



March 16, 2015

AnGes MG, Inc.

AnGes Starts Phase III Clinical Trials of NF-kB Decoy Oligonucleotide Ointment Drug for Atopic Dermatitis in Japan

AnGes MG, Inc. ("AnGes") announced that it has started the phase III clinical trials of its nucleic-acid drug, NF-kB Decoy Oligonucleotide (ointment drug), for Atopic Dermatitis in Japan. The first patient was enrolled on March 13, 2015.

The Phase III clinical trial is a randomized, double-blind and placebo-controlled study with approximately 200 atopic dermatitis patients with moderate to severe atopic skin symptoms on the face. The study will examine the efficacy and safety of the drug, and will be conducted over a period of approximately one year from the first patient administration to the end of the last patient visit. If favourable results are achieved in the study, AnGes will submit an application for drug marketing approval in Japan for the indication of moderate to severe facial atopic dermatitis. Shionogi & Co., Ltd holds the exclusive marketing rights of NF-kB Decoy Oligonucleotide for dermatological diseases including Atopic Dermatitis.

"There is a demand for a new and safe treatment option since currently available drugs do not fully satisfy the medical needs from the perspective of safety, such as dermal irritation and local adverse events. We believe the NF-kB Decoy Oligonucleotide ointment drug will become a new treatment option for atopic dermatitis patients with moderate to severe facial atopic skin symptoms" said Ei Yamada, Ph.D., President and CEO of AnGes. "Realization of our NF-kB Decoy Oligonucleotide drug is an important step toward achieving our vision of becoming a global leader in gene medicines."

The development costs regarding the Phase III clinical trials will occur in the fiscal term ending in December 2015. The impact of this event has already been included in the forecast for 2015 announced on February 6, 2015.

(Reference)

1. NF- κ B (nuclear factor-kappa B)

Genes play an important role in maintaining homeostasis; however most genes are usually not expressed. Transcription factors are proteins that regulate the expressions of genes when needed. NF- κ B is the main transcription factor which when expressed, enables cells to evoke inflammatory and immune reactions when inflammation and immunity are activated, and when there is external stimulus such as oxidant stress due to active enzyme. It has been noted that the activation of NF- κ B causes and worsens abnormal inflammation and immune related diseases such as atopic dermatitis, psoriasis and rheumatic arthritis.

2. Decoy Oligodeoxynucleotide

A genetic expression manifests when a genetic factor bonds to a genome. A decoy is a short, double stranded nucleic acid comprized of the same DNA sequence as the genetic factor, which when introduced into the body neutralizes the genetic expression by preventing the factor from bonding to a genome.

3. NF- κ B Decoy Oligodeoxynucleotide

NF- κ B Decoy Oligodeoxynucleotide is a decoy oligo with the same genetic sequence as the NF- κ B-binding site. As it targets the transcription factor itself, it is expected to have superior efficacy and milder side effects compared to conventional drugs, due to its specificity and definite effects on the molecular target. AnGes is developing therapeutic agents on the basis of its properties, to treat patients suffering from atopic dermatitis, rheumatic arthritis, and restenosis, which are conditions caused by excessive immunological response.

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Disclaimer: This is a translation of the news release posted in Japanese. In case of any deviations between the two language versions, the original document in Japanese shall take precedence.

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