



January 7, 2015

AnGes MG, Inc.

Patient Enrollment Complete for NF- κ B Decoy Oligo Coated PTA Balloon Catheter Clinical Trials for Hemodialysis Shunts

AnGes MG, Inc. (“AnGes”) announced that patient enrollment for NF- κ B Decoy Oligonucleotide Coated PTA Balloon Catheter clinical trials have been completed. The product is being jointly developed with Medikit Co., Ltd. (Head office: Bunkyo-ku, Tokyo; President Nobufumi Kurita; “Medikit”).

AnGes and Medikit started the clinical trial in September, 2012 to evaluate the safety and efficacy of this product by comparing it with conventional PTA balloon catheters in subjects with hemodialysis shunt venous stenosis. The number of enrolled patients reached the number required for statistical analysis, completing patient enrollment. After the proceeding observational period, the data will be analyzed and evaluated. If the results show a significant advantage over conventional balloon catheters, the manufacturing and marketing application will be submitted as early as the first half of 2016.

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

By applying NF- κ B decoy oligonucleotide, a nucleic acid medicine, to the outer surface of a PTA balloon catheter, it is expected to suppress vascular inflammation occurring due to balloon dilation, prolonging the onset of restenosis and potentially avoiding surgery. AnGes and Medikit are developing this product to become the world’s first anti-inflammatory agent coated PTA balloon catheter.

There are approximately 310,000 dialysis patients in Japan, of which approximately 50,000 would be targets of the product with hemodialysis shunt venous stenosis.

(Reference)

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

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

4. Drug Coated PTA Balloon Catheter

PTA balloon catheters are used for percutaneous transluminal angioplasty. The balloon is inserted into a blood vessel at the stenosed site and when inflated, dilates the blood vessel and restores blood flow. The drug coated PTA balloon catheter has a drug coated on the outside of the balloon.

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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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