May 26, 2025
Company Name: AnGes Inc.
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Notice on Publication on the Paper of Results of Late Phase I Clinical Trial of NF-κB Decoy Oligo DNA for the Treatment of Chronic Intervertebral Disc Lumbago in the US

AnGes Inc. has conducted a Phase I clinical trial of NF-κB decoy oligo DNA for chronic discogenic low back pain in the United States from 2018 to 2020. We are pleased to announce that a paper on the results of this clinical trial has been published.

NF-κB decoy oligo DNA has been in late-stage Phase I clinical trials for patients with discogenic back pain in the U.S. since February 2018, and the results obtained in April 2021 have been previously announced in the financial report as follows.

In late phase I clinical trials of NF-κB decoy oligo DNA, no serious adverse events (SAEs) were observed and a high level of safety was confirmed. Efficacy data was also evaluated in an exploratory manner and showed that low back pain was significantly reduced from the early stage of administration, and the suppression of low back pain continued until 12 months after administration.

The paper on the results of this clinical trial has been published in The SPINE JOURNAL, and we are pleased to announce the details of the clinical trial results as follows.

Summary of NF-κB Decoy Oligo DNA (AMG0103) late phase I clinical trial

- Multicenter, placebo-controlled, randomized, double-blind comparative study
- 25 patients enrolled
- Patients with chronic discogenic low back pain
- AMG0103 (0.3 mg, 3 mg or 10 mg) or placebo injected once into the disc
- Observation period 50 weeks (1 year)

Results of NF-κB Decoy Oligo DNA Late Phase I Clinical Trial

- No decline in neurological, sensory, or motor function was observed in the placebo group or in all AMG0103 treatment groups (0.3 mg, 3 mg, or 10 mg) during the one-year observation period. No serious adverse events occurred and no safety issues were observed.
- AMG0103 showed a dose-dependent analgesic effect on low back pain, especially at the highest dose of 10 mg, with an average of 77% pain reduction compared to the pre-treatment level after one year of final observation.
- Disc height decreased in the placebo group, whereas an increase was observed in the 10 mg group, suggesting morphological improvement.
- Improvements were also observed in patient satisfaction (PGIC) and impairment of activities of daily living (RMDQ, ODI). Furthermore, none of the AMG0103 10 mg patients received additional analgesics throughout the study period, suggesting that the analgesic effect was sustained.

These results suggest that AMG0103, after a single administration to the intervertebral disc, clearly improves low back pain, which in turn improves daily life, and the patients are highly satisfied with the results.

For more information on the paper, please click here.

The Spine Journal <in press, 2025>

https://www.thespinejournalonline.com/article/S1529-9430(25)00203-7/fulltext

Although there will be no change in our consolidated earnings forecast for the fiscal year ending December 31, 2025 as a result of the publication of this paper, we believe that it will contribute to the enhancement of our corporate value over the medium term.

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.

About The SPINE JOURNAL

The Spine Journal is a journal published by the North American Spine Society (NASS) that publishes research articles, reviews, and case reports on spine surgery. It is the leading journal in the field of spine diseases and provides bi-weekly high quality, rigorously peer-reviewed articles from around the world.