European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 October 2008
Doc.Ref. EMEA/CHMP/558609/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
OPGENRA

International Non-proprietary Name (INN): ***eptotermin alfa***

On 23 October 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Opgenra, 3.5 mg, powder for suspension for implantation intended for treatment of adult patients with spondylolisthesis where autograft has failed or is contraindicated. This medicinal product should be used by an appropriately qualified surgeon. The applicant for this medicinal product is Howmedica International S. de R. L.

The active substance of Opgenra is eptotermin alfa, a bone morphogenetic protein (ATC Code M05BC02) which initiates bone formation through induction of cellular differentiation in mesenchymal cells.

The benefits with Opgenra are its osteoinductive and osteoconductive effect. Although it was established to be less effective than autograft, Opgenra is an option for patients who have failed prior autograft surgery or where autograft is contra-indicated. Opgenra allows shorter operation time, less blood loss and less pain than autograft. The most common side effects are post-operative infection; wound rupture, secretion or erythema; heterotopic bone formation and pseudarthrosis.

A pharmacovigilance plan for Opgenra, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Opgenra is indicated for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed or is contra-indicated". This medicinal product should be used by an appropriately qualified surgeon.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Opgenra and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu