ACADIA Pharmaceuticals Provides Update on Pimavanserin Collaborative Development Program

October 6, 2009

SAN DIEGO--(BUSINESS WIRE)--Oct. 6, 2009-- 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 provided an update on its Phase III program with pimavanserin for Parkinson's disease psychosis (PDP), which is being pursued in collaboration with Biovail Laboratories International SRL ("Biovail"), a subsidiary of Biovail Corporation. Following the announcement on September 1st of disappointing top-line results from the first Phase III PDP trial, ACADIA and Biovail remain committed to the successful development of pimavanserin and have established a development strategy that they believe will strengthen the PDP program. The parties also intend to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration.

"We remain enthusiastic about pimavanserin's prospects in a number of specialty CNS indications, including schizophrenia where existing data for the molecule as co-therapy are compelling," said Bill Wells, Biovail's Chief Executive Officer. "The steps we're taking today are designed to fully exploit pimavanserin's potential and to bring this novel therapeutic to market as quickly as possible."

ACADIA has conducted a substantial portion of the analysis of the data from its first Phase III PDP trial with pimavanserin (-012 Study). While the -012 Study did not meet its primary endpoint of antipsychotic efficacy and had a larger than expected placebo response, signals of antipsychotic efficacy were observed in the pimavanserin 40 mg study arm. These signals were most prominent in the United States portion of the study, which comprised nearly one-half of the patients in the trial. The efficacy signals also were supported by additional secondary and exploratory measures, including efficacy measures and favorable outcomes in assessments of sleep and caregiver burden. Several findings from the -012 Study will be used in the design of future PDP studies to help mitigate the placebo response and to increase the chances of success. These findings relate to dose selection, the method and application of ratings, and other study design elements.

ACADIA and Biovail have agreed on a development strategy for PDP that involves using the findings from the -012 Study together with those from the second, ongoing Phase III trial (-014 Study), which is testing 10 mg and 20 mg doses of pimavanserin, to arrive at an enhanced study design that may be used in new Phase III trials. Accordingly, the ongoing -014 Study will be concluded at its current enrollment level (about 120 patients) to allow for the analysis of data as soon as practicable. Meanwhile, the parties will begin planning for a new Phase III PDP trial using a 40 mg dose of pimavanserin. Consistent with the terms of the original collaboration agreement, Biovail will be responsible for the cost of this third Phase III trial. This study is expected to start in the first half of 2010. ACADIA will continue its ongoing open-label safety extension studies in patients with PDP.

In addition, Biovail intends to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration. Alzheimer's disease psychosis (ADP) remains the second indication provided for in the collaboration. The parties currently intend to focus their efforts on the PDP and schizophrenia programs, but also are moving forward with planning for an initial study in ADP.

"Together, ACADIA and Biovail are pursuing a development strategy that strengthens our path forward in PDP while opening up potential opportunities for pimavanserin to address unmet medical needs of patients suffering from other psychiatric and neurological disorders, including schizophrenia and ADP," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA.

While pursuing its development strategy for pimavanserin, ACADIA intends to implement cost-saving measures during October to further streamline its operations, reduce its internal operating expenses, and provide added financial flexibility. ACADIA currently anticipates that its cash, investment securities and payments from its collaborations before taking any cost-saving measures will be sufficient to fund its operations into the first half of 2011, and that these measures will further extend ACADIA's cash runway.

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 have formed a collaboration to co-develop and commercialize pimavanserin for neurological and psychiatric indications 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 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's product candidates include pimavanserin in Phase III for Parkinson's disease psychosis in collaboration with Biovail, 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 additional compounds in IND-track development. All of the product candidates in ACADIA's 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 email alerts.

About Biovail Corporation

Biovail Corporation is a specialty pharmaceutical company engaged in the formulation, clinical testing, registration, manufacture, and commercialization of pharmaceutical products. Biovail is focused on the development and commercialization of medicines that address unmet medical needs in niche specialty central nervous system markets. For more information about Biovail, visit the company's web site at www.biovail.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 progress and timing of drug discovery and development programs, including ongoing and future clinical trials and the results and regulatory approvals resulting therefrom, the potential of and the benefits to be derived from product candidates, in each case including pimavanserin, indications to be pursued under the collaboration, the length of ACADIA's cash runway, and the benefits to be provided by cost-saving measures to be undertaken. 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, commercialization and collaborations with others, and the fact that past results of clinical trials may not be indicative of further 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, 2008 as well as ACADIA's subsequent filings with the Securities and Exchange Commission and to Biovail's annual report on Form 20-F for the year ended December 31, 2008. 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 neither ACADIA nor Biovail undertakes any 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.
Lisa Barthelemy, Director, Investor Relations
Uli Hacksell, Ph.D., Chief Executive Officer
858-558-2871