Otonomy and AGTC to Present Preclinical Proof-of-Concept Results for OTO-825 Gene Therapy at ASGCT Annual Meeting

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AAV-mediated gene therapy rescues hearing and cochlear damage in two preclinical models of congenital hearing loss caused by GJB2 deficiency

SAN DIEGO, April 28, 2021 (GLOBE NEWSWIRE) -- Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced the upcoming presentation of preclinical proof-of-concept data for OTO-825 at the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting on May 13, 2021. OTO-825 is the clinical candidate targeting the gap junction beta-2 (GJB2) gene developed under the company's collaboration with Applied Genetic Technologies Corporation (Nasdaq: AGTC). Mutations in the GJB2 gene are the most common cause of congenital hearing loss and typically result in moderate to severe hearing impairment.

"We are excited to present these preclinical results for OTO-825 that build on our previous presentations demonstrating gene expression in support cells of the cochlear, which are the target cells for GJB2 gene therapy, using novel AAV vectors identified through our collaboration with AGTC," said Alan C. Foster, Ph.D., chief scientific officer of Otonomy. "Based on these encouraging results that demonstrate hearing recovery and improved cochlear morphology following OTO-825 administration, the companies have initiated IND-enabling activities and look forward to providing additional details of the program in the next several months."

The oral presentation entitled "AAV-mediated GJB2 gene therapy rescues hearing loss and cochlear damage in a mouse model of congenital hearing loss caused by conditional Connexin26 knockout" by Mathur et al., will be presented on May 13 at 6:30 p.m. EDT.

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 with a focus on 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-825; and statements by Otonomy's chief scientific officer.

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; Otonomy's ability to obtain additional financing; 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 and the nonclinical and clinical results for its product candidates, which may not support further development; 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, including its collaboration agreement with AGTC, 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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