Press Release

CILCARE COMPLETES A €40M SERIES A TO ACCELERATE THE DEVELOPMENT OF INNOVATIVE TREATMENTS FOR EARLY HEARING LOSS

- The funds will support two Phase 2a clinical trials for the drug candidate CIL001, targeting cochlear synaptopathy (a leading cause of difficulty understanding speech in noise, tinnitus, and hyperacusis), as well as the advancement of preclinical development for the candidate CIL003.
- The company will enhance its R&D platform capabilities and establish new strategic partnerships to expand and diversify its portfolio of treatments for hearing disorders.
- A special focus will be placed on leveraging advanced artificial intelligence to identify auditory biomarkers, enabling better patient selection for clinical trials and more precise evaluation of the efficacy of new therapies.

Montpellier, December 4, 2024 **– Cilcare (www.cilcare.com), a biotechnology company specializing in auditory sciences, today announced the closing of its €40 million Series A funding round, including €21 million raised during the latest round. This fundraising attracted new investors such as SHIONOGI & CO., LTD., Sprim Global Investments Pte. Ltd, along with existing investors like Sofilaro, ARIS, SudPME, and UVM Health Capital.**

This funding will enable Cilcare to initiate two Phase 2a clinical trials in 2025 across Europe and the United States for its lead candidate, **CIL001**, a treatment targeting cochlear synaptopathy. This underdiagnosed condition, often referred to as "hidden hearing loss" because it remains undetectable with standard audiograms, threatens over one billion young people and affects 10-15% of adults. Associated with the early stages of age-related hearing loss, cochlear synaptopathy is exacerbated by noise exposure and results in difficulties understanding speech in noisy environments, tinnitus, and hyperacusis. Patients often report significant fatigue and the need for intense concentration, and without treatment, the condition inevitably progresses to deafness.

Currently, **Cilcare is the only company focusing on developing therapies for this early-stage auditory pathology**, leveraging AI-driven detection methods that have never been explored before.

The first clinical trial, scheduled for the second half of 2025, will enroll approximately 100 patients with Type 2 diabetes, a population in which Cilcare has identified a high prevalence of cochlear synaptopathy (nearly 40%), particularly among those with elevated glycated hemoglobin levels and over two years of diabetes. Patients will receive a single local administration of CIL001, with auditory function monitored over several months.

The second Phase 2a trial will target patients with neurodegenerative disorders, using a similar treatment protocol for their cochlear synaptopathy.

Célia Belline, CEO of Cilcare, states: *"This new funding, complemented by strategic agreements such as the exclusive license option signed with Shionogi Ltd. and the support from the France 2030 funds managed by Bpifrance under the Idemo program, represents a decisive milestone in Cilcare's growth. It provides us with the resources to achieve our ambitions, to bring our innovations into clinical trials, closer to patients and healthcare professionals, and to address their needs effectively."*

In recent years, Cilcare has conducted extensive research to identify auditory biomarkers, enabling better patient selection and more precise evaluation of therapies in clinical trials. By integrating advanced auditory data analysis technologies, including artificial intelligence and machine learning, Cilcare has optimized the characterization of auditory function in both preclinical and clinical settings.

These advances significantly increase the success probability of treatments currently in development, particularly CIL001, by targeting high-risk subpopulations for synaptopathy.

At the same time, Cilcare continues to leverage its expertise to support international pharmaceutical companies and researchers in accelerating the development of drugs, gene and cell therapies, and medical devices, further solidifying its position as a global leader in auditory disorder research.

Célia Belline concludes: *"This renewed support and international recognition of our expertise and innovations mark a turning point for Cilcare. Our entire team and partners are driven by a shared mission: to transform auditory healthcare through groundbreaking scientific advancements. We remain steadfast in our commitment to developing or co-developing, alongside strategic partners, disruptive therapeutic solutions for the millions of people affected by auditory disorders worldwide. We will dedicate all our resources, with strength and determination, to this vital mission."*

For this funding round, Cilcare was advised by **Agile Capital Markets** and **McDermott Will & Emery**.

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About Cilcare

Cilcare is a biotechnology company specializing in auditory sciences, developing cutting-edge solutions for the characterization, diagnosis, and treatment of hearing disorders and associated diseases. Founded by three visionary entrepreneurs, the company now employs a team of 45 international collaborators, supported by a scientific advisory board. Since its creation in 2014, Cilcare has dedicated itself to addressing these global challenges by combining an advanced R&D platform, a promising drug candidate portfolio, and the use of artificial intelligence and machine learning to characterize various forms of hearing loss.

For the past 10 years, Cilcare has also made its technology available to industry leaders and researchers in Europe, the United States, and Asia to accelerate the development of drugs, gene and cell therapies, and medical devices for hearing disorders.

To learn more, visit www.cilcare.com

About Cochlear Synaptopathy

Cochlear synaptopathy is a condition of the inner ear that affects the synaptic connections between the inner hair cells and the afferent fibers of the auditory nerve, leading to auditory disorders such as difficulty understanding speech in noisy environments, tinnitus, and hyperacusis, while maintaining normal pure-tone audiometry.

It represents an early stage of age-related hearing loss, clinically manifested by normal hearing thresholds but reduced speech intelligibility in noise (hidden hearing loss).

Often underdiagnosed because it is undetectable by standard audiogram, cochlear synaptopathy affects more than one billion young people and 10 to 15% of adults. It is worsened by noise and aging and is also highly prevalent among patients with chronic inflammatory diseases such as type 2 diabetes and in the early stages of neurodegenerative diseases like Alzheimer's disease.

It is one of the potential causes of tinnitus, a phantom sound that can reach unbearable levels for those affected in its most severe phases and affects one in ten adults globally.

Currently, no treatment exists for cochlear synaptopathy, and hearing aids are ineffective. If left untreated, it can irreversibly progress to deafness.

About CIL001

CIL001 is a new disease-modifying drug candidate for the treatment of cochlear synaptopathy following a single injection through the tympanic membrane. Recent preclinical studies have confirmed the effect of CIL001 in improving the amplitude of the first wave of the auditory brainstem response (ABR) and in promoting cochlear synapse reconnection, linking the inner hair cell to the auditory nerve. CIL001 has a comprehensive safety and CMC dossier, enabling it to proceed directly to a phase 2a clinical trial in humans.