European Medicines Agency
Press office

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Press release
AstraZeneca withdraws its application for Ximelagatran 36-mg film-coated tablets

The European Medicines Agency has been formally notified by AstraZeneca of its decision to withdraw its application for a centralised marketing authorisation for ximelagatran 36-mg film-coated tablets.

AstraZeneca submitted an application for marketing authorisation to the EMEA on 28 December 2005. The indication applied for was the prevention of stroke and other thromboembolic complications associated with atrial fibrillation (irregular heartbeat with ineffective contraction of the upper chambers of the heart). At the time of the withdrawal, ximelagatran 36-mg film-coated tablets were under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

The withdrawal of ximelagatran 36-mg film-coated tablets follows AstraZeneca's announcement on 14 February 2006 to voluntarily withdraw all marketed melagatran- and ximelagatran-containing medicinal products because of a new adverse event report of severe liver injury during longer-term (more than 11 days) treatment. Abnormal hepatic laboratory values had been previously reported during short-term treatment. In Europe, melagatran and ximelagatran are authorised in some Member States through the mutual recognition procedure as Exanta/Exarta. The approved indication is for the prevention of venous thromboembolic events (VTE) in patients undergoing elective hip- or knee-replacement surgery.

Clinical trials with ximelagatran 36-mg film-coated tablets have been stopped. Healthcare professionals have already been informed of the withdrawal by the company and advised on alternative treatments.

A 'question and answer' document will be published on the EMEA website, together with the company's letter of withdrawal, after the next CHMP meeting on 20-23 February 2006.

--ENDS--

NOTES

1. The legal basis for the publication of this withdrawal is Article 11 and Article 80 of Regulation (EC) No 726/2004.
2. Exanta/Exarta were marketed in Europe in the following countries: Austria, Denmark, Finland, France, Germany, Iceland, Norway, Portugal and Sweden.
3. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

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