European Medicines Agency
Press office

London, 22 September 2005
Doc. Ref. EMEA/312626/2005

Press release

European Medicines Agency statement on Herceptin

The European Medicines Agency (EMEA) is aware of public expectations resulting from the publication of preliminary data concerning the possible use of Herceptin in the early-stage treatment of strongly positive HER-2 breast cancer.

The EMEA has not received any application relating to the use of Herceptin in the treatment of early-stage breast cancer.

The general practice of the Agency is not to comment on the status of any ongoing discussions with applicants or authorisation holders. The Agency is however providing this statement in response to the high level of interest of patients and media over recent weeks.

Herceptin (the scientific name is trastuzumab) was approved in Europe in 2000 for the treatment of patients with metastatic breast cancer, either as monotherapy for patients who have undergone at least two chemotherapy regimens or in combination with paclitaxel for the treatment of those who have not received chemotherapy. New data submitted and assessed in 2004 allowed the EMEA to further recommend the use of Herceptin in combination with docetaxel for the treatment of patients who have not received chemotherapy for their metastatic disease.

Roche, the marketing authorisation holder for Herceptin, has not submitted new data to the EMEA to request further changes in the indication. We understand that the company is preparing an application for submission at the beginning of 2006. Similar types of submissions in important oncology indications in the past have been dealt with by the Agency in an expedited review within 2 to 3 months.

--ENDS--

NOTES

1. The current information on Herceptin for patients and healthcare professionals is available here.
2. The preliminary data were announced at the May 2005 annual meeting of the American Society of Clinical Oncology and can be seen here.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at http://www.emea.eu.int

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