## New Direction in the Development of NF-κB Decoy Oligodeoxynucleotide for the Treatment of Atopic Dermatitis in Japan

As noted in today's release, AnGes MG has terminated its joint development with Alfresa Pharma Corporation. However, AnGes MG hopes to move forward to Phase III clinical trials in Japan by forming business collaboration with a new partner. AnGes MG presents its concept for the development of this drug as follows.

The results of Phase II clinical trials of NF- $\kappa$ B decoy oligo deoxynucleotide ointment in atopic dermatitis patients were as follows. (For details, please refer to the release dated February 8, 2008.)

## Outline of the Study Results

- The skin symptom scores for primary endpoints in the medium dose group of NF-κB decoy oligo ointment showed a tendency toward improvement compared with the placebo group, although the result was not statistically significant.
- The skin symptom scores for secondary endpoints (analysis of the above primary endpoints excluding subjects with significant protocol violations) and the clinical global assessment showed statistically improvement in the medium dose group of NF-κB decoy oligo compared with the placebo group.
- Concerning safety, there was no difference in the incidence of side effects between the NF- B group and placebo group, and no significant side effects

were observed.

After AnGes MG carefully evaluated the results of this trial on the basis of the opinions of dermatologists and statisticians, the company reached the following conclusions.

- Concerning the interpretation of efficacy, the medium dose showed a statistically significant difference in several efficacy endpoints compared with the placebo. The medium dose is considered the clinically recommended dose, and it deserves verification in Phase III clinical trials.
- Concerning safety, the fact that there was no significant event observed suggests that the drug has a high level of clinical usefulness in the disease areas where options for new drugs are required.

Ei Yamada, President and CEO of AnGes MG, commented, "AnGes MG considers the move to Phase III trials reasonable and will appoint a partner to achieve this objective, according to the original intention in developing this drug."

###