February 19, 2019

Ono and Seikagaku Announce the Topline Results from a Phase III Confirmatory Study of ONO-5704/SI-613 in Patients with Knee Osteoarthritis in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; "Ono") and Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today that they have obtained positive topline results from a Phase III confirmatory study of ONO-5704/SI-613 in patients with knee osteoarthritis ("the Study"), one of the ongoing three Phase III clinical studies*1 being jointly developed for the treatment of osteoarthritis in Japan by Ono and Seikagaku.

The Study is a randomized, double-blind, placebo-controlled, parallel-group comparative study in 440 patients with knee osteoarthritis. ONO-5704/SI-613 demonstrated a statistically significant improvement in WOMAC (a knee pain evaluation index) scores, a primary endpoint of the Study, compared with a placebo at twelve weeks after the initial injection (three injections every four weeks). No major safety concerns were identified in the ONO-5704/SI-613 group.

Ono and Seikagaku will continue to proceed with the other two Phase III clinical studies and file an application for a manufacturing and marketing approval for ONO-5704/SI-613, aiming at the first half of 2020 after comprehensive evaluation on all data to be made available at the completion of all three studies.

There is no change in the forecast of consolidated financial results for the fiscal year ending March 31, 2019 both for Ono or Seikagaku in connection with this matter.

*1: 1) Phase III confirmatory study in patients with knee osteoarthritis (the Study)
2) Phase III study in patients with osteoarthritis (four joint sites: shoulder, elbow, hip and ankle)
3) Phase III long-term study in patients with osteoarthritis, primarily for safety evaluation

About ONO-5704/SI-613

ONO-5704/SI-613 is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound using a Seikagaku own proprietary technology. The product combines the pain relief and anti-inflammatory effect of diclofenac designed for sustained release*2 with the joint function improving effect of hyaluronic acid. It is expected to provide prompt and long-lasting relief of the pain and inflammation associated with osteoarthritis and enthesopathy. Further, since the product is administered directly into the joint cavity or near the tendon or ligament enthesis as an injectable treatment, systemic exposure to diclofenac is low, and the risk of systemic adverse drug reaction is thought to be low.

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

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