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AnGes MG, Inc.

Pharmaceutical Formulation Patent on NF-κB Decoy-Oligonucleotide Granted in Japan and US

- Covering PLGA particle preparations with enhanced penetration to the site of treatment -

AnGes MG, Inc. announces that the pharmaceutical formulation patent on NF-κB decoy oligodeoxynucleotide, for which the company had filed application jointly with Hosokawa Micron Corporation, was granted in the USA and Japan, and currently the Japanese Patent Gazette (patent No. 4602298) was issued as of December 22. (US application No. 11/812,459)

This invention is related to a completely novel preparation technology in which NF-κB decoy oligodeoxynucleotide is electrostatically bound to the surface and enclosed within PLGA particles. This technology is intended to provide clinically superior preparations which exert both fast-acting and long-acting effects through the action of the decoy eluting out from the surface of the particles immediately after administration, and additionally the continuous action of the decoy gradually released from inside of the particles in a delayed manner.

Conventionally, PTA (percutaneous transluminal angioplasty) balloon catheters have been widely used to dilate peripheral blood vessels stenosed (constricted) due to arteriosclerosis, but the problem of very frequently occurring restenosis after the procedure has been pointed out. Similar form of stenosis that occurs in shunts (blood vessel bypass) bypassing the vein and artery that are created at the time of hemodialysis has also been regarded as a problem. Prevention of restenosis for post-PTA balloon dilation is a high unmet medical need, also from the viewpoint of preservation and maintenance of the patients' invaluable blood vessels.

In order to solve such a problem, AnGes MG has been continuously conducting joint research on PLGA particle preparations containing NF-κB decoy oligodeoxynucleotide in cooperation with Hosokawa Micron Corporation who possesses high-level and extensive nanosphere technologies related to PLGA particles, aiming to develop a NF-κB decoy oligodeoxynucleotide-containing preparation-coated PTA balloon catheter as an innovative medical device which can be expected to exert restenosis-preventive effect. As a result, a completely novel preparation having both short-and long-acting properties was completed, and the patent application was filed.

Following that, both US and Japan patent offices have continuously conducted reviews, and consequently the superior effects of this novel preparation was recognized in both countries, and evaluated for a patent. The Patent Gazette was first issued by the Japan patent office. (The Patent Gazette is also scheduled to be issued by the US patent office.)

PLGA, an additive used in this novel preparation is biodegradable and therefore it features rapid degradation after being absorbed in the living body and causes no concern about residual (accumulation) in tissue as well. And the NF-κB decoy oligodeoxynucleotide-containing PLGA particle-coated PTA balloon catheter which uses this preparation has been under development jointly with Medikit Co., Ltd. and Hosokawa Micron Corporation, aiming for early market launch with focus on the conduct of clinical studies.

The Japanese patent based on this application is valid up to August 2026, and the US patent is valid up to June 2027 indicating that they duly protect AnGes MG's NF-κB decoy oligodeoxynucleotide development project.

In order to make use of the superior pharmacological actions of NF-κB decoy oligodeoxynucleotide, AnGes MG has been filing additional patent applications related to novel preparations suitable for various types of diseases. AnGes MG will continue to make efforts to expand the drug's clinical application.

Meanwhile, there will be no effect of this trend on AnGes MG's business performance during the current fiscal year.

Structure of PLGA particles containing NF-κB decoy oligodeoxynucleotide