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Seikagaku Corporation  
(Securities Code: 4548)

## **Seikagaku announces an additional clinical trial in Japan for SI-6603, indicated for treatment of lumbar disc herniation**

Seikagaku Corporation (Tokyo) hereby announces that it has decided to conduct an additional Phase III clinical trial in Japan for SI-6603, indicated for treatment of lumbar disc herniation.

Seikagaku obtained favorable results from a SI-6603 Phase II/III clinical trial completed in Japan in December 2010 and aimed to file a new drug application for SI-6603 in the second half of this calendar year. However, based on the results of further discussions with the Pharmaceuticals and Medical Devices Agency, Seikagaku judged it necessary to accumulate further data by means of conducting the additional Phase III clinical trial.

Seikagaku will proactively continue the development of SI-6603 in Japan and promptly conduct the additional Phase III clinical trial to obtain an approval. At the same time, Seikagaku will make efforts to progress the Phase II clinical trial in the U.S., in order to provide a new treatment option for lumbar disc herniation patients.

### <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 is an enzyme named condoliase, that specifically degrades glycosaminoglycans (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 be expected to receive benefits in the form of reduced medical costs, including surgical and hospitalization costs.

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