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

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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-HT2A 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