EMA/651476/2010

# European Medicines Agency decision

P/199/2010

of 27 October 2010

on the acceptance of a modification of an agreed paediatric investigation plan for motavizumab (EMEA-000352-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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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/152/2009 issued on 7 August 2009,

Having regard to the application submitted by Abbott Laboratories Limited on 5 July 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

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 motavizumab, solution for injection, intramuscular 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 Abbott Laboratories Limited, Abbott House, Vanwall Business Park, Vanwall Road, SL6 4XE – Maidenhead, United Kingdom.

Done at London, 27 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/651476/2010

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

EMEA-000352-PIP01-08-M01

## Scope of the application

**Active substance(s):**

Motavizumab

**Condition(s):**

Serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Intramuscular use

**Name/corporate name of the PIP applicant:**

Abbott Laboratories Limited

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories Limited submitted to the European Medicines Agency on 5 July 2010 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/152/2009 issued on 7 August 2009.

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

The procedure started on 12 August 2010.

## Scope of the modification

Some measures 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 members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the 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 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

## *1.1. Condition: Serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)*

The waiver applies to:

- Children (from 2 to less than 12 years), adolescents (from 12 to less than 18 years),
- for solution for injection, intramuscular use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

# 2. Paediatric Investigation Plan

## *2.1. Condition: Serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)*

### 2.1.1. Indication(s) targeted by the PIP

Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 2 years.

### 2.1.3. Pharmaceutical form(s)

Solution for injection, intramuscular use

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | - | Not applicable. |
| Non-clinical | - | Not applicable. |
| Clinical | 2 | A Study of MEDI-524 (Motavizumab), an Enhanced Potency Humanised Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Native American Infants.<br><br>A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of MEDI-524, a Humanised Enhanced Potency Monoclonal Antibody Against Respiratory Syncytial Virus (RSV), in Children with Hemodynamically Significant Congenital Heart Disease (HSCHD). |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use: | Yes |
| Date of completion of the paediatric investigation plan: | By March 2009 |
| Deferral for one or more studies contained in the paediatric investigation plan: | No |