



September 20, 2012

AnGes MG, Inc.

**First Patient Enrollment in the Clinical Trial of NF- $\kappa$ B Decoy Oligo Coated PTA Balloon Catheter for Hemodialysis Shunts  
- Development of a Novel Effective Medical Device for Suppressing Restenosis of Blood Vessels -**

AnGes MG, Inc. (“AnGes”) and Medikit Co., Ltd. (Head office: Bunkyo-ku, Tokyo; President Nobufumi Kurita; hereinafter called “Medikit”) submitted a notification of clinical trial plan to Pharmaceuticals and Medical Devices Agency on March 28 for NF- $\kappa$ B decoy oligo coated PTA balloon catheter (“this product”). Since then the two companies prepared for the clinical trial and AnGes is pleased to announce that the first case was enrolled today (first-patient-in) and that the case entry of this clinical trial has started.

With currently available PTA balloon catheters used for hemodialysis shunts and peripheral intravascular therapy for arteriosclerosis etc., the rate of restenosis is high, and consequently there is a strong demand for a development of PTA balloon catheters that is expected to prevent restenosis in clinical practice.

By applying NF- $\kappa$ B decoy oligo, a nucleic acid medicine, on the outer surface of a PTA balloon catheter, it is expected to suppress vascular inflammation occurred due to balloon dilation, to prolong the onset of restenosis and to avoid a surgery. AnGes and Medikit are developing this product with an aim to make it as the world’s first anti-inflammatory agent coated PTA balloon catheter.

This clinical trial aims to validate the safety and efficacy of this product by comparing it with conventional PTA balloon catheters, targeting patients with hemodialysis shunt venous stenosis (177 cases). This clinical trial is a major study (pivotal trial) and an application for approval will be submitted upon the completion of this trial. From this point on, we will proceed with the clinical trial, aiming for an early approval and launch in Japan.

It is said that there are three hundred thousand dialysis patients in Japan, and about fifty thousand of the patients are the product’s target and with hemodialysis shunt venous stenosis.

Meanwhile, this trend will have only minor effects on the business performance for the fiscal year of 2012.

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(Reference)

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

Genes play an important role in maintaining homeostasis; however most genes are not usually expressed. Transcription factors are proteins that regulate the expressions of genes when needed. NF- $\kappa$ B is a genetic factor which expressed to enable 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, etc. It has been pointed out that the activation of NF- $\kappa$ B causes and worsens abnormal inflammation and immune related diseases such as atopic dermatitis, psoriasis and rheumatic arthritis.

### **2. Decoy Oligodeoxynucleotide**

A genetic expression features a switch - genetic factor - bonded to a genome. A decoy is a "compressed" nucleic acid of the same array as the aforementioned genetic factors, which when introduced to the body, neutralizes those "switches" by preventing their bonding to a genome, thereby regulating the transcription process.

### **3. NF- $\kappa$ B Decoy Oligodeoxynucleotide (NF- $\kappa$ B decoy oligo)**

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

### **4. Drug Coated PTA Balloon Catheter**

PTA balloon catheter is used for percutaneous transluminal angioplasty. The balloon is inserted to blood vessel at the stenosed site and when inflated, it dilates blood vessel and restores blood flow. Drug coated balloon PTA balloon catheters are the ones that a drug is applied on the outer surface of this balloon.

*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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