ACADIA Pharmaceuticals Updates Planned Timing of NUPLAZID™ NDA Submission

March 11, 2015

Conference Call Scheduled for Today, March 11, at 5:00 p.m. Eastern Time

SAN DIEGO--(BUSINESS WIRE)--Mar. 11, 2015-- ACADIA Pharmaceuticals Inc. (NASDAQ: ACAD), a biopharmaceutical company focused on the development and commercialization of innovative medicines that address unmet medical needs in neurological and related central nervous system disorders, today provided an update on the planned timing of its NUPLAZID™ (pimavanserin) New Drug Application (NDA) submission.

ACADIA plans to submit its NUPLAZID NDA for the treatment of Parkinson's disease psychosis in the second half of 2015. The company had previously planned to submit the NDA in the first quarter of 2015. The decision to move back the planned submission is based on additional time required to complete the preparation of systems to support commercial manufacturing and supply and, in turn, to support the U.S. Food and Drug Administration's (FDA) review of NUPLAZID. The change in submission timing is not a result of any change to NUPLAZID's clinical or safety profile, nor is it a result of any interaction with or request for information from the FDA.

"We have concluded that additional time is needed to complete the readiness of our commercial manufacturing systems," said Steve Davis, Interim Chief Executive Officer of ACADIA. "While we are very disappointed with the change in timing, we believe that this is the prudent course of action to take. We are working expeditiously to ensure that our systems are robust and ready for FDA review and commercial launch. Importantly, we remain confident in the safety and efficacy package supporting the NDA of NUPLAZID, which received Breakthrough Therapy designation from the FDA last year."

Separately, ACADIA Pharmaceuticals issued a news release today announcing that Uli Hacksell, Ph.D., has retired as its Chief Executive Officer and resigned from its Board of Directors effective today. Steve Davis, Executive Vice President, Chief Financial Officer and Chief Business Officer of ACADIA, has been appointed as Interim Chief Executive Officer.

Conference Call and Webcast Information

ACADIA management will hold a conference call and webcast today, March 11, 2015, at 5:00 p.m. Eastern Time to discuss its planned NDA submission and the management change. The conference call may be accessed by dialing 877-280-4954 for participants in the U.S. or Canada and 857-244-7311 for international callers (reference passcode 18127460). A telephone replay of the conference call may be accessed through March 25, 2015 by dialing 888-286-8010 for callers in the U.S. or Canada and 617-801-6888 for international callers (reference passcode 30031975). The conference call also will be webcast live on ACADIA's website, www.acadia-pharm.com, under the investors section and will be archived there until March 25, 2015.

About NUPLAZID™ (pimavanserin)

NUPLAZID is ACADIA's proprietary small molecule that is a selective serotonin inverse agonist preferentially targeting 5-HT $_{2A}$ receptors believed to play an important role in psychosis. ACADIA has reported positive Phase III trial results with NUPLAZID, which has the potential to be the first drug approved in the United States for psychosis associated with Parkinson's disease. NUPLAZID is administered orally once-a-day. ACADIA discovered NUPLAZID and holds worldwide rights to this new chemical entity. The trade name NUPLAZID has been provisionally accepted by the FDA.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in neurological and related central nervous system disorders. ACADIA has a pipeline of product candidates led by NUPLAZID (pimavanserin), for which we have reported positive Phase III trial results in Parkinson's disease psychosis and which has the potential to be the first drug approved in the United States for this disorder. Pimavanserin is also in Phase II development for Alzheimer's disease psychosis and has successfully completed a Phase II trial in schizophrenia. ACADIA also has clinical-stage programs for chronic pain and glaucoma in collaboration with Allergan, Inc. All product candidates are small molecules that emanate from internal discoveries. ACADIA maintains a website at www.acadia-pharm.com to which we regularly post copies of our 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 planned timing of the submission of an NDA for NUPLAZID (pimavanserin) for the treatment of Parkinson's disease psychosis (PDP); the potential for pimavanserin to be the first drug approved in the United States for PDP, if approved at all; and the progress, timing and results of ACADIA's drug discovery and development programs, either alone or with a partner, including the progress and expected timing of clinical trials. 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 related to the complete implementation of ACADIA's systems related to commercial manufacturing that are needed to support the approval by the FDA of an NDA and the potential future commercial launch of NUPLAZID, and those inherent in drug discovery, development, approval, 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, 2014 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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