ACADIA Pharmaceuticals Initiates Phase III Trial of Pimavanserin for Adjunctive Treatment in Patients with Schizophrenia

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SAN DIEGO--(BUSINESS WIRE)--Nov. 3, 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 ENHANCE-1, a Phase III study to evaluate pimavanserin for adjunctive treatment of schizophrenia in patients with an inadequate response to current antipsychotic therapy. Current antipsychotics approved for schizophrenia primarily target the dopaminergic pathway. As a selective serotonin inverse agonist (SSIA), pimavanserin is a new class of antipsychotic medication with a distinct mechanism of action targeting serotonergic 5-HT_{2A} receptors while avoiding activity at dopamine and other receptors commonly targeted by other antipsychotics.

“About 30 percent of patients with schizophrenia do not achieve an adequate response to a single antipsychotic medication, and as a result more than one in four schizophrenia patients are treated with two or more antipsychotics,” said Serge Stankovic, M.D., M.S.P.H., ACADIA’s Executive Vice President, Head of Research and Development. “We believe pimavanserin, through its highly selective mechanism of action, could provide an important new option for adjunctive treatment of schizophrenia and improve clinical outcomes by both augmenting the efficacy of currently used antipsychotics and lessening the undesirable side effects associated with polypharmacy.”

About ENHANCE-1

ENHANCE-1 is a Phase III, six-week, randomized, double-blind, placebo-controlled, multi-center, outpatient study designed to examine the efficacy and safety of adjunctive use of pimavanserin in patients with schizophrenia who have not achieved an adequate response to their current antipsychotic treatment. Approximately 380 patients will be randomized to receive pimavanserin, or placebo, orally, once daily, in addition to their ongoing antipsychotic in a flexible dosing regimen. The starting daily dose of 20 mg of pimavanserin at baseline may be adjusted to 34 mg or 10 mg during the first three weeks of treatment. The primary endpoint of the study is the change from baseline to week six on the Positive and Negative Syndrome Scale (PANSS) total score. Following participation in ENHANCE-1, patients will be eligible to enroll in a 52-week open-label extension study.

About Schizophrenia

According to the National Mental Health Institute, approximately one percent of the U.S. population develops schizophrenia during their lifetime. Schizophrenia is a chronic, debilitating mental illness characterized by disturbances in thinking, emotional reaction, and behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, and a range of negative symptoms, including loss of interest, emotional withdrawal and cognitive disturbances. Current drugs used to treat schizophrenia have substantial limitations, including severe side effects and a lack of efficacy on the full range of symptoms of the disease.

According to the American Psychiatric Association, about 30 percent of patients with schizophrenia have inadequate response to antipsychotic medications, meaning that they exhibit improvement, but continue to have residual hallucinations or delusions. As a result, about 25 to 50 percent of schizophrenia patients are treated with two or more antipsychotics. This polypharmacy has led to increased dose-related side effects and complicated dosing regimens that can further contribute to poor treatment compliance and subsequent relapse in these patients.

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 schizophrenia. 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 schizophrenia.

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 whether pimavanserin could provide an important new option for adjunctive treatment of schizophrenia or improve clinical outcomes by augmenting the efficacy of currently used antipsychotics and/or lessening the undesirable side effects associated with polypharmacy. 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/20161103005542/en/

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