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Seikagaku Corporation
(Securities Code: 4548)

Seikagaku Announces Top-Line Results from a Phase III Clinical Trial for SI-6603, Indicated for Treatment of Lumbar Disc Herniation, in Japan

Seikagaku Corporation (Tokyo) hereby announces that it has obtained favorable results from its Phase III clinical trial for SI-6603 (generic name: condoliase), indicated for treatment of lumbar disc herniation, in Japan.

The trial was a randomized, double-blind, placebo-controlled trial involving 163 patients with lumbar disc herniation. Compared to the placebo, SI-6603 demonstrated significant improvement in lower limb pain at 13 weeks after the administration, the primary endpoint of the trial. Also, it was well tolerated with no major safety concerns. Based on the results of the trial, Seikagaku will aim for an NDA application in Japan in the fiscal year ending March 2014. Seikagaku will also focus on the progress of the Phase III clinical trials in the U.S.

<SI-6603 for the treatment of lumbar disc herniation>

Lumbar disc herniation is the partial protrusion of the nucleus pulposus at the core of each intervertebral disc or the anulus fibrosus, the disc's outer layer. The resulting pressure on the spinal nerve root causes pain and numbness. SI-6603 is an injectable drug using an enzyme named condoliase that specifically degrades glycosaminoglycans (GAG), which are the main components of the nucleus pulposus. A direct injection of SI-6603 into the intervertebral disc would cause reduction of the pressure on the nerves by shrinking the nucleus pulposus through degrading GAG. Because SI-6603 does not break down proteins, it is thought to have no effect on surrounding tissues such as blood vessels and nerves.

Since currently no fundamental pharmacological therapy for lumbar disc herniation exists, the launch of SI-6603, expected to show improvement comparable to lumbar disc surgery by a single injection, would contribute to the alleviation of the patient's physical load and reduced medical costs, including surgical and hospitalization costs.

*Glycosaminoglycans (GAG): one of the key constituents of complex carbohydrates such as chondroitin sulfate and hyaluronic acid.

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