ACADIA Pharmaceuticals Advances AM-831 to Phase I Clinical Development in Collaboration with Meiji Seika Pharma

November 7, 2011

--FDA Accepts Investigational New Drug Application for AM-831--

SAN DIEGO, Nov 07, 2011 (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 the U.S. Food and Drug Administration has completed its review of ACADIA's Investigational New Drug application to begin Phase I clinical studies with AM-831, an innovative small molecule for the treatment of schizophrenia. AM-831 was discovered by ACADIA and is being developed in collaboration with Meiji Seika Pharma Co., Ltd. The parties plan to proceed with a Phase I study to assess the safety, tolerability and pharmacokinetics of AM-831 in healthy volunteers and to help inform the design of future studies in patients with schizophrenia.

"We are pleased to enter clinical development with AM-831 in collaboration with ACADIA," said Yasushi Murai, Ph.D., Senior Vice President, Research and Development of Meiji Seika Pharma. "This important progress reinforces our mutual belief in the potential of a drug with the novel profile of AM-831 and our commitment to improve the lives of patients suffering from schizophrenia."

"We are excited to initiate clinical studies with AM-831," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "Our preclinical studies have shown that AM-831 has the potential to be the first antipsychotic drug to combine pro-cognitive and antipsychotic effects in patients with schizophrenia, thereby addressing an area of major unmet medical need."

AM-831 is a novel and orally available small molecule that combines muscarinic m1 partial agonism with both dopamine D2 and serotonin 5-HT2A antagonism. AM-831 has demonstrated a unique combination of robust antipsychotic effects in traditional preclinical models of psychosis and pro-cognitive effects in preclinical behavioral models. In contrast, currently prescribed treatments do not effectively address or may exacerbate cognitive dysfunction associated with schizophrenia.

About the ACADIA Pharmaceuticals/Meiji Seika Pharma Collaboration

ACADIA and Meiji Seika Pharma are collaborating to develop AM-831 through completion of proof-of-concept clinical studies as a treatment for patients with schizophrenia and related disorders. Meiji Seika Pharma has exclusive rights to develop and commercialize AM-831 in the Asian territory while ACADIA has retained rights to AM-831 in the rest of the world, including the U.S. and Europe. ACADIA received initial licensing fees and is eligible to receive development and regulatory milestones and royalties on product sales in the Asian territory. Meiji Seika Pharma is responsible for funding the initial development expenses of AM-831 up to a specified level and the parties will share remaining expenses through clinical proof-of-concept, subject to possible adjustment. Meiji Seika Pharma is responsible for all costs associated with the development and commercialization of AM-831 in the Asian territory.

About Schizophrenia

Schizophrenia is a chronic and debilitating mental illness characterized by disturbances in thinking, emotional reaction and behavior, and affects about one percent of the population. Symptoms associated with schizophrenia may include positive symptoms, such as hallucinations and delusions, a range of negative symptoms, including loss of interest and emotional withdrawal, and cognitive dysfunction. This cognitive impairment frequently prevents patients with schizophrenia from integrating into society. Unlike psychosis, cognitive dysfunction is typically unremitting and lacks the episodic exacerbations associated with other symptoms of schizophrenia. As a result, patients with schizophrenia are normally required to be under medical care for their entire lives.

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 has four product candidates in clinical development including pimavanserin, which is in Phase III development as a potential first-in-class treatment for Parkinson's disease psychosis. ACADIA also has a product candidate in Phase II development for chronic pain and a product candidate in Phase I development for glaucoma, both in collaboration with Allergan, Inc., and AM-831 in Phase I development for schizophrenia in collaboration with Meiji Seika Pharma Co., Ltd. All of the product candidates in ACADIA's pipeline emanate from discoveries made using its proprietary drug discovery platform. ACADIA maintains a website at http://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 Meiji Seika Pharma Co., Ltd.

Meiji Holdings Co., Ltd., the parent company of Meiji Seika Pharma, reorganized its operating companies, which resulted in the establishment of Meiji Seika Pharma on April 1, 2011. Meiji Seika Pharma, which inherited the pharmaceuticals business of Meiji Seika Kaisha, Ltd., is a "Specialty and Generic Pharmaceuticals Company" with a focus on the infectious disease field, the central nervous system disorders field, and the generic drugs business. For details on Meiji Seika Pharma, see http://www.meiji-seika-pharma.co.jp/english/index.html.

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 any ongoing or future clinical trials, and the benefits to be derived from ACADIA's product candidates, in each case including AM-831. 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 preclinical studies and 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, 2010 as well as other 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.
Thomas H. Aasen, Executive Vice President,
Chief Financial Officer and Chief Business Officer
858-558-2871