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ASIA EDITION

Sonire Secures $13M NEDO Funding for HIFU Pancreatic Cancer Platform

June 18, 2026 | News

The non-dilutive funding will support manufacturing scale-up, regulatory activities and global commercialisation of Sonireâ??s ultrasound-guided HIFU therapy system.

Sonire Therapeutics has received approximately $13 million in non-dilutive funding through Japan's NEDO Deep-Tech Startups Support Program to advance its ultrasound-guided HIFU therapy platform.

The funding was awarded to Sonire Therapeutics KK, the company's Japan-based group company. It will support manufacturing scale-up, regulatory approval activities in Japan, expansion into additional clinical indications and acceleration of the company's ongoing U.S. clinical development efforts.

This is relevant because pancreatic cancer remains one of the most difficult cancers to treat, with limited effective options for many patients and a five-year survival rate of approximately 13 per cent. New treatment approaches that can reduce procedural burden and expand access are important in a disease where patients are often diagnosed late and may not be suitable for aggressive interventions.

Sonire's next-generation High-Intensity Focused Ultrasound system uses real-time ultrasound guidance to deliver precise, non-invasive tumour ablation. The system is designed to allow physicians to monitor treatment as it is administered, without requiring general anaesthesia.

This differentiates the platform from more invasive treatment approaches by aiming to provide outpatient, image-guided therapy for solid tumours, beginning with pancreatic cancer. If clinically validated and commercially scaled, this type of technology could offer an additional treatment pathway for patients who may not be candidates for surgery or more burdensome interventions.

The NEDO award is commercially important because it supports the full pathway from product development through regulatory approval, manufacturing readiness and market adoption. For deep-tech medical device companies, this stage is often difficult because early clinical promise must be converted into scalable production, regulatory documentation and commercial deployment.

Sonire said the award follows several recent milestones, including initiation of the SUNRISE-II clinical trial in the United States, $18 million in Series A financing and completion of patient enrolment in SUNRISE-I, a randomised controlled trial evaluating the safety and feasibility of its HIFU system for pancreatic cancer in Japan.

The company had previously advanced through earlier STS and PCA phases of the NEDO DTSU Program. The current DMP phase is the programme's most advanced commercialisation stage, focused on manufacturing readiness and market preparation activities.

The development reflects the growing role of public-sector deep-tech funding in supporting advanced medical device commercialisation. For countries such as Japan, funding programmes like NEDO can help domestic or Japan-linked companies bridge the gap between clinical development and global market entry.

Adoption will depend on clinical evidence, procedural training, regulatory approval, reimbursement and whether the technology can fit into oncology care pathways. For pancreatic cancer, commercial success will also depend on how the system is positioned alongside surgery, chemotherapy, radiation therapy and palliative treatment options.

Manufacturing scale-up will be another key factor. Therapeutic ultrasound systems require hardware reliability, treatment planning accuracy, quality systems and service infrastructure. These factors become more important as companies move from clinical trial settings into broader hospital use.

The development positions Sonire at the intersection of oncology, therapeutic ultrasound and minimally invasive care. If the platform can demonstrate safety, feasibility and meaningful clinical benefit, it may support a broader shift toward non-invasive tumour ablation technologies for difficult-to-treat solid cancers.