



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Ziconotide (intraspinal use) for the treatment of chronic pain requiring intraspinal analgesia

First publication	18 July 2007
Rev.1: withdrawal from the Community Register	17 April 2015
Disclaimer 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.	

Please note that this product was withdrawn from the Community Register of designated orphan medicinal products in February 2015 at the end of the period of market exclusivity.

On 9 July 2001, orphan designation (EU/3/01/048) was granted by the European Commission to Elan Pharma International Ltd, Ireland, for ziconotide (intraspinal use) for the treatment of chronic pain requiring intraspinal analgesia.

The sponsorship was transferred to Eisai Limited, United Kingdom, in September 2006.

What is chronic pain requiring intraspinal analgesia?

Chronic pain is often defined as pain that persists for more than three months. Chronic pain has no time limit. The most common conditions associated with chronic pain include low-back pain, headache, recurrent pain in the face, pain associated with cancer, and arthritic pain. Drug therapy, mainly using products called analgesics, is used to ease chronic pain. Analgesics may be administered directly to the spinal cord, inside the spine (intraspinal administration), when the pain cannot be controlled by other routes of administration, such as with tablets, skin patches, or injections. Chronic pain requiring intraspinal analgesia is chronically debilitating.



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

At the time of designation, chronic pain requiring intraspinal analgesia affected approximately 1.55 in 10,000 people in the European Union (EU). This was equivalent to a total of around 59,000 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).

What treatments are available?

At the time of submission of application for orphan drug designation, treatment of chronic pain requiring intraspinal analgesia consisted of authorised products (morphine and other opioids, bupivacaine) in the European Union.

Satisfactory argumentation has been submitted by the sponsor to justify the assumption that ziconotide (intraspinal use) might be of potential significant benefit for the treatment of chronic pain requiring intraspinal analgesia. The assumption will have to be confirmed at the time of marketing authorisation. This will be necessary to maintain the orphan status.

How is this medicine expected to work?

Ziconotide is a man-made equivalent of a molecule composed of a 25-amino acid chain, which is found in the venom of a fish-eating marine snail, *Conus magus*. Ziconotide blocks the action of specific molecules found in nerve tissue, called N-type voltage-sensitive calcium channels. These molecules play an important role in chronic pain. Ziconotide is expected to decrease pain by blocking the function of these molecules.

What is the stage of development of this medicine?

At the time of submission of the application for orphan designation, the effects of ziconotide (intraspinal use) had been evaluated in experimental models, and clinical trials in patients with chronic pain requiring intraspinal analgesia were ongoing.

Ziconotide (intraspinal use) was not marketed anywhere in the world for the treatment of chronic pain requiring intraspinal analgesia, nor designated as an orphan medicinal product elsewhere for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 23 May 2001 recommending the granting of this designation.

Update: Ziconotide (intraspinal use) (Prialt) has been authorised in the EU since 21 February 2005 for the treatment of severe, chronic pain in patients who require intrathecal (IT) analgesia.

More information on Prialt can be found in the European public assessment report (EPAR) on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports

*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.
At the time of designation, this represented a population of 378,800,000 (Eurostat 2001).

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	Ziconotide (intraspinal use)	Treatment of chronic pain requiring intraspinal analgesia
Danish	Ziconotide (intraspinal anvendelse)	Behandling af kroniske smerter, der kræver intraspinal analgesi
Dutch	Ziconotide (intraspinaal gebruik)	Behandeling van chronische pijn welke spinale anesthesie vereist
Finnish	Tsikonotidi (selkäytimenä)	Selkäydinanalgesiaa vaativien kroonisten kiputilojen hoito
French	Ziconotide (Voie intraspinale)	Traitement de la douleur chronique nécessitant une analgésie intraspinale
German	Ziconotide (spinale Applikation)	Behandlung chronischer Schmerzen, die einer Spinalanalgesie bedürfen
Greek	Ziconotide (ενδονωτιαία χρήση)	Θεραπεία του χρόνιου πόνου που απαιτεί ραχιαία αναισθησία
Italian	ziconotide (uso intraspinale)	Trattamento del dolore cronico che richiede analgesia per via intraspinale
Portuguese	Ziconotide (uso intramedular)	Tratamento da dor crónica que requer analgesia intramedular
Spanish	Ziconotide (uso intramedular)	Tratamiento de dolor crónico que requiere analgesia intramedular
Swedish	Ziconotide (intraspinal användning)	Behandling av kronisk smärta som kräver spinalanalgesi

¹ At the time of designation