

SONIRE THERAPEUTICS INC.

Developing a next generation ultrasound-guided high-intensity focused ultrasound therapy system (Development code: Suizenji) for unresectable pancreatic cancer patients

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<https://www.sonire-therapeutics.com/en/>

Founded in 2020
President & CEO: SATOH Tohru
No. of employees: 16
Type of Ownership: Private
Primary stock exchange: N/A

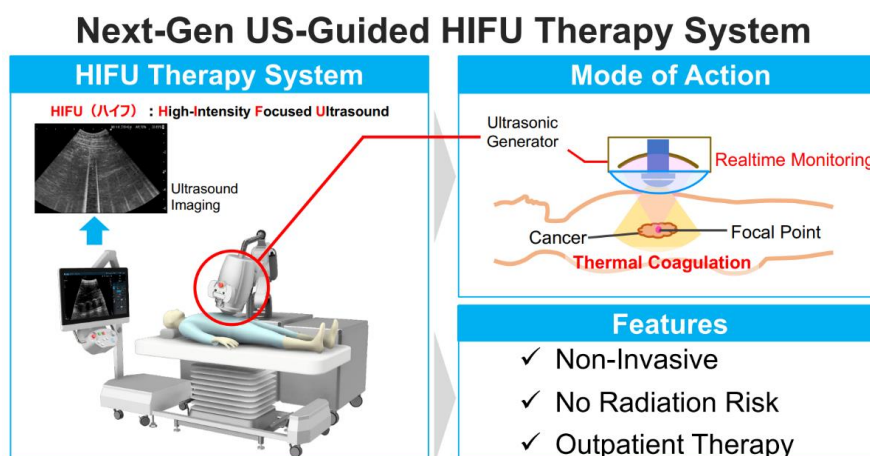
July 2023: Aiming to improve unresectable pancreatic cancer treatment, a multi-center randomized controlled trial of Suizenji (SUNRISE-I Study) is in progress.



Venture Valuation (VV) interviewed Mr. SATOH Tohru, President and CEO.

- VV:** Suizenji, a process jointly developed by three major medical universities in Japan, is designed to visualize target tumors with ultrasound echography and then treat them with high intensity focused ultrasound (HIFU).
- Satoh:** Ultrasound is frequently used for diagnostic purposes. Other applications include therapeutic modalities such as HIFU, histotripsy and Low Intensity Pulsed Ultrasound (LIPUS).

Suizenji-HIFU System ablates tissue from outside of the body by focusing ultrasonic waves from multiple sources on the tumor. It rapidly heats the focal area from 60 to 80 °C for a few seconds causing coagulative necrosis and prompt cell death. Suizenji does not affect tissue outside the focal area.



HIFU System has several advantages. First, it is a non-invasive procedure. Neither anesthesia nor surgery is needed. It can realize outpatient therapy with short-time treatment. Patients can repeat the treatment as much as required because there is no radiation risk. By reducing refractory cancer pain, it may also be considered a palliative treatment.

Second, the Suizenji HIFU System requires little space: it is easily installed in a space equivalent to two single beds within hospitals/clinics.

Third, it is radiation risk-free. Unlike MRI, CT, and X-ray processes, no special room is necessary.

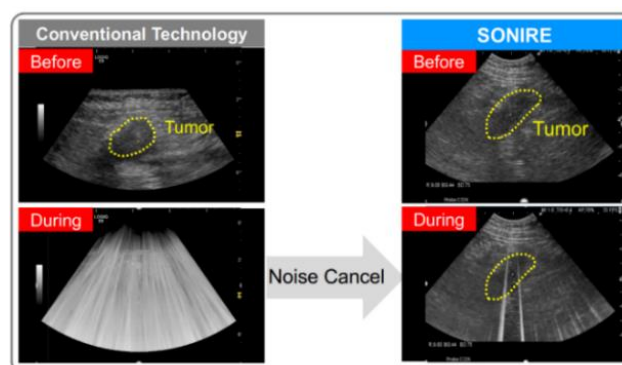
Fourth, the Suizenji HIFU System can be used on abdominal organs moving with the movement of breathing. The System performs precisely by monitoring the treatment area in real time with ultrasound guidance.

Furthermore, it has been reported that HIFU therapy may activate the immune system, the so-called abscopal effect. This means that patients treated with HIFU may get an antitumor effect on distant metastases on condition that the tumor should be within ultrasound range¹.

VV: The Suizenji HIFU System has innovated the conventional HIFU system with higher visualization and precision using robot assisted system.

Satoh The feature of the Suizenji HIFU System is that it utilizes cavitation bubbles generated with strong sound wave. The phenomenon is caused by dropping in the pressure of the liquid in the body, and the bubbles visualize treatment site and enhance further heating efficiency.

As shown below, our technology's noise cancellation feature enables physicians to treat the target tumor while monitoring it in real time.

