Axovant to Present Patient Function and Independence Data Analyses from Phase 2b Study of Investigational Treatment Intepirdine in Alzheimer’s Disease at CTAD 2016

December 5, 2016

HAMILTON, Bermuda, Dec. 5, 2016 /PRNewswire/ -- Axovant Sciences Ltd. (NYSE: AXON), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today announced that data on the investigational use of intepirdine for the treatment of Alzheimer's disease will be presented at the 2016 Clinical Trials in Alzheimer's Disease (CTAD) Meeting on Friday, December 9, 2016 in San Diego. Intepirdine presentations at CTAD will show results of both simple and complex measures of activities of daily living (ADLs) and overall functional dependence – important indicators of treatment benefit.

"The continued ability to independently perform everyday tasks such as making meals and doing laundry is critical to the overall well-being of individuals and families affected by Alzheimer's disease," said Axovant Chief Development Officer Dr. Lawrence Friedhoff. "Axovant is currently evaluating the effectiveness of intepirdine on the core symptoms of dementia, cognition and function, in our MINDSET trial. In addition to using traditional scales, we are also examining the overall impact of treatment using a more specific scale, called the Dependence Scale, which measures a person's ability to maintain their independence. We will be presenting an analysis from our Phase 2b trial related to this topic for the first time at CTAD."

Intepirdine is an investigational 5-HT6 receptor antagonist in development as a potential treatment for individuals with Alzheimer's disease on a stable background of donepezil therapy. It is also in development as a potential treatment for dementia with Lewy bodies. Axovant has incorporated the Dependence Scale into the ongoing intepirdine trials in both Alzheimer's disease and dementia with Lewy bodies. Results from both trials are expected in 2017.

**Intepirdine Function and Independence Data Presentations**

**Oral Presentation:** December 9, 2016, 12:15 p.m. PST

- "An Assessment of Dependence Level Progression Using a Conversion Algorithm of ADCS-ADL to Dependence Scale and Data From a Double Blind Placebo Controlled Trial of Intepirdine (RVT-101)"

**Poster Presentations:** December 9, 2016, 12:30 p.m. to 1:30 p.m. PST

- "The Efficacy of Intepirdine (RVT-101), a 5-HT6 Receptor Antagonist, as an Adjunct to Donepezil in Adults with Mild-to-Moderate Alzheimer's Disease: Completer Analysis of a Phase 2b Study"
- "Intepirdine (RVT-101) as an Adjunct to Donepezil in Adults with Mild-to-Moderate Alzheimer's Disease: ADCS-ADL Subscale Analyses"

In addition, Axovant will make an oral presentation on December 9, 2016 at 8:15 a.m. PST titled "Drug Interaction between Intepirdine (RVT-101), a 5-HT6 Receptor Antagonist, and Memantine in Healthy Subjects."

**About MINDSET**

MINDSET is a Phase 3 international, multi-center, double-blind, placebo-controlled clinical study designed to evaluate the safety, tolerability, and efficacy of intepirdine in patients with mild-to-moderate Alzheimer's disease. The 24-week trial will compare 35 mg, once-daily oral doses of intepirdine to placebo in approximately 1,150 individuals with mild-to-moderate Alzheimer's disease on a stable background of donepezil therapy. The primary efficacy evaluations are the Alzheimer's Disease Assessment Scale - cognitive subscale (ADAS-cog) and the Alzheimer's Disease Cooperative Study - Activities of Daily Living scale (ADCS-ADL), each of which has been used as respective endpoints to obtain regulatory approval of currently-marketed Alzheimer's disease treatments in the United States and Europe.

The MINDSET trial is being conducted pursuant to a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

The MINDSET trial is designed to confirm the results of a 684-patient Phase 2b international, multi-center, double-blind placebo-controlled study in which patients on a stable background of donepezil therapy receiving 35 mg of intepirdine were observed to have statistically significant improvements in their ADAS-cog and ADCS-ADL scores as compared to patients receiving donepezil alone.

**About Axovant Sciences**

Axovant Sciences is a leading clinical-stage biopharmaceutical company focused on acquiring, developing, and commercializing novel therapeutics for the treatment of dementia. Axovant intends to develop a pipeline of product candidates to comprehensively address the cognitive, functional, and behavioral aspects of dementia and related neurological disorders. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of this condition.

**Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding Axovant's clinical development and regulatory strategy, including for intepirdine. 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; the approval and commercialization of our product candidates, including intepirdine and nelotanserin; and increased regulatory requirements. These statements are subject to the risk that clinical trial data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share Axovant's views of the clinical study data. The products discussed are investigational and not approved and there can be no assurance that the clinical programs, including those for intepirdine or nelotanserin will be successful in demonstrating safety and/or efficacy, that we will not encounter problems or delays in clinical development, or 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 on November 7, 2016, 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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