European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends the approval of thalidomide for the treatment of rare bone-marrow cancer

The European Medicines Agency (EMEA) has recommended the approval of Thalidomide Pharmion (thalidomide) for the treatment of multiple myeloma, a rare cancer of the bone marrow.

Meeting on 21-24 January 2008, the Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Thalidomide Pharmion in combination with melphalan and prednisone outweigh its risks for the first-line treatment of multiple myeloma for patients over 65 years of age or who cannot be treated with high-dose chemotherapy. Clinical studies have shown that adding Thalidomide Pharmion to melphalan and prednisone can prolong survival time by about 18 months in newly-diagnosed multiple myeloma patients over 65 years of age, as compared to patients who received conventional chemotherapy.

Thalidomide is teratogenic. This means that there is a high risk that severe birth defects will occur when a foetus is exposed to thalidomide in the womb in the first part of pregnancy. Because of this, the CHMP has consulted representatives of thalidomide victims and myeloma patient groups from across the European Union to develop measures that can effectively minimise the risk of foetal exposure to thalidomide.

The CHMP has approved a risk management plan that includes a number of actions intended to prevent pregnancies in women being treated with thalidomide and exposure of unborn children to the medicine. For example, all women of child-bearing potential who are treated with Thalidomide Pharmion must undergo pregnancy tests before, during and after treatment, in addition to using selected and effective contraception.
Subject to the granting of a marketing authorisation by the European Commission, Thalidomide Pharmion will only be available by prescription, and treatment will be initiated and monitored by a doctor who has experience in the treatment of multiple myeloma. A clear warning will be printed on the boxes containing the medicine, indicating that Thalidomide Pharmion causes birth defects and foetal death.

Prior to the launch of Thalidomide Pharmion in each Member State, Pharmion Ltd. will provide healthcare professionals and patients with educational materials about the treatment-related risks and the precautions required to ensure the safe use of the product .

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Notes:
1. A separate question-and-answer document can be found here.
2. The summary of opinion for Thalidomide Pharmion can be found here.
3. Thalidomide for the treatment of multiple myeloma was designated as an orphan medicinal product in November 2001. See here for the summary of the positive opinion.
4. Thalidomide is also designated as an orphan medicinal product for the treatment of graft versus host disease. See here for the summary of the positive opinion.

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5. Thalidomide is already authorised in other countries for multiple myeloma, including Australia and the USA.
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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