ACADIA Pharmaceuticals Announces Publication in The Lancet of Pivotal Phase III Parkinson's Disease Psychosis Trial with Pimavanserin

November 1, 2013

SAN DIEGO--(BUSINESS WIRE)--Oct. 31, 2013-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on innovative treatments that address unmet medical needs in neurological and related central nervous system disorders, today announced the publication of data from its pivotal Phase III -020 Study with pimavanserin in patients with Parkinson's disease psychosis (PDP) in the November 1, 2013 online issue of *The Lancet*. In the -020 Study, pimavanserin demonstrated significant and clinically meaningful benefits and was safe and well tolerated in patients with PDP. Pimavanserin significantly reduced psychosis and maintained motor control in patients with PDP. Significant benefits were also observed in exploratory measures of nighttime sleep, daytime wakefulness and caregiver burden.

"Among Parkinson's patients, psychosis causes great distress for patients and caregivers and is the leading cause of institutionalization," said Jeffrey Cummings, M.D., Sc.D., Director of Cleveland Clinic Lou Ruvo Center for Brain Health, and lead author. "These data indicate that pimavanserin, a selective 5-HT_{2A} inverse agonist, confers a meaningful clinical benefit in patients with PDP and has the potential to be an important new treatment option for this condition for which there is no approved therapy in the U.S."

Pimavanserin met the primary endpoint in the -020 Study by demonstrating highly significant improvement in psychosis compared to placebo on the 9-item SAPS-PD scale (p=0.001), which was assessed by central, independent raters. The mean change in SAPS-PD score represented a 37% improvement for pimavanserin versus 14% for placebo (p<0.001). Pimavanserin also demonstrated significant improvement on the full 20-item SAPS (hallucinations plus delusions) measure (p=0.001) and on each of the separate hallucinations and delusions domains in supportive analyses.

Significant improvements were observed for pimavanserin over placebo on additional investigator-assessed secondary measures of psychosis benefit, including the Clinical Global Impression Severity, or CGI-S, scale (p<0.001), and the Clinical Global Impression Improvement, or CGI-I, scale (p=0.001). The proportion of CGI-I responders was also higher for pimavanserin versus placebo, (49% vs. 26%, p=0.002). Pimavanserin met the key secondary endpoint for motoric tolerability as measured using Parts II and III of the Unified Parkinson's Disease Rating Scale, or UPDRS. Caregivers in the pimavanserin group also reported significant reduction in caregiver burden (p=0.002), and participants reported significant improvements on nighttime sleep (p=0.045) and daytime wakefulness (p=0.012) for pimavanserin over placebo in exploratory analyses.

Consistent with previous studies, pimavanserin was well tolerated in the -020 Study with no significant safety concerns or impairment in motor function. The most common treatment-emergent adverse events were urinary tract infection (13.5% PIM vs. 11.7% PBO) and falls (10.6% PIM vs. 8.5% PBO). Although adverse event discontinuations were higher in the pimavanserin group compared to placebo, overall drop-outs in the -020 Study were low compared to other reported studies in PDP and similar neuropsychiatric conditions.

"The -020 Study results presented in *The Lancet* suggest that pimavanserin has the potential to provide a safe, well-tolerated, and effective alternative to existing antipsychotic drugs. Current atypical antipsychotics are often used off-label to treat PDP despite increasing evidence that they are associated with serious safety issues and are poorly tolerated in this fragile and elderly patient population," said Clive Ballard, M.D., Professor of Age Related Diseases at King's College London.

Phase III -020 Study Design

The pivotal Phase III trial, referred to as the -020 Study, was a multi-center, double-blind, placebo-controlled study designed to evaluate the efficacy, tolerability and safety of pimavanserin as a treatment for patients with Parkinson's disease psychosis. A total of 199 patients were enrolled in the study and randomized on a one-to-one basis to receive either 40 mg of pimavanserin or placebo once-daily for six weeks, following a two-week screening period including brief psycho-social therapy. Patients also received stable doses of their existing anti-Parkinson's therapy throughout the study. The primary endpoint of the -020 Study was antipsychotic efficacy as measured using the "SAPS–PD" scale, which consists of nine items from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms (SAPS). Additional secondary and supportive measures of efficacy were measured using the Clinical Global Impression Severity (CGI-S) scale, the Clinical Global Impression Improvement (CGI-I) scale, and the full 20-item SAPS. Exploratory measures of nighttime sleep, daytime wakefulness, and caregiver burden were measured using the Scales for Outcome in Parkinson's Disease - Nighttime Sleep (SCOPA-NS), the Scales for Outcome in Parkinson's Disease - Daytime Sleep (SCOPA-DS), and the Caregiver Burden Scale (CBS), respectively. Motoric tolerability was a key secondary endpoint in the study and was measured using Parts II and III of the Unified Parkinson's Disease Rating Scale (UPDRS).

About Pimavanserin

Pimavanserin is ACADIA's proprietary small molecule that acts selectively as an antagonist/inverse agonist on serotonin 5-HT_{2A} receptors. ACADIA has successfully completed a pivotal Phase III trial with pimavanserin for Parkinson's disease psychosis (PDP), potentially positioning it to be the first drug approved in the United States for the treatment of this disorder. Pimavanserin is also in Phase II development for Alzheimer's disease psychosis (ADP) and has completed a Phase II trial as a co-therapy in schizophrenia. Pimavanserin is formulated as a tablet and is administered orally once-a-day. ACADIA discovered pimavanserin and holds worldwide rights to this new chemical entity.

About Parkinson's Disease Psychosis

According to the National Parkinson's Foundation, about one million people in the United States and from four to six million people worldwide suffer from Parkinson's disease. Parkinson's disease psychosis, or PDP, is a debilitating disorder that develops in up to 60 percent of patients with Parkinson's disease. Currently, there is no FDA-approved therapy to treat PDP in the United States. PDP, commonly consisting of visual hallucinations and delusions, substantially contributes to the burden of Parkinson's disease and deeply affects the quality of life of patients. PDP is associated with

increased caregiver stress and burden, nursing home placement, and increased morbidity and mortality. There is a large unmet medical need for new therapies that will effectively treat PDP without compromising motor control in patients with Parkinson's disease.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on innovative treatments that address unmet medical needs in neurological and related central nervous system disorders. ACADIA has a pipeline of product candidates led by pimavanserin, which is in Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. ACADIA also has clinical-stage programs for chronic pain and glaucoma in collaboration with Allergan, Inc. and two advanced preclinical programs directed at Parkinson's disease and other neurological disorders. All product candidates are small molecules that emanate from discoveries made at ACADIA. ACADIA maintains a website at www.acadia-pharm.com to which ACADIA regularly posts copies of its press releases as well as additional information and through which interested parties can subscribe to receive email alerts.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements related to the progress and timing of ACADIA's drug discovery and development programs, either alone or with a partner, including clinical trials, the benefits to be derived from ACADIA's product candidates, in each case including pimavanserin, the potential for pimavanserin to be approved for PDP or be an important new treatment option for PDP sufferers, and the potential of pimavanserin to provide a safe, well-tolerated, and effective alternative to existing antipsychotic drugs. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug discovery, development and commercialization, and collaborations with others, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2012 as well as ACADIA's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

Source: ACADIA Pharmaceuticals Inc.

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