European Medicines Agency
Press office

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PRESS RELEASE
Sanofi-aventis withdraws its marketing authorisation application for Aquilda (satavaptan)

The European Medicines Agency (EMEA) has been formally notified by sanofi-aventis of its decision to withdraw the application for a centralised marketing authorisation for the medicine Aquilda (satavaptan) 5 and 25 mg film-coated tablets. Aquilda was intended to be used for the treatment of euvolaemic and hypervolaemic dilutional hyponatraemia, a metabolic condition in which the body's blood sodium level falls below normal.

The application for marketing authorisation for Aquilda was submitted to the EMEA on 30 May 2007. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Aquilda was based on the request of the CHMP for additional information on the therapeutic safety and efficacy of satavaptan. In the letter, the company informed that it is currently developing this information but that the results will not be available before 2009.

More information about Aquilda 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 EMEA website in due course.

-- ENDS --

Notes:
1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. 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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