

**UK MHRA Approval Received for First-In-Human Trial of Rincell-1,
a First-In-Class Regenerative Cell Therapy for Sensorineural Hearing Loss**

**Rincell-1 addresses a multi \$Bn global market opportunity
where no disease modifying treatments currently exist**

Sheffield, UK, July 1 2025 – Rinri Therapeutics, a world leading company focused on transforming sensorineural hearing loss (SNHL) with regenerative cell therapy, is pleased to announce the approval of its Clinical Trial Application (CTA) from the UK MHRA for its lead asset Rincell-1. Clinical proof-of-concept data from the first-in-human Phase I/IIa trial¹ of Rincell-1, a first-in-class otic neural progenitor cell therapy, is expected within 12 months of trial initiation.

While current standard-of-care treatments like cochlear implants help manage the symptoms of sensorineural hearing loss, their effectiveness depends on the integrity of the cochlear nerve. Rincell-1 has been designed to regenerate damaged auditory neurons, for which no treatment currently exists, bringing the potential to transform the lives of people with neural hearing loss and to play a significant role in healthy aging.

Taking place at three leading hearing research centres in the UK, the randomised open-label trial will involve 20 patients undergoing cochlear implantation for hearing loss, 10 with postsynaptic auditory neuropathy spectrum disorder (ANSN) and 10 with severe-to-profound age-related hearing loss (presbycusis). Within each group, patients will be randomly assigned to receive a single dose of Rincell-1 in addition to cochlear implantation or cochlear implantation alone.

The study is powered to measure safety and detect significant changes in neural health, as measured by telemetry from Advanced Bionics' cochlear implant monitoring AIM™ system, alongside a range of speech perception measures and patient-reported outcomes. Rincell-1 will be delivered to the cochlea during cochlear implant surgery via a novel extension of the current procedure, as previously published in 2024.²

Dr Simon Chandler, CEO of Rinri Therapeutics, said, *'Approval to start our first clinical trial with Rincell-1 in hearing loss is a major milestone and recognition of the potential of our regenerative cell therapy in this area of significant unmet medical need. I'd like to thank our staff and partners for their meticulous work towards this achievement, and our investors, Boehringer Ingelheim Venture Fund, UCB Ventures and Pioneer Group, for their support.'*

Professor Doug Hartley, CMO of Rinri Therapeutics & Chief Investigator on the trial, said, *'Working daily with individuals suffering from hearing loss, I know how devastating it can be, and the acute need for a therapy to change the disease course. It's very exciting to be starting a clinical trial with Rincell-1, working with otologists across the world to develop this promising new approach to auditory nerve regeneration.'*

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¹ First in human, multi-centre open-label randomised trial to assess the safety of Rincell-1 otic neural progenitor cell-based therapy in addition to standard care, compared with standard care alone, in participants with presbycusis or postsynaptic auditory neuropathy who meet UK guidelines for Cochlear Implantation. IRAS Ref: 1006992. Clin trials gov NCT07032038

² [Novel procedure for cell delivery in Rinri Therapeutics' first clinical trial described in peer-reviewed publication](#)

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About Rinri Therapeutics

Rinri Therapeutics is focused on transforming sensorineural hearing loss (SNHL) with regenerative cell therapy, providing new therapeutic options for the treatment of this major global unmet medical need. It is developing first-in-class allogenic cell therapy products to treat hearing loss using its proprietary Otic Sensory Progenitor REgenerative therapY (OSPREY™) platform.

There are currently no approved therapeutics for the estimated more than 7m people living with neural hearing loss globally, giving Rinri Therapeutics' cell therapies a multi-billion dollar sales potential. The company is headquartered in Sheffield, UK, and backed by UCB Ventures, Boehringer Ingelheim Venture Fund and Pioneer Group. For more information, please visit <https://www.rinri-therapeutics.com/> or follow us on [LinkedIn](#).