September 10, 2026
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

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today (September 9, 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), filed in March 2026.

The reason FDA issued the CRL this time is that, in addition to the fact that the deficiencies identified during the inspection of the drug substance manufacturing facility have not yet been fully resolved, deficiencies were also identified during the newly conducted cGMP inspection of the contract manufacturing facility for the drug product, and it was determined that improvements are required. No concerns were expressed regarding the clinical study results, including the efficacy and safety of SI-6603, and no additional clinical studies were required.

Seikagaku will continue to work closely with the FDA and Ferring Pharmaceuticals, with which Seikagaku has entered into a license agreement for SI-6603, and will consider 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, 2027, 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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