ACADIA Pharmaceuticals Announces Presentation of Clinical Experience Data for NUPLAZID (Pimavanserin) at 2018 American Academy of Neurology (AAN) Annual Meeting

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Two Independent Data Sets Confirm NUPLAZID Is Well-Tolerated and Efficacious in Treating Hallucinations and Delusions Associated with Parkinson's Disease Psychosis

SAN DIEGO--(BUSINESS WIRE)--Apr. 27, 2018-- 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 poster presentations of clinical experience data from two studies of NUPLAZID® (pimavanserin) in Parkinson's disease psychosis (PD Psychosis) at the American Academy of Neurology (AAN) Annual Meeting in Los Angeles.

Poster Presentations

Clinical Experience with Pimavanserin for Treatment of Parkinson's Disease Psychosis
(Poster #040)
Researchers at Vanderbilt University Medical Center performed a retrospective chart review of patients treated with NUPLAZID. The objective of the study was to review their prescribing patterns and clinical experiences with NUPLAZID. In this study, the researchers identified a total of 102 patients who were prescribed NUPLAZID between May 2016 and March 2018. Eighty eight of these patients began treatment with NUPLAZID and 14 patients never started treatment. About two-thirds of patients had tried and failed prior antipsychotic therapy. Data from the study show:

- >70% of all patients treated with NUPLAZID reported clinical improvement, while 88% of patients treated longer than four weeks improved.
- 67% of patients have remained on NUPLAZID for an average of 10+ months.
- Only 11% of patients were unable to tolerate NUPLAZID due to adverse events.
- NUPLAZID was effective in both treatment naïve and prior antipsychotic failure patients.
    - For those who failed NUPLAZID, improvement with a subsequent antipsychotic was uncommon.
- There was no increase in mortality detected in users of NUPLAZID.
    - 6 of the 88 patients treated with NUPLAZID died (compared to 5 out of 14 in the group that never started NUPLAZID).

"This retrospective chart review provides relevant clinical experience data on treatment patterns in a Parkinson's disease psychosis cohort," said Daniel Claassen, MD, Associate Professor of Neurology, Vanderbilt University Medical Center. "At about ten months of follow-up, we see that two-thirds of patients have noted a favorable clinical response to NUPLAZID. We look forward to continuing our studies of how to treat psychosis in Parkinson's disease, as we assess treatment strategies for this debilitating symptom."

Pimavanserin Use in a Movement Disorders Clinic: a Single Center Experience
(Poster #065)
Researchers from the Parkinson's Disease and Movement Disorders Center at Henry Ford Hospital assessed NUPLAZID's clinical use by retrospective chart review and telephone interviews with patients and caregivers. Information on demographics, psychotic features, sleep, and adverse events was collected. This assessment of real-life experience in 16 patients diagnosed with PD Psychosis and taking NUPLAZID showed that NUPLAZID was well-tolerated and improved symptoms in most patients. Data from this study show:

- 65% reported improvement of hallucinations with NUPLAZID.
- Six of the nine patients originally prescribed an earlier generation antipsychotic (either quetiapine or olanzapine) were able to discontinue those drugs following NUPLAZID initiation and remained on NUPLAZID monotherapy.
- No major side effects were reported.

"Our study was based on real-life experience and shows that NUPLAZID is a beneficial and well-tolerated treatment for PD Psychosis," said Neepa Patel, MD, Movement Disorder Specialist at Henry Ford Hospital in West Bloomfield, MI.

About Parkinson's Disease Psychosis
According to the Parkinson's Foundation, about one million people in the United States and from four to six million people worldwide suffer from Parkinson's disease. More than 50 percent of people with Parkinson's will experience symptoms of psychosis over the course of their disease. PD Psychosis is characterized by hallucinations and delusions, is associated with significant caregiver burden, and is a major reason for nursing home placement among Parkinson's patients.

About NUPLAZID® (pimavanserin)
NUPLAZID is the first FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a non-dopaminergic, selective serotonin inverse agonist preferentially targeting 5-HT_{2A} receptors that are thought to play an important role in Parkinson's disease psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg (two 17-mg tablets). ACADIA discovered this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

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 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 benefits to be derived from NUPLAZID and to 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:Themost common adverse reactions(≥2% for NUPLAZID and greater than placebo) wereperipheral 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 (eg, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20180427005270/en/

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