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Seikagaku Corporation
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Seikagaku announces on top-line results from phase II/III clinical trial in Japan of SI-6603, indicated for treatment on lumbar disc herniation

Seikagaku Corporation (head office: Chiyoda-ku, Tokyo) is pleased to announce that it has obtained favorable results from its Phase II/III clinical trial conducted in Japan for SI-6603, a development program for the treatment of lumbar disc herniation.

The trial was a randomized, double-blind, placebo-controlled trial involving 195 patients with lumbar disc herniation. The primary end point was the improvement of leg pain 13 weeks after the administration of SI-6603. SI-6603 demonstrated significant improvement in the pain compared to the placebo. Also it was well tolerated with no major safety concerns.

Based on the results of the trial, Seikagaku plans to file a new drug application for SI-6603 in Japan in mid-2011 for indication of lumbar disc herniation. Seikagaku will also continue to proceed with the Phase II clinical trials in the United States.

Seikagaku maintains a highly efficient research and development program focusing primarily on glycosaminoglycans (GAGs)*1 and joint diseases, with the aim of bringing a continuing series of new products to market as rapidly as possible. Lumbar disc herniation can have a serious impact on patients' lives as the pain intensifies. SI-6603, which specifically degrades GAGs, has been developed for the treatment of lumbar disc herniation and is expected to offer an effective treatment option for patients.

*1 Glycosaminoglycans (GAGs) are key components of glycoconjugates. Examples include chondroitin sulfate and hyaluronic acid.

For Your Information

Characteristics of SI-6603

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 nerves around the vertebra causes pain and numbness. SI-6603 consists of chondroitinase ABC (generic name: Condoliase), an enzyme that specifically degrades GAGs, which are the main components of the nucleus pulposus. When SI-6603 is injected into the intervertebral disc, the resulting dissolution of the GAGs is expected to cause the nucleus pulposus to shrink, relieving the pressure on the nerves. Because SI-6603 does not break down proteins, it is believed to have no effect on surrounding tissues, such as blood vessels and nerves. Furthermore, a single dose of SI-6603 is assumed to be as effective as surgery in alleviating symptoms, which means that patients would also expected to receive benefits in the form of reduced medical costs, including surgical and hospitalization costs.

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