ACADIA Pharmaceuticals Announces Results from Phase III Trial of Pimavanserin in Parkinson's Disease Psychosis

September 1, 2009

Pimavanserin Misses Primary Endpoint of Antipsychotic Efficacy; Meets Key Secondary Endpoint of Motoric Tolerability

Conference Call Scheduled for Today, September 1, at 8:00 A.M. Eastern Time

SAN DIEGO--(BUSINESS WIRE)--Sep. 1, 2009-- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced top-line results from the first pivotal Phase III trial with pimavanserin in patients with Parkinson's disease psychosis, or PDP. The study did not meet its primary endpoint of antipsychotic efficacy as measured using the Scale for the Assessment of Positive Symptoms, or SAPS. Pimavanserin met the key secondary endpoint of motoric tolerability as measured using the Unified Parkinson's Disease Rating Scale, or UPDRS. Pimavanserin was safe and well tolerated, with the frequency of adverse events generally similar in the pimavanserin and placebo arms.

The primary endpoint of the study was the mean change in SAPS scores at day 42 compared to baseline for each of the two pimavanserin treatment arms versus placebo. Patients showed marked improvements in the SAPS scores across all study arms. Mean reductions in SAPS scores were 5.9 points in the placebo arm, 5.8 points in the 10 mg pimavanserin arm, and 6.7 points in the 40 mg pimavanserin arm. Statistical significance was not achieved in either pimavanserin arm primarily due to the larger than expected improvement in placebo-treated patients.

"While we obviously are disappointed with the results of this Phase III study, we continue to believe in the potential of pimavanserin based on our clinical experience to date," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "We will thoroughly analyze these data along with the data on other secondary and exploratory endpoints over the next month to better understand the outcome of this study. Meanwhile, we are continuing with the second Phase III PDP trial with pimavanserin."

Trial Design

The Phase III trial was a multi-center, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of pimavanserin in patients with PDP. A total of 298 patients were enrolled in the trial and randomized to one of three study arms, including two different doses of pimavanserin (10 mg or 40 mg) and placebo. Patients received oral doses of either pimavanserin or placebo once daily for six weeks. Patients remained on stable doses of their existing anti-Parkinson's therapy throughout the study. The primary endpoint was antipsychotic efficacy as measured using the hallucinations and delusions domains of the SAPS. The key secondary endpoint was motoric tolerability as measured using Parts II and III of the UPDRS.

About Pimavanserin

Pimavanserin is a 5-HT_{2A} receptor inverse agonist in Phase III development as a treatment for Parkinson's disease psychosis. This new chemical entity, which was discovered by ACADIA, is a small molecule that can be taken orally as a tablet once-a-day. ACADIA and Biovail have formed a collaboration to co-develop and commercialize pimavanserin for neurological and psychiatric indications, including Parkinson's disease psychosis (PDP) and Alzheimer's disease psychosis (ADP), in the United States and Canada. ACADIA retains rights to pimavanserin in the rest of the world.

About Parkinson's Disease Psychosis

According to the National Parkinson Foundation, over 1.5 million people in the United States suffer from Parkinson's disease. Up to 40 percent of patients with Parkinson's disease may develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. Currently there is no therapy in the United States approved to treat PDP. The development of psychosis in patients with Parkinson's disease is associated with increased caregiver burden, nursing home placement, and increased mortality.

Conference Call and Webcast Information

ACADIA will host a conference call and webcast today, September 1, 2009, at 8:00 a.m. Eastern Time to discuss the top-line results from the first pivotal Phase III trial with pimavanserin in patients with PDP. The conference call can be accessed by dialing 866-713-8564 for participants in the U.S. or Canada and 617-597-5312 for international callers (reference passcode 15968327). A telephone replay of the conference call may be accessed through September 15, 2009 by dialing 888-286-8010 for callers in the U.S. or Canada and 617-801-6888 for international callers (reference passcode 88296469). 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 September 15.

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's product candidates include pimavanserin in Phase III for Parkinson's disease psychosis in collaboration with Biovail, a product candidate in Phase II for chronic pain and a product candidate in Phase I for glaucoma, both in collaboration with Allergan, as well as additional compounds in IND-track development. All of the product candidates in ACADIA's pipeline emanate from discoveries made using its proprietary drug discovery platform. ACADIA maintains a website at www.acadia-pharm.com to which ACADIA regularly posts copies of its press releases as well as additional information and through which interested parties can subscribe to receive email alerts.

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 and timing of drug discovery and development programs, including clinical trials and the results therefrom, and the

potential of and the benefits to be derived from product 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, commercialization and collaborations with others, and the fact that past results of clinical trials may not be indicative of further 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, 2008 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, except as required by law.

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