Analyses of Pimavanserin Studies Evaluating Treatment in Alzheimer's Disease Psychosis and Parkinson's Disease Psychosis Published in The Journal of Prevention of Alzheimer's Disease Suggest Potential for Treating Dementia-Related Psychosis

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SAN DIEGO--(BUSINESS WIRE)--Sep. 10, 2018-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD) announced today publication of additional data from a Phase 2 single center, double-blind, placebo-controlled study to examine the safety and efficacy of pimavanserin for the treatment of psychosis in Alzheimer's Disease Psychosis in *The Journal of Prevention of Alzheimer's Disease (JPAD)* . These results further demonstrate that pimavanserin may have the potential to treat dementia-related psychosis, a condition which can be present in neurodegenerative diseases such as Alzheimer's disease, dementia with Lewy Bodies, dementia associated with Parkinson's disease, vascular dementia and frontotemporal dementia-spectrum disorders.

The publication (https://link.springer.com/article/10.14283/jpad.2018.30) focused on the pre-specified analysis in the subgroup of patients who had more pronounced psychotic symptoms at baseline. In this subgroup of patients with more severe delusions and hallucinations, at the primary efficacy endpoint, pimavanserin demonstrated significant improvement relative to placebo with a similar and acceptable tolerability profile. These results were also presented recently at the Alzheimer's Association International Conference in Chicago in July 2018. The primary results from the study were previously reported at the Clinical Trials in Alzheimer's Disease (CTAD) conference in Boston in October 2017 and published in the *Lancet Neurology* in March 2018.

"The robust efficacy of pimavanserin in patients with more severe psychotic symptoms is relevant to the therapeutic benefits of pimavanserin in a patient population with Alzheimer's disease and psychosis," said lead investigator Clive Ballard, MBChB, MRCPsych, Pro-Vice-Chancellor and Executive Dean, University of Exeter Medical School. "These results extend and confirm the results from the primary analysis as well as results from the subgroup analysis of patients with mild dementia in the pivotal Parkinson's disease psychosis study with pimavanserin. These findings, coupled with the results from other studies of pimavanserin, suggest a potential role for pimavanserin in treating dementia-related psychosis in patients across a range of neuropsychiatric conditions."

A separate review published in *JPAD* (https://link.springer.com/article/10.14283/jpad.2018.29) also supports the potential use of pimavanserin in other forms of neurodegenerative diseases, including dementia-related psychosis. A research group led by Jeffrey Cummings, MD, ScD, of the Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, looked at the clinical evidence that has been gathered to date that supports the potential efficacy of pimavanserin in dementia-related psychosis. "Clinical evidence is now available that supports potential efficacy of pimavanserin in dementia-related psychosis. This includes results from a sub-analysis of mildly demented patients in the Phase 3 pivotal study in patients with Parkinson's disease psychosis, and the Phase 2 study in patients with Alzheimer's disease. Based on the overlap in clinical presentation and pathology and the positive clinical trial results in two neurodegenerative patient populations, we think it is important to continue to evaluate pimavanserin's effect in patients with hallucinations and delusions across a number of neurodegenerative disorders," said Dr. Cummings.

ACADIA is currently conducting the Phase 3 HARMONY study in dementia-related psychosis. This is a randomized withdrawal study designed to evaluate the efficacy of pimavanserin in preventing relapse of psychotic symptoms in patients with dementia-related psychosis. Patients whose dementia-related hallucinations and delusions respond to 12 weeks of open-label treatment with pimavanserin are randomized, in a double-blinded manner to continue pimavanserin therapy or to placebo. The primary endpoint of this study is the average time to relapse between pimavanserin and placebo. Studies suggest that 30% of patients with dementia have psychosis, commonly consisting of hallucinations and delusions. Serious consequences have been associated with severe or persistent psychosis in patients with dementia. These consequences can impact both patients and their families. Medications that are currently used off-label to treat dementia related psychosis have been shown to impair cognition in this already impaired population.

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 is commercializing the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. In addition, ACADIA has ongoing clinical development efforts in additional areas with significant unmet need including dementia-related psychosis, schizophrenia inadequate response, schizophrenia-negative symptoms, major depressive disorder 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 in patients with dementia-related psychosis. 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.

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