



November 29, 2023

Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

Notice on the progress of domestic Phase II clinical trials of NF-κB decoy oligo DNA for the treatment of chronic intervertebral disc low back pain

AnGes Inc. in cooperation with Shionogi Inc. is conducting Phase II clinical trials of NF-κB decoy oligo DNA for chronic discogenic low back pain in Japan, and is pleased to announce the progress of the trials.

NF-κB decoy oligo DNA began late-stage Phase I clinical trials in patients with discogenic back pain in the U.S. in February 2018, and results obtained in April 2021 confirmed its high safety profile with no serious adverse events (SAEs). Efficacy data were also evaluated in an exploratory manner. Low back pain was significantly reduced early in the treatment period, and the suppression of low back pain continued until 12 months after treatment.

Based on these results, we have decided to conduct Phase II clinical trials in Japan. The protocol for this Phase II clinical trial is a randomized, placebo-controlled, double-blind, parallel-group study, in which patients will be divided into three treatment groups (20 mg dose, 10 mg dose, and placebo) and receive a single dose of the drug in the intervertebral disc. The protocol for this Phase II clinical trial is a multicenter, randomized, placebo-controlled, double-blind, parallel-group study in which three dosing groups (20 mg, 10 mg, and placebo) will receive a single disc dose.

We plan to confirm safety in the first two patients in the Phase I clinical trial in the U.S. (maximum dose 10 mg) to the maximum dose (20 mg) in the Phase II clinical trial in Japan, and we administered the first dose on October 18, 2023, and have since completed the second dose.

Today, the Independent Data Safety Monitoring Committee confirmed the safety of two previously administered cases. Accordingly, the Phase II clinical trial will be conducted in accordance with the above clinical trial protocol.

Summary of NF-κB Decoy Oligo DNA Phase II Clinical Trial

- The target number of patients is 92 (including 2 cases already treated).
- Chronic discogenic low back pain and evaluate improvement in pain.
- Single intradiscal injection of AMG0103 (10 mg or 20 mg) or placebo.

(Note) This document has been translated from the Japanese original for reference purposes only.
In the event of any discrepancy between this translation and the Japanese original, the original shall prevail.



About NF- κ B Decoy Oligo DNA

NF- κ B is a major transcription factor that is activated when cells are exposed to external stimuli such as oxidative stress caused by reactive oxygen species to induce inflammatory and immune responses.

NF- κ B decoy oligo DNA binds to this NF- κ B transcription factor and inhibits the release of inflammatory cytokines (bioactive substances secreted by cells), and is expected to be effective in the treatment of various diseases caused by excessive inflammatory and immune responses. Until now, treatment for chronic intervertebral disc lumbago has focused on symptomatic treatment with anti-inflammatory and analgesic agents, but NF- κ B decoy oligo DNA is expected to suppress causative agents that induce excessive inflammatory and immune reactions, thereby suppressing the progression of diseases such as intervertebral disc degeneration.