February 19, 2018
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Initiates a Phase III Clinical Trial (Additional Study) in the U.S. for SI-6603, Indicated for Treatment of Lumbar Disc Herniation

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today that it will initiate a Phase III clinical trial (additional study) in the U.S. for SI-6603 (generic name: Condoliase), indicated for the treatment of radicular leg pain (i.e. sciatica) due to a lumbar disc herniation.

As announced in a press release dated November 7, 2017, a previous U.S Phase III study did not meet its primary endpoint - change in worst leg pain at week thirteen (13) - and found no statistically significant improvement when compared to a control group, despite demonstrating the expected pharmacologic effect.

In response to this result, Seikagaku has communicated with the U.S. Food and Drug Administration (FDA) and its licensing partner, Ferring Pharmaceuticals, its intention to conduct an additional study. Building on lessons learned from the previous U.S. Phase III study, Seikagaku anticipates a successful outcome for the new trial.

Seikagaku is committed to provide healthy and better quality of life by offering a new treatment option for the patients with lumber disc herniation with approval for SI-6603 in Japan and the U.S.

The start of enrollment for the additional study is scheduled for the second quarter of 2018, and there is no change to the forecast of consolidated financial results for the fiscal year ending March 31, 2018 because of this matter.

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

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