Research and development for practical application of next-generation focused ultrasound therapy system for refractory cancer (Sonire Therapeutics Inc.)



City	Year of Establishment	Founder	Website
Tokyo Chuo-ku	2020	Tohru Sato Jun Okamoto Shin Yoshizawa	https://www.s onire- therapeutics.c om/

Partner VC	Latest round of Fundraising	Valuation	
_	Series B	JPY 5,000 million	

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Business Plan

The objective of our business is to develop a next-generation High-Intensity Focused Ultrasound (HIFU) treatment device and obtain its approval as a medical device through clinical trials, thereby providing a new treatment method for pancreatic cancer and other cancer patients. This project focuses on cavitation bubbles and aims to dramatically improve safety by developing a "next-generation type" that can visualize cavitation bubbles, and to obtain regulatory approval and insurance coverage in developed countries.

Research Outline

This grant project will accelerate the implementation of pancreatic cancer clinical trials in Japan and expansion to other oncologies, as well as pancreatic cancer clinical trials in the United States, which is the largest market.

In addition, by achieving the PoC listed below, we aim to achieve the following

- (1) Conduct and accelerate domestic clinical trials (pancreatic cancer)
- (2) Start domestic clinical trials (other than pancreatic cancer)
- (3) Start of clinical trials (pancreatic cancer) in the U.S.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2025FY	JPY 971 million	United States

- OInternational collaborative technology demonstration
- Contract with local partners
- Relationship development with potential local partner

The clinical trial protocol will be developed in collaboration with the partner hospital in the United States. In addition, an IDE application will be filed with the FDA to initiate the clinical trial.