March 23, 2018
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

# Seikagaku Announces New Drug Application Approval of HERNICORE® 1.25 Units for Intradiscal Injection in Japan, Indicated for Treatment of Lumbar Disc Herniation.

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that the Japanese Ministry of Health, Labour and Welfare (“MHLW”) has approved the New Drug Application (“NDA”) of HERNICORE® 1.25 units for intradiscal injection (generic name: condoliase, development code: SI-6603) in Japan, indicated for the treatment of lumbar disc herniation.

HERNICORE® 1.25 units for intradiscal injection ( "the agent") is a new treatment option for lumbar disc herniation with the active pharmaceutical ingredient of condoliase. This is the first therapeutic agent in Japan with intradiscal administration. It does not require a general anesthesia and is less invasive to the patient than surgical treatment.

In the Phase III clinical trial in Japan conducted by Seikagaku, a significant improvement was found in the primary endpoint—change in worst leg pain at 13 weeks after administration—compared to the placebo group.

As the promising improvement effects to the symptoms of lumbar disc herniation are expected by a single administration of the agent, Seikagaku believes that this new treatment option is able to contribute to quality of life of the patient. The agent will be sold by Kaken Pharmaceutical Co. Ltd. (Tokyo, Japan) in Japan. Timing of launch will be announced following listing in the National Health Insurance drug price list.

Seikagaku is currently examining the effect of this matter upon its consolidated financial forecasts for the fiscal year ending March 31, 2018 and will disclose the results as soon as they are confirmed.

**<Overview of the agent>**

Product name: HERNICORE® 1.25 Units for Intradiscal Injection
Generic name: condoliase
Efficacy and effects: Lumbar disc herniation by prolapse of the posterior longitudinal ligament for which sufficient improvement cannot be obtained through conservative treatment
Usage and dosage: For adults, 1.25 units of condoliase are administered by a single

injection in the intervertebral disc that is the source of the symptoms.

Mechanism of action: It is expected that condoliase degrades chondroitin sulfate, chondroitin, and hyaluronic acid and also improves the clinical manifestations of herniation by lowering the internal pressure of the intervertebral disc due to dissolving the glycosaminoglycans* within the nucleus pulposus of the intervertebral disc, and lowering the water-holding capacity of the nucleus pulposus.

* Glycosaminoglycans (GAG): A major component of complex carbohydrates. Chondroitin sulfate and hyaluronic acid etc.

**<Regarding lumbar disc herniation and therapies>**

Lumbar disc herniation is the partial protrusion of the nucleus pulposus at the core of each intervertebral disc or the annulus fibrosus, the disc's outer layer. The resulting pressure on the spinal nerve root causes pain and numbness.

Current treatments are generally categorized into conservative treatments for temporal pain relief (rest and pharmaceutical methods such as NSAIDs) and surgical treatments. As this agent specifically degrades GAGs in the nucleus pulposus, resulting in decrease in the pressure on the nerve root, it is positioned as an innovative treatment of lumbar disc herniation.

**<Cautionary Notes>**

This press release contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this press release is not intended to constitute an advertisement or medical advice.

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