ACADIA Pharmaceuticals Presents Favorable Results From Phase Ib/IIa Clinical Trial and PET Study of ACP-103

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PHILADELPHIA, June 29 /PRNewswire-FirstCall/ -- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) presented, at the CNS Diseases Congress held in Philadelphia, results of a Phase Ib/IIa clinical trial of ACP-103 in patients with Parkinson's disease and results from a human brain receptor occupancy study of ACP-103 performed using position emission tomography (PET). Results of these studies demonstrated that ACP-103, ACADIA's proprietary 5-HT2A inverse agonist, was safe and well tolerated in Parkinson's disease patients at drug plasma levels many fold higher than those required for maximal brain occupancy of the 5-HT2A receptors, suggesting a large therapeutic index.

ACP-103 was discovered by scientists at ACADIA and is being developed by ACADIA as a therapy for treatment-induced dysfunction in Parkinson's disease, an indication with no approved therapy in the United States. 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 movements of the limbs referred to as dyskinesias. ACADIA is currently conducting a second Phase II clinical trial of ACP-103 for treatment-induced psychosis in Parkinson's disease. ACP-103 also is being developed by ACADIA as an adjunctive therapy in schizophrenia.

The Phase Ib/IIa double-blind, placebo-controlled clinical trial with ACP-103 involved 12 patients with Parkinson's disease on standard dopamine replacement therapies. This trial followed the completion of two Phase I clinical trials that demonstrated the safety and tolerability of ACP-103 following oral administration in a total of 57 healthy volunteers. The Phase Ib/IIa trial evaluated the safety and tolerability of ACP-103 in Parkinson's disease patients following oral administration of 25 or 100 mg doses once daily for 14 days. ACP-103 was well tolerated at both of these doses with no adverse events reported. Importantly, ACP-103 did not worsen the pre-existing motor deficits of these patients, an effect commonly seen with most other antipsychotic drugs. Together these findings further emphasize the favorable safety profile of ACP-103. In addition, in a subset of patients entering the trial who exhibited treatment-induced dyskinesias, these symptoms were reduced following ACP-103 administration. This initial finding is consistent with the previously demonstrated antidyskinetic activity of ACP-103 in a monkey model of Parkinson's disease. The antidyskinetic activity of ACP-103 will be examined in subsequent Phase II studies.

ACADIA also reported on results from a drug receptor occupancy study conducted at the Karolinska Institute with ACP-103 in healthy volunteers using PET. This study demonstrated that even single, low acute doses of ACP-103, providing peak plasma levels of approximately 10 ng/ml, produce maximal occupancy of the relevant 5-HT2A receptors without blocking the dopamine receptors in brain regions involved in motor control.

ACADIA's presentation at the CNS Diseases Congress was entitled "Technology-Driven Opportunities in the Discovery and Development of CNS Drugs" and was given by Robert E. Davis, Ph.D., ACADIA's Executive Vice President of Drug Discovery and Development. Dr. Davis reported that ACP-103 has a therapeutic index exceeding 23-fold, based on a comparison of the highest well tolerated plasma level at steady state with the dose required to achieve maximal occupancy of the brain 5-HT2A receptors. "This favorable safety profile coupled with pharmacokinetic properties that appear to make ACP-103 suitable for once-daily oral administration should enable us to move forward aggressively with our development plans for ACP-103," said Dr. Davis. "The selectivity of ACP-103 for serotonin 5-HT2A receptors and its lack of affinity for dopamine receptors suggest that ACP-103 may be a promising new therapy for treatment-induced dysfunction in Parkinson's disease."

ACADIA Pharmaceuticals is a biopharmaceutical company focused on the discovery, development and commercialization of small molecule drugs for the treatment of 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 corporate 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 tolerability, safety, 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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