The European Agency for the Evaluation of Medicinal Products

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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 18 to 19 March 2003

Two opinions were adopted for initial applications for marketing authorisation:

- A positive opinion for **Fuzeon** (enfuvirtide) from Roche, which is intended for the treatment in combination with other antiretroviral products for HIV infected patients with few remaining treatment options. It belongs to a new class of antiretroviral products called fusion inhibitors.

  EMEA review began on 21 October 2002 and the opinion was adopted on 19 March 2003, with an active review time of 120 days. Fuzeon was evaluated as an **accelerated procedure**, agreed to by the CPMP at its July 2002 meeting prior to submission of the application.
- A positive opinion for **Busilvex** (busulfan) from Pierre Fabre Médicament, which is a conditioning treatment prior to haematopoietic progenitor cell transplantation in adults. EMEA review began on 26 March 2002 and the opinion was adopted on 19 March 2003, with an active review time of 171 days. Busilvex was designated an orphan medicinal product on 29 December 2000 and is the **tenth orphan medicinal product** to receive a CPMP positive opinion.

Summaries of these opinions are available on the EMEA web site: http://www.emea.eu.int

The CPMP also gave a positive opinion to extend the indication for **Thyrogen** (thryotrophon alfa) from Genzyme to include the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy (THST) to be used with serum thyroglobulin (Tg) testing with or without radioiodine imaging. Thyrogen was first authorised in the European Union in March 2000. Further information on this extension will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

The Committee concluded its Community-wide reviews for **Genotropin** and **Norditropin** (somatropin) from Pharmacia and from NovoNordisk concerning two separate applications under the mutual recognition procedure for new indications to include the treatment of growth-retarded children born small for gestational age (SGA). The CPMP considered that there is a positive benefit-risk balance based on currently available information and recommended the approval of the new indication. The referrals for arbitration were made for Genotropin by Germany and Sweden in December 2001 and for Norditropin by Sweden in May 2002.

The CPMP also concluded its Community-wide review for **Lederfoline** and associated product names (calcium folinate) from Wyeth Research. The purpose of the referral was to harmonise the product information for these products in all EU Member States. The harmonised indications recommended by the Committee are for the product's use to diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy and overdose in adults and children (in cytotoxic therapy this procedure is commonly known as 'Calcium Folinate Rescue') and in combination with 5-fluorouracil in cytotoxic therapy. The procedure was initiated by France in October 2000.

A more detailed CPMP meeting report will be published shortly.

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