



Otonomy obtains rights to gacyclidine data from Ipsen to support development of OTO-311 as a treatment for tinnitus

San Diego (United States) and Paris (France), November 6th, 2014 - Otonomy, Inc. (Nasdaq: OTIC), a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics for diseases and disorders of the inner and middle ear, and Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven pharmaceutical company, today announced that they have entered into an exclusive licensing agreement enabling Otonomy to utilize Ipsen's gacyclidine data in the development and registration of OTO-311. OTO-311 is Otonomy's sustained-exposure formulation of gacyclidine, an N-Methyl-D-Aspartate (NMDA) receptor antagonist, in development for the treatment of tinnitus.

"We are pleased to complete this agreement with Ipsen which supports our plan to initiate OTO-311 clinical trials next year," said **David A. Weber, Ph.D., President and CEO of Otonomy**. *"Additionally, we believe that the clinical data set generated by Ipsen provides important insights into gacyclidine's systemic profile that will inform our development of locally administered OTO-311 for the treatment of tinnitus."*

"Tinnitus is a debilitating disorder for which there are no FDA-approved drug treatments," said **Claude Bertrand, Executive Vice President, Chief Scientific Officer of Ipsen**. *"Through this agreement, we are pleased that prior R&D studies with gacyclidine, conducted by Ipsen, could support Otonomy's development of OTO-311 for use in a population where there is a need for new therapeutic options."*

About the agreement

Under the terms of the agreement, Otonomy will have an exclusive license to use Ipsen's clinical and non-clinical gacyclidine data to support worldwide development and regulatory filings for OTO-311. These data include non-clinical studies which supported Ipsen's initiation of clinical studies for systemic administration of gacyclidine, and clinical data from several Phase 1 and Phase 2 clinical trials conducted by Ipsen. In total, more than 300 patients were treated with systemic gacyclidine as a potential neuroprotectant in various neurologic trauma indications. Financial terms of the agreement were not disclosed.

About gacyclidine

Gacyclidine is a potent and selective antagonist of the NMDA receptor. Clinical studies, including pilot studies conducted with gacyclidine, support the use of NMDA receptor antagonists as a potential treatment for tinnitus. OTO-311 utilizes Otonomy's proprietary drug delivery technology to achieve sustained exposure of gacyclidine in the inner ear from a single intratympanic (IT) injection.



About Tinnitus

Tinnitus is the medical term for hearing noise when there is no outside source of the sound. It is often described as a ringing in the ear but can also sound like roaring, clicking, hissing or buzzing. The American Tinnitus Association¹ reports that approximately 16 million patients in the United States have tinnitus symptoms severe enough to seek medical attention, and about two million patients cannot function on a normal day-to-day basis. Furthermore, the United States Department of Defense reports that tinnitus accounts for the most prevalent service-connected disability among veterans and that the costs of service-related tinnitus are estimated to exceed \$2 billion². While the most common cause of tinnitus is exposure to loud noise, a number of other factors can be involved including heart or blood vessel problems, hormonal changes in women, ear and sinus infections, certain medications and thyroid problems. People with severe tinnitus may have trouble hearing, working, and sleeping. At this time, there is no cure for tinnitus and there are no FDA-approved drugs for treating this debilitating condition.

About Otonomy

Otonomy is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics for diseases and disorders of the ear. Otonomy's proprietary technology provides sustained exposure of drugs to the middle and inner ear following a single intratympanic injection. Otonomy has three product candidates in development. AuriPro™ is an antibiotic that has completed Phase 3 clinical trials in pediatric patients with middle ear effusion at the time of tympanostomy tube placement surgery. OTO-104 is a steroid that is in the first of two pivotal clinical studies for the treatment of patients with Ménière's disease. OTO-311 is an NMDA receptor antagonist in development as a treatment for tinnitus. For additional information, please visit www.otonomy.com.

About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by 3 franchises: neurology, endocrinology and uro-oncology. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2013, R&D expenditure totaled close to €260 million, representing more than 21% of Group sales. Moreover, Ipsen also has a significant presence in primary care. The Group has close to 4,600 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit www.ipsen.com.

Otonomy 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 include, among others, statements concerning Otonomy's plan to initiate OTO-311 clinical trials next year and Otonomy's belief that the clinical data set generated by Ipsen provides important insights into gacyclidine's systemic profile that will inform Otonomy's development of locally administered OTO-311 for the treatment of tinnitus. Forward-looking statements reflect the Company's current views with respect to certain current and future events and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially. Risks, and uncertainties include, but are not limited to, the risk that clinical drug development involves a lengthy and expensive process with uncertain outcome. The risks, uncertainties and assumptions

¹ <http://www.ata.org/for-patients/faqs>

² <http://hearing.health.mil/HearingLoss101/StatsandFigures.aspx>



referred to above are discussed in detail in our reports filed with the Securities and Exchange Commission, including our Prospectus filed on August 13, 2014. The Company does not undertake to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date hereof except as may be required by law.

Ipsen Forward Looking Statements

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.



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