## <u>Pharmaceuticals and Medical Devices Agency Completes Review of</u> <u>Initial IND for NFκB Decoy Oligo</u> <u>– Phase I Clinical Trial in Atopic Dermatitis Underway –</u>

AnGes MG submitted an initial IND (Investigational New Drug Application) for NFκB decoy oligo targeting atopic dermatitis to the Pharmaceuticals and Medical Devices Agency (the PMDA, a certified independent administrative institution in Japan). This notification of the clinical trial plan is an "initial clinical trial plan" as stipulated by the Pharmaceutical Affairs Law (PAL). At this time, AnGes MG is pleased to announce that The PMDA has completed a review of the clinical trial plan based on the PAL. Since completion of the 30-day review process, the Company plans to commence the phase I clinical trial upon concluding agreements with medical institutions where the clinical trial is to be performed.

AnGes MG has been developing NFκB decoy oligo as a gene-based therapy that treats immune inflammatory diseases including atopic dermatitis and rheumatic arthritis. Although there are as many as 1.4 million patients with atopic dermatitis in Japan, no effective drugs have been developed yet for sufferers of severe facial atopic dermatitis. The development of new treatments for the diseases is anxiously awaited.

AnGes MG has prepared a clinical trial in Japan against this background because NFκB decoy oligo can specifically inhibit transcription factors, leading to the possibility for the development of an innovative and effective therapeutic agent with minimal side effects.

This phase I clinical trial is to be conducted to confirm the safety of intradermal administration of NF $\kappa$ B decoy oligo. In addition to the HGF plasmid project, for which clinical trials are ongoing both in the US and Japan, the development of the NF $\kappa$ B decoy oligo project has also moved to the clinical trial phase. The Company's development portfolio has thus been further enriched with the initiation of this clinical trial.

AnGes' NFkB decoy oligo therapy for atopic dermatitis is being jointly developed with Alfresa Pharma Corporation in Japan.

## Reference

## Development Status of NFkB Decoy Oligo

Field of indications	Region	Development Phase	Licensee
Atopic dermatitis	Japan	Phase I clinical trial	Alfresa Pharma
		under preparation	Corporation
Psoriasis		Preclinical	Undecided
Rheumatoid arthritis		Clinical trial under	Seikagaku
		preparation	Corporation
Osteoarthritis		Preclinical	
Prevention of		Clinical trial under	Goodman Co., Ltd
vascular restenosis		preparation	