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

5 May 1998
EMEA/18846/98

PRESS RELEASE

The European Agency for the Evaluation of Medicinal Products (EMEA) has received press enquiries following the extensive media coverage concerning disclosures relating to British Biotech Pharmaceuticals Ltd.'s centralised marketing authorisation application for lexipafant (ZACUTEX).

It has not been the normal practice of the EMEA to provide information on applications for marketing authorisations undergoing evaluation or which have been withdrawn. However with regard to the issues concerning ZACUTEX which have already been subject to public comment, the EMEA can provide the following factual clarification:

- The consolidated list of questions of the scientific committee of the EMEA, the Committee for Proprietary Medicinal Products (CPMP), was sent to the applicant on 19 June 1997.

  The applicant was asked to provide responses within six months to this consolidated list of questions, as is often the case during the evaluation of centralised Marketing Authorisation applications.

- The applicant submitted responses to the consolidated list of questions on 5 December 1997. An assessment of these responses was circulated to all CPMP members on 23 January 1998.

- During its meeting of 23 to 25 February 1998 the CPMP considered that lexipafant was not approvable for the treatment of severe acute pancreatitis on the basis of the submitted data. The request of the applicant for an additional extension of the procedure was not accepted. The Marketing Authorisation application was withdrawn by the company on 24 February 1998.

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