Press Release

October 9th, 2024
SONIRE Therapeutics Inc.

SONIRE's HIFU therapy system has been designated as a Breakthrough Device by FDA

SONIRE Therapeutics Inc. (Headquarters: Tokyo, Japan; President and CEO, Founder: Tohru Satoh; hereinafter referred to as "SONIRE"), announces that the next-generation HIFU (High-Intensity Focused Ultrasound) therapy system (development code: Suizenji) developed by SONIRE has been designated as a breakthrough device by the U.S. Food and Drug Administration (hereinafter referred to as “FDA”) for the treatment of pancreatic cancer.

The Breakthrough Device Program supports the development of medical devices that provide more effective treatment or diagnostic of life-threatening or irreversible human diseases.
Through this program, SONIRE will receive an opportunity to interact with FDA experts through different program options to efficiently address topics as SONIRE arises during premarket review phase. Therefore, it is expected that this program accelerates for patients to access the new treatment provided by Suizenji as soon as possible.

For more information about the Breakthrough Device Program, please refer to the FDA website.
https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

SONIRE will continue to promote our business in order to realize the wish we put in our company name at the time of our foundation: " Sonics brings new future full of hope to many cancer patients and their families as possible.".