October 18, 2023
Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

Notice Regarding the Start of Administration of NF-κB Decoy Oligo DNA for the Treatment of Chronic Intervertebral Disc Lumbago in a Phase II Clinical Trial in Japan

AnGes Inc. announces the start of administration of NF-κB decoy oligo DNA in a Phase II clinical trial for chronic discogenic low back pain in Japan.

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

- Patients with chronic discogenic low back pain evaluated for improvement in pain.
- Target number of cases is 92

1. Development history of NF-κB decoy oligo DNA

NF-κB decoy oligo DNA began Phase I-B 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 and showed that low back pain was significantly reduced early in the treatment period and continued to be suppressed up to 12 months after treatment.

Based on these results, we decided to conduct a Phase II clinical trial in Japan and have been preparing for it.

On March 20, 2023, we entered into an agreement with Shionogi Inc. regarding cooperation in this Phase II clinical trial.

2. About NF-κB Decoy Oligo DNA

NF-κB 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-κB decoy oligo DNA binds to this NF-κB 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-κB 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.

3. Future outlook

This matter has been incorporated into our consolidated earnings forecast for the fiscal year ending December 31, 2023, and will have no impact on our group's consolidated earnings forecast.We plan to promptly announce any further events that should be disclosed in the future.