

ACADIA Clinical Study Shows ACP-103 Improves Clinical Profile of Antipsychotic Drug Treatment

SAN DIEGO, Sep 15, 2004 /PRNewswire-FirstCall via COMTEX/ -- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical company utilizing innovative science to fuel drug discovery and clinical development of novel treatments for central nervous system disorders, today reported results from a clinical study that assessed the ability of ACP-103, ACADIA's proprietary 5-HT_{2A} inverse agonist, to reduce the side effects associated with antipsychotic drug treatment with haloperidol. Results of the clinical study showed that ACP-103 reduced both the motor disturbances and hyperprolactinemia, a condition of elevated prolactin secretion, caused by haloperidol treatment.

ACADIA is developing ACP-103 as a novel therapy for schizophrenia to be used in combination with currently available antipsychotic drugs including haloperidol, Zyprexa, Risperdal and Seroquel. These antipsychotics cause a variety of unfavorable side effects, including hyperprolactinemia, which can adversely affect menstrual and sexual function, and akathisia, an extremely distressful motor disturbance characterized by feelings of inner restlessness and an urge to move. ACP-103, when combined with existing antipsychotic drugs, may reduce the side effects associated with these drugs and expand their range of efficacy.

The double-blind, placebo-controlled clinical study, conducted in Sweden, involved 18 healthy volunteers. All subjects were administered a single 7.5 mg dose of haloperidol and 11 of these subjects developed measurable akathisia. In addition, the haloperidol treatment induced about a three-fold increase in prolactin secretion.

Results of the study indicated that a single treatment with ACP-103 reduced akathisia symptoms in most subjects and, importantly, that four of the subjects had complete disappearance of haloperidol-induced akathisia as measured on the Barnes Subjective-Distress Rating Scale. Researchers observed that maximal reductions appeared at the time of peak plasma levels of ACP-103 following a single 100 mg dose that produced plasma levels approximately equivalent to those achieved at steady state following chronic once daily administration of a 20 mg dose of ACP-103. In addition, ACP-103 reduced haloperidol-induced increases in prolactin secretion by 33%. This reduction is highly statistically significant ($p < 0.001$, paired t-test). The pharmacokinetics of haloperidol and ACP-103 were not affected by their co-administration, indicating a lack of drug-drug interactions between these two drugs. No serious adverse events were reported in this study.

Akathisia and hyperprolactinemia are troubling side effects of most existing antipsychotic drugs. Akathisia can lead to high levels of discomfort and ultimately is a major contributor to patient noncompliance. Patients with schizophrenia displaying hyperprolactinemia may be at high risk of developing osteoporosis and other side effects including decreased libido and the development of breast tissue in men.

"We are delighted that the results of this clinical study suggest that the adjunctive use of

ACP-103 has the ability to reduce the side effects associated with antipsychotic drug treatment," said Mark R. Brann, Ph.D., ACADIA's President and Chief Scientific Officer. "This is the first of a series of studies in our Phase II program that will examine the ability of ACP-103 to work in combination with existing antipsychotic drugs for more optimal drug therapy. ACADIA has discovered that most antipsychotic drugs, including haloperidol and the market leaders Zyprexa, Risperdal and Seroquel, lack sufficient activity at 5-HT_{2A} receptors. By adding ACP-103 on top of these antipsychotic drugs, we believe that one can optimize activity at 5-HT_{2A} receptors relative to activity at D₂ receptors to improve the efficacy and reduce the side effects of this important class of drugs."

About ACP-103

ACP-103 is a small molecule drug candidate that ACADIA discovered and is developing as an adjunctive therapy for schizophrenia and as a therapy for treatment-induced dysfunction in Parkinson's disease. ACP-103 is a potent and selective inverse agonist that blocks the activity of a key serotonin receptor known as the 5-HT_{2A} receptor. ACP-103 has been shown to be safe and well tolerated in all Phase I clinical studies and initial Phase II clinical trials conducted to date. ACADIA is currently conducting a multi-center Phase II clinical trial with ACP-103 designed to evaluate the efficacy and safety of this drug candidate in Parkinson's disease patients who suffer from treatment-induced psychosis.

About Schizophrenia

Schizophrenia is a debilitating mental illness characterized by disturbances such as hallucinations and delusions as well as a range of negative symptoms. Despite the availability of a variety of current antipsychotic drugs with worldwide sales exceeding \$12 billion, many symptoms associated with this disease are poorly addressed by existing therapies. Many patients with schizophrenia stop taking their antipsychotic medication because of lack of efficacy and because of the side effects they experience. Expanding the efficacy profile and reducing the side effects of these drugs represent important medical advances in schizophrenia therapy.

About ACADIA Pharmaceuticals

ACADIA Pharmaceuticals is a biopharmaceutical company utilizing innovative science to fuel drug discovery and clinical development of novel treatments for central nervous system disorders. ACADIA currently has five drug programs in clinical and preclinical development directed at large unmet medical needs and major commercial markets, including Parkinson's disease, schizophrenia, chronic pain, and glaucoma. Using its proprietary drug discovery platform, ACADIA has discovered all of the drug candidates in its product pipeline. ACADIA's headquarters and biological research facilities are located in San Diego, California and its chemistry research facilities are located in Copenhagen, Denmark.

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 efficacy and development of 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 development and commercialization. For a discussion of these and other factors, please refer to the company's registration statement on Form S-1 as well as other subsequent filings with the Securities and Exchange Commission.

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