EMA/647501/2013

European Medicines Agency decision

P/0302/2013

of 29 November 2013

on the granting of a product specific waiver for lanreotide (acetate) (Somatuline LA and associated names), (EMEA-001503-PIP01-13) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Ipsen Pharma on 8 July 2013 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 October 2013 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

(1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.

(2) 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 waiver for lanreotide (acetate) (Somatuline LA and associated names), powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular use, subcutaneous 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 2

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

Done at London, 29 November 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/498792/2013

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001503-PIP01-13

Scope of the application

Active substance(s):

Lanreotide (acetate)

Invented name:

Somatuline LA and associated names

Condition(s):

Treatment of acromegaly

Treatment of pituitary gigantism

Treatment of gastrointestinal fistulae

Treatment of metastases to peritoneum

Treatment of pituitary neoplasms

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and solvent for prolonged-release suspension for injection

Solution for injection in pre-filled syringe

Powder for suspension for injection

Solution for injection

Route(s) of administration:

Intramuscular use

Subcutaneous use

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Name/corporate name of the PIP applicant:

Ipsen Pharma

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Ipsen Pharma submitted to the European Medicines Agency on 8 July 2013 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 15 August 2013.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

London, 11 October 2013

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: treatment of acromegaly

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular and subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition: treatment of pituitary gigantism

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.3. Condition: treatment of gastrointestinal fistulae

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.4. Condition: treatment of metastases to peritoneum

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

1.5. Condition: treatment of pituitary neoplasms

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for prolonged-release suspension for injection, solution for injection in pre-filled syringe, powder for suspension for injection, solution for injection, intramuscular and subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of acromegaly

   Authorised indication(s):

   - Long term treatment of acromegaly when the circulating levels of Growth hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option. Relief of symptoms associated with acromegaly.

2. Treatment of gastrointestinal fistulae

   Authorised indication(s):

   - Treatment of post-operative digestive fistulae.

3. Treatment of metastases to peritoneum

   Authorised indication(s):

   - Palliative treatment of clinical symptoms associated with upper intestinal obstruction due to peritoneal carcinomatosis in inoperable patients in addition to other symptomatic medications.

4. Treatment of pituitary neoplasms

   Authorised indication(s):

   - Treatment of primary thyrotropic adenomas responsible for hyperthyroidism.

5. Treatment of carcinoid syndrome

   Authorised indication(s):

   - Treatment of carcinoid syndrome associated with neuroendocrine tumours.

Authorised pharmaceutical form(s):

Powder and solvent for prolonged-release suspension for injection

Solution for injection in pre-filled syringe

Powder for suspension for injection

Solution for injection

Authorised route(s) of administration:

Intramuscular use

Subcutaneous use