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Committee for Orphan Medicinal Products

Recommendation for maintenance of orphan designation at the time of marketing authorisation

NexoBrid (concentrate of proteolytic enzymes enriched in bromelain) for the treatment of partial deep dermal and full thickness burns

During its meeting of 3-4 October 2012, the Committee for Orphan Medicinal Products (COMP) reviewed the designation EU/3/02/107 for NexoBrid (concentrate of proteolytic enzymes enriched in bromelain, previously known as purified bromelain) as an orphan medicinal product for the treatment of partial deep dermal and full thickness burns. The COMP assessed whether, at the time of marketing authorisation, the medicinal product still met the criteria for orphan designation. The Committee looked at the seriousness and prevalence of the condition, and the existence of other satisfactory methods of treatment. As other satisfactory methods of treatment for patients with this condition are authorised in the European Union (EU), the COMP also looked at the significant benefit of the product over existing treatments. The COMP recommended that the orphan designation of the medicine be maintained[1].

Life-threatening or long-term debilitating nature of the condition

The Committee for Medicinal Products for Human Use (CHMP) recommended the authorisation of NexoBrid for 'removal of eschar in adults with deep partial- and full-thickness thermal burns'. This falls within the scope of the product's designated orphan indication, which is: 'treatment of partial deep dermal and full thickness burns'.

The COMP concluded that there had been no change in the seriousness of the condition since the orphan designation in 2002. Partial deep dermal and full thickness burns remains a condition that is debilitating in the long term and life threatening, particularly due to infection and sepsis (when bacteria and their toxins circulate in the blood and damage the organs), acute respiratory distress syndrome (failure of the lungs causing severe difficulty breathing), hypovolaemia (loss of blood volume) and extensive scarring that might prevent normal mobility.

[1] The maintenance of the orphan designation at time of marketing authorisation would, except in specific situations, give an orphan medicinal product 10 years of market exclusivity in the EU. This means that in the 10 years after its authorisation similar products with a comparable therapeutic indication cannot be placed on the market.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Prevalence of the condition

The sponsor provided updated data on annual numbers of patients hospitalised for burn wounds from available databases and the scientific literature. On the basis of the information provided by the sponsor and the knowledge of the COMP, the Committee concluded that the prevalence of partial deep dermal and full thickness burns remains below the ceiling for orphan designation, which is 5 people in 10,000. At the time of the review of the orphan designation, the prevalence was still estimated to be approximately 1 person in 10,000. This is equivalent to a total of around 51,000 people in the EU.

Existence of other satisfactory methods of treatment

At the time of the review of the orphan designation, other methods were authorised in the EU for the treatment of partial deep dermal and full thickness burns. Surgery was still the most direct method of debridement, which involves the removal of eschar (dead tissue) from the wound before further treatment. Some antibiotic medicines, as well as medicines containing enzymes to clean dead tissue and infected burns, were also authorised for use in burns patients.

Significant benefit over existing treatments

The COMP concluded that the claim of a significant benefit of NexoBrid in the treatment of partial deep dermal and full thickness burns is justified because, when compared with standard debridement treatment in a study involving 156 hospitalised burns patients, it was shown to reduce the need for surgery as well as the extent of skin grafting required (decreasing trauma, pain and scarring for the patient).

Therefore, although other satisfactory methods for the treatment of this condition have been authorised in the EU, the COMP concluded that NexoBrid is of significant benefit for patients affected by partial deep dermal and full thickness burns.

Conclusions

Based on the data submitted and the scientific discussion within the COMP, the COMP considered that NexoBrid still meets the criteria for designation as an orphan medicinal product and that it should remain in the Community Register of Orphan Medicinal Products.

Further information on the current regulatory status of NexoBrid 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.