



## **CORRECTION: Axovant Announces Negative Results for Intepirdine in Phase 2b HEADWAY and Pilot Phase 2 Gait and Balance Studies; Positive Trends in Efficacy Seen in Pilot Phase 2 Nelotanserin Study**

January 9, 2018

BASEL, Switzerland, Jan. 09, 2018 (GLOBE NEWSWIRE) -- Axovant Sciences (NASDAQ:AXON) today announced a correction to the data related to the Company's investigational drug nelotanserin previously reported in its January 8, 2018 press release. In the results of the pilot Phase 2 Visual Hallucination study, the post-hoc subset analysis of patients with a baseline Scale for the Assessment of Positive Symptoms - Parkinson's Disease (SAPS-PD) score of greater than 8.0 was misreported. The previously reported data for this population (n=19) that nelotanserin treatment at 40 mg for two weeks followed by 80 mg for two weeks resulted in a 1.21 point improvement (p=0.011, unadjusted) were incorrect. While nelotanserin treatment at 40 mg for two weeks followed by 80 mg for two weeks did result in a 1.21 point improvement, the p-value was actually 0.531, unadjusted. Based on these updated results, the Company will continue to discuss a larger confirmatory nelotanserin study with the U.S. Food and Drug Administration (FDA) that is focused on patients with dementia with Lewy bodies (DLB) with motor function deficits. The Company may further evaluate nelotanserin for psychotic symptoms in DLB and Parkinson's disease dementia (PDD) patients in future clinical studies.

### **About the Nelotanserin Visual Hallucinations Study**

This multi-center, randomized, double-blind, placebo-controlled, pilot Phase 2 crossover study evaluated the safety, tolerability, and efficacy of nelotanserin over a four-week treatment period and enrolled 30 patients with DLB and PDD who were experiencing frequent and recurrent visual hallucinations. With the crossover design, every patient received placebo for four weeks and nelotanserin for four weeks (two weeks of a 40 mg dose followed by two weeks of an 80 mg dose). Study participants were allowed to be on stable antipsychotic treatments, stable anti-Parkinson's disease treatments, and stable background cholinesterase inhibitor therapy for at least four weeks prior to screening.

The prespecified primary endpoint of the pilot study was safety including assessment of extrapyramidal symptoms as measured by the change in UPDRS scores. In addition, there were multiple exploratory efficacy assessments in the study that included UPDRS Part III, SAPS, SAPS-PD, PGIC-VH and an internally developed patient diary, that evaluated the effects of nelotanserin over a four-week treatment period. Individuals who completed this study were eligible to receive nelotanserin in an extension study.

### **About DLB**

Dementia with Lewy bodies (DLB) is a progressive neurodegenerative disorder characterized by the aggregation of Lewy bodies, abnormal deposits of a protein called alpha-synuclein. Lewy bodies build up in areas of the brain that regulate behavior, cognition and movement. DLB is the second most prevalent cause of neurodegenerative dementia in elderly patients. Approximately 1.1 million patients in the United States have DLB. Patients with DLB can present with a range of symptoms including fluctuations in cognition, attention and alertness; Parkinson's symptoms; visual hallucinations; and REM sleep behavior disorder (RBD), in which people physically act out their dreams, impacting their quality of life and endangering their bed partners. No therapies are approved for the treatment of DLB in the United States or Europe.<sup>1</sup>

### **About Nelotanserin**

Nelotanserin is a selective inverse agonist of the 5-HT<sub>2A</sub> receptor<sup>ii</sup> that was discovered by Arena Pharmaceuticals, Inc.

### **About Axovant Sciences**

Axovant is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative medicines to broadly address multiple forms of dementia and related neurological disorders. Axovant is developing a pipeline of product candidates that focuses on the cognitive, functional and behavioral aspects of debilitating conditions such as Alzheimer's disease, Lewy body dementia and other neurological disorders. For more information, visit [www.axovant.com](http://www.axovant.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding Axovant's plans for the development of nelotanserin. Forward-looking statements can be identified by the words "believe," "anticipate," "continue," "estimate," "project," "expect," "plan," "potential," "intends," "will," "would," "could," "should" or the negative or plural of these words or other similar expressions that are predictions or indicate future events, trends or prospects. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of our product development activities and clinical trials, increased regulatory requirements, and interim results or other preliminary analyses do not ensure that later or final results in a clinical trial or in related or similar clinical trials will replicate those interim results. There can be no assurance that any of our product candidates will ever receive regulatory approval or be successfully commercialized. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Axovant's business in general, see the "Risk Factors" section of our quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 2, 2017, and other filings that Axovant makes with the SEC from time to time. These forward-looking statements are based on information available to Axovant as of the date of this press release and speak only as of the date of this release. Axovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

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ii The Journal of Pharmacology and Experimental Therapeutics. Nelotanserin, a novel selective human 5-hydroxytryptamine<sub>2A</sub> inverse agonist for the treatment of insomnia. <http://www.ncbi.nlm.nih.gov/pubmed/19841476>. 2010 Jan;332(1):281-90. doi: 10.1124/jpet.109.160994. Epub 2009 Oct 19.

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