

Seikagaku Announces Favorable Results from a Pivotal Study for SI-449, an Adhesion Barrier

Seikagaku Corporation (Tokyo, Japan; "Seikagaku") announced today that favorable results were obtained in a pivotal study in Japan for SI-449, a surgical adhesion barrier, in the field of gastroenterological surgery.

The study was a randomized study in patients who underwent open proctectomy. SI-449 showed a statistically significant adhesion formation prevention performance in comparison with an untreated group both in the primary effectiveness endpoint of the presence or absence of post-operative adhesions and the secondary effectiveness endpoints of severity or extent of the adhesions. No safety issues were observed.

Also, no major problems were found with safety and operability of SI-449 in laparoscopic surgery in a pilot study in the field of gynecology conducted for the purpose of expanding the scope of indications for the product.

In light of the outcomes of the two studies, Seikagaku plans to proceed with an application for approval of SI-449 at an early date. Seikagaku will aim to contribute to healthy and fulfilling lives for patients by reducing the risk of occurrence of complications associated with post-operative adhesions.

There is no change in the forecast of consolidated financial results for the fiscal year ending March 31, 2024 in connection with this matter.

Reference Information

<About SI-449 (Adhesion Barrier)>

SI-449 is a powdered adhesion barrier whose main ingredient is cross-linked chondroitin sulfate developed using Seikagaku's own glycosaminoglycan¹ cross-linking 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 formation² 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 also thought to offer excellent usability in laparoscopic surgery, a common surgical procedure.

*1 Glycosaminoglycans (GAGs) are a major component of glycoconjugates. Chondroitin sulfate and hyaluronic acid are GAGs.

*2 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 the main products used as adhesion barriers.

For details, please refer to the following press release.
Seikagaku Initiates a Pivotal Study for SI-449, an Adhesion Barrier
<https://www.seikagaku.co.jp/en/news/news7875686446160281962/main/0/link/20200521-e.pdf>

< Cautionary Notes >

This press release contains forward-looking statements regarding future management strategies or performance forecasts. These descriptions are based on judgments derived from information that is currently available to Seikagaku and are subject to risk and uncertainty. Actual results and developments may differ significantly from these descriptions due to various factors. Information about pharmaceutical products or medical devices (including products currently in development) contained in this press release is not intended to constitute an advertisement or medical advice.

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