



## Option Agreement with Cilcare for Development Compounds Addressing Hearing Loss

**OSAKA, Japan, June 6, 2024** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that Shionogi has entered into an option agreement with Cilcare DEV SAS (Head Office: Montpellier, France; Chief Executive Officer: Celia BELLINE, hereafter "Cilcare") to acquire the exclusive license for the development, manufacturing, and commercialization of CIL001 and/or CIL003, the hearing loss treatment drug candidates worldwide. In conjunction with the signing of the agreement, Shionogi will make an upfront payment of Euros 15 million to Cilcare. If Shionogi exercises its option for both compounds and development and commercialization proceeds successfully, the total of the option payments and development, regulatory, and sales milestones may reach approximately Euros 400 million, plus royalties on net sales.

Cilcare has been developing CIL001, a novel candidate drug for hearing loss treatment with auditory nerve protective effects. Currently, preparatory activities are underway to collect auditory data in patients with type 2 diabetes or mild cognitive impairment. From the fiscal year 2025, Phase 2a studies are planned to evaluate the safety and efficacy of CIL001 in patients with type 2 diabetes who have cochlear synaptopathy. Additionally, preclinical studies for CIL003 are currently underway. 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.

Hearing loss is a major global health issue affecting around 1.5 billion people worldwide. Its incidence is rapidly increasing, with predictions that, by 2050, a quarter of the global population will experience varying degrees of hearing deficiency<sup>1</sup>. Hearing loss, particularly when it primarily affects the cochlear synapses\*<sup>1</sup> in the inner ear, is known as cochlear synaptopathy. This condition is also known to increase the risk of dementia in the elderly and is also an important complication of diabetes<sup>2</sup>. However, there are no effective treatments available, making it a condition with a high unmet need. The economic loss due to unaddressed hearing loss is said to be around 1 trillion dollars annually, and there is a demand for new therapeutic drugs<sup>3</sup>.

Shionogi has identified Contributing to a Healthy and Prosperous Life as a material focus. We are committed to creating a society where everyone can lead a longer, more vibrant life, realizing their goals. Shionogi continues to strive to deliver innovative treatments for diseases with high unmet medical needs, including hearing loss, to patients as quickly as possible.

### Reference:

- 1: [Hearing Loss Disease Treatment Market Size & Growth to 2028 \(kbvresearch.com\)](https://www.kbvresearch.com)
- 2: Livingston G. et al. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet* 2020; 396: 413-416
- 3: [Estimating the global costs of hearing loss](#)

### **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 CIL001**

CIL001 is a novel candidate drug for hearing loss treatment with auditory nerve protective effect, licensed by Sanofi to Cilcare in 2020. 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)\*<sup>2</sup>.

### **About Hearing loss**

Hearing loss is a major global health issue affecting around 1.5 billion people worldwide. The significant surge in its incidence is attributed to the growing global population and an increase in the elderly demographic. If this trend continues, it will result in higher health insurance costs, social isolation, poverty, and a decrease in productivity, leading to substantial losses for society. One of the challenges with hearing loss is its gradual onset, making it difficult for patients to recognize and leading to low diagnosis rates. It is known to hinder various social activities, including communication with others, and is also considered a risk factor for central nervous system diseases.

\*<sup>1</sup> Cochlear synapse: The site of information transmission in the cochlea of the inner ear, connecting sensory cells (hair cells) and nerve cells.

\*<sup>2</sup> Auditory brainstem response (ABR) Wave I: The first electrical signal generated by cochlear nerve cells in response to an auditory stimulus, believed to reflect the function of the cochlear synapse.

### **Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

### **For Further Information, Contact:**

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>