Otonomy Announces Top-Line Results for the Phase 3 Clinical Trial of OTIVIDEX® in Patients with Ménière's Disease

February 22, 2021

SAN DIEGO, Feb. 22, 2021 (GLOBE NEWSWIRE) -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced that the Phase 3 clinical trial of OTIVIDEX in patients with Ménière's disease did not achieve the primary endpoint, which was the count of definitive vertigo days (DVD) in Month 3 for OTIVIDEX vs. placebo for the intent-to-treat (ITT) population (n = 148; p value = 0.312) using the Negative Binomial Model. This analysis did achieve statistical significance for the per protocol (PP) population (n = 136; p value = 0.031). These results were similar using the Generalized Poisson model (p value = 0.340 for ITT and p value = 0.030 for PP).

“We are disappointed by the top-line results for the primary intent-to-treat population and are undertaking an assessment to understand the difference observed with the per protocol analysis. We thank the many patients, clinical investigators and study site staff who supported this effort,” said David A. Weber, Ph.D., president and CEO of Otonomy. “Our focus turns to the strong pipeline we have built as recently highlighted by the successful clinical trial results for OTO-313 in tinnitus and OTO-413 in hearing loss. OTO-313 and OTO-413 each address a large patient population with significant unmet need and no approved drug therapy. These programs provide an attractive opportunity for the company with clinical readouts anticipated in mid-2022. We expect that our existing cash balance will permit us to achieve these clinical readouts as well as advance our preclinical hearing loss programs including OTO-825, a gene therapy for congenital hearing loss."

The company previously reported a cash balance including cash, cash equivalents, and short-term investments totaling $86.3 million as of December 31, 2020, GAAP operating expenses for full year 2020 of $42.6 million and non-GAAP operating expenses, which exclude stock-based compensation, for full year 2020 of $36.5 million.

About OTIVIDEX Phase 3 Trial

The OTIVIDEX Phase 3 trial was a four month, prospective, randomized, double-blind, placebo-controlled trial of patients with unilateral Ménière’s disease conducted in the United States and Europe. Following an initial one month lead-in period, eligible subjects were randomized 1:1 to a single intratympanic injection of OTIVIDEX or placebo and then followed for three months. A total of 149 patients were randomized into the study. The primary endpoint was the count of definitive vertigo days in Month 3 for OTIVIDEX vs. placebo assessed using the Negative Binomial model.

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, OTO-413 and OTO-825, and Otonomy’s other preclinical programs, including with respect to patient populations; anticipated timing of clinical readouts for OTO-313 and OTO-413; Otonomy’s expectation that its existing cash balance will permit the company to achieve such clinical readouts as well as advance its preclinical hearing loss programs; expectations regarding Otonomy’s ability to advance its pipeline; 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; risks and uncertainties related to the impact of this announcement on the Company’s business, financial condition and the price of the Company’s securities; 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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