

May 14, 2024
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Announces the Biologics License Application for SI-6603 Has Been Accepted for Filing by the U.S. FDA

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announces that its Biologics License Application ("BLA") for SI-6603 (generic name: condoliase, "SI-6603"), a drug under development in the United States intended to treat radicular leg pain associated with lumbar disc herniation, has been accepted for filing by the U.S. Food and Drug Administration ("FDA").

This application is based on the results of a Phase III clinical trial (Study 6603/1133) in the United States.

Seikagaku and licensee Ferring Pharmaceuticals ("Ferring"), will aim to provide a potential new treatment option for radicular leg pain associated with lumbar disc herniation through the development of this drug.

There is no change in Seikagaku's forecast of consolidated financial results for the fiscal year ending March 31, 2025 in connection with this matter.

Reference Information

<About SI-6603 >

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is an investigational product intended to treat radicular leg pain associated with lumbar disc herniation via a single direct injection into the intervertebral disc.

SI-6603 was developed by Seikagaku. 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 privately-owned, research-driven, specialty biopharmaceutical group committed to building families and helping people live better lives. In the United States, Ferring is a leader in reproductive medicine and maternal health, and in areas of gastroenterology and orthopaedics. Ferring is at the forefront of innovation in microbiome-based therapeutics and uro-oncology intravesical gene therapy.

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

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