



September 7, 2015

AnGes MG, Inc.

Last Patient Out in Clinical Trial of the NF- κ B Decoy Oligo Coated PTA Balloon Catheter for Hemodialysis Shunts

AnGes MG, Inc. ("AnGes") announced that the last patient has completed the follow-up period of its pivotal clinical trial for the NF- κ B Decoy Oligonucleotide Coated PTA Balloon Catheter. The product is being jointly developed in cooperation with Medikit Co., Ltd. (Head office: Bunkyo-ku, Tokyo; President: Nobufumi Kurita; "Medikit").

The clinical trial of the NF- κ B Decoy Oligonucleotide Coated PTA Balloon Catheter evaluates the safety and efficacy of the product by comparing it with conventional PTA balloon catheters used in subjects with that suffer from hemodialysis shunt venous stenosis. AnGes and Medikit started the clinical trial in September 2012.

The clinical trial is a pivotal study, with the data of each subject collected and analyzed upon the completion of the follow up period. If results show a significant difference than conventional balloon catheters, the application for manufacturing and marketing will be submitted as early as the first half of 2016.

The currently available PTA balloon catheters used for hemodialysis shunts and arteriosclerosis exhibit a high rate of restenosis. For this reason, there is strong demand for PTA balloon catheters that can prevent restenosis in clinical practice.

It is believed that vascular inflammation caused by balloon dilation can be suppressed by applying NF- κ B decoy oligonucleotide, a nucleic acid medicine, to the outer surface of a PTA balloon catheter. The suppression of inflammation will help to prolong the onset of restenosis and potentially avoid surgery. In developing this product, AnGes and Medikit are working together to develop the world's first PTA balloon catheter coated with an anti-inflammatory agent.

(Reference)

1. NF-κB (nuclear factor-kappa B)

Genes play an important role in maintaining homeostasis, but normally most genes are not expressed. Transcription factors are proteins that regulate the expression of genes when necessary. NF-κB is the main transcription factor which, when expressed, enables cells to evoke inflammatory and immune reactions when inflammation and immunity occur, and when there is external stimulus such as oxidant stress caused by an active enzyme. It has been noted that the activation of NF-κB causes and aggravates abnormal inflammation and immune-related diseases such as atopic dermatitis, psoriasis, and rheumatic arthritis.

2. Decoy Oligonucleotide

A genetic expression is made 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. When it is introduced into the body, it neutralizes the genetic expression by preventing the factor from bonding to a genome.

3. NF-κB Decoy Oligonucleotide (NF-κB decoy oligo)

NF-κB decoy oligo is a decoy oligonucleotide with the same genetic sequence as the NF-κB-binding site. It targets the transcription factor itself, and thus is expected to exhibit superior efficacy and milder side effects than conventional drugs due to its specificity and definitive effect on the molecular target. AnGes is developing therapeutic agents based on the properties of NF-κB decoy oligo to treat patients that suffer from atopic dermatitis, rheumatic arthritis, and restenosis, all of which are conditions caused by an 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 it dilates the blood vessel and restores blood flow. A drug coated PTA balloon catheter has a drug coating on the outside of the balloon. The NF-κB decoy oligo-coated PTA balloon catheter has NF-κB decoy oligo infused PLGA particles from the Hosokawa Micron Corporation on the surface of the Medikit balloon catheter.

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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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