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Ono and Seikagaku Announce Initiation of a Late-Stage Phase II Clinical Trial of SI-613 for Treatment of Enthesopathy

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; "Ono") and Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced that they have initiated a late-stage Phase II clinical trial of SI-613 for the treatment of enthesopathy (development code: SI-613-ETP) in Japan. SI-613 has been jointly developed for an osteoarthritis treatment between Ono and Seikagaku in Japan.

The purpose for this study is to obtain an indication for the treatment of enthesopathy, in addition to osteoarthritis for which Phase III clinical trials of SI-613 are ongoing in Japan. Enthesopathy is an inflammatory disorder which occurs at the attachment site of a tendon or ligament with a bone or muscle of knee, elbow, heel, etc. It is usually caused by excessive load on the sites. Typical examples of enthesopathy include lateral epicondylitis (tennis elbow), plantar fasciitis, patellar tendinitis (jumper's knee), and Achilles tendonitis. Approximately 900,000 patients per year are estimated to receive drug therapy for these disorders in Japan.

Ono and Seikagaku have committed to co-development with the aim of obtaining indication of enthesopathy in addition to osteoarthritis for the purpose of contributing to the health of greater numbers of patients and maximizing the product value of SI-613.

About SI-613

SI-613 is a formulation in which hyaluronic acid and a non-steroidal anti-inflammatory drug (NSAID) are chemically bound using Seikagaku's own proprietary technology. SI-613 was designed to provide pain relief and anti-inflammatory effect by sustained release* of NSAID, and the 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 and enthesopathy. Since SI-613 is administered directly into the joint cavity or near the tendon or ligament enthesis as an injectable treatment, the transfer of the NSAID into the systemic blood is extremely low, and it is expected to mitigate the risk of side effects reported in oral or transdermal administration of NSAID.

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

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