ACADIA Pharmaceuticals Reports Results From Phase II Study of ACP-103 in Schizophrenia Patients With Haloperidol-Induced Akathisia

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SAN DIEGO, Dec. 1 /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 disorders, today reported results from a Phase II study that showed that ACP-103 reduced haloperidol-induced akathisia, a debilitating extrapyramidal side effect, in patients with schizophrenia.

This study is one of two Phase II clinical trials in ACADIA's program using ACP-103 adjunctively with other antipsychotic drugs to provide an improved therapy for schizophrenia patients. The study involved 34 patients with schizophrenia and was designed to evaluate the ability of ACP-103 to treat akathisia, a side effect often induced by antipsychotic drugs. In addition to this study, ACADIA is currently conducting a Phase II trial with up to 400 patients, which is designed to evaluate the ability of ACP-103 to improve both the efficacy and safety profile of current antipsychotic drugs.

"We are encouraged by the ability of ACP-103 to treat haloperidol-induced akathisia in patients with schizophrenia," said Uli Hacksell, Ph.D., ACADIA's Chief Executive Officer. "This study is an important demonstration of our ACP-103 adjunctive therapy approach to improve the quality of care for patients suffering from schizophrenia."

Trial Design

The double-blind, randomized, placebo-controlled Phase II study enrolled 34 patients with a clinical diagnosis of schizophrenia or schizoaffective disorder, who also experienced haloperidol-induced akathisia. Results from the study presented in the accompanying table are based on 30 patients who completed the study protocol and exclude 4 subjects who had major protocol violations. Fourteen of these 30 patients received once-daily oral administration of 60 mg of ACP-103 and 16 were administered placebo over a five-day period. Subjects were maintained on their pre-study dose of haloperidol during the course of the study.

Patients were evaluated using the Barnes Akathisia Scale (BAS), a four-item rating scale widely used to assess this particular side effect of antipsychotic drugs. This scale consists of the following items: objective akathisia (Item 1), subjective awareness of restlessness (Item 2), subjective distress related to restlessness (Item 3), and global clinical assessment of akathisia (Item 4). Results from the study reflect measurements with the BAS performed on day 1, day 3, and day 5.

Trial Results

Overall, the results of the study showed that ACP-103 reduced akathisia relative to placebo. There were no statistically significant differences between ACP-103-treated and placebo-treated subjects for BAS Item 4 on day 5, a priori defined as the primary outcome measure of the study, due to a large placebo response. However, ACP-103 significantly reduced BAS Item 1 on day 5 ($p = 0.04$) and there were statistically significant improvements (p