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Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

Notice on the Decision to Develop NF-κB Decoy Oligo DNA for the Treatment of Chronic Intervertebral Disc Lumbago in Japan

AnGes Inc. announces that its Board of Directors today approved a resolution to commence development of NF-κB decoy oligo DNA for the treatment of chronic discogenic low back pain in Japan.

1. Background of the Decision

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 the results of this study, we will consider our future development policy on the premise of partnering with other companies. Since there are many patients with chronic discogenic low back pain in Japan, we have decided today to conduct a Phase II clinical trial in Japan, based on our judgment that the product has good business potential if commercialized in the domestic market. We will now proceed with negotiations with the authorities, including protocols for clinical trials.

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.

(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.



3. Future outlook

The cost of this domestic development in the Group's R&D expenses is insignificant, and this cost will be incorporated into the forecast for the current fiscal year, which will be disclosed in the future.