ACADIA Pharmaceuticals Announces Multiple Presentations of Data from Phase III Pimavanserin Program at the 17th International Congress of Parkinson's Disease and Movement Disorders

June 18, 2013

SAN DIEGO--(BUSINESS WIRE)--Jun. 18, 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, presented data today from its Phase III program with pimavanserin for Parkinson's disease psychosis (PDP), including data from its pivotal -020 Study and the related, open-label safety extension study, at a poster session at the 17th International Congress of Parkinson's Disease and Movement Disorders, which is taking place in Sydney, Australia from June 17 - 20, 2013.

"Data from our open-label safety extension study indicate that long-term administration of pimavanserin is generally safe and well tolerated in PDP patients and suggest that duration of antipsychotic effect may be maintained for longer than the six weeks investigated in our pivotal -020 Study," said Uli Hacksell, Ph.D., ACADIA's Chief Executive Officer. "The overall efficacy and safety profile observed to date shows that pimavanserin has the potential to offer a new treatment option that may provide significant advantages relative to current antipsychotics used off-label for the treatment of PDP."

Key poster presentations:

1. "Long Term Pimavanserin Treatment for Parkinson's Disease Psychosis (PDP): An Interim Analysis of Safety and Tolerability Data from Study ACP-103-015." The interim analysis of the Phase III open-label safety extension trial (-015 Study) reflects data assembled in the database as of March 21, 2013. A total of 458 PDP patients from 14 countries with a mean age at study-entry of 71 years had rolled over into the -015 Study from the six-week pivotal, placebo-controlled efficacy, tolerability and safety trial (-020 Study) and two earlier six-week placebo-controlled trials (-012 and -014 Studies). Study evaluations occur at week 2 and at months 1, 3, 6, 9 and 12, as well as every 6 months thereafter. About half of the patients stayed in the open-label study for more than a year. The data suggest that long-term administration of 40 mg of pimavanserin is generally safe and well tolerated in patients with PDP. In addition, the rate of discontinuation due to adverse events in the -015 Study appears to be lower than that recently reported in a third-party study of patients over 40 years old who used one of four commonly prescribed atypical antipsychotic drugs.

Although there are no formal efficacy endpoints in the open-label -015 Study, antipsychotic effect was measured at one month using the SAPS-PD scale and at all study visits using the Clinical Global Impression Improvement, or CGI-I, scale, and the Clinical Global Impression Severity, or CGI-S, scale. The CGI data are intended to provide the investigator with information to determine whether patients continue to derive benefit from pimavanserin during the open-label study. Patients who entered the -015 Study from the 40 mg treatment arm of the previous six-week studies maintained about the same mean improvement in SAPS-PD scores one month later. Patients who entered the -015 Study from the placebo arm of the previous six-week studies displayed a marked improvement in mean SAPS-PD scores after one month in the -015 Study. In addition, the long-term CGI data indicate durability of treatment effect for patients remaining in the open-label study.

2. *"Improved Nighttime Sleep and Increased Daytime Wakefulness in Patients with PD Psychosis Treated with Pimavanserin."* In addition to the assessments of antipsychotic efficacy, effects on sleep and daytime wakefulness were assessed in the previously reported six-week pivotal -020 Study. Although the study did not require sleep impairment at entry, pimavanserin demonstrated a significant improvement in nighttime sleep at weeks 4 and 6 compared to placebo. Consistent with previous pimavanserin studies, this sleep improvement was not accompanied by any sedation or "hang-over effect." Instead, pimavanserin produced a significant improvement in daytime wakefulness at week 6 compared to placebo. Patients who entered the -020 Study with severe nighttime disturbances (i.e., those having a baseline score of at least 7 on the Scales for Outcome in Parkinson's Disease - Nighttime Sleep, or SCOPA-NS) benefitted the most from pimavanserin therapy and showed highly significant nighttime sleep improvements at weeks 2, 4 and 6 compared to placebo. The positive effect of pimavanserin on nighttime sleep and daytime wakefulness did not correlate with antipsychotic measures, thus indicating that the sleep and wakefulness improvements of pimavanserin seen in the -020 Study may represent treatment benefits independent from the antipsychotic efficacy.

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.

ACADIA has reported results from its pivotal Phase III -020 Study evaluating the efficacy, tolerability, and safety of pimavanserin in patients with PDP. Results of the study showed that pimavanserin demonstrated highly significant antipsychotic efficacy in patients with PDP and allowed for maintained motor control. Pimavanserin also showed significant improvements in all secondary efficacy measures and on the exploratory measures of nighttime sleep, daytime wakefulness, and caregiver burden. Consistent with previous studies, pimavanserin was safe and well tolerated in the -020 Study.

In April 2013, ACADIA announced an expedited path to a New Drug Application (NDA) filing for pimavanserin following a meeting with the Food and Drug Administration (FDA). ACADIA is currently focused on completing the remaining elements of its pimavanserin PDP program and is targeting an NDA submission near the end of 2014.

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 (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 and timing of filing an NDA, the benefits to be derived from ACADIA's product candidates, in each case including pimavanserin, the potential sleep improvements or long-term antipsychotic benefits from treatment with pimavanserin, and the potential benefits of pimavanserin in comparison to off-label use of current antipsychotics and in comparison to commonly prescribed atypical antipsychotics. 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.

ACADIA Pharmaceuticals Inc.
Uli Hacksell, Ph.D., Chief Executive Officer
Lisa Barthelemy, Director of Investor Relations
(858) 558-2871