



EMA/COMP/386616/2009 Rev.1  
Committee for Orphan Medicinal Products

## Public summary of opinion on orphan designation

Afamelanotide for the treatment of solar urticaria

First publication	7 September 2009
Rev.1: sponsor's contact details updated	1 July 2013
<b>Disclaimer</b> Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 24 July 2009, orphan designation (EU/3/09/648) was granted by the European Commission to Clinuvel UK Limited, United Kingdom, for afamelanotide for the treatment of solar urticaria.

### What is solar urticaria?

Solar urticaria is a skin disease in which exposure to ultraviolet (UV) light, or sometimes visible light, results in an acute allergic skin reaction. Patients with solar urticaria develop itching, swelling, rash and pain in the skin within minutes of exposure to light. These symptoms tend to disappear within a few hours after exposure to the light has stopped.

Solar urticaria is a long-term debilitating disease that has an impact on the patient's quality of life because it affects the ability of patients to expose themselves to sunlight.

### What is the estimated number of patients affected by the condition?

At the time of designation, solar urticaria affected approximately 3.6 in 10,000 people in the European Union (EU). This was equivalent to a total of around 182,000 people<sup>\*</sup>, and is below the ceiling for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

---

<sup>\*</sup>Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 27), Norway, Iceland and Liechtenstein. At the time of designation, this represented a population of 504,800,000 (Eurostat 2009).



## **What treatments are available?**

At the time of designation, the main way to manage solar urticaria was to avoid or minimise exposure to sunlight. Common treatments included anti-allergic medicines such as antihistamines and sunscreens that reflect sunlight off the skin. In some cases, phototherapy was used. This is a technique in which the patient's skin is gradually exposed to light in a controlled manner, to improve the skin's ability to tolerate exposure to light.

The sponsor has provided sufficient information to show that afamelanotide might be of significant benefit for patients with solar urticaria because it might offer protection to a broader range of different types of light and might be given less often than existing treatments. These assumptions will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

## **How is this medicine expected to work?**

Afamelanotide is a copy of the natural hormone 'melanotropin', which stimulates production of 'eumelanin' in skin cells. Eumelanin is the black-brown pigment in the skin that protects cells from the damage caused by exposure to sunlight. The way in which afamelanotide works in solar urticaria is not fully understood, but it is thought that it stimulates eumelanin production in skin cells independently of light exposure. This is expected to reduce the damage to the skin of patients with solar urticaria caused by sunlight, because the eumelanin that is produced is able to absorb UV and visible light.

Afamelanotide will be available as an implant that is placed under the skin once every two months. The implants dissolve under the skin so they do not need to be removed.

## **What is the stage of development of this medicine?**

The effects of afamelanotide have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials in patients with solar urticaria were ongoing.

At the time of submission, afamelanotide was not authorised anywhere in the EU for solar urticaria or designated as orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 4 June 2009 recommending the granting of this designation.

---

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the EU) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

## For more information

Sponsor's contact details:

Clinuvel UK Limited  
C/ Reed Smith  
Broadgate Tower  
Third Floor  
20 Primrose Street  
London EC2A 2RS  
United Kingdom  
Telephone: +44 20 3116 3000  
Telefax: +44 20 3116 3999  
E-mail: [mail@clinuvel.com](mailto:mail@clinuvel.com)

For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases which includes a directory of patients' organisations registered in Europe.
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

## Translations of the active ingredient and indication in all official EU languages<sup>1</sup>, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Afamelanotide	Treatment of solar urticaria
Bulgarian	Афамеланотид	Лечение на слънчева уртикария
Czech	Afamelanotid	Léčba solární urtikárie
Danish	Afamelanotide	Behandling af soludløst urtikaria
Dutch	Afamelanotide	Behandeling van solaire urticaria
Estonian	Afamelanotiid	Päikese urtikaaria ravi
Finnish	Afamelanotidi	Aurinkourtikarian hoito
French	Afamélanotide	Traitement de l'urticaire solaire
German	Afamelanotide	Behandlung von Sonnenurticaria
Greek	Αφամελανοτίδη	Θεραπεία της ηλιακή κνιδωση
Hungarian	Afamelanotide	Napfény okozta urticaria kezelése
Italian	Afamelanotide	Trattamento dell'orticaria solare
Latvian	Afamelanotīds	Saules nātrene ārstēšana
Lithuanian	Afamelanotidas	Urtikarijos, sukeltos saulės spindulių, gydymas
Maltese	Afamelanotide	Kura tal-urtikarja tax-xemx
Polish	Afamelanotyd	Leczenie pokrzywki świetlnej
Portuguese	Afamelanotide	Tratamento da urticária solar
Romanian	Afamelanotidă	Tratamentul urticariei solare
Slovak	Afamelanotid	Liečba solárnej urtikárie
Slovenian	Afamelanotide	Zdravljenje sončne urtikarije
Spanish	Afamelanotida	Tratamiento de urticaria solar
Swedish	Afamelanotid	Behandling av solutlöst urtikaria
Norwegian	Afamelanotid	Behandling av solutløst urticaria
Icelandic	Afamelanótíð	Meðferð á sólar ofsakláða

<sup>1</sup> At the time of designation