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SEIKAGAKU CORPORATION
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Seikagaku Initiates Phase III Study of SI-613 for Treatment of Osteoarthritis in Japan

Seikagaku Corporation ("Seikagaku") (head office: Tokyo, Japan) hereby announces the start of Phase III study of SI-613, a joint improving agent indicated for treatment of osteoarthritis(*1) , in Japan.

The purpose of the study is to verify the efficacy and safety of SI-613, for which clinically effective results were confirmed in Phase II clinical trials conducted for the indication of knee osteoarthritis. The study also evaluates the efficacy and safety of SI-613 for other joints (hip, ankle, elbow, and shoulder) in addition to the knee joint with the aim of expanding the target patient population.

SI-613 is a formulation in which hyaluronic acid and a non-steroidal anti-inflammatory drug (NSAID) are chemically bound using a proprietary technology. Combining the pain relief and anti-inflammatory effect of an NSAID designed for sustained release(*2) with the joint function improving effect of hyaluronic acid is expected to provide prompt and long-lasting relief of the intense pain and inflammation associated with osteoarthritis. Further, since SI-613 is an injectable treatment administered directly into the joint cavity, transfer of the NSAID into the systemic blood circulation is low, it can be expected to mitigate NSAID side effects compared with oral or transdermal administration.

Seikagaku estimates that approximately 8.7 million patients receive treatment for osteoarthritis (five major areas: knee, hip, ankle, elbow, and shoulder) in Japan each year. Seikagaku assumes that SI-613 would be administered principally to patients suffering from intense pain from osteoarthritis who are currently prescribed oral or topical NSAIDs or intraarticular steroids.

Seikagaku positions SI-613 as a global product, including Japan and the U.S., and plans to accelerate future development with the aim of contributing to the enhancement of healthful, rewarding living for patients.

< Reference Information >

(*1) Osteoarthritis

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 joint is moved. The occurrence of osteoarthritis is said to be associated with aging, obesity, external injury, excessive exercise, genetic predisposition, and other factors. It is common among men and women over the age of 50, especially women. Approximately 40% of men and 70% of women in their 70s are said to suffer from osteoarthritis of the knee, a joint that bears body weight[1].

[1] Source: Osteoarthritis of the Knee — Epidemiology, Biomechanics, and Conservative Treatment, ed. Yoshio Koga, Nankodo, 2008

(*2) Sustained release

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

< 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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