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Press Office

Press release

Sanofi-aventis withdraws its marketing authorisation application for Mulsevo (semuloparin sodium)

The European Medicines Agency has been formally notified by Sanofi-aventis of its decision to withdraw its application for a centralised marketing authorisation for the medicine Mulsevo (semuloparin sodium), 20 mg, solution for injection. Mulsevo was intended to be used for the primary prophylaxis of venous thromboembolism (VTE) in cancer patients receiving chemotherapy for locally-advanced or metastatic solid tumours.

The application for the marketing authorisation for Mulsevo was submitted to the Agency on 29 September 2011. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its withdrawal letter, the company stated that they have decided to withdraw all applications globally following comments by regulatory agencies.

More information about Mulsevo and the state of the scientific assessment 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 CHMP meeting of 16-19 July 2012.

Notes

1. This press release, together with all related documents, is available on the Agency's website
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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