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AnGes MG, Inc.

**Announcement of Results of Phase II Clinical Trials of  
NF-κB Decoy Oligodeoxynucleotide on Atopic Dermatitis**

AnGes opened the keys-code of its Phase II clinical trials conducted in Japan, with NF-κB decoy oligodeoxynucleotide ointment for atopic dermatitis. We are pleased to announce the results as follows.

**Study Outline**

The study population was atopic dermatitis patients having moderate to severe lesions in the face. The study was a randomized, placebo-controlled, double-blind study consisting of 3 dose groups (low dose, mid dose, high dose) of NF-κB decoy oligodeoxynucleotide ointment. The drug product was applied twice a day for 4 weeks (28 days) to the anthema lesion of the subject's face. 162 subjects were evaluated for efficacy and 165 for safety.

**Analysis Result**

As for efficacy evaluation, no statistically significant difference was confirmed in the primary endpoint, which was "Skin Symptom's Score", however, trend of improvement was observed in the mid dose group compared to placebo.

In the secondary endpoints, which were "Skin Symptom's Score" (difference compared to primary endpoint: analysis is done after excluding subjects with major deviation) and clinical global improvement, statistically significant difference in improvement compared to placebo was observed in the mid dose group, respectively.

As for safety, no difference was observed compared to the placebo group. Furthermore, no side effect causing potential concerns was observed.

AnGes will conduct more detailed data analysis, and consider the conduct of Phase III clinical trial.

## <Reference>

### - Glossary -

#### **1. NF- $\kappa$ B (nuclear factor-kappa B)**

NF- $\kappa$ B is a transcription factor regulating the gene expression of molecules such as cytokines and adhesion factors related to immune response. Once NF- $\kappa$ B attaches to the genome of its binding site, it causes excessive gene expression related to immune responses. This is why NF- $\kappa$ B has been indicated as one of the causes of atopic dermatitis, psoriasis and rheumatic arthritis.

#### **2. Decoy nucleotides**

Gene expression is caused by the genomic binding of transcription factors. Decoy is a short double stranded nucleic acid consisting of the same sequence as the binding site of certain transcription factors. The administration of decoy suppresses the excessive gene expression by inhibiting the binding of transcription factors to the genome.

#### **3. NF- $\kappa$ B decoy oligodeoxynucleotide**

NF- $\kappa$ B decoy oligodeoxynucleotide is a decoy against NF- $\kappa$ B. AnGes MG is trying to develop NF- $\kappa$ B decoy oligodeoxynucleotide as a pharmaceutical product for immune related diseases such as atopic dermatitis, psoriasis and rheumatic arthritis.

#### **4. Atopic dermatitis**

Atopic dermatitis is a skin disorder with itchy eczema, which often persists for a long time with cyclic deterioration and improvement of symptoms. It is thought to be caused by allergic reactions resulting from excessive immune response. It may also be caused by food and drink such as eggs or milk, by environmental factors such as dust and mite, and by stress. The number of patients is increasing and it is now estimated that there are about 1.4 million in Japan.