



ACADIA Announces Positive Results From ACP-103 Phase II Schizophrenia Co-Therapy Trial

March 19, 2007

-- Enhanced Antipsychotic Efficacy --

-- Faster Onset of Action --

-- Less Weight Gain --

-- Conference Call Scheduled for Today, March 19, 2007, at 9:00 a.m. Eastern Time --

SAN DIEGO--(BUSINESS WIRE)--ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced positive top-line results from its Phase II schizophrenia co-therapy trial with ACP-103, ACADIA's proprietary and selective 5-HT_{2A} inverse agonist. The trial evaluated ACP-103 co-therapy when used together with either risperidone, a commonly prescribed atypical antipsychotic drug, or haloperidol, a generic typical antipsychotic drug. The co-therapy arms with ACP-103 demonstrated statistically significant antipsychotic efficacy as measured by the reduction in the Positive and Negative Syndrome Scale (PANSS), the primary endpoint of the trial. In addition, the co-therapy arm combining ACP-103 with low-dose risperidone demonstrated a statistically significant improvement in antipsychotic efficacy as compared to low-dose risperidone plus placebo, and comparable efficacy to high-dose risperidone plus placebo. Co-therapy with ACP-103 also led to a faster onset of antipsychotic action and an improved side effect profile.

"These data clearly demonstrate the advantages of co-therapy with ACP-103 and show the importance of 5-HT_{2A} receptor antagonism in schizophrenia therapy," said Herbert Y. Meltzer, M.D., Professor of Psychiatry and Pharmacology and Director of the Psychosis Program at the Vanderbilt University School of Medicine. "Current antipsychotic agents used to treat schizophrenia and related neuropsychiatric disorders have many dose-related limitations. The use of ACP-103 in co-therapy with risperidone or other modern atypical antipsychotics may result in enhanced efficacy and an improved side effect profile, suggesting a formula for a new and improved treatment paradigm for patients with schizophrenia."

Trial Design

The Phase II clinical trial was a multi-center, randomized, double-blind, placebo-controlled, six-week study designed to evaluate the ability of ACP-103, when used together with either risperidone or haloperidol, to provide an improved therapy for patients with schizophrenia. The trial enrolled 423 patients across sites in both the United States and Brazil. Patients were randomly assigned to one of five study arms: ACP-103 plus low-dose risperidone (ACP-103/risperidone); low-dose risperidone plus placebo (risperidone LD); high-dose risperidone plus placebo (risperidone HD); ACP-103 plus haloperidol (ACP-103/haloperidol); or haloperidol plus placebo (haloperidol arm). The primary endpoint of the study was antipsychotic efficacy as measured after day 42 compared to baseline in each of the two ACP-103 co-therapy arms using the PANSS.

Trial Results

The ACP-103/risperidone co-therapy arm showed a 23.0 point (27.4%) improvement in the PANSS as measured after day 42 compared to baseline (p less than 0.0001), a primary endpoint in the study. In addition to meeting the primary endpoint, the ACP-103/risperidone arm demonstrated a statistically significant enhancement of antipsychotic efficacy as compared to the risperidone LD arm ($p=0.01$), and similar efficacy to the risperidone HD arm ($p=NS$). The significant efficacy enhancement over risperidone LD was observed for both positive and negative symptoms.

Study Arms	Baseline Mean	Mean Change	Percentage Change

ACP-103 (20 mg) plus low-dose risperidone (2 mg)	84.8	-23.0	27.4%

Low-dose risperidone (2 mg) plus placebo	87.5	-16.6	19.0%

High-dose risperidone (6 mg) plus placebo	86.4	-23.2	26.4%

Data based on the PANSS using the Intent to Treat Population and Last Observation Carried Forward Methodology.

Co-therapy with ACP-103 also provided a significantly faster onset of antipsychotic action. After only two weeks of therapy, about 50% more patients in the ACP-103/risperidone arm responded to treatment compared to each of the risperidone LD (p less than 0.008) and risperidone HD (p less than 0.03) arms. A responder was defined as a patient showing at least a 20% reduction in the PANSS.

Importantly, patients in the ACP-103/risperidone co-therapy arm also had 50% less gain in weight than patients in the risperidone HD arm. This difference trended to statistical significance ($p=0.078$).

