



## ACADIA Pharmaceuticals Issues Statement Reaffirming Benefit/Risk Profile of NUPLAZID

April 27, 2018

*- Concurrently, the Company Has Issued a Press Release Announcing the Presentation of Clinical Experience Data for NUPLAZID at the American Academy of Neurology (AAN) Annual Meeting*

SAN DIEGO--(BUSINESS WIRE)--Apr. 27, 2018-- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today issued the following statement:

NUPLAZID® (pimavanserin) is the only medicine approved in the United States to treat hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID was approved by the FDA based on a pivotal Phase 3 study that demonstrated clinically robust and highly statistically significant efficacy, combined with other supportive studies. We are confident in NUPLAZID's efficacy and positive benefit/risk profile and stand firmly behind it.

ACADIA's top priority has been, and continues to be, patient safety. NUPLAZID was approved and launched in 2016. As the manufacturer of a newly launched drug, we are routinely in contact with the FDA regarding requests for additional information on NUPLAZID, including postmarketing safety surveillance information as part of the FDA's ongoing safety monitoring.

In a statement released to the media on April 10, 2018, the FDA stated, "The FDA continues to monitor adverse events reported with NUPLAZID that are submitted to the FDA Adverse Event Reporting System (FAERS). We have noted that the cases typically involve geriatric patients with advanced-stage Parkinson's disease, as well as numerous medical conditions, who are frequently taking concomitant medications with risks for serious adverse events, including death. Based on these data, the FDA has, at this time, not identified a specific safety issue that is not already adequately described in the product labeling."

On April 25, 2018, the FDA stated that its evaluation does not mean the Agency has determined the medicine has a new risk and does not suggest healthcare providers should not prescribe it nor that patients should stop taking the medication. The Agency also has confirmed this statement does not represent a change from the safety review and monitoring activities the FDA referred to in its statement of April 10. As always, we will continue to work with the FDA and medical community to answer any questions related to NUPLAZID.

ACADIA collects and analyzes postmarketing events for NUPLAZID as part of our ongoing commitment to monitor the medication's safety profile. These events are submitted to the FDA and incorporated into the FDA's FAERS public reporting system. Because NUPLAZID is distributed through a specialty distribution channel, we have frequent (in most cases monthly) contact with patients and caregivers through our distribution partners. This increased interaction naturally results in dramatically higher adverse event collection and reporting compared to products without such a distribution method. Approximately 93 percent of the reported adverse events associated with NUPLAZID are considered "solicited" due to this direct interaction with patients and caregivers, while only approximately 7 percent of these events are considered "spontaneous" reports, which are voluntary reports originating from consumers or healthcare professionals. In contrast, most other antipsychotics are distributed through retail channels, which rely almost entirely on "spontaneous" reporting. Consequently, only a small fraction of actual adverse events are collected for these drugs.

### NUPLAZID Recent Studies Update

Since NUPLAZID's approval, additional studies have further demonstrated its efficacy and benefit/risk profile. Simultaneous with this release, ACADIA announced the results of two independent studies presented this week at the American Academy of Neurology Annual Meeting. In the first study, a retrospective 102-patient chart review conducted by researchers at Vanderbilt University Medical Center, more than 70 percent of all patients treated with NUPLAZID reported clinical improvement, while 88 percent of patients treated longer than four weeks improved. Importantly, NUPLAZID was tolerated without significant side effects in the majority of patients. In this study, there was no increase in mortality reported for patients taking NUPLAZID. The second study, conducted by researchers from the Parkinson's Disease and Movement Disorders Center at Henry Ford Hospital, involved a survey of real-life experience among 16 patients diagnosed with moderate to severe Parkinson's disease psychosis, which showed that NUPLAZID was a well-tolerated and effective treatment in these patients.

As part of this statement, ACADIA is providing updated safety information from two recent clinical studies. Following the approval of NUPLAZID for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis, ACADIA has conducted two placebo-controlled clinical studies in an aggregate of more than 300 patients with Alzheimer's disease (AD). In these controlled studies in frail elderly patients with dementia, there was no difference in the number of deaths reported between NUPLAZID (four) and placebo (four).

In addition, ACADIA has completed or is in the process of completing all of the postmarketing commitments included with the NUPLAZID approval letter, in full compliance with the timelines defined by the FDA.

Of the approximately one million individuals in the United States living with Parkinson's disease, over 50 percent will experience hallucinations and delusions associated with Parkinson's disease psychosis over the course of their disease. NUPLAZID fills a significant, previously unmet need in the treatment of Parkinson's disease psychosis. Patients and healthcare professionals recognize the value of NUPLAZID, and we receive positive feedback about the benefits it provides to patients and their families. We look forward to working closely and expeditiously with the FDA and the Parkinson's disease community to ensure the best and safest care of patients with Parkinson's disease psychosis. We thank healthcare providers for their ongoing support in raising awareness around this debilitating condition and take pride in the meaningful impact NUPLAZID has made in the lives of patients with Parkinson's disease psychosis and the people who care for them.

### 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 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 benefits to be derived from NUPLAZID (pimavanserin), the outcome of any ongoing or future evaluation by the FDA of NUPLAZID, or the timing or results of any future studies with NUPLAZID. 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 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, 2017 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.

#### **Important Safety Information and Indication for NUPLAZID (pimavanserin) tablets**

##### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.**

NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

**Contraindication:** NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.

**QT Interval Prolongation:** NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics. NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

**Adverse Reactions:** The most common adverse reactions ( $\geq 2\%$  for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

**Drug Interactions:** Strong CYP3A4 inhibitors (e.g., ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half. Strong CYP3A4 inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

**Pregnancy:** Use of NUPLAZID in pregnant women has not been evaluated and should therefore be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

**Pediatric Use:** Safety and efficacy have not been established in pediatric patients.

**Dosage and Administration:** Recommended dose: 34 mg per day, taken orally as two 17-mg tablets once daily, without titration.

For additional Important Safety Information, including boxed warning, please see the full Prescribing Information for NUPLAZID at [https://www.nuplazid.com/pdf/NUPLAZID\\_Prescribing\\_Information.pdf](https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf).

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