# Seikagaku Announces the Conclusion of an Exclusive Worldwide License Agreement (excluding Japan) for SI-6603, a Novel Treatment for Lumbar Disc Herniation

Seikagaku Corporation ("Seikagaku") (head office: Tokyo, Japan) and Ferring Pharmaceuticals ("Ferring") (head office: Saint Prex, Switzerland) today announced that the companies have entered into an exclusive worldwide license agreement (excluding Japan) for SI-6603 (condoliase), a potential treatment for lumbar disc herniation. The agreement is based on a letter of intent concluded on June 15, 2016.

Under the license agreement, Ferring acquires exclusive development and commercialization rights to SI-6603 worldwide, excluding Japan. Seikagaku will receive an upfront payment of US \$5 million and milestone payments up to a maximum total amount of US \$90 million over multiple years upon future progress in development and commercialization.

SI-6603 is a product Seikagaku has been developing in Japan and the U.S. In the U.S., Seikagaku is conducting two Phase III clinical trials (a pivotal double-blind study and an open-label safety study). Seikagaku intends to accelerate the development of SI-6603 in the U.S. in order to achieve early entry to the U.S. market, where high growth potential is expected.

There will be no revision to the forecast of consolidated results for the fiscal year ending March 31, 2017, which was publicly disclosed on May 12, 2016, as the impact of this agreement has already been incorporated in the forecast.

## < Reference >

Ferring disclosed the press release regarding this agreement on August 29, 2016 (local time). Please refer to website of Ferring;

http://www.ferring.com/en/media/press-releases/

## < About Ferring Pharmaceuticals >

Headquartered in Saint-Prex, Switzerland, Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group active in global markets. The company identifies, develops and markets innovative products in the areas of reproductive health, urology, gastroenterology, endocrinology, and orthopaedics. Ferring has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries. Following Europe, the U.S. is Ferring's second-largest market, and approximately 30% of its U.S.

revenue comes from the orthopaedics segment.

## < About 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 annulus 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.

In Japan, Seikagaku submitted a new drug application to the Ministry of Health, Labor and Welfare of Japan in January 2014 and it is now under review. On December 25, 2012, Seikagaku Corporation and Kaken Pharmaceutical Co., Ltd. (head office: Bunkyo-ku, Tokyo) concluded an exclusive distributorship agreement in Japan for SI-6603.

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

#### < Cautionary Notes >

This press release contains forward-looking statements regarding future management strategies or performance forecasts. These statements 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 any forward-looking statements on this press release.

Information about pharmaceutical products or agents (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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