PK, safety, tolerability & antiviral activity of GSK1349572 in HIV-1 infected children and adolescents from 6 weeks to less than 18 years of age Study 2) Multicentre, open-label, non-comparative study to evaluate PK, safety, tolerability and antiviral activity of GSK1349572 in HIV-1 infected in infants and children from birth to less than 6 weeks of age

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes