



ACADIA Pharmaceuticals Presents Integrated Data from Its Phase III Program with NUPLAZID™ (Pimavanserin) for Parkinson's Disease Psychosis at the 19th International Congress of Parkinson's Disease and Movement Disorders

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Data from Integrated Analysis of Two Phase III Studies Show Robust and Consistent Efficacy of NUPLAZID Across a Wide Array of Study Measures

Data from Two Open-Label Studies Demonstrate Attractive Safety and Tolerability Profile and Potential for Long-Term Effectiveness of NUPLAZID in Parkinson's Disease Psychosis

SAN DIEGO--(BUSINESS WIRE)--Jun. 16, 2015-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on innovative treatments that address unmet medical needs in neurological and related central nervous system disorders, today announced the presentation of integrated efficacy and tolerability data from its Phase III program with NUPLAZID™ (pimavanserin) at the 19th International Congress of Parkinson's Disease and Movement Disorders held in San Diego.

"Data from the integrated analysis of Phase III studies continue to support the potential for NUPLAZID to safely and effectively treat Parkinson's disease psychosis, a condition for which there is no approved therapy in the United States," said Roger Mills, M.D., Executive Vice President, Development and Chief Medical Officer. "Furthermore, data from our open-label safety extension studies indicate that long-term administration of NUPLAZID is generally safe and well tolerated in patients with Parkinson's disease psychosis and that duration of antipsychotic effect may be maintained for longer than the six weeks investigated in our Phase III placebo-controlled efficacy studies."

Poster Presentations

Efficacy and Tolerability of NUPLAZID™ (pimavanserin) in PD Psychosis: Analysis of an Integrated Phase 3 Placebo-Controlled Dataset (Abstract #156)

An integrated analysis was performed on efficacy and tolerability data from two six-week Phase III placebo-controlled clinical trials with NUPLAZID (40 mg) in Parkinson's disease psychosis (PDP). In this large pooled sample of 268 patients from North America, NUPLAZID showed highly significant improvement in psychosis compared to placebo on the 9-item SAPS-PD scale ($p < 0.001$). NUPLAZID demonstrated significant improvement on each of the separate hallucinations and delusions domains and also on secondary psychoses measures, including the Clinical Global Impression-Improvement (CGI-I) and the Clinical Global Impression-Severity (CGI-S) scales. In addition, NUPLAZID demonstrated significant improvement on nighttime sleep, daytime wakefulness and caregiver burden, representing additional potential clinically impactful benefits. Results were consistent across all subgroups of interest, showing greater improvement with NUPLAZID over placebo regardless of age, sex, race group or MMSE screening score.

Pooled analysis of data from all Phase III placebo-controlled clinical trials with NUPLAZID showed that NUPLAZID was well tolerated and had no impairment on motor function. The adverse event profile of NUPLAZID was similar to placebo.

Long-Term Effectiveness of NUPLAZID™ (pimavanserin) in PD Psychosis: Data from 2 Open-Label Studies (Abstract #149)

Data from two open-label safety extension studies were presented, including final data from a completed Phase II open-label study (-010 Study) of 39 PDP patients and interim data from an ongoing Phase III open-label study (-015 Study) of 459 PDP patients. The interim analysis of the ongoing -015 Study reflects data entered into the database as of December 13, 2013. PDP patients in the -015 Study rolled in after completing 6 weeks of blinded treatment in a Phase III placebo-controlled efficacy, tolerability and safety trial. PDP patients in the -010 Study rolled in following completion of the 4-week treatment period in a Phase II placebo-controlled efficacy, tolerability and safety trial. In both open-label studies, patients remained on treatment for a median duration of over 15 months.

Data from the two open-label studies suggest that long-term administration of NUPLAZID is generally safe and well tolerated in patients with PDP. Although there are no formal efficacy endpoints in the open-label studies, persistent antipsychotic benefit has been observed in one or both studies across measures including SAPS-PD, other SAPS-based outcomes, CGI-I and CGI-S. In the -015 Study, patients who rolled in from a placebo arm showed a highly significant improvement in SAPS-PD and CGI-S scores at Week 4 compared to their score at the end of the 6-week randomized study. This improvement was observed for the combined U.S. and rest-of-world patients. Persistent benefit on caregiver burden with NUPLAZID has also been observed.

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, 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, 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

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. 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. All product candidates are small molecules that emanate from internal discoveries. 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 progress and timing of ACADIA's drug discovery and development programs, either alone or with a partner, including clinical trials, the benefits to be derived from ACADIA's product candidates, in each case including NUPLAZID (pimavanserin), the potential for NUPLAZID to be the first drug approved in the United States for Parkinson's disease psychosis (PDP), the potential for NUPLAZID to safely and effectively treat PDP, and the potential for NUPLAZID to be effective for long-term treatment of PDP, including beyond the 6-week treatment period of prior placebo-controlled clinical trials. 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, 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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