March 12, 2025
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Announces Receipt of a Complete Response Letter Concerning the Biologics License Application in the U.S. for SI-6603 (Generic Name: Condoliase)

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today (March 11, U.S. time) that it has received from the U.S. Food and Drug Administration (FDA) a complete response letter (CRL)* concerning Seikagaku’s biologics license application (BLA) in the U.S. for SI-6603 (generic name: condoliase), a treatment that reduces leg pain associated with lumbar disc herniation.

No concerns about the clinical study results, including the efficacy and safety of SI-6603, were expressed by the FDA, and no additional clinical studies are required. However, additional observations were made, mainly concerning manufacturing facility, control of drug substance and drug product.

Seikagaku will now work closely with the FDA and Ferring Pharmaceuticals, which has concluded a license agreement for SI-6603 with Seikagaku, and consider a prompt resubmission in preparation for regulatory approval.

Seikagaku is currently assessing the effect of this matter on the forecast of consolidated financial results for the fiscal year ending March 31, 2025 and will promptly disclose any matters requiring disclosure should they arise.

*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

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