ACADIA Announces Presentation of Data from Its Pivotal Phase III Parkinson's Disease Psychosis Study with Pimavanserin at the American Academy of Neurology Annual Meeting

March 21, 2013

SAN DIEGO--(BUSINESS WIRE)--Mar. 20, 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, announced that Jeffrey Cummings, M.D., Sc.D., Director of Cleveland Clinic Lou Ruvo Center for Brain Health, presented detailed results today from ACADIA's pivotal Phase III -020 Study with pimavanserin in patients with Parkinson's disease psychosis at the Emerging Science session of the 65 th American Academy of Neurology (AAN) Annual Meeting. The analysis of the full data set from the Phase III -020 Study showed robust and consistent efficacy of pimavanserin across a wide array of study measures and confirmed the positive top-line results previously reported.

Pimavanserin met the primary endpoint in the -020 Study by demonstrating highly significant antipsychotic efficacy on the 9-item SAPS-PD scale (p=0.001). Pimavanserin also 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. Dr. Cummings presented new data from the -020 Study showing highly significant improvements in all secondary efficacy measures, including the Clinical Global Impression Severity, or CGI-S, scale (p<0.001), the Clinical Global Impression Improvement, or CGI-I, scale (p=0.001), and a CGI-I responder analyses (p=0.002). The CGI-I responder results showed that approximately twice as many subjects in the pimavanserin treatment arm, as compared to placebo, were rated as very much improved or much improved at the conclusion of the study. In addition, pimavanserin demonstrated significant improvements using the full 20-item SAPS scale and each of the separate hallucinations and delusions domains in supportive analyses. Statistically significant benefits were also observed in exploratory measures of nighttime sleep, daytime wakefulness, and caregiver burden.

"The significant and consistent results observed across measures in the Phase III -020 Study are impressive and potentially very encouraging for Parkinson's patients who suffer from the psychosis frequently associated with this disease," said Dr. Jeffrey Cummings. "Importantly, regardless of whether assessments were performed by independent blinded raters, site investigators or caregivers, clear benefits were observed and clinical measures were well aligned. The results of this study suggest that a selective, non-dopaminergic-based therapy has the potential to transform the standard of care by providing an effective, safe and well tolerated treatment for patients suffering from this large unmet medical need."

Safety and Tolerability Profile

Consistent with previous studies, pimavanserin was safe and well tolerated in the -020 Study. The most common adverse events were urinary tract infection (11.7% PBO vs. 13.5% PIM) and falls (8.5% PBO vs. 10.6% PIM). Adverse events were generally characterized as mild to moderate in nature. The only serious adverse events that occurred in more than one patient were urinary tract infection (1-PBO vs. 3-PIM) and psychotic disorder (0-PBO vs. 2-PIM). Over ninety percent of the patients who completed the clinical phase of this trial elected to roll over into the ongoing open-label safety extension study. Patients were only eligible to participate in the extension study if the treating investigator also deemed them to be likely to benefit from continued treatment with pimavanserin.

About the Trial 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, or SAPS. These nine items have been shown to be particularly relevant to the expression of psychotic symptoms in patients with Parkinson's disease and to have high inter-rater reliability for assessment of severity. 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, or UPDRS.

About Pimavanserin

Pimavanserin is ACADIA's proprietary small molecule that acts selectively as an antagonist/inverse agonist on serotonin 5-HT $_{2A}$ receptors and is in Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. Pimavanserin can be taken orally as a tablet 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 benefit of pimavanserin to PDP sufferers, and the potential of a selective, non-dopaminergic-based therapy to transform the standard of care for PDP patients by providing an effective, safe and well-tolerated treatment. 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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