



ACADIA Pharmaceuticals to Present Pimavanserin Clinical Data at the 2020 American Society of Clinical Psychopharmacology Virtual Annual Meeting

May 21, 2020

SAN DIEGO--(BUSINESS WIRE)--May 21, 2020-- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced that multiple scientific presentations and abstracts evaluating pimavanserin in clinical studies for the treatment of various central nervous system (CNS) disorders will be highlighted at the 2020 American Society of Clinical Psychopharmacology (ASCP) Virtual Annual Meeting on May 29-30, 2020.

"Our research presentations at ASCP underscore the potential clinical utility of pimavanserin in serious CNS disorders," said Serge Stankovic, M.D., M.S.P.H., ACADIA's President. "We look forward to sharing data from our pivotal studies in negative symptoms of schizophrenia and major depressive disorder where pimavanserin has demonstrated the potential to be an important treatment option for patients, as well as new long-term safety and tolerability data of NUPLAZID® in Parkinson's disease psychosis."

ASCP Accepted Scientific Presentations include:

Negative Symptoms of Schizophrenia

- Pharmaceutical Pipeline Oral Presentation: *ADVANCE: Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Adjunctive Pimavanserin in Patients with Negative Symptoms of Schizophrenia* on Saturday, May 30, 2020, 4:55 p.m. - 5:05 p.m. Eastern Time.
- Poster Presentation: *ADVANCE: Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Adjunctive Pimavanserin in Patients with Negative Symptoms of Schizophrenia* on Saturday, May 30, 2020, 12:45 p.m. - 2:15 p.m. Eastern Time.

Depression

- Poster Presentation: *Effect of Adjunctive Pimavanserin on Suicidality in Patients with Major Depressive Disorder: Secondary Analysis from CLARITY* on Friday, May 29, 2020, 12:30 p.m. - 2:00 p.m. Eastern Time.
- Poster Presentation: *Effect of Adjunctive Pimavanserin on Insomnia and Function in Patients with Major Depressive Disorder: Secondary Analysis from CLARITY* on Saturday, May 30, 2020, 12:45 p.m. - 2:15 p.m. Eastern Time.
- Poster Presentation: *Pimavanserin for the Treatment of Comorbid Depression in Patients with Parkinson's Disease* on Friday, May 29, 2020, 12:30 p.m. - 2:00 p.m. Eastern Time.

Parkinson's Disease Psychosis

- Poster Presentation: *Long-Term Evaluation of Open-Label Pimavanserin Safety and Tolerability in Parkinson's Disease Psychosis* on Saturday, May 30, 2020, 12:45 p.m. - 2:15 p.m. Eastern Time.
- Poster Presentation: *Improvement and Durability in SAPS-PD Assessment over 10 Weeks of Pimavanserin Treatment for Parkinson's Disease Psychosis* on Saturday, May 30, 2020, 12:45 p.m. - 2:15 p.m. Eastern Time.

About Pimavanserin

Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-HT_{2A} receptors. These receptors are thought to play an important role in psychosis, schizophrenia, depression and other neuropsychiatric disorders. In vitro, pimavanserin demonstrated no appreciable binding affinity for dopamine (including D₂), histamine, muscarinic, or adrenergic receptors. ACADIA is evaluating pimavanserin in an extensive clinical development program across multiple indications with significant unmet need including dementia-related psychosis, adjunctive major depressive disorder, and the negative symptoms of schizophrenia. Pimavanserin was approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis by the U.S. Food and Drug Administration in April 2016 under the trade name NUPLAZID®. NUPLAZID is not approved for dementia-related psychosis, schizophrenia, major depressive disorder or depression 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 central nervous system disorders. ACADIA has developed and commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA also has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, major depressive disorder, the negative symptoms of schizophrenia, and Rett syndrome. This press release and further information about ACADIA can be found at: www.acadia-pharm.com.

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 benefits of pimavanserin as adjunctive treatment for major depressive disorder, the negative symptoms of schizophrenia or other central nervous system disorders as well as the potential results of clinical trials of pimavanserin in other indications. 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 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, 2019 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)

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.**
- **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:**
 - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
 - Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Indication: NUPLAZID is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Dosage and Administration: Recommended dose: 34 mg capsule taken orally once daily, without titration.

NUPLAZID is available as 34 mg capsules and 10 mg tablets.

Please see the full [Prescribing Information](#) including **Boxed WARNING** for NUPLAZID.

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