Otonomy Provides Corporate and Product Pipeline Update

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Three programs with clinical trial results in 2020 including OTIVIDEX™ Phase 3 trial in Ménière's disease

Current capital funds operations into 2021

SAN DIEGO, Jan. 09, 2020 (GLOBE NEWSWIRE) -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today provided an update on its product pipeline and financial guidance. Consistent with previously stated timing, the company expects to have results for the Phase 3 trial of OTIVIDEX in Ménière's disease in the third quarter of 2020, the Phase 1/2 trial of OTO-313 in tinnitus patients in the second quarter of 2020, and the Phase 1/2 trial of OTO-413 in patients with hearing loss in the second half of 2020.

The company finished 2019 with approximately $61 million in cash, cash equivalents and short term investments and expects that its current capital is sufficient to fund operations through the three clinical trials and into 2021.

"We are excited to begin 2020, a potentially transformational year for Otonomy driven by our three clinical trial readouts, each of which is a meaningful milestone given the significant patient population, high disease burden, and lack of approved drug treatments," said David A. Weber, Ph.D., president and CEO of Otonomy. "While successful completion of these clinical trials is our highest priority, we also continue to advance multiple preclinical programs including our gene therapy collaboration targeting congenital hearing loss."

Product Pipeline Update

- **OTIVIDEX: Enrollment in Phase 3 Clinical Trial in Ménière's Disease is Ongoing with Results Expected in the Third Quarter of 2020.** Otonomy has completed one successful Phase 3 trial and is conducting this additional pivotal trial to support a submission for U.S. registration of OTIVIDEX in Ménière's disease. The company plans to enroll approximately 160 patients in the United States and Europe.

- **OTO-313: Enrollment in Phase 1/2 Clinical Trial in Tinnitus is Ongoing with Results Expected in the Second Quarter of 2020.** Otonomy has successfully completed the initial safety cohort of this randomized, double-blind, placebo-controlled trial, and is enrolling approximately 50 patients with persistent tinnitus in the exploratory efficacy study cohort. OTO-313 is a sustained-exposure formulation of the potent and selective NMDA receptor antagonist gacyclidine.

- **OTO-413: Enrollment in Phase 1/2 Clinical Trial in Hearing Loss is Ongoing with Results Expected in the Second Half of 2020.** Otonomy is enrolling hearing loss patients in a Phase 1/2 clinical trial of OTO-413, which is a sustained-exposure formulation of brain-derived neurotrophic factor (BDNF). 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.

- **Advancing multiple preclinical programs for treatment and prevention of hearing loss.**
  - **GJB2 gene therapy program:** Otonomy and Applied Genetic Technologies Corporation (AGTC) are collaborating to co-develop and co-commercialize an AAV-based gene therapy to restore hearing in patients with hearing loss caused by a mutation in the gap junction protein beta 2 gene (GJB2) -- the most common cause of congenital hearing loss.
  - **OTO-6XX:** development program targeting hair cell regeneration for severe hearing loss.
  - **OTO-510:** otoprotection program for patients at risk for cisplatin-induced hearing loss.

Financial Updates and Guidance

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled approximately $61 million as of December 31, 2019. This balance includes proceeds from a $15 million term loan completed in December 2018.

- **Operating Expenses:** Otonomy expects that non-GAAP operating expenses for 2020 will be in the range of $35-$38 million, and that GAAP operating expenses will be in the range of $45-$48 million.

- **Cash Runway:** Otonomy expects that its current cash, cash equivalents, and short term investments will be sufficient to fund the company through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO-413 Phase 1/2 trial in 2020, and will support company operations into 2021.

Non-GAAP Operating Expenses

In this press release, Otonomy's operating expenses are provided in accordance with generally accepted accounting principles (GAAP) in the United States and also on a non-GAAP basis. Non-GAAP operating expenses exclude stock-based compensation. Non-GAAP operating expenses are provided as a complement to operating expenses provided in accordance with GAAP because management believes non-GAAP operating expenses help indicate underlying trends in the company's business, are important in comparing current results with prior period results and provide additional information regarding the company's financial position. Management also uses non-GAAP operating expenses to establish budgets and operational goals that are communicated internally and externally and to manage the company's business and to evaluate its performance.

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 for, and design and conduct of, the Phase 3 clinical trial for OTIVIDEX, and expectations regarding submission for U.S. registration; timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-313; timing of results, patient recruitment and enrollment plans for, and design and conduct of, the Phase 1/2 clinical trial for OTO-413; expectations regarding the status, timing and nature of upcoming milestones; expectations regarding advancement of preclinical programs; the potential benefits of and activity under the collaboration agreement between AGTC and Otonomy, including but not limited to development and commercialization activity; expectations regarding operating expenses for 2020; expectations that current capital is sufficient to fund the company through completion of the OTIVIDEX Phase 3 trial, OTO-313 Phase 1/2 trial, and OTO-413 Phase 1/2 trial, and will support company operations into 2021; 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; the risks of the occurrence of any event, change or other circumstance that could give rise to the termination of the collaboration agreement between AGTC and Otonomy; 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; 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 November 5, 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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