Otonomy Provides Update on Clinical Trials and Development Programs

June 15, 2020

- ***Results from Phase 3 trial of OTIVIDEX® in Ménière's disease expected in first quarter of 2021***
- ***Results from Phase 1/2 trial of OTO-313 in tinnitus expected in July 2020***
- ***Results from Phase 1/2 trial of OTO-413 in hearing loss expected in fourth quarter of 2020***
- ***Current capital funds operations through all clinical trial readouts***

Conference call and webcast today at 4:30 p.m. ET

SAN DIEGO, June 15, 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 the timeline to results for the company's three ongoing clinical trials, including the Phase 3 trial of OTIVIDEX in Ménière's disease. The company will host a conference call and webcast today at 4:30 p.m. ET to review these updates.

"We have been able to mitigate the impact of the COVID-19 pandemic on our clinical trials by taking steps to ensure the integrity of data collection from enrolled patients and supporting the increasing number of sites able to reinitiate recruitment of new patients," said David A. Weber, Ph.D., president and CEO of Otonomy. "While the timing of our trial results has been adjusted due to the pandemic, what remains the same is that we have clinical trial catalysts in the coming months for three novel product candidates that each address significant unmet medical needs in neurotology for which there are no FDA-approved drug treatments. We are excited about the transformational opportunity these multiple readouts provide beginning with the announcement of our Phase 2 tinnitus results next month."

Otonomy Program Updates

- **OTIVIDEX Phase 3 clinical trial in Ménière's disease: patient enrollment is ongoing with results expected in the first quarter of 2021.** This trial is being conducted at approximately 60 trial sites dispersed across different regions of the United States and multiple countries in Europe. We believe there is minimal impact of COVID-19 on the integrity of efficacy data being collected because patients report their vertigo episodes via a daily telephone diary and compliance remains high. New patient enrollment was impacted beginning in March due to quarantine restrictions but we are now seeing renewed activity across numerous sites in multiple countries. We expect to complete patient enrollment during the third quarter of 2020 and announce results in the first quarter of 2021.

- **OTO-313 Phase 1/2 clinical trial in tinnitus: results from exploratory efficacy cohort expected in July 2020.** We have completed enrollment in the exploratory efficacy cohort of this randomized, double-blind, placebo-controlled trial and are currently conducting study completion activities. This cohort enrolled 35 patients with at least moderate tinnitus severity assessed during a two-week lead-in period using the Tinnitus Functional Index (TFI), a clinically-validated tinnitus questionnaire. Patients were randomized 1:1 to a single intratympanic injection of OTO-313 (sustained exposure formulation of the NMDA receptor antagonist gacyclidine) or placebo, and followed for eight weeks. In addition to scoring the severity of their tinnitus at regular intervals using the TFI, patients also reported their tinnitus loudness and annoyance using a daily telephone diary during the follow-up period. While not powered for statistical significance, we believe this patient number and study design will be sufficient to assess a clinical signal with OTO-313 treatment and inform next steps for the program. We expect to announce study results in July.

- **OTO-413 Phase 1/2 clinical trial in hearing loss: patient enrollment is ongoing with results expected in the fourth quarter of 2020.** This is an ascending single dose safety and exploratory efficacy study for OTO-413, a sustained exposure formulation of brain-derived neurotrophic factor (BDNF). We have successfully escalated through three dose levels totaling 24 patients and recently initiated enrollment for the high dose cohort. We expect to enroll approximately 16 patients in this cohort, randomized 3:1 for a single intratympanic injection of OTO-413 or placebo. Patients enrolled in this trial have a speech-in-noise hearing deficit measured at baseline and can have normal up to moderately-severe hearing loss by conventional testing. Following treatment, patients undergo repeated testing for safety and exploratory efficacy over 3 months. We expect to announce results from this trial in the fourth quarter of 2020.

- **GJB2 gene therapy program: preclinical results support selection of product candidate.** 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 beta-2 (GJB2) gene -- the

most common cause of congenital hearing loss. Preclinical results presented at the American Society of Gene & Cell Therapy (ASGCT) meeting in May 2020 demonstrated that a gene of interest can be expressed in support cells of the cochlea, which are the relevant target cells for treating GJB2 deficiency, using novel and proprietary AAV capsids. Also, consistent gene expression can be observed in these cells for at least 12 weeks following a single local administration. These results support the selection of a product candidate for further development.

- **OTO-510: preclinical data presented for novel and proprietary class of otoprotectant agents.** Cisplatin is a potent chemotherapeutic agent that is widely used to treat a variety of cancers in adults and children, however, it is commonly associated with severe adverse effects including cisplatin-induced hearing loss (CIHL). Otonomy has presented preclinical results demonstrating varying degrees of otoprotection against CIHL for several classes of therapeutic agents. In particular, a novel class of agents that potently binds to cisplatin demonstrated greater otoprotection than anti-oxidant and anti-apoptotic molecules, and increased potency relative to other cisplatin-binding molecules currently in development.

- **OTO-6XX: preclinical development ongoing for regenerative hearing loss program.** Otonomy has demonstrated regeneration of hair cells in a preclinical proof-of-concept model using a class of small molecules formulated for sustained-exposure local delivery, and has selected a lead compound for development. The OTO-6XX program is targeting hair cell regeneration for the treatment of severe hearing loss.

- **OTIPRIO® Co-Promotion Agreement completed with ALK-Abelló, Inc. (ALK).** Otonomy recently entered a co-promotion agreement that provides ALK with an exclusive right to promote OTIPRIO for acute otitis externa (AOE) to office-based health care professionals in the United States including ear, nose and throat (ENT) physicians, pediatricians and primary care physicians. During the multi-year agreement, Otonomy will receive co-promotion fees and reimbursement of a proportion of product support costs while also retaining a share of adjusted gross profits from the sale of OTIPRIO for use in AOE.

- **Financial Guidance:**
  - **2020 Operating Expenses:** Otonomy continues to expect that non-GAAP operating expenses will be in the range of $35-$38 million, and 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 company operations to mid-2021, through readouts for our three ongoing clinical trials.

Webcast and Conference Call

Otonomy management will host a webcast and conference call regarding these program updates at 4:30 p.m. ET / 1:30 p.m. PT today. The live call may be accessed by dialing (877) 305-6769 for domestic callers and (678) 562-4239 for international callers with conference ID code number: 3655435. A live webcast of the call will be available online in the investor relations section of Otonomy's website at www.otonomy.com and will be archived there for 30 days.

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 timing of results, patient recruitment and activity for, conduct of, and the impact of COVID-19 on, ongoing clinical trials; the potential benefits and opportunities of, and activities under the collaboration agreement between Otonomy and AGTC and the co-promotion agreement between Otonomy and ALK; expectations regarding preclinical programs, including development activities; expectations regarding operating expenses for 2020 and cash runway; 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 give rise to the termination of the collaboration agreement between AGTC and Otonomy or the co-promotion agreement between ALK and Otonomy, 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; 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; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on May 7, 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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