European Medicines Agency
Press office

London, 24 July 2008
Doc. Ref. EMEA/CHMP/382256/2008

PRESS RELEASE
Studies assessed by the EMEA indicate no increased risk of developing cancer for patients who have taken Viracept contaminated with ethyl mesilate

Following a review of a number of toxicology studies, the European Medicines Agency (EMEA) confirms that there is no increased risk of development of cancer for patients who have taken contaminated Viracept (nelfinavir).

Viracept is an antiviral medicine, used in combination with other antiviral medicines to treat adults, adolescents and children over three years of age who are infected with human immunodeficiency virus (HIV-1), the virus that causes acquired immune deficiency syndrome (AIDS).

In June 2007, the European Commission, on the recommendation of the EMEA, suspended the marketing authorisation for Viracept because some batches of the medicine had become contaminated with high levels of ethyl mesilate, a known genotoxic substance, which may damage the DNA.

Evidence was subsequently provided by Roche, the marketing authorisation holder, that the manufacturing problems that led to the contamination had been resolved. In October 2007 the EMEA's Committee for Medicinal Products for Human Use (CHMP) recommended that the suspension of the marketing authorisation be lifted. As part of this the CHMP requested a number of toxicology studies to be conducted to better assess the potential harm to patients using Viracept contaminated with ethyl mesilate.

The studies carried out by Roche showed that it is possible to calculate a threshold value below which ethyl mesilate does not cause any irreversible damage (mutations) in the DNA. The CHMP noted that patients or children born to mothers who had taken contaminated Viracept were exposed to ethyl mesilate levels well below this threshold, and therefore that there was no increased risk of developing cancer for these patients compared with those patients who were not exposed to the contaminant.

The Committee therefore concluded that there was no need to monitor patients who had been exposed to high levels of contaminated Viracept through specific patient registries.

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Notes:
1. More information on Viracept is available in a question-and-answer document.
2. The EMEA has previously communicated on Viracept. Press releases were issued on 6 June 2007, 21 June 2007 and 20 September 2007.
3. Viracept had been authorised as an oral powder 50 mg/g, 250 mg tablets and 250 mg film-coated tablets. The marketing authorisation holder is Roche Registration Limited. More information can be found in the European public assessment report for Viracept: http://www.emea.europa.eu/humandocs/Humans/EPAR/viracept/viracept.htm.
4. 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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