

Seikagaku Announces Resubmission of Application to Obtain Approval in the U.S. for SI-6603

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that it has resubmitted to the U.S. Food and Drug Administration (FDA) a biologics license application (BLA) for SI-6603 (generic name: condoliase), a potential treatment for lumbar disc herniation.

In March 2025, Seikagaku received from the FDA a complete response letter (CRL)* concerning SI-6603. In the CRL, the FDA expressed no concerns about the clinical study results, including the efficacy and safety of SI-6603. However, the FDA did cite observations related to the manufacturing facility, control of drug substance and drug product. In response to this, Seikagaku has proceeded with preparations for resubmission of the BLA for SI-6603.

In collaboration with Ferring Pharmaceuticals, which has a license agreement for SI-6603 in the U.S., Seikagaku will continue to seek to obtain regulatory approval for SI-6603 to enable provision of a new non-surgical treatment option that reduces leg pain associated with lumbar disc herniation.

There is no change in Seikagaku’s forecast of consolidated financial results for the fiscal year ending March 31, 2026 in connection with this matter.

*Complete response letter (CRL): a notice issued by the FDA upon completion of the review for an application indicating that the application will not be approved in its present form

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.

<About Ferring Pharmaceuticals>

Ferring Pharmaceuticals is a privately-owned, 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 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, please visit: 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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