ACADIA Pharmaceuticals Announces Encouraging Interim Results From Ongoing Phase II Trial of ACP-103 for Treatment-Induced Psychosis in Patients With Parkinson's Disease

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SAN DIEGO, June 22 /PRNewswire-FirstCall/ -- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for central nervous system (CNS) disorders, today reported encouraging results from a planned interim trend analysis of its ongoing multi-center Phase II clinical trial of ACP-103 for treatment-induced psychosis in patients with Parkinson's disease.

The ongoing double-blind, placebo-controlled, dose-escalation Phase II clinical trial is designed to evaluate the efficacy and tolerability of ACP-103 in 60 Parkinson's disease patients who suffer from treatment-induced psychosis. The results of the interim trend analysis were based on data from the first 30 patients to complete the study, of which 13 patients were treated with ACP-103 and 17 patients were administered placebo. The interim analysis examined trends relative to the trial's endpoints of antipsychotic efficacy, comparing baseline to 28-day performance on two rating scales used in the trial, the Clinical Global Impression - Severity of Illness scale (CGI-S) and the Scale for the Assessment of Positive Symptoms (SAPS). Results of the interim analysis demonstrated that the ACP-103 treatment group showed a greater reduction in psychotic symptoms on both rating scales, relative to the placebo treatment group. The changes in SAPS were driven by reductions in hallucinations and delusions. Only two patients dropped from the study, one on placebo and one on ACP-103. No serious adverse events were reported.

"These interim results are encouraging and increase our confidence that ACP-103 may prove to be an effective therapy for the debilitating drug-induced psychosis suffered by many Parkinson's disease patients," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "We remain on track to complete patient enrollment and report results from the complete Phase II trial in late-2005 or early-2006."

All patients encompassed in the interim trend analysis were appropriately included based on their pre-existing level of psychosis as estimated by scores on the Neuropsychiatric Inventory (NPI). Demographics were consistent with expectations based on the patient population. The interim findings are limited to trends relative to the trial's endpoints of efficacy and are not necessarily indicative of the final results to be announced from the complete Phase II clinical trial. ACADIA is continuing to enroll patients in the study and, as previously announced, expects to report results from a complete statistical analysis of all clinical endpoints on all 60 patients in late-2005 or early-2006.

About ACP-103

ACP-103 is a small molecule drug candidate that was discovered and is being developed by ACADIA as a new therapy for treatment-induced dysfunction in patients with Parkinson's disease, an indication with no approved therapy in the United States. ACP-103 is a potent and selective 5-HT2A inverse agonist, a compound that acts to block the activity of the neurotransmitter serotonin at this key target that plays an important role in the treatment of various neuropsychiatric disorders. In a previous Phase Ib/IIa clinical trial in patients with Parkinson's disease reported in 2004, ACP-103 was shown to be well tolerated and to not worsen the core motor symptoms of this disease, unlike most existing antipsychotics that further impair motor performance in these patients. Initial indications of antidyskinetic activity also were seen in this earlier trial.

About Parkinson's Disease

Parkinson's disease is a chronic, progressive neurological disorder that results from the degeneration of neurons in a region of the brain that controls movement. It is marked by a number of debilitating symptoms, including tremors, limb stiffness, slowness of movements, and difficulties with posture and balance. The severity of these symptoms tends to worsen over time. According to the American Parkinson's Disease Association, over 1.5 million people in the United States suffer from Parkinson's disease and that number is expected to grow as the population ages. Parkinson's disease patients are currently treated with dopamine replacement therapies and the use of these agents frequently results in a range of drug-induced side effects, including neuropsychiatric abnormalities such as hallucinosis and psychosis as well as uncontrollable and excessive movements of the limbs referred to as dyskinesias.

About ACADIA Pharmaceuticals

ACADIA Pharmaceuticals is a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for CNS disorders. ACADIA currently has four drug programs in clinical development as well as a portfolio of preclinical and discovery assets directed at large unmet medical needs, including schizophrenia, Parkinson's disease, neuropathic pain, and glaucoma. Using its proprietary drug discovery platform, ACADIA has discovered all of the drug candidates in its product pipeline. ACADIA's corporate headquarters is located in San Diego, California and it maintains research and development operations in both San Diego and Scandinavia.

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 development programs and related trials and the benefits to be derived from ACP-103. 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. In particular, interim results and results from Phase I and Phase II clinical trials are not guarantees of future results in complete trials or future trials or of ACADIA's ability to obtain regulatory approval for ACP-103. 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, 2004 filed with the United States Securities and Exchange Commission as well as other subsequent filings with the Securities and Exchange Commission, including ACADIA's quarterly report on Form 10-Q for the quarter ended March 31, 2005. 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.

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