Otonomy Initiating Phase 1/2 Clinical Trial of OTO-413 in Hearing Loss

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Results expected in second half of 2020

SAN DIEGO, Sept. 17, 2019 (GLOBE NEWSWIRE) -- Otonomy, Inc. (NASDAQ: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced the initiation of a Phase 1/2 clinical trial of OTO-413, a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF), in patients with hearing loss. The Phase 1/2 trial is a randomized, double-blind, placebo-controlled, single ascending dose study designed to evaluate the safety and exploratory efficacy of OTO-413 in patients with speech-in-noise hearing difficulty.

“Recent scientific research in the neurotology field has demonstrated that damage or loss of synaptic connections between inner ear hair cells and spiral ganglion neurons, known as cochlear synaptopathy, is involved in the hearing difficulty that many people experience in a loud environment, and that this pathology may also play a role in age-related and noise-induced hearing loss,” said Andrea Vambutas, M.D., Director for the Center of Hearing & Balance at the New York Head & Neck Institute. “Repair of the synaptic connection through local administration of a neurotrophic factor such as BDNF holds promise for patients with speech-in-noise hearing difficulty, and this Phase 1/2 clinical trial provides an exciting first opportunity to evaluate this therapeutic approach.”

“Initiating this clinical trial as planned keeps us on track to have results for three clinical programs in 2020 – the OTIVIDEX™ Phase 3 trial in Ménière’s disease in the first half of 2020, the OTO-313 Phase 1/2 trial in tinnitus patients in the first half of 2020, and this OTO-413 Phase 1/2 trial in the second half of 2020,” said David A. Weber, Ph.D., president and CEO of Otonomy. “Furthermore, advancing this program into clinical development also highlights our leadership in neurotology with clinical-stage programs addressing hearing loss, tinnitus, and balance disorders, the largest indications and market opportunities in this emerging field.”

About OTO-413

OTO-413 is a proprietary, sustained-exposure formulation of brain-derived neurotrophic factor (BDNF), which is a naturally occurring protein involved in neuron growth and repair. Nonclinical studies have demonstrated that local administration of BDNF repairs ribbon synapses damaged due to noise trauma or exposure to ototoxic chemicals, and restores hearing function. The initial indication for OTO-413 is speech-in-noise hearing difficulty, a type of hearing loss believed to be caused by cochlear synaptopathy that affects an estimated 9 million people in the United States. A Phase 1/2 clinical trial evaluating the safety and exploratory efficacy of OTO-413 in patients with speech-in-noise hearing difficulty is expected to have results in the second half of 2020.

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, timing of results, patient recruitment and enrollment plans, and trial design and conduct for the Phase 1/2 clinical trial for OTO-413, timing of results for the OTIVIDEX Phase 3 trial in Ménière’s disease and the OTO-313 Phase 1/2 trial in tinnitus patients, 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: Otonomy’s limited operating history and its expectation that it will incur significant losses for the foreseeable future; 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; Otonomy’s ability to obtain regulatory approval for its product candidates; 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; Otonomy’s dependence on third parties for the manufacture of its product candidates; Otonomy’s dependence on a small number of suppliers for raw materials; Otonomy’s ability to protect its intellectual property related to its product candidates in the United States and throughout the world; 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; 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 August 1, 2019, 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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