ACADIA Pharmaceuticals Announces Initiation of New Phase III Trial with Pimavanserin for Parkinson's Disease Psychosis

July 29, 2010

SAN DIEGO, Jul 29, 2010 (BUSINESS WIRE) --

ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for central nervous system disorders, today announced that it has initiated a new Phase III trial designed to evaluate the efficacy, tolerability and safety of pimavanserin as a treatment for patients with Parkinson's disease psychosis (PDP).

"This Phase III trial builds on the signals of efficacy observed in our earlier PDP studies and uses a refined study design that we expect will help mitigate the placebo response, reduce variability and enhance sensitivity in measuring the efficacy of pimavanserin in PDP patients," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA Pharmaceuticals. "We believe pimavanserin has an ideal profile to effectively treat PDP without impairing motor function and, therefore, provides the potential for an important advance in therapy for patients suffering from this large unmet medical need."

Trial Design

The new Phase III trial (the -020 Study) is a multi-center, double-blind, placebo-controlled study designed to evaluate the efficacy, tolerability and safety of pimavanserin in patients with PDP. The -020 Study is expected to enroll about 200 patients at clinical sites located in North America. Patients in the trial will be randomized on a one-to-one basis to two study arms and will receive oral doses of either 40 mg of pimavanserin or placebo once-daily for six weeks. Patients also will continue to receive stable doses of their existing dopamine replacement therapy used to manage the motoric symptoms of Parkinson's disease. The primary endpoint of the -020 Study is antipsychotic efficacy as measured using a group of nine items from the hallucinations and delusions domains of the Scale for the Assessment of Positive Symptoms (SAPS). The primary endpoint will be assessed using centralized ratings. Motoric tolerability will be a key secondary endpoint in the trial and will be measured using Parts II and III of the Unified Parkinson's Disease Rating Scale (UPDRS).

In addition to the -020 Study, ACADIA is continuing to conduct an open-label safety extension study (the -015 Study) that enrolled patients who completed either of two earlier Phase III PDP trials. Patients who complete the -020 Study also will have the opportunity to enroll in the -015 Study if, in the opinion of the treating physician, the patient may benefit from continued treatment with pimavanserin.

About Pimavanserin

Pimavanserin is a 5-HT_{2A} receptor inverse agonist in Phase III development as a treatment for Parkinson's disease psychosis. This new chemical entity, which was discovered by ACADIA, is a small molecule that can be taken orally as a tablet once-a-day. ACADIA and Biovail Laboratories International SRL (Biovail), a subsidiary of Biovail Corporation, have formed a collaboration to develop and commercialize pimavanserin for neurological and psychiatric indications, including Parkinson's disease psychosis, schizophrenia, and Alzheimer's disease psychosis, in the United States and Canada. ACADIA retains rights to pimavanserin in the rest of the world.

About Parkinson's Disease Psychosis

According to the National Parkinson Foundation, over 1.5 million people in the United States suffer from Parkinson's disease. Up to 40 percent of patients with Parkinson's disease may develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. Currently, there is no therapy in the United States approved to treat PDP. The development of psychosis in patients with Parkinson's disease often disrupts their ability to perform many of the activities of daily living and is associated with increased caregiver burden, nursing home placement, and increased mortality.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for central nervous system disorders. ACADIA is developing a portfolio consisting of four product candidates including pimavanserin, which is being developed for three separate neurological and psychiatric indications in collaboration with Biovail. These indications are Parkinson's disease psychosis, which is in Phase III development, co-therapy for schizophrenia, which is in Phase III planning, and Alzheimer's disease psychosis, for which ACADIA is planning to initiate a Phase II feasibility study. In addition to pimavanserin, ACADIA has a product candidate in Phase II for chronic pain and a product candidate in Phase I for glaucoma, both in collaboration with Allergan, as well as a product candidate in IND-track development for schizophrenia in collaboration with Meiji Seika Kaisha. All of the product candidates in ACADIA's product pipeline emanate from discoveries made using its proprietary drug discovery platform. 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.

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 design, progress and timing of ACADIA's drug discovery and development programs, including the -020 Study and ACADIA's other clinical trials and the results therefrom, and the potential of and the benefits to be derived from clinical trials and product candidates, including pimavanserin. 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, 2009 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.

ACADIA Pharmaceuticals Inc.
Uli Hacksell, Ph.D., Chief Executive Officer
(858) 558-2871