ACADIA Pharmaceuticals Initiates Phase II Trial of Pimavanserin for Adjunctive Treatment in Patients With Major Depressive Disorder

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SAN DIEGO--(BUSINESS WIRE)--Dec. 1, 2016-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on innovative treatments that address unmet medical needs in central nervous system (CNS) disorders, today announced the initiation of CLARITY, a Phase II study to evaluate pimavanserin for adjunctive treatment in patients with major depressive disorder (MDD) who have an inadequate response to first-line therapies for clinical depression. Pimavanserin is a selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors that may play a role in depression.

“Major depressive disorder affects millions of people in the United States every year and many do not respond adequately to currently available treatments,” said Professor Maurizio Fava, M.D., Executive Vice Chair, Department of Psychiatry, Massachusetts General Hospital (MGH) and Associate Dean for Clinical & Translational Research, Harvard Medical School. “With its highly selective mechanism of action, pimavanserin may provide a new approach to the adjunctive treatment of patients with major depressive disorder and may represent an opportunity to improve clinical outcomes in these patients.”

“We are committed to the development of pimavanserin in additional CNS disorders that are underserved by currently available therapies and represent a significant unmet medical need. Inadequate response to current antidepressants is one such condition,” said Serge Stankovic, M.D., M.S.P.H., ACADIA’s Executive Vice President, Head of Research and Development. “We are gratified to be able to leverage the vast knowledge and expertise of our colleagues at MGH and conduct this study in collaboration with the MGH Clinical Trials Network & Institute.”

About CLARITY

CLARITY is a Phase II, 10-week, randomized, double-blind, placebo-controlled, multi-center study designed to examine the efficacy and safety of adjunctive use of pimavanserin in patients with major depressive disorder who have an inadequate response to standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). Approximately 188 patients will be randomized to receive either 34 mg of pimavanserin or placebo, orally, once daily, in addition to their ongoing antidepressant for 10 weeks. The primary endpoint of the study is the change from baseline on the Hamilton Depression Rating Scale (HAM-D) total score.

About Major Depressive Disorder (MDD)

According to the National Institute of Mental Health, MDD affects approximately 16 million adults in the United States and is the leading cause of disability for ages 15-44. MDD is a condition characterized by depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities for more than two weeks, as well as impaired social, occupational or other important functioning. The majority of people who suffer from MDD do not respond to initial antidepressant therapy.

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 depression. 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 adjunctive treatment of patients with major depressive disorder.

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, the benefits to be derived from NUPLAZID (pimavanserin) and ACADIA’s product candidates, including whether pimavanserin can effectively be used to adjunctively treat MDD, provide a new approach to the adjunctive treatment of patients with MDD or represent an opportunity to improve clinical outcomes for patients with MDD, and ACADIA’s future development efforts in CNS disorders that are underserved by currently available therapies and represent a significant unmet medical need. 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/20161201005387/en/

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