Seikagaku Corporation

(Securities Code: 4548)

Seikagaku Corporation submits Amendment to Premarket Approval Application for Gel-200 to U.S. Food and Drug Administration

Seikagaku Corporation ("Seikagaku") (head office: Chiyoda-ku, Tokyo) today announced its submission of an Amendment to its Premarket Approval Application (PMA) to the U.S. Food and Drug Administration (FDA) regarding the company's Gel-200 product, a treatment for knee osteoarthritis. The PMA was submitted in response to review results provided by the FDA.

Seikagaku received notification that its original application for premarket approval to the FDA was not approvable on January 5, 2010 and has worked diligently in the ensuing months to address the agency's concerns. Seikagaku believes that Gel-200 can provide American patients with a viable option in the treatment and therapy of knee osteoarthritis. The company remains committed to working with the FDA to achieve premarket approval of Gel-200 in the United States.

Gel-200 is an intra-articular injection utilizing cross-linked hyaluronate hydrogel and was developed to provide long-term pain relief with a single injection. Seikagaku's PMA was originally submitted to the FDA in July 2008.

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