The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PUBLIC STATEMENT ON
VITRAVENE (fomivirsen)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 29 July 1999 the European Commission granted a marketing authorisation for the whole European Union to CIBA Vision Europe Ltd. (on 5 March 2001 the name of the Marketing Authorisation Holder (MAH) changed to Novartis Ophthalmics Europe Ltd) for VITRAVENE (fomivirsen), indicated for the local treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

On 23 May 2002 the MAH notified the European Commission of his decision to voluntarily withdraw the Marketing Authorisation for VITRAVENE. The MAH confirmed that this decision was based on commercial reasons and not due to any safety related concerns. Vitravene is still authorised in Switzerland and the MAH will be able to supply Vitravene to European Member States from Switzerland on a named patient basis. According to the MAH the demand for Vitravene is less than 100 units/ year. Therefore, the MAH believes that the withdrawal of Vitravene will have no negative impact on the patients in Europe.

On 30 July 2002 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "VITRAVENE". Pursuant to this decision the European Public Assessment Report for VITRAVENE has been removed from the EMEA website.

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