## Development of New Medical Material and its Clinical Studies using Functional Silk- Elastin was adopted by AMED as Competitive Funding Programs of ACT-M (Acceleration Transformative research for Medical innovation)

-Development of the effective Silk Elastin for healing wound to the Medical Materials

"Development of New Medical Material and its Clinical Studies using Functional Silkelastin" is the corporate work of Sanyo Chemical Industries, Ltd., and Katsuya Kawai, an associate professor in Department of Plastic and Reconstructive Surgery, Graduate school of Medicine, Kyoto University. This project was adopted by AMED (The Japan Agency for Medical Research and Development) as a funding support program of ACT-M (Acceleration Transformative research for Medical innovation)

## [Details]

•We aim the biomedical business expansion through development for the healing wound while utilizing the characteristics of the Silk Elastin.

•This project was the selected program of A-STEP (Adaptable & Seamless Technology Transfer Program through Target-driven R & D) by JST (Japan Science and Technology Agency) from Feb. 2014 to Jan. 2015. The comparison tests and investigation of the combination effects with conventional agents, and the microbiological safety tests were conducted during this period.

•Based on these results, we applied for ACT-M of AMED, which took over the activities in medical-related field from JST. This project was evaluated to progress to the next stage and adopted as the program of competitive funding support.

•ACT-M is a support program to create innovation by accelerating practical applications through the collaboration among universities, companies and hospitals, etc. It supports the projects in "verification phase of practicability", which is after the pre-stage of the development in the "potential validation phase", to establish POC (Proof of Concept) for patients on clinical study and gain the evaluation.

Project	Acceleration Transformative Research for Medical Innovation in FY2016
	Research and development of innovative medical technologies and
	medical materials to support the rapid declining birthrate and aging
	society
Subject	: Development of New Medical Material and its Clinical Studies using
	Functional Silk-Elastin
Researcher	: Sanyo Chemical Industries, Ltd.
	Kyoto University, a national university in Japan
Period	: Oct.2016-Mar.2019
Research Pla	an : To receive data in non-clinical investigation, clarify the
	mechanism, conduct biological evaluation and move to
	investigator initiated clinical trials

[Outcomes of this study under A-STEP of JST]

- 1. It was found that Silk-elastin was hardly bacterial infected and effective to reduce bacterial infection and bacterial growth of the wounds.
- 2. Expression system in Escherichia coli contributes to a stable production of Silk-elastin without risk of virus infection.
- 3. The product can be prepared in various forms such as sponge, film, liquid, and so on.

These findings show that Silk-elastin is more probable to be an effective treatment of intractable cutaneous ulcers (ex. diabetic lower extremity ulcer; sever patients need a leg amuputation). Such diseases are difficult to remedy by conventional conservative and surgical treatments because of their terrible skin deficiency and high risks of infection.

## [Plans]

•Investigator initiated clinical trials will be done during this program. After a sponsor initiated clinical trial, marketing approval and examination by relevant institutes for medical materials, we will launch the products to the market.

•Not limited to Silk-elastin, we will put greater focus on developing our unique technologies to contribute to biomedical field.