ACADIA Pharmaceuticals Initiates Phase II Study of Pimavanserin in Alzheimer's Disease Agitation

October 31, 2016

SAN DIEGO--(BUSINESS WIRE)--Oct. 31, 2016-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on innovative treatments that address unmet medical needs in central nervous system disorders, today announced the initiation of SERENE, a Phase II study with pimavanserin for the treatment of agitation in patients with Alzheimer's disease (AD Agitation). There is currently no drug approved by the FDA for the treatment of AD Agitation. Pimavanserin is a selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors, with a distinct mechanism of action compared to other currently available medicines used off-label to treat AD Agitation.

"AD Agitation is a common condition and a major cause of distress for Alzheimer's patients, their families and caregivers," said Serge Stankovic, M.D., M.S.P.H., ACADIA's Executive Vice President, Head of Research and Development. "It also is associated with more rapid decline and earlier institutionalization of patients with AD Agitation. With no FDA-approved therapy for AD Agitation, there is a large, unmet need for a new treatment option for patients."

About the SERENE Study

SERENE is a Phase II, randomized, double-blind, placebo-controlled, multi-center outpatient study designed to examine the efficacy and safety of pimavanserin in approximately 430 patients with Alzheimer's disease who have agitation and/or aggression symptoms. Patients will be randomized to receive once daily oral doses of 34 mg pimavanserin, 20 mg pimavanserin or placebo for 12 weeks. The primary endpoint in the study is a reduction in total score on the Cohen-Mansfield Agitation Inventory (CMAI). Following participation in SERENE, patients will be eligible to enroll in an open-label safety extension study.

About Alzheimer's Disease Agitation (AD Agitation)

According to the Alzheimer's Association, around 5.4 million people in the United States are living with Alzheimer's disease and approximately half are diagnosed with the disease. Studies suggest that 40 to 50 percent of patients diagnosed with Alzheimer's disease in the United States exhibit agitation. AD Agitation is characterized by verbal aggression, physical aggression, and excessive motor activities. These behavioral symptoms have been associated with more rapid cognitive decline, greater caregiver burden, and earlier institutionalization.

About Pimavanserin

Pimavanserin is a selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors. These receptors are thought to play an important role in AD Agitation. Pimavanserin is being evaluated in an extensive clinical development program by ACADIA across multiple indications. Pimavanserin (34 mg) was approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis by the U.S. Food and Drug Administration in April 2016 under the trade name NUPLAZID™. NUPLAZID is not approved for the treatment of AD Agitation.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA maintains a website at www.acadia-pharm.com to which we regularly post copies of our press releases as well as additional information and through which interested parties can subscribe to receive e-mail 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 ACADIA's drug discovery and development programs, the expected design and scope of ACADIA's clinical trials, and the benefits to be derived from NUPLAZID™ (pimavanserin) and ACADIA's product candidates, including the potential effectiveness of pimavanserin in AD Agitation patients. 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, approval and commercialization, and in collaborations with others, 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, 2015 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.

Important Safety Information and Indication for NUPLAZID (pimavanserin) tablets

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

QT Interval Prolongation: NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic

medications, and certain antibiotics. NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

Adverse Reactions: The most common adverse reactions (≥2% for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

Drug Interactions: Strong CYP3A4 inhibitors (eg, ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half. Strong CYP3A4 inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

Renal Impairment: No dosage adjustment for NUPLAZID is needed in patients with mild to moderate renal impairment. Use of NUPLAZID is not recommended in patients with severe renal impairment.

Hepatic Impairment: Use of NUPLAZID is not recommended in patients with hepatic impairment. NUPLAZID has not been evaluated in this patient population.

Pregnancy: Use of NUPLAZID in pregnant women has not been evaluated and should therefore be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

Pediatric Use: Safety and efficacy have not been established in pediatric patients.

Dosage and Administration: Recommended dose: 34 mg per day, taken orally as two 17-mg tablets once daily, without titration.

For additional Important Safety Information, including boxed warning, please see the full Prescribing Information for NUPLAZID at https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf.

View source version on businesswire.com: http://www.businesswire.com/news/home/20161031005429/en/

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