May 26, 2023
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Announces the Topline Results from a Phase III Clinical Study (Additional Study) in the U.S. for SI-6603, a Treatment for Lumbar Disc Herniation

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today that favorable results were obtained in a Phase III clinical study (additional study) in the U.S. for SI-6603, a treatment for lumbar disc herniation (generic name: Condoliase) currently in development.

The study was a randomized, double-blind, controlled, parallel-group, comparative study of SI-6603 in 352 patients with lumbar disc herniation. SI-6603 showed statistically significant improvement compared to the control group in worst leg pain reduction at 13 weeks after injection, the primary endpoint of the study. SI-6603 was generally well-tolerated.

In light of the study's outcome, Seikagaku plans to proceed with preparations for a Biologics License Application (BLA) to US FDA at an early date. Seikagaku and licensee Ferring Pharmaceuticals (Saint Prex, Switzerland "Ferring") will aim to contribute to improved quality of life for patients by providing a therapeutic option through development of SI-6603.

There is no change in Seikagaku's forecast of consolidated financial results for the fiscal year ending March 31, 2024 in connection with this matter.

Reference Information

<About SI-6603 (Treatment for Lumbar Disc Herniation)>

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is intended to treat lumbar disc herniation via a single direct injection into the intervertebral disc. It has the potential benefit of not requiring general anesthesia and being less invasive to patients than surgical treatment. In addition, the single injection regimen tested in the Phase III trial has the potential to contribute to improving patients' quality of life as a new treatment option.

Marketing approval in Japan for SI-6603 was obtained from the Ministry of Health, Labour and Welfare in March 2018, and SI-6603 has been sold as HERNICORE® 1.25 units for intradiscal injection through sales partner Kaken Pharmaceutical Co., Ltd. (Tokyo, Japan) since August 1, 2018.

<About Ferring Pharmaceuticals>

Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. In the United States, Ferring is a leader in reproductive medicine and maternal health, uro-oncology and in specialty areas within gastroenterology, including microbiome therapeutics, and orthopaedics.

For more information, https://www.ferringusa.com.

<Alliance with Ferring Pharmaceuticals>

Seikagaku and Ferring entered into a license agreement for SI-6603 in August 2016. Under the license agreement, Ferring has acquired exclusive development and commercialization rights to SI-6603 worldwide, excluding Japan.

For details, please refer to the following press release.
Seikagaku Announces the Conclusion of an Exclusive Worldwide License Agreement (excluding Japan) for SI-6603, a Novel Treatment for Lumbar Disc Herniation
https://www.seikagaku.co.jp/en/news/news-2557126754645424970/main/0/link/20160829_e.pdf

< 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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