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Press Office

Press release

Merck Serono Europe Limited withdraws its marketing authorisation application for Movectro (cladribine)

The European Medicines Agency has been formally notified by Merck Serono Europe Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine Movectro (cladribine), 10 mg tablets.

Movectro was intended to be used for the treatment of relapsing-remitting multiple sclerosis.

The application for the marketing authorisation for Movectro was initially submitted to the Agency on 6 July 2009. On 23 September 2010, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for Movectro. On the request of the company, the CHMP re-examined its initial opinion and confirmed the refusal of the marketing authorisation on 20 January 2011. At the time of withdrawal, the final CHMP recommendation for the refusal of the marketing authorisation was pending European Commission (EC) decision.

In its official letter, the company stated that their decision to withdraw the application was based on the CHMP's adopted opinion that the data available to date did not allow the Committee to adopt a positive opinion recommending the granting of a marketing authorisation for Movectro.

More information about Movectro and its scientific assessment, which was concluded at the time of withdrawal, 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 Agency's website after the next CHMP meeting on 14 - 17 February 2011.

Notes

1. This press release is available on the Agency's website.
2. The CHMP Assessment Report will be published on the Agency's website at a later stage.
3. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
4. The company informed the CHMP that it intends to continue clinical trials with Movectro.

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5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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