

Press Release

January 5, 2026

SONIRE Therapeutics Inc.

Clinical Research Results on Focused Ultrasound Therapy, the Technological Foundation of SONIRE Therapeutics, Published in "Ultrasound in Medicine & Biology"

SONIRE Therapeutics Inc. (Head Office: Chuo-ku, Tokyo; President & CEO: Tohru Satoh; hereinafter "the Company") is pleased to announce that the results of clinical research on Sonodynamic Therapy (SDT) using High-Intensity Focused Ultrasound (HIFU), which serves as the technological foundation of our company, have been published in the academic journal *Ultrasound in Medicine & Biology*.

This paper summarizes the research results conducted prior to the Company's establishment under a joint research framework led by Tokyo Women's Medical University, Tohoku University, and Tokyo Medical University. The study was supported by the Medical Device Development Promotion Research Project of the Japan Agency for Medical Research and Development (AMED).

Paper Overview :

Title : First-in-Human Safety and Efficacy Study on Combination of High-Intensity Focused Ultrasound Sonication and Micellar Nanoparticle-Encapsulated Epirubicin, K-912: A Novel Sonodynamic Therapy for the Treatment of Refractory Abdominal Cancers.

Journal : *Ultrasound in Medicine & Biology*

URL : <https://www.sciencedirect.com/science/article/abs/pii/S0301562925004193>

Research Summary :

This clinical study is the first-in-human clinical trial to evaluate the safety and efficacy of a new Sonodynamic Therapy (SDT) that combines a focused ultrasound therapy device equipped with a trigger pulse sequence and a specific drug (Epirubicin micelle/K-912). The study was conducted on a total of 12 cases, including unresectable pancreatic cancer (11 cases) and intrahepatic cholangiocarcinoma (1 case).

Future Outlook:

The technology and treatment concepts established in this study were created primarily by the founding members of our company. We position this treatment method as one of the future



prospects for the focused ultrasound therapy currently under development by the Company.

The Company will use the research results published this time as an important scientific foundation to promote research and development and collaboration with related institutions, aiming for the social implementation of focused ultrasound therapy.

Note: The Sonodynamic Therapy (SDT) reported in this paper is an unapproved treatment currently under development and is not yet approved for clinical or commercial use at this time.