EMA/895487/2018

# European Medicines Agency decision

P/0035/2019

of 29 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800) IZINOVA (and associated names) (EMEA-000816-PIP02-10-M02) 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/0214/2011 issued on 2 September 2011 and decision P/0169/2016 issued on 17 June 2016,

Having regard to the application submitted by Ipsen Pharma on 10 September 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 December 2018, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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***

Changes to the agreed paediatric investigation plan for sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800) (IZINOVA (and associated names)), concentrate for oral solution , oral use, including changes to the deferral, 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.

This decision is addressed to IPSEN Pharma, 65 quai George Gorse, 92100 - Boulogne-Billancourt, France.

EMA/PDCO/660520/2018
London, 14 December 2018

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

EMEA-000816-PIP02-10-M02

## Scope of the application

**Active substance(s):**

Sodium sulphate / potassium sulphate / magnesium sulphate heptahydrate (BLI800)

**Invented name:**

IZINOVA (and associated names)

**Condition(s):**

Diagnosis of organic and/or functional bowel diseases

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Concentrate for oral solution

**Route(s) of administration:**

Oral use

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

Ipsen Pharma

**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, Ipsen Pharma submitted to the European Medicines Agency on 10 September 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0214/2011 issued on 2 September 2011 and decision P/0169/2016 issued on 17 June 2016.

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

The procedure started on 16 October 2018.

## Scope of the modification

Some 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 and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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 annexes and appendix.

# 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 (PIP)

# 1. Waiver

## *1.1. Condition*

Diagnosis of organic and/or functional bowel diseases

The waiver applies to:

- newborns and infants from birth to less than 6 months of age;
- for oral solution, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

# 2. Paediatric Investigation Plan

## *2.1. Condition*

Diagnosis of organic and/or functional bowel diseases

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

Bowel cleansing prior to any procedure requiring a clean bowel in patients above 6 months of age

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

From 6 months to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Oral solution

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 0 | Not applicable. |
| Non-clinical | 0 | Not applicable. |
| Clinical | 4 | Study 1<br>Dose-ranging, open-label, study to assess efficacy of BLI800 in adolescents of 12 to less than 18 years of age.<br>Study 2<br>Efficacy, safety, and tolerability, active-controlled study of BLI800 in adolescent subjects undergoing colonoscopy. |

| | | |
|---|---|---|
| | | Study 3<br><br>Efficacy, safety, and tolerability, active-controlled study of BLI800 in children of 3 to less than 12 years of age.<br><br>Study 4<br><br>Open-label study to assess the safety of BLI800 in children 6 months to less than 3 years of age. |

# 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 2021 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s)

1. Diagnostic of organic and/or functional bowel diseases

Authorised indication(s):

- Izinova is indicated in adults for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure).
  Izinova is not a treatment for constipation.

## Authorised pharmaceutical form(s)

Concentrate for oral solution

## Authorised route(s) of administration

Oral use