Announcement of Results of Phase IIa Clinical Trials of STAT-1 Decoy Oligodeoxynucleotide on Psoriasis in Europe

In August 2005, AnGes MG, Inc. (AnGes) executed a cross license agreement with a German biotech, Avontec GmbH (Avontec). Through this alliance, AnGes received an exclusive license of STAT-1 decoy oligodeoxynucleotide (STAT-1) in Asia for skin diseases, and has aimed to strengthen the development pipeline in this area.

This time, Avontec conducted a Phase IIa trial to evaluate the efficacy and safety of AVT-02 UE ointment in the treatment of mild to moderate psoriasis vulgaris. This Phase IIa study was a multicenter, randomized, double-blind, placebo-controlled, intra-individual-comparison. We are pleased to announce the results as follows.

The Phase IIa study enrolled 60 male outpatients with mild-to-moderate psoriasis vulgaris and compared 2% AVT-02 UE ointment with placebo as assessed by the Sum of Scores (SOS) of marker plaques during a four-week treatment.

For a subset of 28 subjects, immune histological biomarkers of skin biopsies were assessed at baseline and upon completion of treatment. The investigations were performed by Professor Jim Krueger, Rockefeller University, New York, in a double-blinded fashion. It included histology to determine epidermal thickness, immunohistochemistry and polymerase chain reaction (PCR) of disease-related and Signal Transducer and Activation of Transcription (STAT)-dependant biomarkers.

The excellent safety and tolerability of AVT-02 UE ointment was demonstrated in psoriatic patients and confirms previous results obtained in healthy volunteers and psoriatic patients.

In addition, the potential of AVT-02 UE ointment to inhibit STAT pathways in the psoriatic skin compartment was revealed. Treatment with AVT-02 UE (verum) showed a statistically significant effect versus placebo treatment (ointment base) when the response for the combined effect on histology and a marker specific of keratinocyte proliferation was considered. Relevant biomarkers specific for skin inflammation and activated STAT pathways were substantially reduced nicely matching the proposed role of Th17 and Th1 cells in psoriasis pathogenesis.

It was concluded that STAT-1 and STAT-3 were specifically hit, the drug candidate was biologically active and worth to maximize its clinical effect in a 3 month trial. In fact, the clinical response was less pronounced than one could expect from the profound effect on the biomarkers, which is "possibly explained by the short treatment period", said Prof. Jim Krueger.

Prof. Krueger further commented: "The molecular data I have seen with AVT-02 UE are extremely promising as STAT-1 and STAT-3 are known to be key factors driving different inflammatory features of psoriasis. From the molecular medicine point of view STAT-1 and STAT-3 inhibition by AVT-02 UE is a novel molecular mechanism that targets key pathogenic cytokines associated with Th17 cells. New studies in psoriasis show that Th17-associated cytokines eg. IL-17, IL-22, IL-23 and IL-12 are very interesting therapeutic targets for this disease. It is exciting to have a novel topical drug that targets these pathways."

<For more information>

- Corporate Profile -

Company name	: Avontec GmbH
Head office	: Fraunhoferstrasse 15, D-82152 Martinsried, Germany
Representative	: Dr. Thomas Schulze, President & CEO
Date founded	: 2001
Employees	: 5 (as of October, 2008)
Scope of business	: Research & development of genetic medicine specialized in the
	development of novel nucleic acid based therapeutic treatment
	targeting transcription factors
Investors	: VCG Venture Capital Gesellschaft GmbH & Co. Fonds III KG (28%)
	Bio Sight Innovation 1st Investment Limited Partnership (22%)