European Medicines Agency
Press office

London, 2 June 2006
Doc. Ref. EMEA/203163/2006

PRESS RELEASE

European Medicines Agency adopts first positive opinion for a medicinal product derived from transgenic biotechnology

The European Medicines Agency has adopted the first positive opinion for a medicinal product derived from transgenic biotechnology. ATryn, from Genzyme Europe, contains antithrombin alfa, a recombinant-DNA human anti-clotting blood protein. Antithrombin alfa is extracted from the milk of goats which have the human antithrombin gene inserted, that enables them to produce the human protein in their milk.

The Agency's Committee for Medicinal Products for Human Use (CHMP) adopted the positive opinion at its meeting of 29 May to 1 June 2006, recommending that ATryn should be authorised for use in patients with congenital antithrombin (AT) deficiency (inherited reduction of antithrombin) undergoing surgery, for the prophylaxis of deep-vein thrombosis (formation of clots in the vessels of the legs) and thromboembolism (formation of clots in other vessels of the body).

In February 2006, ATryn received a negative opinion. At the request of the company, the Committee started a procedure to re-examine its opinion, as part of which further expert advice was obtained.

At the end of this procedure the CHMP concluded that the benefits of ATryn outweigh its risks, and subsequently adopted a final positive opinion recommending that ATryn be granted a marketing authorisation.

--ENDS--

Notes

1. A question and answer document with background information is available here.
2. A summary of opinion for ATryn is available here.
3. Congenital antithrombin deficiency is a rare condition that affects about 1 in 3.000 to 5.000 people.
4. The CHMP recommended the granting of a marketing authorisation under exceptional circumstances for ATryn. Such authorisations are permissible, in accordance with Article 14(8) of Regulation (EC) 726/2004, for medicinal products for which the applicant can demonstrate that comprehensive data cannot be provided, for example because of the rarity of the condition, so long as it can be demonstrated that the benefits outweigh the risks. For more information see the relevant guideline here.
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the EMEA website at: www.emea.eu.int

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail: press@emea.eu.int