

December 24 2014 AnGes MG, Inc.

## AnGes to Develop Disc Degeneration Drug Using NF-kB Decoy Nucleotide in the US

AnGes MG, Inc. ("AnGes") announced that it has revised its development strategy for the NF-kB Decoynucleotide drug for lower-back pain disorders including disc degeneration. Clinical development of the drug will commence in the US under the new development plan.

Under the revised plan, AnGes is planning to initiate a Phase I/II clinical trial at University of California, San Diego (UCSD) in 2016 after obtaining FDA IND approval. Details of the plan are scheduled to be released in due course.

AnGes' decision to revise the plan and develop the drug in the US were due to the potential market size with a large number of patients with disc degeneration, the large number of doctors who are well-practiced with the treatment approach (injection of the drug to the location identified as the source of pain by discography), and the fact that the drug which potentially suppresses disc degeneration, would match the standardized treatment policy\* of the US.

Regarding development of the drug in Japan, AnGes announced today in "The Termination of the Contract with Nippon Zoki for Disc Degeneration Drug Using NF-kB Decoy Oligonucleotide and Revision of the Development Plan" that they have terminated the contract with Nippon Zoki Pharmaceutical Co., Ltd.

NF-kB Decoy Oligonucleotide inhibits the inflammatory cytokine (physiological active substance released from cells) and is expected to be effective as treatment for disorders caused by inflammation and immunological responses. AnGes is developing NF-kB Decoy Oligonucleotide as a treatment for inflammatory diseases such as atopic dermatitis and restenosis. For treatment of lower-back pain caused by disc degeneration, the drug is expected to be effective for analgesia and disc degeneration by suppressing the factors that promote pain and degeneration.

Current treatments for disc degeneration related lower-back pain are limited to symptomatic treatment such as administering antiphlogistic analgetic. There is a demand for treatments that can inhibit the progression of disc degeneration or promote reparation, and AnGes will pursue the development to meet such medical needs.

There will be no impact to the business performance of the fiscal term ending Dec 2014.

\*NSAID (non-steroid anti-inflammatory drug) or mild narcotic analgetic are initially used to treat patients with lower-back pain. However, efficacy is limited for about two-thirds of patients, who end up undergoing surgical treatment such as disc replacement procedures, if disc degeneration progresses. Of these, approximately 15 % are said to be disc pain patients. For this reason, there is a need for treatments that are not only effective in relieving pain, but also in preventing or delaying the need for surgical treatment by suppressing disc degeneration.

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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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