



Contact:

Vida Communication (On behalf of Otonomy)

Stephanie Diaz (investors)

415-675-7400

sdiaz@vidacommunication.com

Tim Brons (media)

415-675-7400

tbrons@vidacommunication.com

FOR IMMEDIATE RELEASE

Otonomy Presents Positive New Findings from Phase 1b Study of OTO-104 in Ménière's Disease at International Conference

Observed Clinical Activity Suggests OTO-104 Provides Clinically Meaningful Reduction in Vertigo Frequency and Improvement in Tinnitus

San Diego, CA, September 29, 2011 -- Otonomy, Inc., a clinical stage biopharmaceutical company developing innovative therapeutics for diseases and disorders of the inner and middle ear, today announced that researchers presented positive new data from a Phase 1b study of the company's lead product candidate, OTO-104, in patients with Ménière's disease. The presented data showed that patients treated with OTO-104 experienced clinically meaningful reductions in vertigo frequency and improvements in tinnitus as compared to placebo. These results were presented today in an oral presentation at the 28th Politzer Society Meeting in Athens, Greece.

Researchers presented findings showing clinically meaningful reductions in vertigo frequency at three months with the 12 mg OTO-104 dose as compared to placebo. Prior to treatment, patients in both the 12 mg OTO-104 and placebo groups experienced an average of eight days with definitive vertigo episodes during a baseline period of one month. Following a single intratympanic (IT) injection, patients in the 12 mg OTO-104 group experienced a month-over-month reduction in vertigo frequency throughout the three month follow-up period, and achieved an approximate six day reduction in the number of definitive vertigo days in the third month versus baseline. When compared to placebo, at three months following treatment, the 12 mg study group experienced a 70 percent greater reduction from baseline in the number of days with definitive vertigo episodes. There was no clinically meaningful difference in vertigo frequency between the 3 mg OTO-104 and placebo groups at three months following treatment.

Additionally, the presented study data demonstrated that both the 3 mg and 12 mg OTO-104 doses were associated with improvement in tinnitus as measured by the Tinnitus Handicap Inventory (THI-25). THI is a clinically validated patient-reported measure that can be used to quantify the impact of tinnitus on activities of daily living. Both OTO-104 doses resulted in reductions in THI Total Score from baseline as early as one month following treatment. Furthermore, these THI Total Scores continued to decrease throughout the entire three month follow-up period, suggesting continued improvement in tinnitus symptoms experienced by patients treated with OTO-104. By contrast, the study's placebo group demonstrated little change in THI Total Score from baseline during the three month follow-up period.

As previously reported, results from this study showed OTO-104 to be safe and well-tolerated at both doses tested when delivered via a single IT injection. It is important to note that despite demonstrating meaningful clinical activity in the areas of vertigo and tinnitus, this study was not powered to demonstrate statistical significance. Based on these study results, Otonomy will initiate a Phase 2 clinical trial of OTO-104 in Ménière's disease during the fourth quarter of 2011.

"These new results provide the first demonstration of OTO-104's clinical activity in a cohort of Ménière's disease patients experiencing frequent vertigo episodes," stated Paul R. Lambert, M.D., professor and chair of the department of otolaryngology – head and neck surgery, Medical University of South Carolina, and the study's lead investigator. "Furthermore, the continued reduction in vertigo frequency and improvement in tinnitus symptoms for the 12 mg OTO-104 group observed through three months of follow-up provides a strong rationale for initiating broader clinical evaluations of this sustained release product."

A total of 44 patients with unilateral Ménière's disease were enrolled in this prospective, randomized, double-blind, placebo-controlled multicenter study. Patients participated in a one-month baseline period to characterize disease status, followed by randomization to receive a single IT injection of OTO-104 (3 mg or 12 mg) or placebo. Patients were monitored over a three-month observation period following injection. The study's primary objective was the evaluation of the safety and tolerability of OTO-104. Additionally, the study evaluated various indicators of OTO-104 clinical activity including changes in vertigo, tinnitus, hearing function and patient quality of life.

"Following a meeting with the United States Food and Drug Administration regarding these Phase 1b results and our proposed plans for continued clinical development of OTO-104, we are now in a strong position to move this program forward," said David A. Weber, Ph.D., president and chief executive officer of Otonomy. "Importantly, our upcoming Phase 2 study will include a much greater number of patients and be powered to deliver statistically significant findings with regard to clinical efficacy. As such, we look forward to the initiation of this study as we seek to establish the therapeutic potential of OTO-104 to help patients suffering from the debilitating symptoms of Ménière's disease."

About OTO-104

OTO-104 is a sustained release formulation of the steroid dexamethasone that has been designed for intratympanic (IT) injection into the middle ear for the potential treatment of a broad range of inner ear disorders including vertigo, hearing loss and tinnitus. OTO-104 is based on Otonomy's proprietary formulation technology which is intended to overcome the limitations associated with the use of unapproved short acting solutions in the ear. These include limited drug exposure, large variability of delivered dose and the need for multiple IT injections.

About Ménière's Disease

Ménière's disease is a disorder of the inner ear characterized by acute episodes of vertigo, fluctuations in hearing, tinnitus and aural fullness. The underlying cause of Ménière's disease is unknown and there are currently no FDA-approved drug treatments. According to the National

Institute on Deafness and Other Communication Disorders (NIDCD), approximately 615,000 individuals have been diagnosed with Ménière's disease in the United States.

About Otonomy

Otonomy is a clinical stage biopharmaceutical company developing innovative therapeutics for diseases and disorders of the inner and middle ear. There are currently no FDA-approved drug treatments for the nearly 30 million Americans that are affected by debilitating hearing and balance diseases and disorders such as Ménière's disease, sudden sensorineural hearing loss, noise-induced hearing loss, age-related hearing impairment and tinnitus. Otonomy's core technology is a sustained release formulation developed for optimal delivery of drugs to the middle and inner ear with a single IT injection. This technology has broad applicability across a range of therapeutic classes and two products based on this platform are in active development.

Otonomy's lead product candidate, OTO-104, is a sustained release formulation of the steroid dexamethasone. The company has finalized plans for a Phase 2 clinical trial in Ménière's disease patients and plans to initiate the study during the fourth quarter of 2011. Additional future studies of OTO-104 are being planned in other inner ear disorders. OTO-201, the company's second product candidate, is a novel sustained release antibiotic being developed in the field of otitis media. OTO-201 clinical trials are expected to begin in 2011. Additional product candidates are expected to target acute and chronic forms of hearing loss, balance disorders, and tinnitus.

For more information visit: www.otonomy.com.

###