Axovant Announces Dosing of First Patient in Second Cohort of SUNRISE-PD Phase 2 Trial of AXO-Lenti-PD

April 30, 2019

-Up to 6 patients to be enrolled in the second cohort, initial data expected in fourth quarter 2019-

-Oral presentation at the Annual Meeting of the American Society of Gene and Cell Therapy-

BASEL, Switzerland, April 30, 2019 (GLOBE NEWSWIRE) -- Axovant Gene Therapies Ltd. (NASDAQ: AXGT), a clinical-stage company developing innovative gene therapies, announced the dosing of the first patient of the second cohort in the SUNRISE-PD Phase 2 trial of AXO-Lenti-PD in Parkinson's disease patients. To date, the patient has experienced no complications related to the surgery or to administration of the vector and has been discharged home as planned with no serious adverse events observed. Up to 6 patients will be dosed in this second cohort, at a dose of 1.4 x 10^7 TU, which is approximately 3-fold higher than the dose evaluated in the first cohort. The primary outcome measure in this second cohort is safety and tolerability and a key efficacy measure will be UPDRS Part III (motor) OFF score. Axovant expects initial data from this cohort to be available in the fourth quarter of 2019.

"We are pleased to begin enrolling additional patients in the SUNRISE-PD study at a higher dose level, following encouraging 3-month data from the first cohort," said Dr. Gavin Corcoran, Axovant's Chief Research and Development Officer. "We look forward to exploring the full clinical potential of AXO-Lenti-PD in patients with Parkinson's disease, building upon the safety profile and improvements in motor symptoms that have been observed in 17 patients evaluated across the ProSavin and AXO-Lenti-PD programs. Our focus remains on the rapid execution of the clinical study to evaluate this important potential therapy in patients with Parkinson's disease."

These details will be included in Axovant's oral presentation of previously announced clinical results from the AXO-Lenti-PD study at the 22nd Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) taking place in Washington, DC, April 29 - May 2, 2019.

Title: AXO-LENTI-PD: a second-generation lentiviral gene therapy for the treatment of Parkinson's Disease (Abstract #222)
Session date/time: April 30, 2019, 3:30-3:45pm ET
Location: Monroe

Additional information on the meeting can be found on the ASGCT website: http://www.asgct.org

About Axovant Gene Therapies

Axovant, part of the Roivant family of companies, is a clinical-stage gene therapy company focused on developing a pipeline of innovative product candidates for debilitating neurological and neuromuscular diseases. The company's current pipeline of gene therapy candidates targets GM1 gangliosidosis, GM2 gangliosidosis (including Tay-Sachs disease and Sandhoff disease), Parkinson's disease, oculopharyngeal muscular dystrophy (OPMD), amyotrophic lateral sclerosis (ALS) and frontotemporal dementia. Axovant is focused on accelerating product candidates into and through clinical trials with a team of experts in gene therapy development and through external partnerships with leading gene therapy organizations. For more information, visit www.axovant.com.

About Roivant

Roivant Sciences aims to improve health by rapidly delivering innovative medicines and technologies to patients. It does this by building Vants – nimble, entrepreneurial biotech and healthcare technology companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization. For more information, please visit www.roivant.com.

Forward Looking Statements and Information

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "might," "will," "expect," "plan," and other similar expressions are intended to identify forward-looking statements. The product candidate discussed is investigational and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Axovant will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Axovant's management that, although Axovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Axovant expected. In addition, Axovant's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Axovant's product candidates; the availability or commercial potential of product candidates; and Axovant's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Axovant's most recent Quarterly Report on Form 10-Q for the quarterly period ended December 31, 2018, filed with the Securities and Exchange Commission on February 7, 2019, as updated by its subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Axovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Contacts:

Media
Mike Beyer
Sam Brown Inc.
(312) 961-2502
mikebeyer@sambrown.com
media@axovant.com

Investors
Tricia Truehart
Axovant
(631) 892-7014
investors@axovant.com

Source: Axovant Sciences Ltd.