European Medicines Agency
Press office

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PRESS RELEASE
Celgene Europe Limited withdraws its marketing authorisation application for Lenalidomide Celgene Europe (lenalidomide)

The European Medicines Agency (EMEA) has been formally notified by Celgene Europe Limited of its decision to withdraw the application for a centralised marketing authorisation for Lenalidomide Celgene Europe (lenalidomide), 5 mg and 10 mg hard capsules.

Lenalidomide Celgene Europe was intended to be used for the treatment of anaemia due to myelodysplastic syndromes. It was designated as an orphan medicine for use in this condition.

The application for marketing authorisation for Lenalidomide Celgene Europe was submitted to the EMEA on 25 September 2005. On 24 January 2008, the Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion recommending the refusal of the marketing authorisation. Following a re-examination procedure and confirmation of the CHMP's negative opinion on 30 May 2008, the company decided to withdraw the application before the adoption of a formal decision by the European Commission.

In its official letter, the company stated that the withdrawal of Lenalidomide Celgene Europe was based on the CHMP's view that the available data, obtained from a single-arm phase II study, did not allow it to conclude on a positive benefit-risk balance.

More information about the withdrawal of Lenalidomide Celgene Europe will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

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Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about the negative opinion is available in a question-and-answer document.
3. 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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