

February 21, 2011
AnGes MG, Inc.

Industry-Academia Joint R&D Project on “Oral Drug Delivery System (DDS) Using PLGA Nanoparticle Technology Containing Nucleic Acid” That Enables Definitive Therapy of Intractable Inflammatory Bowel Disease, Adopted as “Regional Innovation R&D Project”, a Strategic Technology Aid Program

AnGes MG, Inc. (“AnGes MG”) with 4 other parties, Hosokawa Micron Corporation (“Hosokawa Micron”), Morishita Jintan Co.,Ltd. (“Morishita Jintan”), Osaka University Graduate School of Medicine (Professor Morishita’s research group, “Osaka University”), and Aichi Gakuin University, School of Pharmacy (Associate Professor Yamamoto’s research group, “Aichi Gakuin University”), have been proactively engaged in the R&D of a new drug that enables definitive therapy of intractable inflammatory bowel disease, for which a complete cure is difficult to achieve currently. This industry-academia joint R&D project has been adopted as a “Regional Innovation R&D Project,” a strategic technology aid program, by the Ministry of Economy, Trade and Industry’s national project. AnGes MG hereby states that an official announcement regarding subsidy grant totalling 88.49 million yen was made to this 5 party joint project (project representative: Hiroyuki Tsujimoto of Hosokawa Micron).

<R&D Background>

- 1) Inflammatory bowel disease (ulcerative colitis, Crohn’s disease) often occurs in men and women in their late teens to early thirties, and frequently causes melena, diarrhea or abdominal pain resulting from erosions or ulcers on the gastrointestinal mucosa. Autoimmune abnormalities and inflammations can be prevented, but in many cases, large intestine resection will be inevitable after repeated onset and treatment.
- 2) In recent years, monoclonal antibodies have been developed, and currently more than 1.25 million people in about 100 countries worldwide (about 105,000 people in Japan) are being benefitted from such a treatment. Although patients need to be given intravascular infusions at hospitals and cope with high treatment costs, definitive therapy is still difficult to achieve. Therefore, the establishment of a safe and inexpensive definitive therapy that may reduce patients’ burden is eagerly awaited.

<Development of oral DDS using oligonucleotide medicine that enables the world’s first permanent treatment>

- Given the above background, the 5 industry-academia parties, intend to co-develop a safe and inexpensive definitive therapy that can reduce patient's burden by bringing forth their unique technologies (patents) and combining the advanced therapeutic agent "oligonucleotide medicine" with the "nano-DDS technology".

<Role Assignment of the 5 Parties>

1) AnGes MG developed a nucleic acid medicine "NF- κ B decoy oligodeoxynucleotide" that successfully inhibits production of proinflammatory factors at the gene level, which is expected to lead to advancement in definitive therapy.

2) With its advanced nanotechnology, Hosokawa Micron designs and produces composite nanoparticles in which the above oligonucleotide medicine is encapsulated in biocompatible PLGA macromolecule.

3) Morishita Jintan develops gastric acid-resistant capsule formulation that will degrade in the intestine in order to deliver the nucleic acid medicine-encapsulated PLGA nano-particles. Morishita Jintan also establishes quality and stability evaluation methods and a GMP-compatible production method.

4) Aichi Gakuin University and Hosokawa Micron jointly develop a tablet formulation containing the composite nano-particles mentioned in above 2), and also establishes quality and stability evaluation methods and GMP-compatible production methods.

5) In collaboration with AnGes MG, Osaka University evaluates the efficacy, safety and stability of the capsule and tablet mentioned in above 3) and 4), and verifies the feasibility of the product towards clinical application.

Meanwhile, this trend will have no effect on AnGes MG's business performance for the current fiscal year.