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Seikagaku Corporation  
(Securities Code: TSE 4548)

## **Seikagaku Submits New Drug Application for SI-6603 in Japan for Treatment of Lumbar Disc Herniation**

Seikagaku Corporation (Tokyo, Japan) hereby announces that it has submitted a new drug application (NDA) for SI-6603 (generic name: condoliase), indicated for the treatment of lumbar disc herniation, to the Ministry of Health, Labour and Welfare of Japan.

As announced in a press release issued on August 7, 2013, Seikagaku obtained favorable results from a Phase III clinical trial in which SI-6603 demonstrated significant improvement in lower limb pain compared to the placebo at 13 weeks after administration, the primary endpoint of the trial, and was well tolerated with no major safety concerns. The NDA is based on these clinical trial results in Japan.

Since currently no fundamental pharmacological therapy for lumbar disc herniation exists, the launch of SI-6603, of which a single injection treatment is expected to be comparable to lumbar disc surgery in improving symptoms, would contribute to the alleviation of physical burden and improvement of quality of life (QOL) of the patients. Seikagaku is also focusing on the progress of the Phase III clinical trials underway 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.

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

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