



ACADIA Pharmaceuticals Announces Positive Top-Line Results From Phase II Study of Pimavanserin for Alzheimer's Disease Psychosis

December 20, 2016

Data Support Moving Forward With Further Development in Alzheimer's Disease Psychosis

Conference Call and Webcast to Be Held Today, December 20, 2016, at 8:30 a.m. Eastern Time

SAN DIEGO--(BUSINESS WIRE)--Dec. 20, 2016-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD) today announced positive top-line results from its Phase II exploratory study (-019 Study) of pimavanserin in patients with Alzheimer's disease psychosis (AD Psychosis). As a selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors, pimavanserin has a different biological mechanism than other marketed antipsychotics. Pimavanserin has been approved by the United States Food and Drug Administration (FDA) for hallucinations and delusions associated with Parkinson's disease psychosis and currently is being studied in several other disease states, including AD Psychosis. The FDA has not approved any drug to treat AD Psychosis.

In this Phase II exploratory study, pimavanserin met the primary endpoint showing a statistically significant reduction in psychosis versus placebo as measured by the Neuropsychiatric Inventory-Nursing Home (NPI-NH) Psychosis score at week 6 of dosing ($p=0.0451$). Pimavanserin was generally well tolerated and the safety profile was consistent with what has been observed in previous studies.

"Alzheimer's disease patients suffer from a number of debilitating symptoms, of which psychosis carries a poor prognosis and is associated with earlier placement into nursing homes," said Steve Davis, ACADIA's President and Chief Executive Officer. "Data from the -019 Study provide solid evidence that pimavanserin can improve psychosis in another major neurological disorder and provide strategic momentum for the further development of pimavanserin to address the needs of AD Psychosis patients."

About the Phase II -019 Study

The Phase II -019 Study was a double-blind, placebo-controlled exploratory trial designed to evaluate the efficacy and safety of pimavanserin as a treatment for patients with AD Psychosis. A total of 181 patients were enrolled in the study in the United Kingdom and randomized on a one-to-one basis to receive either 34 mg of pimavanserin or placebo once daily. The primary endpoint of the study was antipsychotic efficacy as measured by the mean change in the NPI-NH Psychosis score (combined hallucinations and delusions domains) from baseline to week 6 of dosing. Patients continued dosing through week 12 to gather information on secondary endpoints, including changes in cognition.

Pimavanserin demonstrated efficacy on the primary endpoint of the -019 Study with a 3.76 point improvement in psychosis at week 6 compared to a 1.93 point improvement for placebo, representing a statistically significant treatment improvement in the NPI-NH Psychosis score ($p=0.0451$). Baseline mean scores for the pimavanserin and placebo treated groups were 9.52 and 10.00, respectively.

Atypical antipsychotics have been associated with a statistically significant worsening of cognitive function in patients with Alzheimer's disease. In the -019 Study, over the course of 12 weeks of treatment, pimavanserin did not impair cognition as measured by the Mini-Mental State Examination (MMSE) score and was similar to placebo. On the secondary endpoint of mean change in NPI-NH Psychosis score at week 12, pimavanserin maintained the improvement on psychosis observed at the week 6 primary endpoint, but did not statistically separate from placebo.

In the -019 Study, pimavanserin was generally well tolerated and the safety profile was consistent with what has been observed in previous studies. Based on a preliminary analysis of safety data, the most common adverse events reported were falls, urinary tract infection and agitation. The mortality rate was the same in the pimavanserin and placebo treatment groups. The mean age of patients in the study was 86 years.

The data analysis of the Phase II -019 Study is ongoing and ACADIA plans to present data from this study at a future medical conference.

Conference Call and Webcast Information

ACADIA will host a conference call and webcast today, December 20, 2016 at 8:30 a.m. Eastern Time to discuss top-line results from its Phase II trial with pimavanserin in patients with Alzheimer's disease psychosis. The conference call can be accessed by dialing 844-821-1109 for participants in the U.S. and Canada and 830-865-2550 for international callers (reference passcode 43052480). The conference call will be webcast live on ACADIA's website, www.acadia-pharm.com, under the investors section and will be archived there until January 3, 2017. A telephone replay also may be accessed through January 3, 2017 by dialing 855-859-2056 for participants in the U.S. and Canada and 404-537-3406 for international callers (reference passcode 43052480).

About Alzheimer's Disease Psychosis (AD Psychosis)

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 25 to 50 percent of patients diagnosed with Alzheimer's disease may develop psychosis, commonly consisting of hallucinations and delusions. AD Psychosis is associated with more rapid cognitive and functional decline, greater caregiver burden, and earlier institutionalization. The FDA has not approved any drug to treat AD Psychosis.

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 Psychosis. Pimavanserin is being evaluated in an extensive clinical development program by ACADIA across multiple other indications including Alzheimer's disease agitation, schizophrenia – inadequate response, schizophrenia – negative symptoms, and major depressive disorder. Pimavanserin (34 mg) was approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis by the FDA in April 2016 under the trade name NUPLAZID®. NUPLAZID is not approved for patients with AD Psychosis.

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 benefits to be derived from NUPLAZID (pimavanserin) and ACADIA's product candidates, including whether pimavanserin can improve psychosis in another major neurological disorder or be used to treat AD Psychosis; whether the data from the -019 Study support moving forward with further development in AD Psychosis or provide strategic momentum for the further development of pimavanserin to address the needs of AD Psychosis patients; and ACADIA's plans to present data from the -019 Study. 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 ($\geq 2\%$ 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/20161220005379/en/>

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