November 10, 2011 Seikagaku Corporation (Securities Code: 4548)

## Seikagaku announces the start of a Phase III clinical trial in Japan for SI-6603, indicated for treatment of lumbar disc herniation

Seikagaku Corporation (Tokyo) hereby announces that it has submitted to the Pharmaceuticals and Medical Devices Agency a clinical trial notification for a Phase III clinical trial in Japan for SI-6603 (generic name: condoliase), indicated for treatment of lumbar disc herniation.

As announced in our press release issued on August 10, 2011, the purpose of this clinical trial is to accumulate further data to supplement the results of a Phase II/III clinical trial obtained in December 2010. The trial will examine the improvement on symptoms of lumbar disc herniation and safety.

Seikagaku aims for promptly conducting this trial so as to obtain approval in Japan for SI-6603 in the shortest possible time. At the same time, Seikagaku will make efforts to progress with the Phase II clinical trial in the U.S. as it focuses on the development of SI-6603 as a novel treatment option for patients with lumbar disc herniation.

## 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 reap benefits in the form of the patient's physical load and reduced medical costs, including surgical and hospitalization costs.

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