European Medicines Agency

Doc. Ref. EMEA/31310/2009
P/6/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 27 January 2009**

**on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver casopitant, EMEA-000154-PIP01-07 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 Glaxo Group Limited on 13 December 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 December 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation 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 and on the granting of a waiver,

(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.

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[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 casopitant, powder for solution for infusion, film coated tablet, intravenous infusion, oral 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 casopitant, powder for solution for infusion, film coated tablet, intravenous infusion, oral 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*

A waiver for casopitant, powder for solution for infusion, film coated tablet, intravenous infusion, oral 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 4*

This decision is addressed to Glaxo Group Limited, Greenford Road, UB6 0NN Greenford.

Done at London, 27 January 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency

Doc. Ref. EMEA/31310/2009
EMEA-000154-PIP01-07

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

## Scope of the application

Active substance:
Casopitant

Condition:
Nausea and vomiting

Pharmaceutical forms:
Powder for solution for infusion
Film-coated tablet

Routes of administration:
Intravenous infusion
Oral use

Name/corporate name of the PIP applicant:
Glaxo Group Limited

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Glaxo Group Limited submitted for agreement to the EMEA on 13 December 2007 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 January 2008.

Supplementary information was provided by the applicant on 6 October 2008.

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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,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with
  Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and

  Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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, 12 December 2008

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 AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

**A. CONDITION(S)**
Nausea and vomiting

**B. WAIVER**

- **Condition**

Chemotherapy-induced nausea and vomiting

The waiver applies to:

Newborn and infants from birth to less than 6 months for powder for solution for infusion
Newborn and infants from birth to less than 6 months for film-coated tablet

on the grounds that the specific medicinal product is likely to be unsafe and
on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered

- **Condition**

Post-operative nausea and vomiting

The waiver applies to:

Newborn and infants from birth to less than 6 months for powder for solution for infusion
Newborn and infants from birth to less than 6 months for film-coated tablet

on the grounds that the specific medicinal product is likely to be unsafe and
on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered

**C. PAEDIATRIC INVESTIGATION PLAN**

- **Condition to be investigated**

**C.1** Chemotherapy-induced nausea and vomiting
**C.2** Post-operative nausea and vomiting

- **Proposed PIP indication**

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

From 6 months to less than 18 years.

- **Formulation(s)**

Powder for solution for infusion
Film-coated tablet

- **Studies**

| Area | Number of studies | Description |
|---|---|---|
| Quality | | Development of an age-appropriate formulation |
| Non-clinical | | Preliminary toxicity study in the juvenile rat<br>Toxicity study in the pre-weaning juvenile rat (GLP)<br>28-day toxicity study in the juvenile rat (GLP) |
| Clinical | | Open label study of casopitant PK (dose-finding), ifosfamide drug interaction, safety and clinical benefit in subjects from 12 to less than 18 years who have failed to achieve emetic control in their last pre-study cycle of chemotherapy<br><br>Open label study of casopitant pharmacokinetics, safety and clinical benefit in subjects from 6 months to less than 12 years who have failed to achieve emetic control in their last pre-study cycle of chemotherapy.<br><br>Open-label single dose IV pharmacokinetic (dose-finding) study of casopitant in subjects from 6 months to less than 18 years who undergo routine inpatient or outpatient surgery under general anaesthesia.<br><br>Randomised, double-blind, placebo-controlled efficacy/safety study in subjects from 6 months to less than 18 years who undergo routine inpatient or outpatient surgery under general anaesthesia. |

| | |
|---|---|
| **Measures to address long term follow-up of potential safety issues in relation to paediatric use:** | **Yes** |
| **Date of completion of the paediatric investigation plan:** | **By May 2013** |
| **Deferral for some or all studies contained in the paediatric investigation plan:** | **Yes** |