

Sanyo Chemical Industries, Ltd.

Sanyo Chemical's Silk-Elastin Shows Promise in Wound Healing

Clinical Trial Results Published in *Scientific Reports* — Seeking U.S. Partners for Market Entry —

KYOTO, JAPAN — [April 7, 2025] — Sanyo Chemical's Silk-Elastin, a novel recombinant protein, has demonstrated exceptional efficacy and safety in clinical trials for chronic wound healing. The findings, published in *Scientific Reports*, confirm its safety and efficacy in accelerating healing and reducing infection risks. With regulatory approval anticipated in Japan, preparations for FDA submission are underway as part of Sanyo Chemical's plan for U.S. market expansion. To bring this breakthrough treatment to patients as swiftly, Sanyo Chemical is seeking marketing and distribution partners in the U.S.

"The publication in Scientific Reports provides strong scientific validation for Silk-Elastin's efficacy," said Akinori Higuchi, President & CEO of Sanyo Chemical. "This groundbreaking material, with its high biocompatibility and resistance to infection, offers a promising new option for chronic wound treatment. With Japan market entry prepared pending regulatory approval, we are actively seeking strategic partners for U.S. expansion. We welcome collaboration with global companies that share our vision for advancing regenerative medicine, particularly through innovative material science."

Breakthrough in Chronic Wound Treatment

Chronic wounds, such as diabetic ulcers and pressure sores, pose significant healthcare challenges worldwide, leading to prolonged suffering and rising medical costs. These wounds often enter a cycle of delayed healing and increased infection risk, making treatment difficult. Current treatments often fail to achieve complete healing. Silk-Elastin offers a regenerative solution, promoting tissue repair while reducing inflammation and bacterial colonization, leading to better patient outcomes and improved quality of life.



Application of Silk-Elastin wound dressing for intractable skin ulcar on the lower leg

Sanyo Chemical

Clinical Applications and Development Status

Developed in collaboration with Kyoto University, Silk-Elastin has demonstrated remarkable efficacy in both investigator-initiated studies and a multicenter Phase III clinical trial in Japan. Based on these promising results, Sanyo Chemical submitted a regulatory approval application in Japan in April 2024, with approval anticipated. It would become Japan's first gene-engineered medical device. Sanyo Chemical is now preparing for an FDA submission, marking a key step toward global commercialization.

Published Study in Scientific Reports

- **Title:** A prospective multicenter phase III clinical trial evaluating the efficacy and safety of silk elastin sponge in patients with skin defects
- Authors: Eiichi Sawaragi, Naoki Morimoto, et al.
- **Publication Date:** 02 April 2025
- **Summary:** This first human trial of Silk-Elastin sponges demonstrated their safety, feasibility, and efficacy in promoting wound healing. The study showed high rates of wound bed preparation in chronic wounds and successful treatment completion in most patients, positioning Silk-Elastin as a promising option for wounds unresponsive to existing treatments.
- Reference: <u>https://www.nature.com/articles/s41598-025-88150-w</u>

About Silk-Elastin

Silk-Elastin is a recombinant protein combining the strength of silk fibroin (derived from silk) with the elasticity and biocompatibility of elastin (found in human skin). Its gel supports tissue regeneration while minimizing inflammation. This novel approach offers hope for conditions with limited conventional options.

About Sanyo Chemical

Sanyo Chemical established in 1949 in Kyoto, Japan, is a global manufacturer and seller of performance chemicals. Beginning as a manufacturer of soap and texture agents we have since diversified our product portfolio to meet the needs of the market, Today, we feature over 3,000 diverse types of products and have established an international presence. Our portfolio of chemicals spans a variety of industries and types, from automotive components to daily-use electronics, as well as cosmetics and medical equipment, all with the aim of creating safe and environmentally friendlier offerings, improving lives and societies across the world. We aim to contribute to realize a sustainable society through our corporate activities **https://www.sanyo-chemical.co.jp/eng**

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