

## **Seikagaku and Ono Reach a Basic Agreement Related to Co-development and Marketing Collaboration on Gel-One for the Treatment of Osteoarthritis in Japan**

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) and Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced that they have reached a basic agreement related to co-development and marketing collaboration on Gel-One under development by Seikagaku for the treatment of osteoarthritis (“Gel-One”) in Japan. The companies will further discuss to sign a definitive agreement on Gel-One.

In Japan, three Phase III clinical studies are being conducted, a study for osteoarthritis of the knee, a study for osteoarthritis of the hip, and a long-term safety study for both joints. The companies are committed to facilitating these clinical studies as quickly as possible to obtain an approval for manufacturing and marketing authorization for the product at an earlier date.

<Reference Information>

### **About Gel-One**

Gel-One is an intra-articular injection whose active ingredient is a cross-linked hyaluronate, utilizing Seikagaku’s unique cross-linking technology. Since Gel-One remains in the joint for a long period of time, a single injection of Gel-One is expected to provide long-term pain relief. The product has been available in overseas markets since 2012 as Gel-One® (U.S.) and HyLink® (Taiwan and Italy) indicated for osteoarthritis of the knee.

Additionally, whereas the indication for Gel-One in overseas markets is the knee joint, in Japan, Seikagaku is concurrently conducting a study of Gel-One for osteoarthritis of the hip alongside the knee study with the aim of expanding the target patient population.

### **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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