European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 24 April 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral for regadenoson (EMEA-000410-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 CV Therapeutics Europe Ltd on 12 September 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 3 April 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral,

(2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a deferral.

[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 regadenoson, solution for injection, intravenous 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

A deferral for regadenoson, solution for injection, intravenous 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 granted.

Article 3

This decision is addressed to CV Therapeutics Europe Ltd, 15 Meadway Court, Rutherford Close, Stevenage, Hertfordshire, SG1 2EF, United Kingdom.

Done at London, 24 April 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/163599/2008
EMEA-000410-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL

Scope of the application

Active substance(s):
Regadenoson

Condition(s):
Myocardial perfusion disturbances

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
CV Therapeutics Europe Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, CV Therapeutics Europe Ltd submitted for agreement to the EMEA on 12 September 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 16 October 2008.

Supplementary information was provided by the applicant on 22 January 2009.

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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 18 of said Regulation,

- to grant a deferral in accordance with Article 21 of said Regulation,

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 agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 3 April 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION(S)

Myocardial perfusion disturbances

B. WAIVER

Not applicable.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Myocardial perfusion disturbances

- **Proposed PIP indication**

Diagnostic evaluation of myocardial perfusion disturbances

- **Subset(s) of the paediatric population concerned by the paediatric development**

From birth to less than 18 years.

- **Formulation(s)**

Solution For Injection

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable
Clinical	1	An Open-label, Single Ascending-dose, Pharmacokinetic, Pharmacodynamic and Safety Study of Regadenoson in Paediatric Patients with Cardiovascular Conditions and Diseases.

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By Oct 2018**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**