European Medicines Agency
Press office

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PRESS RELEASE
Antigenics Therapeutics Limited withdraws its marketing authorisation application for Oncophage (vitespen)

The European Medicines Agency has been formally notified by Antigenics Therapeutics Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine Oncophage (vitespen), 20 µg solution for infusion.

Oncophage was expected to be used as an adjuvant treatment for localised renal cell carcinoma (RCC) patients at increased risk of recurrence with the following features: primary tumour stage T1b or T2 with high grade (3 or 4) histology with no nodal involvement.

Oncophage was designated an orphan medicine for renal cell carcinoma on 11 April 2005. The application for the marketing authorisation for Oncophage was submitted to the Agency on 29 September 2008. Oncophage received a negative opinion from the Committee for Medicinal Products for Human Use (CHMP) on 19 November 2009 and at the time of withdrawal a European Commission decision was pending.

In its official letter, the company stated that the withdrawal of the application was based on the CHMP's view that the information submitted is not sufficient to demonstrate efficacy of Oncophage at this point in time.

More information about Oncophage 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 14-17 of December 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. The question and answer document on the negative opinion for Oncophage can be found here: http://www.emea.europa.eu/pdfs/human/opinion/Oncophage_Q&A_72978109en.pdf
3. 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

Media enquiries only to:
Monika Benstetter
Tel. (44-20) 74 18 84 27, Email press@emea.europa.eu

* The date of the press release has been corrected from October to November