



Otonomy Initiates Phase 2 Clinical Trial of OTO-313 in Tinnitus

March 25, 2021

- **Phase 2 study design based on successful Phase 1/2 trial including use of Tinnitus Functional Index (TFI) responder analysis for primary efficacy endpoint**
- **Patient enrollment criteria refined to enrich study population**
- **Top-line results expected in mid-2022**

SAN DIEGO, March 25, 2021 (GLOBE NEWSWIRE) -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced the initiation of a Phase 2 clinical trial of OTO-313 in patients with unilateral tinnitus. The randomized, double-blind, placebo-controlled Phase 2 study will enroll approximately 140 patients with persistent, early onset tinnitus of at least moderate severity. Following the successful Phase 1/2 trial, the primary efficacy endpoint will be a responder analysis based on the proportion of patients reporting a clinically meaningful improvement in TFI from baseline to both Month 1 and Month 2 following treatment. Top-line results are expected in mid-2022.

"Tinnitus is a common problem that negatively impacts millions of people by disrupting their ability to sleep, concentrate at work, and enjoy leisure activities. This often leads to anxiety and depression that can be quite severe, as sadly reported in a recent case of a prominent post-COVID patient experiencing unrelenting tinnitus," said David A. Weber, Ph.D., president and CEO of Otonomy. "Unfortunately, there are no approved drug treatments for tinnitus and current therapy focuses on coping and masking mechanisms. OTO-313 was designed to address the underlying pathology producing the false perception of sound, with the Phase 1/2 trial demonstrating a clinically meaningful reduction in tinnitus severity in a group of responders. We are excited to be initiating the trial and advancing the OTO-313 program for this important unmet need."

The Phase 2 trial will be conducted at approximately 50 clinical sites in the U.S. and Europe. Following a lead-in period, patients will be randomized to a single intratympanic injection of OTO-313 or placebo and then followed for four months. Consistent with the Phase 1/2 trial results, the primary endpoint will be a responder analysis based on the reduction in TFI score from baseline to both Month 1 and Month 2 following treatment. In order to assess durability of the treatment benefit, patients will be followed for an additional two months. Other measures of efficacy include tinnitus loudness, tinnitus annoyance, and patient global impression of change.

About Tinnitus

Tinnitus is the medical term for the perception of noise when there is no sound. It is often described as a ringing in the ear but can also sound like roaring, clicking, hissing or buzzing. Tinnitus is often caused by cochlear injury due to excessive noise, physical trauma, persistent ear infection or exposure to an ototoxic agent, leading to over-activation of auditory nerve fibers and the perception of noise in the absence of an external stimulus. Approximately 10 percent of U.S. adults suffer from the condition, which can severely impact daily activities and result in anxiety and depression. Tinnitus also accounts for the most prevalent service-connected disability among veterans with an estimated cost exceeding \$2 billion. There are currently no FDA approved drug treatments for tinnitus.

About OTO-313

OTO-313 is a sustained-exposure formulation of the potent and selective N-Methyl-D-Aspartate (NMDA) receptor antagonist gacyclidine. We believe that gacyclidine can reduce the severity of tinnitus symptoms following cochlear injury by decreasing the over-activation of damaged auditory nerve fibers in the cochlea and their connections. OTO-313 utilizes a novel, patent-protected formulation technology to provide several weeks of gacyclidine drug exposure in the inner ear following a single intratympanic injection. In 2020, we reported positive results from a Phase 1/2 trial of OTO-313 in patients with unilateral tinnitus of at least moderate severity. This trial demonstrated a positive clinical response for OTO-313 using the Tinnitus Functional Index (TFI) that was correlated with improvements in tinnitus loudness, tinnitus annoyance and patient global impression of change measures.

About Otonomy

Otonomy is a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology. The company pioneered the application of drug delivery technology to the ear in order to develop products that achieve sustained drug exposure from a single local administration. This approach is covered by a broad patent estate and is being utilized to develop a pipeline of products addressing important unmet medical needs including Ménière's disease, hearing loss, and tinnitus. For additional information please visit www.otonomy.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or the future financial or operating performance of Otonomy. Forward-looking statements in this press release include, but are not limited to, statements related to plans and expectations regarding OTO-313, including with respect to patient populations and the Phase 2 trial of OTO-313; anticipated timing of topline results of the Phase 2 clinical trial of OTO-313; and statements by Otonomy's president and CEO.

Otonomy's expectations regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties. Actual results may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not

limited to: delays and disruption resulting from the COVID-19 pandemic and governmental and site responses to the pandemic, including current and future impacts to Otonomy's operations, the manufacturing of its product candidates, the progression of its current clinical trials, and patient conduct and compliance; Otonomy's ability to accurately forecast financial results; Otonomy's ability to obtain additional financing; Otonomy's dependence on the regulatory success and advancement of its product candidates; the uncertainties inherent in the clinical drug development process, including, without limitation, Otonomy's ability to adequately demonstrate the safety and efficacy of its product candidates, the nonclinical and clinical results for its product candidates, which may not support further development, and challenges related to patient enrollment, conduct and compliance in clinical trials; the integrity of patient-reported outcomes in its current and future clinical trials; the risks of the occurrence of any event, change or other circumstance that could impact the performance under or give rise to the termination of Otonomy's collaboration, co-promotion or license agreements, or that could impact Otonomy's ability to repay or comply with the terms of the loan provided by Oxford Finance LLC; side effects or adverse events associated with Otonomy's product candidates; competition in the biopharmaceutical industry; Otonomy's dependence on third parties to conduct nonclinical studies and clinical trials, and for the manufacture of its product candidates; Otonomy's ability to protect its intellectual property in the United States and throughout the world and to ensure compliance with various laws and regulations in countries in which it conducts clinical trials; expectations regarding potential therapy benefits, market size, opportunity and growth; Otonomy's ability to manage operating expenses; implementation of Otonomy's business model and strategic plans for its business, products and technology; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in Otonomy's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 11, 2021, and Otonomy's future reports to be filed with the SEC. The forward-looking statements in this press release are based on information available to Otonomy as of the date hereof. Otonomy disclaims any obligation to update any forward-looking statements, except as required by law.

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