The study also evaluated ACP-103 as a co-therapy with haloperidol. The ACP-103/haloperidol arm showed a 21.6 point (25.6%) improvement in the PANSS as measured after day 42 compared to baseline (p less than 0.0001), a primary endpoint in the study. The haloperidol arm showed a robust antipsychotic effect and there was no statistical difference compared to the ACP-103/haloperidol arm after day 42. However, the ACP-103/haloperidol arm did appear to result in a faster onset of antipsychotic action after only two weeks of treatment as compared to the haloperidol arm. In addition, patients in the ACP-103/haloperidol co-therapy arm had less gain in weight compared to patients in the haloperidol arm.

Study Arms	Baseline Mean	Mean Change	Percentage Change
ACP-103 (20 mg) plus haloperidol (2 mg)	85.6	-21.6	25.6%
Haloperidol (2 mg) plus placebo	86.4	-25.1	29.2%

Data based on the PANSS using the Intent to Treat Population and Last Observation Carried Forward Methodology.

Each of the treatments was generally safe and well tolerated. Adverse events were comparable among the five study arms and were generally characterized as mild to moderate. The most common adverse events were sedation, headache, and agitation. There were three serious adverse events (SAEs) in the study that were deemed to be drug-related, each of which occurred in a risperidone plus placebo arm. Two of these SAEs were cardiovascular in nature and occurred in the risperidone HD arm. No drug-related SAEs were observed in either of the ACP-103 co-therapy arms.

"We are very excited about these top-line results, which demonstrate several key advantages of co-therapy with ACP-103," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "While achieving effective antipsychotic treatment comparable to a standard dose of risperidone, ACP-103 when added to a three-fold lower dose of risperidone provided substantial advantages, including a faster onset of antipsychotic action and 50% less weight gain. We believe that co-therapy with ACP-103 may provide important clinical advantages compared to current antipsychotic drug therapy."

Conference Call and Webcast Information

ACADIA will host a conference call and webcast with slides today, March 19, 2007, at 9:00 a.m. Eastern Time to discuss the results from this ACP-103 Phase II schizophrenia co-therapy trial. The conference call can be accessed by dialing 800-435-1261 for participants in the U.S. or Canada and 617-614-4076 for international callers (reference passcode 63511928). A telephone replay of the conference call may be accessed through April 2, 2007 by dialing 888-286-8010 for callers in the U.S. or Canada and 617-801-6888 for international callers (reference passcode 33087234). The conference call also will be webcast live on ACADIA's website, www.acadia-pharm.com, under the investors section and will be archived there until April 2, 2007.

About ACP-103

ACP-103 is a small molecule drug candidate that ACADIA discovered and is developing as a co-therapy to be used together with other antipsychotic drugs to treat schizophrenia. ACP-103 can be taken orally and is a novel, potent, and selective 5-HT_{2A} inverse agonist, meaning that it blocks the activity of the 5-HT_{2A} receptor. By adding ACP-103 to existing treatment regimens, ACADIA believes that the optimal combination of 5-HT_{2A} inverse agonism and dopamine receptor blockade can be achieved, thereby resulting in enhanced efficacy and fewer side effects relative to existing treatments. ACADIA also is developing ACP-103 for the treatment of Parkinson's disease psychosis and sleep maintenance insomnia.

About Schizophrenia

Schizophrenia is a chronic, debilitating mental illness characterized by disturbances in thinking, emotional reaction, and behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, and a range of negative symptoms, including loss of interest, emotional withdrawal and cognitive disturbances. Approximately one percent of the population develops schizophrenia during their lifetime and more than two million people in the United States suffer from this disease. Worldwide sales of drugs used to treat schizophrenia and other psychoses exceeded \$15 billion in 2005. Despite their commercial success, current drugs used to treat schizophrenia have substantial limitations, including severe side effects and a lack of efficacy on all symptoms of the disease.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for central nervous system disorders. ACADIA currently has five clinical programs, as well as a portfolio of preclinical and discovery assets, directed at large unmet medical needs, including schizophrenia, Parkinson's disease psychosis, sleep maintenance insomnia, and neuropathic pain. All of the drug candidates in ACADIA's product pipeline emanate from discoveries made using its proprietary drug discovery platform. ACADIA's corporate headquarters is located in San Diego, California and it maintains research and development operations in both San Diego and Malmo, Sweden.

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 benefits to be derived from ACADIA's drug development programs, including the potential advantages of the use of ACP-103 as a co-therapy for schizophrenia. 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 clinical trials, and drug development and commercialization, including the uncertainty of whether results in testing of ACP-103 to date will be predictive of results in later stages of development. 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, 2006 as well as other 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.

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