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## PRESS RELEASE

### Committee for Proprietary Medicinal Products Meeting of 16 to 18 October 2001

The CPMP adopted 4 opinions on initial marketing authorisation applications at this meeting:

- Positive opinions for the double application **Protopic** (tacrolimus) and **Protopy** (tacrolimus) from Fujisawa GmbH indicated for the treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies, for both 0.1% and 0.03% ointment strengths.

The indication for the 0.03% strength only also includes the treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies. Review by the EMEA began on 16 August 2000 and the opinion was adopted on 18 October 2001, with a total active review time of 207 days.

- A positive opinion for **Trisenox** (arsenic trioxide) from Cell Therapeutics (UK) Ltd indicated for induction of remission and consolidation in adult patients with relapsed/refractory acute promyelocytic leukaemia (APL), characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene. Previous treatment should have included a retinoid and chemotherapy. The CPMP recommends the granting of a marketing authorisation under exceptional circumstances. Review by the EMEA began on 27 February 2001 and the opinion was adopted on 18 October 2001, with an active review time of 178 days.

Trisenox was designated an orphan medicinal product on 18 October 2000. This is the fourth orphan medicinal product to receive a positive opinion from the CPMP.

- A positive opinion for **Viread** (tenofovir disoproxil) from Gilead Science International Ltd indicated in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Further details on the complete indication are given in the summary of opinion. The CPMP recommends the granting of a marketing authorisation under exceptional circumstances. Review by the EMEA began on 22 May 2001 and the opinion was adopted on 18 October 2001, with a total active review time of 85 days.

Viread was evaluated under an accelerated procedure, agreed to by the CPMP at its April 2001 meeting prior to submission of the application.

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

The Committee recommended the lifting of the suspension of sertindole-containing medicinal products on the basis of additional data provided by the marketing authorisation holders. Member States' marketing authorisations were first suspended by the European Commission in January 2000 followed the CPMP opinion of June 1999 concerning cardiovascular safety concerns. Sertindole is an atypical antipsychotic agent, used in the treatment of schizophrenia.

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The first meeting of the ad hoc expert working group on gene therapy was held on 12 October 2001. The group, composed of CPMP experts, academia and industry specialists, initiated a review of the scientific evidence available on dose standardisation and definition of specific classes of gene transfer medicinal products.

The first meeting of the ad hoc paediatric expert group was held on 21 September 2001. Discussion focused on priorities in the different areas in term of therapeutic needs, pre-clinical and clinical development of medicinal products for children including paediatric formulations, and information to health professionals.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 15 October 2001.

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