Otonomy Provides Update on OTIVIDEX® and OTO-313 Programs

November 30, 2020

- ***FDA's review confirms use of Negative Binomial model for analysis of primary endpoint in ongoing OTIVIDEX Phase 3 trial in Ménière's disease; results still expected in first quarter of 2021***
- ***Company finalizing design of Phase 2 trial for OTO-313 in tinnitus and expects to start study in the first quarter of 2021***

SAN DIEGO, Nov. 30, 2020 (GLOBE NEWSWIRE) -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today provided updates regarding the statistical analysis plan for the ongoing Phase 3 trial of OTIVIDEX in Ménière's disease, and outlined plans for a Phase 2 trial of OTO-313 in tinnitus.

- **OTIVIDEX: FDA's review of the OTIVIDEX statistical analysis plan confirms use of the Negative Binomial model for analysis of the primary endpoint in the ongoing Phase 3 clinical trial in Ménière's disease.** In July 2020, Otonomy submitted a revised statistical analysis plan for the ongoing trial to the U.S. Food and Drug Administration (FDA) that proposed use of the Negative Binomial model for primary analysis of the daily vertigo count data reported by patients. Otonomy believes that this statistical test provides the best fit of the OTIVIDEX clinical data based on the Phase 2b trial, the AVERTS-2 Phase 3 trial, and the integrated dataset from both trials. As previously reported, the ongoing Phase 3 clinical trial has completed enrollment and results are expected in the first quarter of 2021. Assuming positive results, submission of a New Drug Application to the FDA is planned for the third quarter of 2021.

- **OTO-313: Phase 2 trial design to be based on the successful Phase 1/2 trial, and initiation is expected in the first quarter of 2021.** In July 2020, Otonomy reported positive top-line 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 a single intratympanic injection of OTO-313 using the Tinnitus Functional Index (TFI) that was correlated with tinnitus loudness, tinnitus annoyance and patient global impression of change measures. Based on continued analysis of this data, input from key opinion leaders, and feedback from the FDA in a Type C meeting, Otonomy intends to evaluate the same dose for OTO-313 in a Phase 2 trial that will enroll an enriched unilateral tinnitus patient population. To enrich the study population, Otonomy intends to exclude patients with severe hearing loss and increase the minimum TFI score required for entry. The company will also expand the unilateral patient population eligible for enrollment by increasing the time from tinnitus onset, and will extend the observation period to assess durability of the treatment effect.

"We appreciate the timely feedback from the FDA that supports our plan to analyze the OTIVIDEX Phase 3 trial results and, together with input from tinnitus clinical experts, will help us finalize the OTO-313 Phase 2 trial design," said David A. Weber, Ph.D., president and CEO of Otonomy. "We are looking forward to having the OTIVIDEX results and initiating the OTO-313 Phase 2 trial in the first quarter of 2021. In the meantime, we are working to complete the OTO-413 Phase 1/2 trial in patients with speech-in-noise hearing deficit, and expect to announce results in December."

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 relating to the design of (including without limitation regarding dose and patient population), initiation of, development activity for, and advancement of clinical trials; statements relating to the timing of results, activity for, and conduct of ongoing clinical trials; statements relating to the updated statistical analysis plan for the ongoing Phase 3 clinical trial of OTIVIDEX and expectations regarding the Negative Binomial model; statements regarding plans to submit a New Drug Application for OTIVIDEX; 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 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, enrollment in its current and future 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 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 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 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; Otonomy's ability to manage operating expenses; 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 (the "SEC") on November 4, 2020, 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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