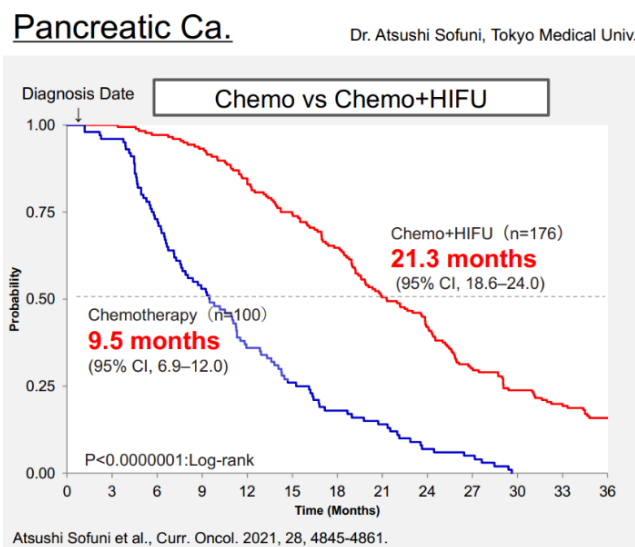


¹ [High-intensity focused ultrasound therapy for pancreatic cancer | SpringerLink](#)

VV: A multi-center randomized controlled study with unresectable pancreatic cancer (stage III and IV) is in the process of enrolling 90 patients.

Satoh: Pancreatic cancer is a dreadful disease with the lowest survival rates of all cancers. Chemotherapy and chemoradiotherapy are currently the only standard cares but the outcomes are not enough to improve a patient’s life.

It has been proven (see the graph below) that the combination of HIFU therapy with chemotherapy is an alternative treatment approach that prolongs patient survival time by controlling tumor advancement and providing a palliative effect.



The coming study is a randomized controlled trial, and it designed to compare a group that receives the combination treatment with a chemotherapy only group. We are enrolling patients with unresectable pancreatic cancer refractory or intolerant to primary chemotherapy.

The study’s primary endpoint is overall survival, and the secondary endpoint is efficacy and safety.

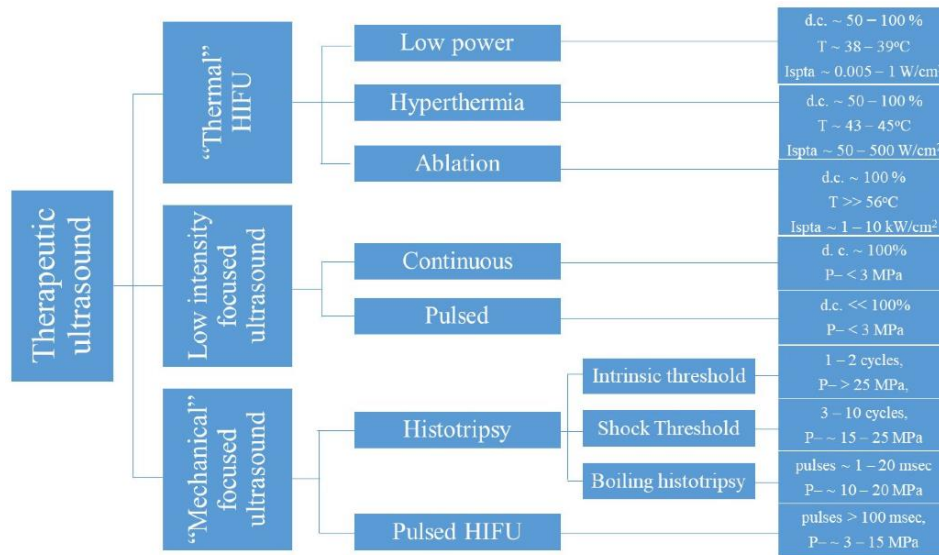
Hopefully the Suizenji HIFU System will be approved sooner than expected and available for patients by 2026.

We are also planning clinical trials with the Suizenji HIFU System to treat patients with unresectable pancreatic cancer in the U.S. next year.

Pancreatic cancer is our first target disease. Our pipeline includes other indications such as liver, kidney, breast, ovarian, prostate cancers.

VV Comments after the interview:

The academic paper “Latest Advances in the Use of Therapeutic Focused Ultrasound in the Treatment of Pancreatic Cancer”², published on 27 January 2022, summarizes different modalities of therapeutic focused ultrasound (see the chart below).



The paper concludes that “...Despite encouraging clinical results and the lack of severe effects from therapeutic focused ultrasound treatments, no randomised controlled trial to test whether focused ultrasound can provide a significant survival benefit to patients with pancreatic cancer has ever been undertaken.”

Sonire Therapeutics will publish results of the randomised controlled study in the near future. One hopes that it will contribute to advancing the medical technology available to patients.

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Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this “Let’s Interview Series” with companies with interesting technologies and services. We select and interview thriving companies and organizations especially in Switzerland and Japan.

² <https://www.mdpi.com/2072-6694/14/3/638>