Decibel Therapeutics Announces Approval of Clinical Trial Application by the Spanish Agency of Medicines and Medical Devices (AEMPS) to Initiate Clinical Development of Lead Gene Therapy Candidate DB-OTO

May 12, 2023

CTA authorization provides approval for the Company to expand its planned CHORD™ Phase 1/2 clinical trial of DB-OTO to patients in Spain aged two years and younger

BOSTON, May 12, 2023 (GLOBE NEWSWIRE) -- Decibel Therapeutics (Nasdaq: DBTX), a clinical-stage biotechnology company dedicated to discovering and developing transformative treatments to restore and improve hearing and balance, today announced approval of its Clinical Trial Application (CTA) by the Spanish Agency of Medicines and Medical Devices (AEMPS) to initiate a Phase 1/2 clinical trial in pediatric patients of DB-OTO, its lead gene therapy product candidate. DB-OTO is being developed in collaboration with Regeneron Pharmaceuticals, Inc. and is a cell-selective, adeno-associated virus (AAV) gene therapy product candidate designed to provide durable, physiological hearing in individuals with profound, congenital hearing loss caused by mutations of the otoferlin gene.

The CTA in Spain is part of an international regulatory strategy for clinical development of DB-OTO, which also includes a regulatory clearance for an Investigational New Drug (IND) application in the United States in October 2022 and a CTA approval by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) in January 2023. Decibel expects that clinical trial participants in the U.K. and Spain will be infants two years of age and younger. The Company anticipates reporting the initial safety and tolerability data and preliminary efficacy data, as measured by ABR, from the first patients in the Phase 1/2 clinical trial in the first quarter of 2024.

“Spain is an important country within our DB-OTO clinical development strategy, and our trial will leverage the collaborations and natural history work that we have pursued there over the past several years,” said Laurence Reid, Ph.D., Chief Executive Officer at Decibel. “Our team believes that DB-OTO could be a transformative treatment for individuals with otoferlin-related hearing loss, and this approval broadens the opportunity to evaluate its potential in infants two years of age and younger.”

The Phase 1/2 dose escalation clinical trial, known as CHORD™, is designed to evaluate the safety, tolerability and efficacy of DB-OTO in pediatric patients with congenital hearing loss due to an otoferlin deficiency. In addition to safety and tolerability endpoints, the auditory brainstem response (ABR) -- an objective, clinically accepted, physiologic measure of hearing sensitivity -- will be used as an efficacy endpoint in the clinical trial. The ABR, which was used to characterize dose-response of DB-OTO after intra-cochlear delivery in translational studies in animal models, provides an opportunity to rapidly assess hearing functionality and sensitivity.

DB-OTO received Orphan Drug and Rare Pediatric Disease designations from the U.S. Food and Drug Administration in 2021 and was granted European Orphan Drug status by the European Medicines Agency (EMA) Committee on Orphan Medicinal Products (COMP) in March 2023.

About Decibel Therapeutics
Decibel Therapeutics is a clinical-stage biotechnology company dedicated to discovering and developing transformative treatments to restore and improve hearing and balance, one of the largest areas of unmet need in medicine. Decibel has built a proprietary platform that integrates single-cell genomics and bioinformatic analyses, precision gene therapy technologies and expertise in inner ear biology. Decibel is leveraging its platform to advance gene therapies designed to selectively replace genes for the treatment of congenital, monogenic hearing loss and to regenerate inner ear hair cells for the treatment of acquired hearing and balance disorders. Decibel’s pipeline, including its lead gene therapy product candidate, DB-OTO, to treat congenital, monogenic hearing loss, is designed to deliver on our vision of creating a world of connection for people with hearing and balance disorders. For more information about Decibel Therapeutics, please visit www.decibeltx.com or follow us on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Decibel’s strategy, future operations, prospects, plans, objectives of management, the therapeutic potential for Decibel’s product candidates and preclinical programs, the potential benefits of cell-selective expression, the design of the Phase 1/2 clinical trial of DB-OTO and the expected timelines for initiating a Phase 1/2 clinical trial of DB-OTO and announcing data from the trial constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” or “would,” or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Decibel may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the timing of and Decibel’s ability to obtain approval to initiate clinical development of its program candidates, whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials, whether Decibel’s cash resources are sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements, uncertainties related to the impact of the COVID-19 pandemic on Decibel’s business and operations, as well as the risks and uncertainties identified in Decibel’s filings with the Securities and Exchange Commission (SEC), including those risks detailed under the caption “Risk Factors” in Decibel’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in other filings Decibel may make with the SEC. In addition, the forward-looking statements included in this press release represent Decibel’s views as of the date of this press release. Decibel

anticipates that subsequent events and developments will cause its views to change. However, while Decibel may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Decibel's views as of any date subsequent to the date of this press release.

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