



## **ACADIA Pharmaceuticals Receives FDA Breakthrough Therapy Designation for NUPLAZID™ (Pimavanserin) for Parkinson's Disease Psychosis**

September 2, 2014

### **FDA Decision Highlights Significant Unmet Need in the Treatment of Parkinson's Disease Psychosis**

SAN DIEGO--(BUSINESS WIRE)--Sep. 2, 2014-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), 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, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to NUPLAZID™ (pimavanserin) for the treatment of Parkinson's disease psychosis. NUPLAZID is a selective serotonin inverse agonist and, if approved, will establish a new and distinctly different pharmacological approach to treating psychosis. NUPLAZID has successfully completed a pivotal Phase III trial in Parkinson's disease psychosis, which the FDA has agreed can serve as the basis, together with supportive data from other studies, for a New Drug Application (NDA). ACADIA plans to submit the NUPLAZID NDA to the FDA near the end of this year.

"The hallucinations and delusions in Parkinson's disease psychosis are devastating to patients and contribute to a dramatic rise in caregiver burden," said Joyce Oberdorf, President and Chief Executive Officer of the National Parkinson Foundation. "Parkinson's disease psychosis is a leading cause of nursing home placement for Parkinson's patients and, with no FDA-approved therapy for this serious condition, there is a great unmet medical need for an effective, safe, and well-tolerated treatment option for patients."

"The Breakthrough Therapy designation for NUPLAZID reinforces the urgent need for a treatment for patients with Parkinson's disease psychosis," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "NUPLAZID represents a potential new class of psychosis medication and could be the first drug approved in the United States for patients with Parkinson's disease psychosis."

The Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. For indications without an approved therapy, drugs qualifying for this designation must show a substantial and clinically meaningful effect on an important outcome when compared with placebo. The Breakthrough Therapy designation is distinct from priority review, which can also be granted to the same drug if the relevant criteria are met. The FDA informs the applicant of a standard or priority review designation within 60 days of the receipt of the original NDA.

#### *About NUPLAZID™ (pimavanserin)*

NUPLAZID is ACADIA's proprietary small molecule that is a selective serotonin inverse agonist preferentially targeting 5-HT<sub>2A</sub> receptors believed to 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 ([www.parkinson.org](http://www.parkinson.org)), 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. We are currently completing NDA-enabling clinical and manufacturing activities for NUPLAZID and are planning to submit an NDA to the FDA near the end of this year. 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. and two preclinical programs directed at Parkinson's disease and other neurological disorders. All product candidates are small molecules that emanate from internal discoveries. ACADIA maintains a website at [www.acadia-pharm.com](http://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 submission of an NDA for NUPLAZID for PDP; the potential for NUPLAZID to be the first drug approved in the United States for PDP, if approved at all; the approval of NUPLAZID for PDP establishing a new and different pharmacological approach to treating psychosis; 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; and the progress of ACADIA's NDA-enabling clinical and manufacturing activities. 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, 2013 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.

Source: ACADIA Pharmaceuticals Inc.

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