ACADIA Pharmaceuticals Announces Initiation of Phase II Trial with Pimavanserin for Alzheimer's Disease Psychosis

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SAN DIEGO--(BUSINESS WIRE)--Nov. 14, 2013-- 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 that it has initiated a Phase II feasibility trial designed to examine the efficacy and safety of pimavanserin as a treatment for patients with Alzheimer's disease psychosis (ADP). No drug is approved in the United States to treat ADP and the off-label use of current antipsychotics is linked to increased mortality, serious adverse events, and cognitive decline in elderly patients with dementia-related psychosis.

"The development of psychosis and related behavioral disturbances in patients with Alzheimer's disease carries a poor prognosis and often has a devastating impact on both patients and their caregivers," said Clive Ballard, M.D., Professor of Age Related Diseases at King's College London. "Finding new therapies that can effectively treat ADP without compromising safety is an important priority for the neurology community and society as a whole. Pimavanserin's attractive efficacy, tolerability and safety profile observed in a Phase III trial in patients with Parkinson's disease psychosis suggests that it may offer the potential for an important new therapeutic advance for patients suffering from ADP."

The Phase II feasibility trial, referred to as the -019 Study, is a randomized, double-blind, placebo-controlled study designed to examine the efficacy and safety of pimavanserin in about 200 patients with ADP. The study is being conducted through a large network of research care homes established as part of the National Institute for Health Research (NIHR) Maudsley Biomedical Research Unit. Following a screening period that includes brief psycho-social therapy, patients will be randomized on a one-to-one basis to receive either 40 mg of pimavanserin or placebo once-daily for 12 weeks. The -019 Study will assess several key efficacy endpoints, including use of the Neuropsychiatric Inventory - Nursing Home (NPI-NH) scale to measure psychosis (hallucinations and delusions), agitation/aggression, and sleep/nighttime behavior, as well as use of the Cohen-Mansfield Agitation Inventory - Short Form (CMAI-SF) scale and the Alzheimer's Disease Cooperative Study - Clinical Global Impression of Change (ADCS-CGIC) scale. Key efficacy endpoints will be based on the change at week six from baseline. The study will also assess additional exploratory endpoints, including the cognitive status of patients using the Mini-Mental State Examination (MMSE) scale, and the durability of response to pimavanserin through twelve weeks of therapy.

"We are delighted to pursue this clinical study in collaboration with Professor Ballard and King's College London," said Roger G. Mills, M.D., ACADIA's Executive Vice President of Development and Chief Medical Officer. "We believe that their unique clinical research infrastructure and expertise will provide access to a pool of well-characterized ADP patients and enable the use of a small and geographically-focused group of highly trained raters, which we expect to enhance study precision."

About Alzheimer's Disease Psychosis

According to the Alzheimer's Association, 5.4 million people in the United States are living with Alzheimer's disease. While the criteria for diagnosing Alzheimer's disease are mostly focused on cognitive deficits, it is often the psychiatric and related behavioral symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. An estimated 25 to 50 percent of Alzheimer's patients may develop Alzheimer's disease psychosis (ADP), which is commonly characterized by disturbing visual hallucinations and delusions. The diagnosis of ADP is associated with more rapid cognitive and functional decline and institutionalization. There currently is no therapy approved for the treatment of ADP in the United States.

About Pimavanserin

Pimavanserin is ACADIA's proprietary small molecule that acts selectively as an antagonist/inverse agonist on serotonin 5-HT $_{2A}$ receptors. ACADIA has successfully completed a pivotal Phase III trial with pimavanserin, which demonstrated robust efficacy, tolerability and safety in patients with Parkinson's disease psychosis (PDP), potentially positioning it to be the first drug approved in the United States for the treatment of this disorder. Pimavanserin is also in Phase II development for Alzheimer's disease psychosis (ADP) and has completed a Phase II trial as a co-therapy in schizophrenia. Pimavanserin is formulated as a tablet and is administered orally once-a-day. ACADIA discovered pimavanserin and holds worldwide rights to this new chemical entity.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on innovative treatments that address unmet medical needs in neurological and related central nervous system disorders. ACADIA has a pipeline of product candidates led by pimavanserin, which is in Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. ACADIA also has clinical-stage programs for chronic pain and glaucoma in collaboration with Allergan, Inc. and two advanced preclinical programs directed at Parkinson's disease and other neurological disorders. All product candidates are small molecules that emanate from discoveries made at ACADIA. ACADIA maintains a website at www.acadia-pharm.com to which ACADIA regularly posts copies of its press releases as well as additional information and through which interested parties can subscribe to receive e-mail alerts.

About NIHR Maudsley Biomedical Research Centre

The National Institute for Health Research (NIHR) Mental Health Biomedical Research Centre and Dementia Unit (BRC/U) at South London and Maudsley NHS Foundation Trust and Institute of Psychiatry, King's College London aim to turn the latest scientific knowledge in mental health into improved medical treatments for the benefit of all patients and carers. We are the only BRC/U specialising in mental health research.

We are part of King's Health Partners Academic Health Sciences Centre, a pioneering collaboration between King's College London, and Guy's and St Thomas', King's College Hospital and South London and Maudsley NHS Foundation Trusts (http://brc.slam.nhs.uk/).

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, including clinical trials and the results therefrom, and the potential of and the benefits to be derived from product candidates, in each case including pimavanserin. These statements also include any suggestion that the results from trials with pimavanserin in PDP will be predictive of results in the -019 Study for ADP or whether the use of a geographically-focused group of raters will enhance precision in the -019 Study. 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 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, 2012 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.

Source: ACADIA Pharmaceuticals Inc.

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