March 28, 2012

AnGes MG, Inc.

Commencement of Clinical Trial on NF-κB Decoy Oligo Coated PTA Balloon Catheter for Hemodialysis Shunts

- Development of a Novel Effective Medical Device for Suppressing Restenosis of Blood Vessels -

In this January, AnGes MG, Inc. ("AnGes MG") and Medikit Co., Ltd. (Head office: Bunkyo-ku, Tokyo; President Nobufumi Kurita; hereinafter called "Medikit") entered into a joint development agreement on NF-κB decoy oligo coated PTA balloon catheter ("this product") in Japan. AnGes MG is pleased to announce that the preparation for a clinical trial for venous stenosis treatment has completed and that the notification of clinical trial plan was submitted to Pharmaceuticals and Medical Devices Agency today.

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-κB decoy oligo on the outer surface of a PTA balloon catheter, it is expected to suppress vascular inflammation due to balloon dilation, to prolong the onset of restenosis and to avoid a surgical bypass surgery. AnGes MG 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 demonstrate the safety and efficacy of this product by comparing it with conventional PTA balloon catheters, targeting patients with venous stenosis. From this point on, AnGes MG will proceed with the clinical trial, aiming for an early approval and launch in Japan.

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

[Reference]

1. NF-κB (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-κB 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-κB 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-κB Decoy Oligodeoxynucleotide (NF-κB decoy oligo)

NF-κB decoy oligo is a decoy oligo with the same genetic sequences as NF-κB-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.

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