ACADIA Pharmaceuticals Announces FDA Priority Review of NUPLAZID™ (Pimavanserin) New Drug Application for Parkinson's Disease Psychosis

November 2, 2015

PDUFA Date Set for May 1, 2016

SAN DIEGO--(BUSINESS WIRE)--Nov. 2, 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 that the New Drug Application (NDA) for NUPLAZID ™ (pimavanserin) has been accepted for review by the U.S. Food and Drug Administration (FDA) and the agency has granted it Priority Review. ACADIA is seeking FDA approval of NUPLAZID for the treatment of psychosis associated with Parkinson's disease. The FDA granted NUPLAZID Breakthrough Therapy designation for this indication in 2014.

The FDA grants Priority Review to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. Priority Review accelerates the review timeline from 10 months to six months from the date of acceptance of filing. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of May 1, 2016.

"The FDA Priority Review designation underscores the potential for NUPLAZID to provide an important treatment to patients with Parkinson's disease psychosis, a condition for which there is no FDA-approved therapy," said Steve Davis, ACADIA's President and Chief Executive Officer. "We look forward to working with the FDA during the review."

NUPLAZID is a new class of non-dopaminergic antipsychotic that acts as 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.

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, a diminished quality of life, and significant caregiver burden.

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 showed statistical improvement on all primary and secondary efficacy endpoints with no worsening of motor function. Detailed results of the -020 Study were published in The Lancet.

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. The NDA for NUPLAZID for the treatment of psychosis associated with Parkinson's disease is currently under Priority Review with the FDA. 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. The safety and efficacy of NUPLAZID have not been fully evaluated by any regulatory authority.

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 glaucoma and, in collaboration with Allergan, Inc., for chronic pain. 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; the potential benefits to be derived from ACADIA's product candidates, including NUPLAZID; 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 and past regulatory decisions may not be indicative of future trial results or regulatory decisions, respectively. 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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