European Medicines Agency
Press office

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PRESS RELEASE
GlaxoSmithKline withdraws its marketing authorisation application for Zunrisa (casopitant mesilate)

The European Medicines Agency has been formally notified by GlaxoSmithKline Research and Development Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine Zunrisa (casopitant mesilate), 50 mg and 150 mg film coated tablets.

Zunrisa was expected to be used in the prevention of post-operative nausea and vomiting and chemotherapy-induced nausea and vomiting.

The application for the marketing authorisation for Zunrisa was submitted to the Agency on 2 July 2008. 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 the application was based on the company's assessment that further safety data would be required to support the registration of casopitant on a worldwide basis and that it would take considerable time to produce these data. The company further stated that consequently all ongoing applications for authorisation are being withdrawn.

More information about Zunrisa 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 next CHMP meeting of 19-22 October 2009.

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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. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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