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SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Initiates a Pivotal Study for SI-449, an Adhesion Barrier

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") hereby announces the start of a pivotal study of SI-449, an adhesion barrier, in Japan.

In the previous pilot study, safety, efficacy and usability of SI-449 were exploratorily examined and favorable results were obtained. Accordingly, the pivotal study will be undertaken to further evaluate the effectiveness (prevention of post-operative adhesion formation¹), safety, and usability of SI-449.

SI-449 is a powdered adhesion barrier whose main ingredient is cross-linked chondroitin sulfate developed using Seikagaku's own glycosaminoglycan² proprietary technology. SI-449 consists of substances naturally present in the body, including the cross-linking agent, and is thought to be highly biocompatible. SI-449, which has the property of absorbing moisture and swelling, is expected to prevent or mitigate post-operative adhesion formation by forming a barrier between the surgical wound site and surrounding tissues after application. Since SI-449 is a powdered formulation, it adheres well to uneven tissue surfaces, and is thought to offer excellent usability in laparoscopic surgery, a common surgical procedure.

Seikagaku is advancing development of SI-449 as a Class IV specially controlled medical device. The scope of its development is not limited to the Japanese market, but also will be expanded to a global rollout. Through the development of SI-449, Seikagaku aspires to contribute to improving patients' quality of life by offering new options to reduce the risk of complications caused by post-operative adhesion formation.

Giving the top priority to the prevention of COVID-19 spreading among patients, medical facilities and contract research organizations, Seikagaku is carefully seeking to find the appropriate time to start subject enrollment for this pivotal study.

This matter will have only a negligible effect on consolidated financial results for fiscal 2020.

<Reference Information>

1. Post-operative adhesion formation is a phenomenon by which a surgical wound site and surrounding tissues that are normally separated adhere together in the healing process of sites where tissue loss or damage has occurred in surgery (open abdominal surgery, laparoscopic surgery, etc.). The incidence of post-operative adhesions is 50% to 90% when no treatment is performed, and adhesions are a major cause of postsurgical complications (intestinal blockage, chronic abdominal pain, infertility, etc.) in abdominal or gynecological surgery. Sheet or gel products are currently used as adhesion barriers.

2. Glycosaminoglycan (GAG) are a major component of glycoconjugates. Chondroitin sulfate and hyaluronic acid are GAGs.

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