



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 August 2010
EMA/COMP/234320/2010
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Tranilast for the prevention of scarring post glaucoma filtration surgery

On 27 July 2010, orphan designation (EU/3/10/756) was granted by the European Commission to Altacor Ltd, United Kingdom, for tranilast for the prevention of scarring post glaucoma filtration surgery.

What is scarring post glaucoma filtration surgery?

Glaucoma is a disease in which the pressure in the eye rises because the fluid inside the eye cannot drain away. The pressure affects the optic nerve (the nerve that sends signals from the eye to the brain) and can cause loss of vision. Glaucoma can be treated using 'filtration surgery', when the surgeon makes a small hole in the sclera (the white of the eye), so that the fluid that has built up in the eye can drain away. Scarring can occur after surgery if too much collagen (a type of protein) is laid down in the channel during healing. This can seal the channel up and cause the pressure inside the eye to build up again.

Scarring post glaucoma filtration surgery is a serious and long-term debilitating condition because it may lead to loss of vision.

What is the estimated number of patients at risk of developing the condition?

At the time of designation, the number of patients at risk of scarring post glaucoma filtration surgery was estimated to be less than 3 in 10,000 people in the European Union (EU)*. This is equivalent to a total of fewer than 152,000 people, and is below the threshold 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).

What methods of prevention are available?

At the time of designation, no satisfactory methods were authorised in the EU for the prevention of scarring post glaucoma filtration surgery. Medicines that stop the growth of cells, such as 5-fluorouracil

*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. This represents a population of 506,500,000 (Eurostat 2010).



and mitomycin C (which are also used to treat cancer), were applied to the eye during surgery to slow down the formation of scar tissue and prevent the channel sealing up.

How is this medicine expected to work?

Tranilast is expected to work by blocking the release of 'transforming growth factor beta' (TGF- β), a protein involved in wound healing that can cause excessive collagen production and scarring. The reduction of TGF- β levels is expected to help the wound in the eye to heal without excessive scarring.

What is the stage of development of this medicine?

The sponsor of this application has not conducted any studies with tranilast. However, it has provided the results of studies in experimental models and of clinical trials from the published literature to support its application for orphan designation.

Tranilast is already marketed in Japan and South Korea for allergic conditions (including allergic conjunctivitis) and scarring of the skin.

At the time of submission, tranilast was not authorised anywhere in the EU for the prevention of scarring post glaucoma filtration surgery or designated as an 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 8 April 2010 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

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Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Tranilast	Prevention of scarring post glaucoma filtration surgery
Bulgarian	Траниласт	Превенция на белези след филтрираща операция при глаукома
Czech	Tranilast	Prevence zjizvení post glaukomatozní filtrační operace
Danish	Tranilast	Forebyggelse af ardannelse efter glaukomfiltreringsoperation
Dutch	Tranilast	Preventie van littekenvorming na glaucoomfiltratiechirurgie
Estonian	Tranilast	Glaukoomi filtratsioonkirurgia järgsete armide ennetamine
Finnish	Tranilasti	Arpikudoksen kasvun esto glaukooman kirurgisen hoidon jälkeen
French	Tranilast	Prévention des cicatrices après chirurgie filtrante du glaucome
German	Tranilast	Prävention von Narbenbildung nach Glaukom-Filtrations-Operation
Greek	Τρανιλάστη	Πρόληψη ουλών μετά από εγχείριση διήθησης γλαυκώματος
Hungarian	Tranilast	Zöldhályog-szűrő műtét utáni hegesedés megakadályozása
Italian	Tranilast	Prevenzione delle cicatrici post intervento chirurgico filtrante per glaucoma
Latvian	Tranilasts	Rētaudu veidošanās profilakse pēc glaukomas filtrēšanas operācijas
Lithuanian	Tranilastas	Randų po glaukomos filtracinės operacijos prevencija
Maltese	Tranilast	Prevenzjoni ta' cikatrici wara kirurgija ta' filtrazzjoni għal glawkoma
Polish	Tranilast	Zapobieganie bliznom po operacji udroznienia kąta przesączania w jaskrze
Portuguese	Tranilast	Prevenção de cicatrização pós-cirurgia de filtração glaucoma
Romanian	Tranilast	Prevenirea cicatrizării după intervenția chirurgicală de filtrare în glaucom
Slovak	Tranilast	Prevenia jazvenia po filtračnej operácii glaukómu
Slovenian	Tranilast	Preprečevanje brazgotin po filtracijski operaciji glavkoma
Spanish	Tranilast	Prevenición de la cicatrización posterior a la cirugía de filtración del glaucoma
Swedish	Tranilast	Förebyggande av ärrbildning efter glaukom filtrerings ingrepp
Norwegian	Tranilast	Forebygging av ardannelse etter glaukom-filtrasjonskirurgi
Icelandic	Tranílast	Til að koma í veg fyrir örmyndun eftir síunaraðgerð vegna gláku

¹ At the time of designation