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Seikagaku Corporation
(Securities code: 4548)

The application of SUPARTZ[®] was submitted to FDA for additional indication of treatment of pain associated with shoulder osteoarthritis

Seikagaku Corporation (head office: Chiyoda-ku, Tokyo) announced that a PMA supplement was submitted to the Food and Drug Administration (FDA) in the U.S. on September 25 (local U.S. time) SUPARTZ[®] for use in the treatment of pain associated with shoulder osteoarthritis.

The effective ingredient in SUPARTZ[®] is highly purified sodium hyaluronate (hyaluronic acid). Formulated for intra-articular injection, it was granted FDA approval in the U.S. in 2001 as a medical device for use in the treatment of pain due to knee osteoarthritis. It is manufactured and sold in Japan as ARTZ Dispo[®] 25mg injection. In addition to the treatment of knee osteoarthritis, ARTZ Dispo[®] has also been approved in Japan for use in the treatment of shoulder periarthritis and knee-joint pain associated with rheumatoid arthritis.

In the U.S., Seikagaku Corporation and its U.S. distribution partner, Smith & Nephew, Inc., conducted a Phase III clinical trial involving patients suffering from shoulder osteoarthritis. Shoulder osteoarthritis is caused by cartilage degeneration and loss, mainly as a result of the prolonged exposure of the shoulder joints to excessive loads. It causes swelling and pain. When the condition becomes advanced, motor functions may be critically impaired, and in some cases patients become unable to lead a normal life. When the condition is treated with SUPARTZ[®], the cartilage is thought to be protected by the hyaluronic acid, having excellent viscoelastic characteristics and reduction in pain is expected.

To date, no hyaluronic acid formulations have been approved in the U.S. for use in the treatment of pain associated with shoulder osteoarthritis. Approval for this indication is expected to enhance the clinical value of SUPARTZ[®] and provide an effective therapy for patients affected by this condition.