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Results of a Phase II Clinical Trial for Ranirestat - Therapeutic Agent for Diabetic Complications

Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) and KYORIN Pharmaceutical Co., Ltd. ("Kyorin") (Head office: Chiyoda-ku, Tokyo, President: Keiji Hirai, Ph.D.), a wholly owned subsidiary of KYORIN Holdings, Inc., announce the results of a phase IIb clinical trial in Japan (hereby stated as "trial") from the joint development of the original aldose reductase inhibitor ranirestat (general name, development code: AS-3201) to treat diabetic complications.

This trial was a double blind, placebo controlled comparison involving patients with diabetic peripheral neuropathy randomly assigned to treatment with placebo or 10 mg, 20 mg, or 40 mg/day ranirestat. The primary endpoint was the summed changes in sensory-motor nerve conduction velocity (summed nerve conduction velocity)^{*1}, and the secondary endpoint was the modified Toronto Clinical Neuropathy Score (mTCNS),^{*2} an index for evaluating clinical symptoms.

The results of the trial showed that although a clear dose response relationship was not established, a significant increase in summed nerve conduction velocity as the primary endpoint was seen in all ranirestat arms compared to before administration.

In the secondary endpoint of mTCNS, although a statistically significant improvement vs placebo could not be demonstrated due to a larger than expected placebo effect, according to the analysis excluding subjects who showed a large change in symptoms during the observation period, the results suggesting efficacy for ranirestat were obtained. Additionally, no safety issues were observed for ranirestat.

(Outline of the clinical trial and outline of ranirestat are attached)

(Reference)

(About the Trial)

Dosage and Administration: Two tablets administered orally once a day after breakfast.

Trial Period: Drug treatment period 58 weeks

Observation period (6 weeks) : Placebo

Treatment period (52 weeks) : Ranirestat 10 mg, 20 mg, 40 mg and Placebo

Observation period after trial (4 weeks)

Target number of subjects: 70 per arm.

Primary Endpoint: Sum of the changes in sensory-motor nerve function (summed nerve conduction velocity)

Secondary Endpoint: Modified Toronto Clinical Neuropathy Score (mTCNS), etc.

- *1 Summed changes in sensory-motor nerve function (summed nerve conduction velocity):
Summation of the Sensory Nerve Conduction Velocity (SNCV) (average of the bilateral sural and proximal median nerves), and the Motor Nerve Conduction Velocity (MNCV) (tibial nerve, median nerve).
- *2 Modified Toronto Clinical Neuropathy Score (mTCNS): An evaluation index for clinical conditions in diabetic neuropathy as designed by Professor Vera Bril of the Division of Neurology, Toronto University, Canada. It is composed of a symptom score that evaluates positive symptoms (spontaneous pain, numbness, etc) and a sensory examination score that evaluates negative symptoms (paresthesia and other objective tests for abnormal symptoms, etc.)

(About ranirestat)

Ranirestat (general name, development code: AS-3201) is a compound created by Dainippon Sumitomo Pharma Co., Ltd. as a therapeutic agent for diabetic complications. Ranirestat is an aldose reductase inhibitor that acts by reducing sorbitol accumulation in cells and it is hoped to treat diabetic neuropathy, a diabetic complication.

In Japan, Dainippon Sumitomo Pharma Co., Ltd. and KYORIN Pharmaceutical Co., Ltd. are cooperating in joint development aiming to put this medicine on the market as soon as possible. Moreover, in September 2005, Dainippon Sumitomo Pharma Co., Ltd. executed a license agreement with Eisai Co., Ltd. for overseas development and commercialization rights and currently Eisai Co., Ltd. is conducting Phase II/III clinical trials in the US, Canada and Europe.