December 25, 2015
Seikagaku Corporation
(Securities Code: TSE 4548)

Seikagaku Announces U.S. FDA Approval for VISCO-3™, a Joint Function Improving Agent Supplied as a Three-Injection Kit

Seikagaku Corporation (Tokyo) today announced that U.S. Food and Drug Administration (FDA) approval was obtained for VISCO-3™, a medical device indicated for knee osteoarthritis, on December 21, 2015 (U.S. local time).

VISCO-3™ is a three-injection kit product for administering a three-dose treatment cycle (three doses given once weekly) of a joint function improving agent whose main ingredient is hyaluronic acid.

The hyaluronic acid injection market in the U.S. has continued to grow steadily, and especially, sales of three-injection products are increasing. We conducted a non-inferiority clinical trial comparing VISCO-3™ with the three-injection product of a competitor beginning in March 2014. As a result of the trial, the FDA approved VISCO-3™.

In addition, accompanying a labeling change following FDA approval of the safety of retreatment injection of SUPARTZ® in March 2015, we changed the brand name from SUPARTZ® to SUPARTZ FX™ on October 12, 2015 and SUPARTZ FX™ is on sale in the U.S. now.

An aging population in the U.S. has led to an upward trend in the incidence of knee osteoarthritis, and continued expansion of the market for joint function improving agents is expected. Seikagaku is seeking to strengthen its market presence in the U.S., which is a key region for its growth strategy, by enhancing its product line in response to the range of demand. With the launch of VISCO-3™, Seikagaku will offer a three-injection treatment option in addition to its existing Gel-One® single-injection treatment and SUPARTZ FX™ five-injection treatment.

< Knee osteoarthritis >
Knee osteoarthritis is a disease characterized by the degeneration of articular cartilage and consequent swelling and pain. Injection of hyaluronic acid is a therapy used to curb the progress of symptoms.

########