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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 21 – 22 October 2003

1. The Committee gave four positive opinions on the initial marketing authorisation applications for:

   - **Advate** (octocog alfa), from Baxter AG, intended for the prophylaxis of bleeding in haemophilia A patients. EMEA review began on 21 October 2002 and the opinion was adopted on 22 October 2003, with an active review time of 200 days.
   - **Bonviva** (ibandronic acid) and **Ibandronic acid Roche 2.5 mg film-coated tablet** (ibandronic acid), from Roche Registration Ltd, intended for the treatment and prevention of osteoporosis in post-menopausal women. EMEA review began on 22 July 2002 and the opinion was adopted on 22 October 2003, with an active review time of 175 days.
   - **Litak** (cladribine), from Lipomed GmbH, intended for the treatment of hairy cell leukaemia. EMEA review began on 22 July 2002 and the opinion was adopted on 22 October 2003, with an active review time of 201 days.
     Litak was designated an orphan medicinal product on 18 September 2001 and is the **fourteenth orphan medicinal product** to receive a positive CPMP opinion.

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

2. The Committee also gave positive opinions on the extension of indication for three medicinal products that are already authorised in the EU:

   - **Infergen** (interferon alfacon-1), from Yamanouchi Europe, to include combination therapy with Ribavirin. Infergen was first authorised in the European Union on 1 February 1999.
   - **Lumigan** (bimatoprost), from Allergan Pharmaceuticals Ireland, to include its use as first line therapy in the reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension, as monotherapy or as adjunctive therapy to beta-blockers. Lumigan was first authorised in the European Union on 8 March 2002.
   - **NovoSeven** (eptacog alfa (activated)), from Novo Nordisk, to include its use in the treatment of Glanzmann's thrombasthenia and also in factor VII deficiency. NovoSeven was first authorised in the European Union on 23 February 1996.

   Further information on these extensions will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

A more detailed CPMP meeting report will be published shortly.

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Media enquiries only please contact Martin Harvey Allchurch
EMEA press officer, Tel. (44-20) 74 18 84 27, E-mail: martin.harvey-allchurch@emea.eu.int

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int