ACADIA Pharmaceuticals Initiates Second Phase III Trial with Pimavanserin in Patients with Parkinson's Disease Psychosis

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SAN DIEGO--(BUSINESS WIRE)--March 31, 2008--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 announced that it has initiated its second Phase III trial designed to evaluate the safety and efficacy of pimavanserin as a treatment for Parkinson's disease psychosis (PDP).

"The start of our second Phase III pivotal trial represents another important step forward toward our goal of providing a first-in-class treatment for patients with PDP," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA Pharmaceuticals. "We believe pimavanserin may provide a unique combination of antipsychotic efficacy, motoric tolerability and safety and, therefore, provides the potential for an important advance in therapy for patients suffering from this debilitating disorder."

The Phase III trial is a multi-center, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of pimavanserin in approximately 240 patients with PDP. Patients in the trial will be randomized to three different study arms, which will include two different doses of pimavanserin and one placebo arm. Patients will receive oral doses of either pimavanserin or placebo once daily for six weeks in addition to stable doses of their existing dopamine replacement therapy. The primary endpoint of the trial is antipsychotic efficacy as measured by the Scale for the Assessment of Positive Symptoms, or SAPS. Motoric tolerability will be an important secondary endpoint in the trial and will be measured using the Unified Parkinson's Disease Rating Scale, or UPDRS.

ACADIA is also currently conducting an open-label safety extension study under which patients who have completed either of the Phase III PDP trials will have the opportunity to enroll if, in the opinion of the physician, the patient may benefit from continued treatment with pimavanserin.

About Pimavanserin

Pimavanserin tartrate is a novel, potent, and selective 5-HT2A inverse agonist that ACADIA discovered and is developing as a treatment for PDP. ACADIA is currently conducting two Phase III pivotal trials in its program with pimavanserin as a treatment for PDP. ACADIA has also reported positive results from a Phase II trial in its program with pimavanserin as a co-therapy for schizophrenia.

About Parkinson's Disease Psychosis (PDP)

Parkinson's disease is a chronic neurological disorder that results from the degeneration of neurons in a region of the brain that controls movement. According to the American Parkinson's Disease Association, over 1.5 million people in the United States suffer from this disease. Studies have suggested that up to 40 percent of patients with Parkinson's disease will develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. The development of psychosis in patients with Parkinson's disease often disrupts their ability to perform many of the activities of daily living that keep them independent and active. As a result, Parkinson's disease psychosis is associated with increased caregiver burden, nursing home placement, and increased mortality.

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 mid-to-late stage clinical programs as well as a portfolio of preclinical and discovery assets, directed at diseases with 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 the progress of ACADIA's drug discovery and development programs and the benefits to be derived from ACADIA's drug candidates, in each case, including pimavanserin. 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 discovery, development and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. 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, 2007 as well as ACADIA's 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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