



To all:

January 31st, 2023  
SONIRE Therapeutics Inc.

Announcement of First Patient Enrolled in a Randomized Phase 2 study of SONIRE's Novel HIFU  
Therapy System for Unresectable Pancreatic Cancer Patients in Japan

SONIRE Therapeutics Inc. (Headquarters: Shinjuku-ku, Tokyo; President and CEO: Tohru Satoh; hereinafter referred to as "SONIRE"), announces that a randomized phase 2 study for the treatment of unresectable pancreatic cancer with SONIRE's next-generation High-Intensity Focused Ultrasound (HIFU) therapy system (development code: Suizenji) has been commenced.

The 5-year survival rate of pancreatic cancer is very low at 8.5%\*, and the number of deaths in Japan in 2020 was estimated to be 37,677 patients\*, ranking fourth after lung cancer, colorectal cancer, and stomach cancer, and increasing every year. In addition, treatment options for pancreatic cancer are limited, and there is a strong need for innovative treatment modalities. In this clinical trial, the efficacy of Suizenji in combination with second-line chemotherapy will be evaluated in patients with unresectable pancreatic cancer who are refractory or intolerant to first-line chemotherapy, with overall survival as the primary endpoint (expected enrollment 90 participants).

Details of the study can be found on the following website

Japan Registry of Clinical Trials (<https://jrct.niph.go.jp/en-latest-detail/jRCT2032220428>)

ClinicalTrials.gov

(<https://clinicaltrials.gov/ct2/show/NCT05601323?term=NCT05601323&draw=2&rank=1>)

SONIRE was established in February, 2020 to develop a next-generation ultrasound-guided HIFU therapy system by utilizing the technology and clinical know-how established by Tokyo Women's Medical University, Tohoku University and Tokyo Medical University over the past years. HIFU therapy is expected to become a new treatment modality for cancer because it is minimally invasive, less burdensome to the body, and can be performed repeatedly without radiation exposure. SONIRE is developing the HIFU therapy system as a new treatment modality for pancreatic cancer, which is one of the most difficult-to-treat cancers.

\*. Data from the National Cancer Center Cancer Information Service, Statistical Information by Cancer Type, Pancreatic (updated on October 05, 2022)