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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxylic acid for the prevention of scarring post glaucoma filtration surgery

On 4 June 2014, orphan designation (EU/03/14/1279) was granted by the European Commission to Clanotech AB, Sweden, for 4-(4-methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxylic acid 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 properly. 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), to create a drainage channel, so that the fluid that has built up in the eye can drain away. After surgery, as part of the body's normal healing process, specialised cells called fibroblasts build up scar tissue which helps to repair the wound. However, scarring can sometimes be excessive and seal the channel up, causing the pressure inside the eye to build up again.

Scarring post glaucoma filtration surgery is a 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 approximately 1.9 people in 10,000 in the European Union (EU). This was equivalent to a total of around 97,000 people *, 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).

*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 28), Norway, Iceland and Liechtenstein. This represents a population of 511,100,000 (Eurostat 2014).

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 block and kill fibroblasts, such as mitomycin C or 5-fluorouracil (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 from sealing up.

How is this medicine expected to work?

This medicine is expected to work by preventing the migration and adhesion of fibroblasts to the wound area. This is expected to help the wound in the eye to heal without excessive scarring, thus preventing pressure in the eye from building up again following glaucoma surgery.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, the evaluation of the effects of the medicine in experimental models was ongoing.

At the time of submission, no clinical trials with the medicine in patients with scarring post glaucoma filtration surgery had been started.

At the time of submission, the medicine was not authorised anywhere in the EU for 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 9 April 2014 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:

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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 languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxylic acid	Prevention of scarring post glaucoma filtration surgery
Bulgarian	4-(4-метокси-фениламино)-6-метилкарбамил-хинолин-3-карбоксилова киселина	Превенция на белези след филтрираща операция при глаукома
Croatian	4-(4-metoksi-fenilamino)-6-metilkarbamil-kinolin-3-karboksilatna kiselina	Prevenција ožiljkavanja nakon filtracijske operacije glaukoma
Czech	4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxylic acid	Prevence jizvení po glaukomatozní filtrační operace
Danish	4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinolin-3-carboxyl syre	Forebyggelse af ardannelse efter glaukom filterings-operation
Dutch	4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxyliczuur	Preventie van littekenvorming na glaucoomfiltratiechirurgie
Estonian	4-(4-Metoksü-fenüülamino)-6-metüülkarbamüül-kinoliin-3-karboksüülhape	Glaukoomi filtratsioonkirurgia järgsete armide ennetamine
Finnish	4-(4-metoksifenyyliamino)-6-metyylikarbamyylikinoliini-3-karboksyylihappo	Arpikudoksen kasvun esto glaukooman kirurgisen hoidon jälkeen
French	Acide 4-(4-méthoxy-phénylamino)-6-méthylcarbamyl-quinoline-3-carboxylique	Prévention des cicatrices après chirurgie filtrante du glaucome
German	4-(4-Methoxy-phenylamino)-6-Methylcarbamyl-quinoline-3-carbonsäure	Prävention von Narbenbildung nach Glaukom-Filtrations-Operation
Greek	4-(4-Μεθοξυ-φαινυλαμινό)-6-μεθυλκαρβαμυλ-κινολινο-3-καρβοξυλικό οξύ	Πρόληψη ουλών μετά από εγχείριση διήθησης γλαυκώματος
Hungarian	4-(4-metoxi-fenilamino)-6-metilkarbamil-kinolin-3-karboxil sav	Glaucoma filtrációs műtétet követő hegesedés kialakulásának megelőzése
Italian	Acido 4-(4-metossi-fenilamino)-6-metilcarbamil-chinolina-3-carbossilico	Prevenzione delle cicatrici post intervento chirurgico filtrante per glaucoma
Latvian	4-(4-Metoksi-fenilamino)-6-metilkarbamil-kinolīna-3-karboksilik skābe	Rētaudu veidošanās profilakse pēc glaukomas filtrēšanas operācijas
Lithuanian	4-(4-Metoksi-fenilamino)-6-metilkarbamil-kvinolino-3-karboksirūgštis	Randų po glaukomos filtracijos operacijos prevencija
Maltese	4-(4-Methoxy-phenylamino)-6-methylcarbamyl-quinoline-3-carboxylic acid	Prevenzjoni ta' ċikatriċi wara kirurġija ta' filtrazzjoni għal glawkoma
Polish	Kwas 4-(4-metoksy-fenylamino)-6-metylkarbamil-chinolino-3-karboksylowy	Zapobieganie bliznom po operacji udrożnienia kąta przesączania w jaskrze
Portuguese	Ácido 4-(4-Metoxi-fenilamino)-6-metilcarbamil-quinolino-3-carboxílico	Prevenção de cicatrizes no pós-operatório de filtração do glaucoma

¹ At the time of designation

Language	Active ingredient	Indication
Romanian	Acid 4-(4-metoxi-fenilamino)-6-metilcarbamil-chinolină-3-carboxilic	Prevenirea cicatrizării după intervenția chirurgicală de filtrare în glaucom
Slovak	Kyselina 4-(4-metoxý-fenylamino)-6-metylcarbamyľ-chinolín-3-karboxylová	Prevenia jazvenia po filtračnej operácii glaukómu
Slovenian	4-(4-metoksi-fenilamino)-6-metilcarbamil-kinolin-3-karboksilna kislina	Preprečevanje brazgotin po filtracijski operaciji glavkoma
Spanish	4-(4-Methoxy-phenilamino)-6-methylcarbamil-quinolino-3-del acido carboxilico	Prevención de la cicatrización posterior a la cirugía de filtración del glaucoma
Swedish	4-(4-Metoxý-fenylamin)-6-metylcarbamyľ-kinolin-3-karboxylsyra	Förebyggande av ärrbildning efter fistulerande ingrepp för behandling av glaukom
Norwegian	4-(4-Metoksy-fenylamino)-6-metylcarbamyľ-kinolin-3-karboksytsyre	Forebygging av arrdannelse etter filtrasjonskirurgi for glaukom
Icelandic	4-(4-Metoxý-phenýlamínó)-6-metyýlcarbamyýl-quinóólín-3-carboxýl sýra	Til að koma í veg fyrir örmyndun eftir síunaraðgerð vegna gláku