Otonomy Reports Results from Phase 2 Clinical Trial of OTO-313 in Patients with Tinnitus

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- *OTO-313 demonstrated no clinically meaningful improvement versus placebo for primary and secondary endpoints across all timepoints*
- *Company to discontinue development of OTO-313 and implement other measures to extend its cash runway*
- *Clinical focus shifts to OTO-413 following positive Phase 2a results in April 2022; top-line results for evaluation of higher dosing still expected in fourth quarter of 2022*

SAN DIEGO, Aug. 01, 2022 (GLOBE NEWSWIRE) -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced that the OTO-313 Phase 2 trial in tinnitus demonstrated no clinically meaningful benefit versus placebo for primary and secondary endpoints across all timepoints.

The randomized, double-blind, placebo-controlled Phase 2 trial enrolled 153 patients with persistent, unilateral tinnitus of at least moderate severity. Patients were randomized 1:1 to a single intratympanic injection of OTO-313 (n=77) or placebo (n=76) and followed for 4 months. The primary endpoint was a responder analysis based on the proportion of patients who reported a clinically meaningful improvement, defined as a reduction of 13 points or more in the Tinnitus Functional Index (TFI), from baseline to both Months 1 and 2 following treatment. The trial failed to meet this primary endpoint as well as secondary endpoints for the total study population. Although OTO-313 did show a higher response rate than placebo in a prospectively defined patient subgroup with tinnitus duration of less than 6 months (population studied in Phase 1/2 trial), the overall results do not support further development of OTO-313.

"These results were unexpected with a much higher placebo response than observed in the prior Phase 1/2 study," said David A. Weber, Ph.D., president and CEO of Otonomy. "In addition to this trial, we have also reviewed preliminary top-line results for the one-month safety evaluation of higher and bilateral dosing of OTO-313 and did not observe a treatment benefit that is convincing in light of the Phase 2 results. Therefore, we must make the difficult decision for all stakeholders including patients and clinicians who were highly supportive of this trial to discontinue further work on OTO-313. We also intend to implement other measures to extend our cash runway."

The company's clinical focus shifts to OTO-413 for the treatment of hearing loss. Positive Phase 2a results for OTO-413 were announced in April 2022, which corroborated findings from an earlier Phase 1/2 study. In addition, enrollment is complete for evaluation of higher dosing with top-line results expected in the fourth quarter of 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 in neurotology. 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 regarding Otonomy's intention to discontinue OTO-313; Otonomy's intention to implement measures to extend cash runway; Otonomy's shift in clinical focus to OTO-413; and Otonomy's expectation of the timing of top-line results of the higher dose cohorts for OTO-413. 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: 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 implement measures to extend its cash runway and manage operating expenses; Otonomy's ability to obtain additional financing; Otonomy's ability to develop product candidates that have viable commercial prospects; delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including current and future impacts to Otonomy's operations, the initiation and progression of, and enrollment in, its clinical trials, and patient conduct and compliance; 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 and the potential for clinical trials to differ from preclinical, early clinical, preliminary, top-line or expected results, 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 clinical trials; Otonomy's ability to repay or comply with the terms of the loan provided by Oxford Finance LLC; 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 collaboration or license agreements; 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; 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 July 25, 2022, 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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