November 7, 2017
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Announces the Results of SI-6603 Phase III Clinical Trials in the U.S., Indicated for Treatment of Lumbar Disc Herniation

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that in a U.S. Phase III clinical trial, SI-6603 (generic name: Condoliase), demonstrated the expected pharmacologic effect but failed to meet its primary endpoint, change in worst leg pain at week thirteen (13).

Seikagaku conducted a randomized, double-blind, placebo-controlled, parallel-group comparison study for the purpose of evaluating efficacy and safety (the “double-blind study”) and an open-label study in the U.S. and Europe mainly for the purpose of evaluating safety (the “open-label study”) as required to obtain FDA regulatory approval for SI-6603 in the U.S. The double-blind study involving 385 patients with lumbar disc herniation did not meet its primary endpoint. No major safety concerns were found in either the double-blind or the open-label study, and the safety of SI-6603 was confirmed.

Seikagaku will work with the licensing partner, Ferring Pharmaceuticals and communicate with the U.S. Food and Drug Administration for initiation of a new Phase III clinical trial (the double-blind study) in the U.S. at an early date.

A new drug application of SI-6603 has been submitted in Japan, and it is currently under review. Seikagaku believes that these clinical trial results will have no impact on obtaining approval in Japan as the Japanese trial met its primary endpoint – worst leg pain at thirteen (13) weeks.

The impact of this matter to the forecast of consolidated financial results for the fiscal year ending March 31, 2018 will be minor. Should it become clear that the matter would have a material impact on the financial results, Seikagaku will promptly make an announcement.

< Cautionary Notes >
This press release contains forward-looking statements regarding future management strategies or performance forecasts. These statements 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 forward-looking statements due to various factors.
Information about pharmaceutical products or medical devices (including products currently in development) included in this press release is not intended to constitute an advertisement or medical advice.

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