ACADIA Pharmaceuticals Announces Publication of Data from Its -015 Open Label Safety Study in Parkinson's Disease Psychosis in the Journal of the American Medical Directors Association

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SAN DIEGO--(BUSINESS WIRE)--Aug. 6, 2015-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on the development and commercialization of innovative medicines that address unmet medical needs in neurological and related central nervous system disorders, today announced the publication of new data from its ongoing open-label safety extension study, the -015 Study, with NUPLAZID™ in patients with Parkinson's disease psychosis (PDP) in the July 31 online issue of the Journal of the American Medical Directors Association (www.jamda.com). This is the first published report evaluating the long-term impact of antipsychotics on mortality and serious adverse events in patients with PDP.

Currently marketed antipsychotics are not approved for PDP and have a black box warning for use in elderly patients with dementia due to increased mortality and morbidity. NUPLAZID was granted Breakthrough Therapy designation from the FDA in 2014 and has the potential to be the first drug approved for the treatment of PDP in the United States. In the -015 study, all patients received NUPLAZID (40 mg). Of 423 patients assessed, 357 received NUPLAZID only, while 66 patients received a currently marketed antipsychotic prescribed by their physician at some point during the study in addition to NUPLAZID. The two groups were well matched at baseline with regard to age (mean of 71-72 years) and other demographic and baseline variables. In a post-hoc analysis, there was a significant increase in the mortality rate of patients who received concurrent treatment with a currently marketed antipsychotic (18.8 deaths per 100 person-years since the first concurrent antipsychotic dose) compared to those who received NUPLAZID only (4.5 deaths per 100 person-years).

There also was a significant increase in treatment emergent serious adverse events in patients who received concurrent treatment with a currently marketed antipsychotic (52.5 first-occurrence events per 100 person-years since the first concurrent antipsychotic dose) compared to those who received NUPLAZID only (17.8 first-occurrence events per 100 person-years).

About NUPLAZID™ (pimavanserin)

NUPLAZID is ACADIA's proprietary small molecule that is a selective serotonin inverse agonist preferentially targeting 5-HT $_{2A}$ receptors that play an important role in psychosis. ACADIA has reported positive Phase III trial results with NUPLAZID, which has the potential to be the first drug approved in the United States for psychosis associated with Parkinson's disease. NUPLAZID is administered orally once-a-day. ACADIA discovered NUPLAZID and holds worldwide rights to this new chemical entity. The trade name NUPLAZID has been provisionally accepted by the FDA.

About Parkinson's Disease Psychosis

According to the National Parkinson Foundation, about one million people in the United States and from four to six million people worldwide suffer from Parkinson's disease. Parkinson's disease psychosis (PDP) is a debilitating disorder that occurs in an estimated 40 percent of Parkinson's patients. Currently, there is no FDA-approved therapy to treat PDP in the United States. PDP, which commonly consists of visual hallucinations and delusions, substantially contributes to the burden of Parkinson's disease and deeply affects the quality of life of patients. PDP also is associated with increased caregiver stress and burden, nursing home placement, and increased morbidity and mortality. There is a large unmet medical need for new therapies that will effectively treat PDP without compromising motor control in patients with Parkinson's disease.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in neurological and related central nervous system disorders. ACADIA has a pipeline of product candidates led by NUPLAZID™ (pimavanserin), for which we have reported positive Phase III trial results in Parkinson's disease psychosis and which has the potential to be the first drug approved in the United States for this disorder. Pimavanserin is also in Phase II development for Alzheimer's disease psychosis and has successfully completed a Phase II trial in schizophrenia. ACADIA also has clinical-stage programs for chronic pain and glaucoma in collaboration with Allergan, Inc. All product candidates are small molecules that emanate from internal discoveries. 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 potential for pimavanserin to be the first drug approved in the United States for PDP, if approved at all; the progress, timing and results of ACADIA's drug discovery and development programs, either alone or with a partner; and the benefits to be derived from ACADIA's product candidates, 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, approval and commercialization, and 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, 2014 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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