European Medicines Agency
Press office

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PRESS RELEASE
ISTA Pharma Ltd withdraws its marketing authorisation application for Vitragan

The European Medicines Agency (EMEA) has been formally notified by ISTA Pharma Ltd of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Vitragan (hyaluronidase [ovine]), 1020 IU/ml, powder for solution for injection.

Vitragan was expected to be used for the treatment of vitreous haemorrhage (bleeding within the vitreous humour in the central chamber of the eye). This was intended to improve visual acuity (acuteness and clarity of vision) and to facilitate the physician's ability to diagnose the underlying retinal pathology (damage to the retina at the back of the eye).

The application for marketing authorisation for Vitragan was submitted to the EMEA on 7 October 2005. 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 Vitragan was based on the CHMP's request for additional information, to which the company was unable to respond within the permitted timeframe.

More information about Vitragan 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 after the next meeting of the CHMP on 21-24 May 2007.

--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 about the work of the EMEA, can be found on the EMEA website: http://www.emea.europa.eu

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