

Seikagaku Initiates a Phase II Clinical Trial for SI-613, Indicated for Treatment of Knee Osteoarthritis

Seikagaku Corporation (Tokyo) hereby announces the start of a Phase II clinical trial for SI-613, indicated for treatment of knee osteoarthritis^(*1), in Japan.

SI-613 is a new formulation in which hyaluronic acid and a non-steroidal anti-inflammatory drug (NSAID) are chemically bound using a drug binding technology unique to Seikagaku. Having the knee pain relief and anti-inflammatory effect of an NSAID designed for sustained release^(*2) in addition to the joint function improving effect of hyaluronic acid, it is expected to provide prompt and long-term relief of intense pain and inflammation associated with knee osteoarthritis. Further, since SI-613 is an injectable treatment administered directly into the joint cavity, transfer of NSAID into the systemic blood circulation is extremely low, and it can be expected to mitigate side effects of NSAID compared with oral or topical NSAIDs such as poultices.

SI-613 would be administered principally to patients suffering from intense pain from knee osteoarthritis who are currently prescribed therapies oral or topical NSAIDs or intraarticular steroid, and Seikagaku positions SI-613 as a product for global development including Japan and the U.S.

Seikagaku aims to enhance its product line in the field of orthopedic disorders, which the company has designated as a high-priority field in its basic policy on research and development, and contribute to a more healthy and fulfilling quality of life for patients by providing SI-613, a new therapeutic option for the treatment of knee osteoarthritis.

Reference Information

^(*1) Knee osteoarthritis

Knee osteoarthritis is a disease primarily associated with aging whose occurrence is said to be related to body weight, exercise, posture and other lifestyle. A decrease in hyaluronic acid, which supplies nutrients to the cartilage within joints, causes cartilage damage and joint inflammation. Pain occurs because the cartilage becomes unable to absorb impact when the joint is moved. Knee osteoarthritis is considered to be the main cause of the knee pain that occurs in daily life. It is common among people over the age of 50, especially in women. Approximately 70% of women are said to suffer from knee osteoarthritis in their 70s.

^(*2) Sustained release

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