

**MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG****Elidel® cream provides fast relief for infants with atopic dermatitis**

*New study shows benefits of non-steroid Elidel cream 1% in less than three days*

Basel, 10 June 2003 – Infants with atopic dermatitis may feel the benefit of Elidel® (pimecrolimus) Cream as quickly as 48 hours after the first application. Results of a large study of patients of 3-23 months with mild to very severe atopic dermatitis (eczema) show fast relief of symptoms, such as itching and disturbed sleep, for the infants and improved quality of life for the parents.

**Within 2-3 days of treatment, infants experienced less itching and slept better**

Already after two days of treatment, significantly more patients could be classified as 'responders' with at least a 50% reduction of their itching with Elidel (27.3%) compared to the control group treated with vehicle (12.1%) (p=0.018). After 72 hours of treatment, the responder criterion was achieved by 46.1% in the Elidel group compared to 10.6% in the control group (p<0.001). Also on day 3, a =50% improvement in sleep loss was reported by 49.2% in the Elidel group and 25.8% in the control group (p= 0.002).

More than two thirds of the infants in the Elidel group achieved a =50% improvement in itching and sleep loss compared to the control group (p=0.001) after four weeks of treatment. Pruritus and sleep loss were assessed using a Visual Analog Scale ranging from 0-10 by the primary caregiver.

**Body area affected by disease and eczema severity decreased significantly after 3 days**

Three days after starting treatment, Eczema Area and Severity Index (EASI) scores fell by 38.5% from an average of 17.7 to 10.8 in infants treated with Elidel Cream compared to a small increase of 1.8 in those who used the control. At the end of the four week study, the EASI score had fallen to 5.5 in the Elidel group (69% reduction) compared to a rise of 0.9 in the control group.

'We knew that pimecrolimus was safe and effective at relieving atopic dermatitis in children and adults of all ages, but this study has shown just how quickly our youngest patients can start to feel the benefit,' commented Professor Roland Kaufmann, from the Dermatological Clinic of the Johann Wolfgang Goethe University, Frankfurt in Germany.

**Treatment with Elidel improved parents' quality of life**

In addition to measuring atopic dermatitis scores, the new study also assessed the impact of treatment on the quality of life of the infants' parents, according to a five domain, 26 item questionnaire. At the end of the four-week study, statistically significant improvements (p<0.05) were seen in all five domains in parents of infants treated with Elidel: psychosomatic well being, social life, confidence in medical treatment, emotional coping and acceptance of disease.

Professor Ulrich Wahn, Director of the Department of Pediatric Pneumology and Immunology of the Charité Clinic, Berlin, Germany, underlined that sleep loss due to night-

time itching associated with atopic dermatitis can have a considerable impact on quality of life for both children and parents. 'Within a short time of their infants starting Elidel, parents were reporting significant improvements in the social and emotional aspects of their everyday lives, suggesting that they were having fewer disturbed nights and less distress arising from their children's symptoms,' he said.

At the end of the four-week, double-blind phase of the trial, infants from the control group were transferred to Elidel during a 12-week open label phase. During this time, their EASI scores also fell by 12 from 17.5 to 5.5 (69% reduction). During a further four-week follow up, during which no treatment was given, there was no indication of rebound symptoms. Elidel was well tolerated throughout the study, with adverse events suspected to be related to study medication reported in 3.8% of those using Elidel cream compared with 4.5% in the control group.

### **About Elidel**

Elidel Cream is a new non-steroid selective inhibitor of inflammatory cytokines which is licensed for the treatment of atopic dermatitis. Discovered by the Novartis Research Institute in Vienna, Austria, Elidel contains the active ingredient pimecrolimus, which is derived from ascomycin, a natural substance produced by the bacterium *Streptomyces hygroscopicus* var. *ascomyceticus*. Pimecrolimus selectively blocks the production and release of inflammatory cytokines from T-cells in the skin. It is these cytokines which trigger processes leading to the inflammation, redness and itching associated with eczema. Elidel is the first and only non-steroid prescription medication proven to help prevent disease flares in infants with atopic dermatitis when used at the first signs and symptoms<sup>1</sup>.

This release contains certain "forward-looking statements", relating to the Group's business, which can be identified by the use of forward-looking terminology such as "may feel", "can start", "suggesting", or similar expressions, or by express or implied discussions regarding potential future sales of Elidel or potential new indications for Elidel. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Elidel will reach any particular sales levels, or that Elidel will be approved for any new indications in any market. In particular, management's expectations could be affected by, among other things, new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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### **References**

1 Kapp A, Papp K, Bingham A et al. Long-term management of atopic dermatitis in infants with topical pimecrolimus, a non-steroid anti-inflammatory drug. *J Allergy Clin Immunol* 2002; 110: 277-284 ###