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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Nimodipine for the treatment of aneurysmal subarachnoid haemorrhage

On 9 October 2015, orphan designation (EU/3/15/1554) was granted by the European Commission to Dr Stefan Blesse, Germany, for nimodipine for the treatment of aneurysmal subarachnoid haemorrhage.

What is aneurysmal subarachnoid haemorrhage?

Aneurysmal subarachnoid haemorrhage is a form of stroke that occurs when part of the wall of a blood vessel in the brain that has weakened and expanded (a cerebral aneurysm) subsequently bursts, so that bleeding occurs into the subarachnoid space (the space between the 'arachnoid membrane' and the 'pia mater', two membranes that surround the brain) damaging the brain tissue. In addition, blood vessels near the site of the aneurysm go into spasm (vasospasm) reducing blood supply to the brain and therefore the supply of oxygen and essential nutrients to brain cells.

Aneurysms in the brain are considered to be acquired (they are not present at birth but develop over a lifetime). However, evidence indicates that genetic factors make some people more likely to develop them.

Aneurysmal subarachnoid haemorrhage is life threatening and can be debilitating because it could lead to oxygen shortage in the brain cells and thus to impairment of brain functions.

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

At the time of designation, aneurysmal subarachnoid haemorrhage affected approximately 1 in 10,000 people in the European Union (EU). This was equivalent to a total of around 51,000 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 512,900,000 (Eurostat 2015).

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What treatments are available?

At the time of designation, nimodipine was already authorised in the form of tablets and solution for infusion in the EU for the prevention and treatment of complications due to vasospasm following subarachnoid haemorrhage.

The sponsor has provided sufficient information to show that this medicine might be of significant benefit for patients with aneurysmal subarachnoid haemorrhage because it will be available as a sustained release formulation to be given directly into the brain at the site of injury ('intraventricular' formulation). Early results in patients suggest that a single administration may lead to a more favourable outcome than a standard treatment course of nimodipine taken by mouth. In addition, the currently available tablets and solution for infusion need to be taken for up to 21 days, while this new formulation would be given as a single dose. 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?

Nimodipine blocks calcium channels on the walls of the blood vessels, causing the muscles in the wall to relax and the blood vessels themselves to widen. This action thus helps to overcome the effects of vasospasm. By preventing or reversing vasospasm, nimodipine helps to avoid oxygen shortage to the brain cells and thus the impairment of brain functions.

What is the stage of development of this medicine?

The sponsor has provided non-clinical and clinical data with nimodipine from the published literature to support its application for orphan designation.

At the time of submission of the application for orphan designation, clinical trials with this medicine in patients with aneurysmal subarachnoid haemorrhage were ongoing.

At the time of submission, this medicine was not authorised anywhere in the EU for aneurysmal subarachnoid haemorrhage. Orphan designation for this medicine has been granted in the United States for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 3 September 2015 recommending the granting of this designation.

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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

For details of the current sponsor of the orphan designation please refer to the information on the main web page of this Public Summary of Opinion.

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[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	Nimodipine	Treatment of aneurysmal subarachnoid haemorrhage
Bulgarian	Нимодипин	Лечение на субарахноидален кръвоизлив, причинен от аневризма
Croatian	Nimodipin	Liječenje aneurizmatskog subarahnoidalnog krvarenja
Czech	Nimodipin	Léčba subarachnoidálního krvácení z aneurysmatu
Danish	Nimodipin	Behandling af aneurysmatisk subaraknoidalblødning
Dutch	Nimodipine	Behandeling van aneurysmatische subarachnoïdale bloeding
Estonian	Nimodipiin	Aneurüsmaatilise subarahnoidse e hemorraagia ravi
Finnish	Nimodipiini	Lukinkalvoon liittyvän valtimoverenvuodon hoito
French	Nimodipine	Traitement de l'hémorragie subarachnoïdienne par rupture d'anévrysme
German	Nimodipin	Behandlung von aneurysmalen Subarachnoidalblutungen
Greek	Νιμοδιπίνη	Θεραπεία της ανευρυσματικής υπαραχνοειδούς αιμορραγίας
Hungarian	Nimodipin	Aneurysmális eredetű subarachnoidealis vérzés kezelése
Italian	Nimodipina	Trattamento dell'emorragia da aneurisma subaracnoideo
Latvian	Nimodipīns	Subarahnoidāla asinsizplūduma no aneirismas ārstēšana
Lithuanian	Nimodipinas	Aneurizminės subarachnoidinės hemoragijos gydymas
Maltese	Nimodipine	Kura ta' emorraġija minn anewriżma subaraknojde
Polish	Nimodypina	Leczenie krwotoku podpajęczynówkowego tętniaka
Portuguese	Nimodipina	Tratamento da hemorragia sub-aracnóideia aneurismática
Romanian	Nimodipină	Tratamentul hemoragiei subarahnoidiane anevrismală
Slovak	Nimodipín	Liečba subarachnoidálneho krvácania z aneuryzmy
Slovenian	Nimodipin	Zdravljenje anevrizemske subarahnoidalne krvavitve
Spanish	Nimodipino	Tratamiento de la hemorragia subaracnoidea por rotura de aneurisma
Swedish	Nimodipin	Behandling av aneurysmal subaraknoidalblödning
Norwegian	Nimodipine	Behandling av aneurysmal subaraknoidalblødning
Icelandic	Nímódipín	Meðferð æðagúlsinnanskúms blæðingar

[1] At the time of designation