

March 24, 2017 AnGes MG, Inc.

Investigational New Drug (IND) Application Submitted to the FDA

Initiating a clinical trial with NF-kappaB decoy for the treatment of discogenic lower back pain

AnGes MG, Inc. ("AnGes") announced today that it submitted on March 23, 2017 an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for a clinical trial with NF-kappaB decoy oligo DNA (hereinafter, NF-kappaB decoy), which the company is planning to conduct in the United States for the treatment of discogenic lower back pain (DLBP).

AnGes seeks to develop a therapeutic agent for the treatment of DLBP using NF-kappaB decoy, which suppresses inflammations. If it does not receive a notification by the FDA within 30 days of the application, then the clinical trial has been approved, and a phase Ib clinical trial will be initiated at several clinical sites, including San Diego State University, from the middle of this year.

NF-kappaB decoy suppresses inflammatory cytokines (physiologically active substances that are released by cells) and therefore has the potential to become an effective therapeutic agent for the treatment of various disorders caused by excessive inflammatory reactions and immune responses. Currently, the only therapy for the treatment of DLBP is symptomatic treatment by use of anti-inflammatory analgesics. NF-kappaB decoy differs from existing analgesics, because it exerts its analgesic effect by inhibiting the causative agent. The results of basic research suggest that NF-kappaB decoy is also effective for the treatment of intervertebral disc degeneration, and therefore NF-kappaB decoy is also expected to help to restore and suppress the progression of disease states that cannot be treated with existing therapeutic agents. AnGes will continue its efforts to further develop this groundbreaking therapeutic agent for the treatment of DLBP.

AnGes anticipates no impact from this announcement on its business performance for the term that ends in December 2017.

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Disclaimer: This is a translation of a news release published in Japanese. In the event of any deviations between the two language versions, the original document in Japanese shall take precedence.

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