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# Japan to revolutionise Alzheimer's Disease treatment with LIPUS-Brain Device

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**Anticipating the completion of the pivotal clinical trial by the end of 2026, with the goal of achieving medical device approval in 2027**

Japan's Sound Wave Innovation Co., Ltd. (SWI) and Sumitomo Heavy Industries, Ltd. (SHI) have announced the signing of a business alliance agreement for the manufacturing and distribution of the "LIPUS-Brain Transcranial Low-Intensity Pulsed Ultrasound Therapeutic Device".

This strategic partnership aims to jointly promote the social implementation of this innovative medical device, targeting early-stage Alzheimer's disease patients.

With the global increase in ageing populations, Alzheimer's disease and other forms of dementia have become pressing societal challenges. There is a strong demand for new treatment options that are less burdensome for patients and contribute to improving the Quality of Life (QOL) for both patients and their families.

Notably, LIPUS-Brain has demonstrated high safety and showed results suggesting high efficacy in a physician-led exploratory clinical trial concluded in 2022. Following these promising results, LIPUS-Brain was designated as the first "Breakthrough Medical Device" by the Japanese Ministry of Health, Labour and Welfare (PMDA) on September 30, 2022. Subsequently, SWI began a pivotal clinical trial in October 2023.

Through this alliance, both companies are committed to:
• Providing new medical options for Alzheimer's disease treatment
• Contributing to the improvement of patient QOL
• Accelerating the early practical application and widespread use of the LIPUS-Brain therapeutic device
• Solving the social challenge of improving QOL for patients and their families

Under the terms of the agreement:
• Sound Wave Innovation will continue to promote the pivotal clinical trials for LIPUS-Brain and license the intellectual property related to the device
• Sumitomo Heavy industries will fund the trial through a strategic equity investment in Sound Wave Innovation
• Sumitomo Heavy Industries will be responsible for the manufacturing and distribution of the device

The companies anticipate the completion of the pivotal clinical trial by the end of 2026, with the goal of achieving medical device approval in 2027. Following approval, both companies will collaborate to expand treatment availability to medical institutions nationwide.