



ACADIA Pharmaceuticals Announces FDA Advisory Committee Meeting to Review NUPLAZID™ (Pimavanserin) for the Treatment of Parkinson's Disease Psychosis

January 29, 2016

Advisory Committee Meeting Scheduled for March 29, 2016

SAN DIEGO--(BUSINESS WIRE)--Jan. 29, 2016-- 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 (CNS) disorders, today announced that the Psychopharmacologic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) will review data included in ACADIA's New Drug Application (NDA) for NUPLAZID™ (pimavanserin) for the treatment of psychosis associated with Parkinson's disease. The Advisory Committee Meeting is scheduled for March 29, 2016.

"Parkinson's disease psychosis is a debilitating condition for which there are no FDA-approved treatment options available to patients," said Steve Davis, ACADIA's President and Chief Executive Officer. "We look forward to discussing our data from the NUPLAZID clinical program with the members of the Committee."

The Prescription Drug User Fee Act (PDUFA) action date for completion of FDA review of the NUPLAZID NDA is May 1, 2016. The FDA has granted the NUPLAZID NDA Priority Review status and designated NUPLAZID for the treatment of psychosis associated with Parkinson's disease as a Breakthrough Therapy.

About The Psychopharmacologic Drugs Advisory Committee

The Committee is an independent panel of experts that reviews and evaluates data regarding the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields and makes appropriate recommendations to the FDA.

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 in Parkinson's disease psychosis. 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 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.

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 (NDA) 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. The FDA has classified the NUPLAZID NDA as having Priority Review status. 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 NUPLAZID (pimavanserin) to be the first drug approved in the United States for Parkinson's disease psychosis (PDP) and the potential timing of such approval, if approved at all, by the FDA; the timing or outcome of any discussion with the FDA or an advisory committee; 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 and past regulatory decisions may not be indicative of future trial results or future 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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