Otonomy Announces Publication of Phase 1/2 Trial Results Showing Tinnitus Improvement in Patients Receiving OTO-313

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- ***Results published in Otology & Neurotology, a leading journal in field***
- ***OTO-313 was well-tolerated and demonstrated a statistically significant higher proportion of responders than placebo across consecutive visits (Weeks 4 and 8)***
- ***Patient enrollment in Phase 2 trial is ongoing with results expected in mid-2022***

SAN DIEGO, Oct. 12, 2021 (GLOBE NEWSWIRE) -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced the publication of its OTO-313 Phase 1/2 clinical trial results in *Otology & Neurotology*, a leading peer-reviewed journal in otolaryngology. These are the first published results to demonstrate a reduction in tinnitus severity for a drug treatment compared to placebo using the Tinnitus Functional Index (TFI), a clinically-validated instrument.

“Publication of these positive clinical results is an important milestone for the millions of people suffering from tinnitus, which can negatively impact sleep and relaxation, disrupt life at work and home, and create feelings of distress and anxiety,” said David Baguley, Professor of Hearing Sciences at the University of Nottingham, former Head of Audiology at Cambridge University Hospitals NHS Foundation Trust, and an internationally recognized tinnitus expert who is a co-author on the publication. “This is also an encouraging moment for clinicians who currently lack any drug therapy to reduce the severity of tinnitus that patients experience. I am particularly pleased to see the good concurrence between TFI and the other endpoint measures at multiple timepoints for responders in this trial, which demonstrates a robust treatment benefit.”

"Availability of the Phase 1/2 trial results is constructive for our efforts to maintain the favorable pace of patient enrollment in the ongoing Phase 2 trial that is on-track with our anticipated timing for results in mid-2022,” said David A. Weber, Ph.D., president and CEO of Otonomy.

The exploratory efficacy cohort of the Phase 1/2 trial included 31 evaluable patients with persistent unilateral tinnitus of at least moderate severity based on the TFI. Patients were randomized to a single intratympanic injection of OTO-313 or placebo (1:1 randomization) and then followed for 8 weeks. In the trial, 43% of OTO-313 patients reported a clinically meaningful improvement on the TFI at both Week 4 and Week 8 compared to 13% of placebo patients (ad hoc p-value < 0.05). Furthermore, OTO-313 patients who were TFI responders also reported improvements in tinnitus loudness and annoyance levels, and improvement in the Patient Global Impression of Change.

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. A Phase 2 trial is currently underway with results expected in mid-2022.

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 with a focus on 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, expectations regarding the potential benefits, development activity and advancement of the OTO-313 program; statements related to plans and expectations regarding OTO-313, including with respect to patient recruitment and activity for the ongoing OTO-313 Phase 2 clinical trial; anticipated timing of topline results of the Phase 2 clinical trial of OTO-313; statements relating to potential treatment for patients suffering from the high burden of persistent tinnitus; statements by a co-author of the OTO-313 Phase 1/2 publication; 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 expectation that it will incur significant losses for the foreseeable future; 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 any promotional, collaboration 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; Otonomy's ability to obtain regulatory approval and successfully commercialize its product candidates, if approved; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 4, 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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