ACADIA Pharmaceuticals Submits New Drug Application for NUPLAZID™ for the Treatment of Parkinson's Disease Psychosis

September 3, 2015

SAN DIEGO--(BUSINESS WIRE)--Sep. 3, 2015-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders, today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for NUPLAZID ™ (pimavanserin) for the treatment of psychosis associated with Parkinson's disease.

NUPLAZID is an SSIA (selective serotonin inverse agonist) preferentially targeting 5-HT_{2A} receptors. Through this novel mechanism, NUPLAZID has demonstrated significant efficacy in Parkinson's disease psychosis (PDP) and has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved for use in PDP patients. The FDA granted NUPLAZID Breakthrough Therapy designation for PDP in 2014.

"NUPLAZID holds promise for patients with Parkinson's disease psychosis who currently have no FDA-approved treatment options," said Steve Davis, ACADIA's Chief Executive Officer. "Psychosis is the leading cause for Parkinson's patients moving from their homes to nursing homes or other institutions and leads to an increased risk of mortality, a diminished quality of life and significant caregiver burden. If approved, NUPLAZID would represent a new and distinctly different pharmacological approach to treating psychosis and would be the first drug approved in the United States for psychosis associated with Parkinson's disease."

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. An estimated 40 percent of these patients have Parkinson's disease psychosis, which is characterized by hallucinations and delusions. Currently, there is no FDA-approved therapy to treat Parkinson's disease psychosis.

ACADIA's NDA submission is based on data from a comprehensive development program assessing the safety and efficacy of NUPLAZID for Parkinson's disease psychosis. The NDA includes data from the pivotal Phase III -020 Study, in which NUPLAZID met all primary and secondary endpoints with statistical significance, along with supportive data from other studies with NUPLAZID. The -020 Study demonstrated that NUPLAZID significantly reduced psychosis compared to placebo in patients with Parkinson's disease psychosis with no worsening of motor function. These results were further supported by significant improvements in all secondary efficacy measures and by significant benefits in exploratory efficacy measures of nighttime sleep, daytime wakefulness and caregiver burden. Consistent with previous studies, NUPLAZID was safe and well tolerated in the -020 Study. Detailed results of the -020 Study have been published in The Lancet.

ACADIA has requested a Priority Review of its NDA. If granted, Priority Review status would accelerate the review timeline from ten months to six months following the conclusion of the 60 calendar day filing review period that begins on the FDA's receipt of the NDA. The FDA informs the applicant of a Standard or Priority Review designation following the conclusion of this 60 calendar day period.

Separately, ACADIA issued a news release today announcing that its Board of Directors has appointed Steve Davis as Chief Executive Officer.

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 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 has a pipeline of product candidates led by NUPLAZID™ (pimavanserin), for which we have submitted a New Drug Application in Parkinson's disease psychosis to the FDA and which has the potential to be the first drug approved in the United States for this condition. 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 timing of the potential approval of an NDA for NUPLAZID (pimavanserin); the potential for NUPLAZID to be the first drug approved in the United States for Parkinson's disease psychosis; whether, if approved, NUPLAZID would represent a new and distinctly different pharmacological approach to treating psychosis; the potential for NUPLAZID to avoid many of the debilitating side effects of existing antipsychotics; and the progress, timing and results of ACADIA's drug discovery and development programs, either alone or with a partner, including the progress and expected timing of clinical trials. 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, 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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Source: ACADIA Pharmaceuticals Inc.

Investors:
ACADIA Pharmaceuticals Inc.
Steve Davis, Chief Executive Officer
Lisa Barthelemy, Director of Investor Relations
858-558-2871
or
Media:
Russo Partners
David Schull
212-845-4271 or 858-717-2310
david.schull@russopartnersllc.com