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Media Contact

Heidi Chokeir, Ph.D.

Russo Partners

O (619) 528-2217

M (858) 380-6584

heidi.chokeir@russopartnersllc.com

Otonomy Receives FDA Clearance to Initiate Clinical Trial In Patients with Ménière's Disease

Clinical Trial is First for a Sustained Release Otic Injection

SAN DIEGO, Feb. 17, 2010 – Otonomy, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted clearance of the company's Investigational New Drug (IND) application for the clinical trial of OTO-104 in patients with Ménière's disease, a debilitating disorder of the inner ear affecting balance and hearing.

The FDA clearance enables Otonomy to move forward with the first clinical trial of a sustained release drug delivered by direct otic injection. Using an approach called intratympanic (IT) injection, otolaryngologists deposit drug into the middle ear via a small perforation in the tympanic membrane (eardrum). IT drug delivery results in increased drug exposure to the inner ear where the organs for balance and hearing are located, and minimizes systemic exposure that can cause side effects.

"This marks an important milestone for the company and completes our rapid transition to a clinical-stage organization after less than eighteen months from the start of OTO-104 development", said Jay Lichter, Ph.D., CEO and co-founder of Otonomy. "Furthermore, this advancement demonstrates the utility of our novel, patent-protected formulation approach and enables us to move other development programs toward clinical trials."

The study is a prospective, randomized, placebo-controlled, multicenter, Phase 1b study of OTO-104 given as a single IT injection in subjects with unilateral Ménière's disease. While the primary endpoint of the study is safety and tolerability, a number of efficacy endpoints will be

monitored, including the frequency of vertigo attacks experienced by patients pre- and post-treatment.

“Intermittent attacks of vertigo, hearing loss, tinnitus, and aural fullness can be very disruptive and debilitating for Ménière’s disease patients,” said Jeffrey Harris, M.D., Ph.D., chief of the Division of Otolaryngology-Head & Neck Surgery at University of California San Diego, and a co-founder of Otonomy. “Although there are no FDA-approved drug treatments to control these symptoms, IT steroid injections appear to provide relief for many patients as demonstrated in numerous independent physician-sponsored clinical studies.”

OTO-104 is a proprietary formulation of the steroid dexamethasone designed to provide sustained drug release to the inner ear from a single IT injection. A key component of this formulation is a thermosensitive gel which increases residence time in the middle ear thereby enabling higher levels of drug exposure to the inner ear. Preclinical studies confirm the extended release profile of OTO-104 and significant advantage over aqueous formulations which rapidly drain from the middle ear through the eustachian tube. Sustained release is important to maximize therapeutic effect, enhance drug distribution to the inner ear, and reduce response variability.

About Ménière’s Disease

Ménière's disease is a disorder of the inner ear affecting balance and hearing. It is named after the French physician Prosper Ménière, who first described the syndrome in 1861. This debilitating disease is characterized by episodes of vertigo, fluctuations in hearing, tinnitus and aural fullness. The exact cause of Ménière's disease is not known, and there is no FDA-approved drug treatment. Approximately 600,000 patients have been diagnosed with Ménière's disease in the United States.

About Otonomy, Inc.

Otonomy is a clinical stage biopharmaceutical company developing novel drug therapies for disorders of the inner and middle ear such as Ménière's disease, sudden sensorineural hearing loss, noise-induced hearing loss, age-related hearing impairment, tinnitus and otitis media. The company’s core technology is a sustained release formulation developed for optimal delivery of drugs to the middle ear from a single IT administration. Broad applicability of this delivery and formulation technology has already been established across a number of therapeutic classes. Otonomy is advancing two products into active development. The first, OTO-104, is a sustained release formulation of the steroid dexamethasone. A clinical trial is being initiated in Ménière’s disease patients, and future studies are being planned for acute hearing loss. Otonomy’s second product, OTO-203, is a sustained release anti-infective being developed for the treatment of otitis media. Both OTO-104 and OTO-203 are covered by an extensive patent estate filed by Otonomy to broadly protect the delivery of sustained release drug treatments for otic disorders.