

Press Release

Cilcare and Shionogi Announce Exclusive Option Agreement for Innovative Hearing Disorder Treatments

Montpellier and Osaka, June 6th, 2024 – Cilcare, a leading biotech company specializing in auditory sciences, is pleased to announce a landmark agreement with Shionogi, an impact-driven pharmaceutical company. This exclusive option agreement grants Shionogi the right to license global rights to CIL001 and/or CIL003, two promising drug candidates aimed at treating hearing disorders, with a particular focus on addressing the increasing prevalence of hidden hearing loss and tinnitus.

Under the terms of the agreement:

- Shionogi will receive an exclusive option to license global rights to CIL001 and/or CIL003.
- Cilcare will receive an upfront payment of €15 million.
- Cilcare is eligible to receive up to €400 million in milestone payments upon successful development and commercialization of the drug candidates.
- Shionogi will decide whether to exercise the option right based on the results of the Phase 2a studies of CIL001 and preclinical study data of CIL003, both to be conducted by Cilcare.

Driven by its pioneering approaches from preclinical research to drug development, which harness AI-driven auditory markers known as Digital Auditory Signatures, Cilcare is dedicated to advancing therapies for auditory-related diseases. The agreement with Shionogi underscores Cilcare's commitment to external innovation and collaboration to address critical unmet needs in hearing disorders.

CIL001, a disease-modifying small molecule, holds promise for treating cochlear synaptopathy and associated disorders through a single and painless transtympanic administration. Supported by robust preclinical and clinical safety data, CIL001 is poised to enter Phase 2a trials in 2025 in Europe and United States of America. Additionally, preclinical studies for CIL003 are currently underway.

Celia Belline, CEO of Cilcare, expressed her pride in the recognition of Cilcare's expertise by a global pharmaceutical leader. She emphasized the partnership's potential to expand the pipeline and drive innovation in hearing disease therapeutics.

Shionogi echoed Cilcare's enthusiasm for the partnership, citing the alignment with their strategic focus on improving global health and well-being.

Hearing loss affects approximately 1.5 billion people worldwide, with hidden hearing loss, or cochlear synaptopathy, emerging as a significant challenge despite normal hearing tests. This condition, affecting about 15% of the population, underscores the urgent need for innovative therapies to address speech comprehension difficulties and other associated symptoms.

The collaboration between Cilcare and Shionogi represents a pivotal step in addressing the urgent global health crisis posed by hearing disorders, offering hope for millions of individuals worldwide.

For this option agreement, Cilcare was advised by Agile Capital Markets and McDermott Will & Emery.

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About Cilcare Development

Cilcare is a biotech established in 2014, dedicated to harnessing auditory sciences to reshape the future of care via early diagnosis and targeted treatment. Cilcare's mission is to ensure hearing impairments are addressed earlier and with precision, as they are often associated with chronic diseases from their very early stages. As a catalyst in the development of pharmaceuticals, medical devices, gene therapies, and cell therapies for hearing loss and tinnitus, Cilcare is driving transformative breakthroughs.

For more information, please visit [Cilcare's website](#)

About Shionogi Ltd.

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "*Supplying the best possible medicine to protect the health and well-being of the patients we serve*." Shionogi has discovered and developed novel antibiotics, medicines for HIV and influenza and currently markets medicines for infectious diseases and central nervous system disorders. Shionogi's global pipeline includes research programs in infectious disease, pain/CNS, metabolic disorders, rare disease, oncology and stroke.

For more information, visit [Shionogi's website](#)

About CIL001

CIL001 is a novel candidate drug for hearing loss treatment with auditory nerve protective effect. In preclinical studies to date, CIL001 has been confirmed to have an organic effect that repairs inner ear cochlear synapses, and a functional effect that improves the first wave of the auditory brainstem response (ABR).