AnGes Announces FDA Clearance of Investigational New Drug (IND) Application for NF-kappaB decoy oligo DNA to treat discogenic lower back pain

AnGes MG, Inc. (“AnGes”) announced today that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for NF-kappaB decoy oligo DNA (NF-kappaB decoy) for the treatment of discogenic lower back pain (DLBP).

AnGes submitted the IND application to the FDA on March 23, 2017 and the IND is now active. The company plans to initiate a phase Ib clinical trial from the middle of this year at several clinical sites including University of California San Diego.

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 with the 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 in treating intervertebral disc degeneration, and therefore NF-kappaB decoy is also expected to help restore and suppress the progression of disease states that cannot be treated with existing therapeutic agents. AnGes will continue its efforts to 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.