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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 20 to 22 May 2003

Three positive opinions were adopted for initial applications for marketing authorisation:

- Positive opinions for **Humira** and **Trudexa** (adalimumab) from Abbott Laboratories, which are intended for the treatment of moderate to severe active rheumatoid arthritis. EMEA review began on 22 April 2002 and the opinion was adopted on 22 May 2003, with an active review time of 153 days.
- A positive opinion for **Ventavis** (iloprost) from Schering AG, which is intended for the treatment of primary pulmonary hypertension. EMEA review began on 28 January 2002 and the opinion was adopted on 22 May 2003, with an active review time of 205 days.
  Ventavis was designated an orphan medicinal product on 29 December 2000 and is the **eleventh 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 Committee also gave positive opinions for a number of new indications for medicinal products that are already authorised in the EU:

- Extension of indication for **Actos** and **Glustin** (pioglitazone) from Takeda Europe to allow its use as a second-line monotherapy, particularly in overweight type 2 diabetes patients where other measures (such as diet and exercise) have failed and treatment with metformin is not suitable. Actos and Glustin were first authorised in the European Union in October 2000.
- Extension of indication for **Aranesp** (darbepoetin alfa) from Amgen and **Nespo** (darbepoetin alfa) from Dompé Biotec to include the treatment of anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Aranesp and Nespo were first authorised in the European Union in June 2001.
- Extension of indication for **Avandia**, **Nyracta** and **Venvia** (rosiglitazone) from GlaxoSmithKline to allow its use as a second-line monotherapy, particularly in overweight type 2 diabetes patients where other measures (such as diet and exercise) have failed and treatment with metformin is not suitable. Avandia, Nyracta and Venvia were first authorised in the European Union in July 2000.
- Extension of indication for **Cerezyme** (imiglucerase) from Genzyme to include type 3 Gaucher's disease. Cerezyme was first authorised in the European Union in November 1997.

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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