Dendrogenix, an innovative biotechnology company based in Liège (Belgium) announced today positive results from its first Phase 1 clinical trial evaluating its drug candidate DX243. Building on these encouraging data, the company plans to initiate a Phase 2a clinical trial in the first quarter of 2026 in the field of age-related hearing loss (presbycusis).

Located at the heart of the biomedical research ecosystem of CHU Sart-Tilman and GIGA Neuroscience, Dendrogenix is developing a novel proprietary class of compounds called "Dendrogenin", with DX243 as its first clinical candidate. These compounds are intended for the treatment of neurodegenerative diseases, with a particular focus on age-related auditory disorders.

Stéphane SILVENTE, Chief Executive Officer, Dendrogenix. © Dendrogenix

Phase 1 clinical results: excellent tolerability supporting advancement to Phase 2a

Phase 1 clinical study DX243-101 was a randomized, double-blind, placebo-controlled trial designed to primarily assess the safety, tolerability, and pharmacokinetic profile of single and multiple ascending subcutaneous doses of DX243.

The results demonstrated excellent systemic tolerability, with no toxicity signals and no serious adverse events (SAEs) reported. Vital signs, electrocardiograms (ECGs), and laboratory parameters remained within normal ranges throughout the study. Local tolerability at the injection site was acceptable and did not interfere with daily activities. Observed reactions (mild pain, transient erythema) were comparable to those typically reported with other subcutaneously administered therapies.

"These results represent a major milestone for Dendrogenix and confirm the potential of DX243 as an innovative therapeutic approach for age-related hearing disorders" said Stéphane Silvente, CEO of Dendrogenix.

Next key milestone: launch of Phase 2a in Q1 2026

Based on these results, Dendrogenix is preparing to initiate a Phase 2a clinical trial consisting of a multiple ascending dose study in patients with age-related hearing loss (presbycusis) and

impaired speech intelligibility in noisy environments. The objective of this study is to generate the first clinical proof-of-concept and efficacy signals for DX243.

About Dendrogenix

Dendrogenix is a biopharmaceutical company based in Liège, Belgium, within the CHU Sart-Tilman campus, specializing in the development of New Chemical Entities (NCEs) known as Dendrogenins.

The company aims to advance these therapeutic candidates through early clinical development to address major unmet medical needs, particularly in neurological disorders associated with neuronal and synaptic dysfunction.

The first therapeutic indication targeted is age-related hearing loss, more commonly referred to as presbycusis, which to date is managed exclusively through medical devices.

About Dendrogenin 243 (DX243)

DX243 belongs to a new generation of first-in-class small molecules known as Dendrogenin. This new chemical entity (NCE) exhibits both neuroprotective and neuroregenerative properties. Given its distinctive mechanism of action, DX243 has strong therapeutic potential for the treatment of multiple conditions associated with neuronal damage, including hearing loss, as well as other potential indications such as neurodegenerative diseases following ischemic stroke and traumatic brain injury.

About Presbycusis: a major market opportunity and unmet medical need

Presbycusis represents a global market involving several hundred million patients, with growth strongly correlated with population aging.

The prevalence of hearing loss increases with age, and presbycusis is the leading cause of hearing impairment in adults. It affects approximately 50% of individuals aged 60 to 69 and up to 80% of those aged 85, who experience severe hearing loss significantly impacting daily communication. The primary symptom is difficulty understanding speech in noisy environments, even when sound volume is increased.

To date, no pharmacological treatment has been approved for presbycusis; management therefore relies exclusively on medical devices, including hearing aids and cochlear implants.

The global presbycusis market was estimated at USD 10 / 11 billion in 2025 and is expected to reach USD 16.8 / 17.6 billion by 2032 – 2033 (Source: Age-related Hearing Loss – Global Market Report 2025).

Further information on Dendrogenix can be found on www.dendrogenix.com
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