

## **Seikagaku Initiates Phase II Study of SI-613 for Treatment of Knee Osteoarthritis in the U.S.**

Seikagaku Corporation (“Seikagaku”) (head office: Tokyo, Japan) hereby announces the start of Phase II study of SI-613 in patients with osteoarthritis of the knee<sup>(\*)</sup>, in the U.S.

Seikagaku is developing SI-613 as a medical drug product, a formulation in which hyaluronic acid and a non-steroidal anti-inflammatory drug (NSAID) are chemically bound using its proprietary technology. SI-613 was designed to provide pain relief and anti-inflammatory effect by sustained release<sup>(\*\*)</sup> of NSAID, and joint function improving effect by hyaluronic acid. It is expected to provide prompt and sustained relief of the severe pain and inflammation associated with osteoarthritis of the knee. SI-613 is administered directly into the joint cavity, thus the transfer of the NSAID into the systemic blood is very low, and it is expected to mitigate a risk of side effects reported in oral or topical administration. Seikagaku has been conducting the Phase III study of SI-613 in Japan for patients with osteoarthritis since February 2017.

Seikagaku will accelerate development of SI-613 in Japan and the U.S. to enhance its product line in the field of orthopedic disorders, which it has designated as a high-priority field in its basic policy on research and development, with the aim of contributing to the enhancement of the quality of life for patients.

There will be no revision to the forecast of consolidated results for the fiscal year ending March 31, 2018, which was publicly disclosed on May 12, 2017, as the impact of this matter has already been incorporated in the forecast.

### **< Reference Information >**

(\*1) Knee osteoarthritis

Knee osteoarthritis is a disease in which joint tissue degenerates and inflammation and pain occur due to the wearing of articular cartilage. Since bones come into direct contact with one another as the condition and cartilage wear progress, intense pain occurs when the knee joint is moved. The occurrence of knee osteoarthritis is said to be associated with aging, obesity, external injury, excessive exercise, genetic predisposition, and other factors.

(\*2) Sustained release

Sustained release is the gradual release of the active pharmaceutical ingredients of a drug to achieve a sustained therapeutic effect.

### **< 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.