

## Seikagaku Announces Initiation of Phase III Clinical Studies of Gel-One<sup>®</sup>, a Treatment of Osteoarthritis, in Japan

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today that the development of Gel-One<sup>®</sup>, for treatment of osteoarthritis of the knee and the hip has been initiated in Japan.

In Japan, three Phase III clinical studies are planned, a study for osteoarthritis of the knee, a study for osteoarthritis of the hip, and a long-term safety study for both joints. Administration of Gel-One<sup>®</sup> to the first subject has started.

Gel-One<sup>®</sup> is an intra-articular injection whose main ingredient is a cross-linked hyaluronate hydrogel, utilizing Seikagaku's unique cross-linking technology. Since highly viscoelastic hyaluronate remains in the joint cavity for a long period of time, a single injection of Gel-One<sup>®</sup> is expected to provide long-term pain relief. The product has been available in overseas markets since 2012 as Gel-One<sup>®</sup> (USA) and HyLink<sup>®</sup> (Taiwan and Italy) indicated for osteoarthritis of the knee.

Additionally, whereas the indication for Gel-One<sup>®</sup> in overseas markets is the knee joint, in Japan, Seikagaku will concurrently conduct a study of Gel-One<sup>®</sup> for osteoarthritis of the hip alongside the knee study with the aim of expanding the target patient population.

### <Reference Information>

#### **Osteoarthritis**

Osteoarthritis is a disease in which joint tissue degenerates, and inflammation and pain occur due to wear of articular cartilage. Since bones come into direct contact with one another as cartilage wear progresses, intense pain occurs when the joint is moved. The occurrence of osteoarthritis is reported to be associated with aging, obesity, external injury, excessive exercise, genetic predisposition, and other factors.<sup>1</sup>

About 73% of patients with osteoarthritis are older than 55 years, and 60% are female.<sup>2</sup> It is reported that about 25 million people have radiographic changes in osteoarthritis and that 18 million people are symptomatic.<sup>3</sup>

<sup>1</sup> Knee Osteoarthritis – Pathology and Conservative Treatment. Edited by Yoshio Koga. Nankodo Co., Ltd., 2008.

<sup>2</sup> World Health Organization Fact Sheet – Osteoarthritis July 14, 2023

<sup>3</sup> Knee Osteoarthritis Treatment Guidelines 2023

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