FDA Grants Fast Track Designation to Axovant's Nelotanserin for Visual Hallucinations in Dementia with Lewy Bodies

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BASEL, Switzerland, June 19, 2017 /PRNewswire/ -- Axovant Sciences (NYSE: AXON) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its investigational drug nelotanserin for the treatment of visual hallucinations disorder in dementia with Lewy bodies (DLB).

Dementia with Lewy bodies is the second-leading form of progressive dementia and affects over 1 million people in the United States. Currently, there are no approved therapies for the disease in the United States or in Europe.

"We are pleased that the FDA has granted nelotanserin Fast Track designation," said David Hung, M.D., chief executive officer of Axovant. "Patients in the United States with DLB who experience frequent visual hallucinations have no approved treatment options and we hope to work closely with the FDA as we seek to address the needs of this underserved patient population as quickly and efficiently as possible."

Nelotanserin is a novel $5HT_{2A}$ inverse agonist being investigated in a Phase 2 double-blind, randomized, placebo-controlled crossover safety study involving more than 20 subjects diagnosed with Lewy body dementia who experience frequent visual hallucinations. In addition, nelotanserin is being investigated in a Phase 2 double-blind, randomized, placebo-controlled study involving up to 60 subjects diagnosed with Lewy body dementia who have REM sleep disorder.

Fast Track designation is a process designed to facilitate the development, and expedite the review, of important new drugs to treat serious conditions which fill unmet medical needs in order to get them to patients earlier. Early and frequent communications between the FDA and the sponsor throughout the drug development and review process help ensure that questions are resolved quickly, often leading to earlier drug approval.

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 late- and early-stage 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.

Forward-Looking Statement
This press release contains forward-looking statements, including statements regarding Axovant's expectations about timing of the results for the Phase 3 MINDSET study of intepirdine in patients with Alzheimer's disease, the Phase 2b HEADWAY-DLB study of intepirdine in patients with DLB, the Phase 2 gait and balance study, DLB and PDD, the Phase 2 study of nelotanserin in patients with LBD suffering from visual hallucinations, the Phase 2 study of nelotanserin in patients with LBD suffering from RBD, the proof of concept and related studies of RVT-103 and RVT-104 in patients with Alzheimer's disease and DLB, and other elements of its clinical development and regulatory strategy. 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 intepirdine, nelotanserin, RVT-103, and RVT-104; 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. There can be no assurance that the clinical programs for intepirdine, nelotanserin, RVT-103, or RVT-104 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 annual report on Form 10-K filed with the Securities and Exchange Commission on June 13, 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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SOURCE Axovant Sciences

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