The European Agency for the Evaluation of Medicinal Products

London, 27 February 2004
Doc. Ref: EMEA/CPMP/857/04

PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products 24-26 February 2004

The Committee adopted three positive opinions on the initial marketing authorisation applications for:

- **Abilify** (aripiprazole), from Otsuka Pharmaceuticals Europe Ltd, intended for the treatment of schizophrenia. EMEA review began on 24 December 2001 and the opinion was adopted on 26 February 2004, with an active review time of 206 days.
- **Levemir** (insulin detemir), from Novo Nordisk, intended for the treatment of diabetes mellitus. EMEA review began on 18 November 2002 and the opinion was adopted on 26 February 2004, with an active review time of 179 days.
- **TachoSil** (human fibrinogen and human thrombin), from Nycomed. Tochosil is a medicated sponge intended as supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient. EMEA review began on 22 July 2002 and the opinion was adopted on 26 February 2004, with an active review time of 225 days.

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

The Committee also gave a positive opinion on the extension of indication for **Enbrel** (etanercept), from Wyeth Europe Ltd, to include its use with methotrexate in adults with rheumatoid arthritis. Enbrel was first authorised in the European Union on 3 February 2000.

Further information on this extension 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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