ACADIA Pharmaceuticals Announces Completion of Enrollment in Phase III Pimavanserin Trial in Parkinson's Disease Psychosis

September 5, 2012

Top-Line Data Expected in November 2012

SAN DIEGO--(BUSINESS WIRE)--Sep. 5, 2012-- 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 completion of enrollment in its ongoing pivotal Phase III trial with pimavanserin in patients with Parkinson's disease psychosis (PDP). Top-line results from this trial are expected to be announced by the end of November 2012.

The Phase III trial, referred to as the -020 Study, is a multi-center, double-blind, placebo-controlled study designed to evaluate the efficacy, tolerability and safety of pimavanserin as a treatment for patients with PDP. The -020 Study incorporates several design enhancements that were guided by previous data in ACADIA's PDP program. A total of 198 patients have been enrolled in the study and were randomized on a one-to-one basis to receive either 40 mg of pimavanserin or placebo once-daily for six weeks. The primary endpoint of the -020 Study is antipsychotic efficacy as measured using nine items from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms, or SAPS. An independent group of centralized raters is used to assess the primary endpoint in the study. Motoric tolerability is a key secondary endpoint in the study and is 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 and holds worldwide rights to pimavanserin.

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 preclinical programs directed at Parkinson's disease and other neurological disorders. All of ACADIA's product candidates are small molecules that emanate from discoveries made using its proprietary drug discovery platform. 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 regarding expected timing for disclosure of top-line results from ACADIA's Phase III trial with pimavanserin in patients with PDP, as well as statements related to the progress and timing of ACADIA's drug discovery and development programs, either alone or with a partner, and the benefits to be derived from ACADIA's product candidates, in each case including pimavanserin. 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, 2011 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.

ACADIA Pharmaceuticals Inc.
Thomas H. Aasen, Executive Vice President,
Chief Financial Officer and Chief Business Officer
(858) 558-2871