ACADIA Initiates Clinical Trials for ACP-103 - Initially Targets Treatment-Induced Dysfunction in Parkinson's Disease

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SAN DIEGO, CA and COPENHAGEN, DK, January 22, 2003 - ACADIA Pharmaceuticals announced today that it has initiated Phase I clinical trials for ACP-103, a small molecule drug candidate that represents an important new approach to amelioration of treatment-induced dysfunction in Parkinson's disease as well as a range of neuropsychiatric disorders. ACP-103 originates entirely from ACADIA's internal discovery and development efforts and represents the first of two proprietary small molecule drugs that ACADIA plans to move into clinical testing this year.

"The advancement of ACP-103 from initial discovery to the clinic is a major milestone for ACADIA and a strong validation of the strength of our integrated discovery and development organization," said Uli Hacksell, Ph.D., ACADIA's Chief Executive Officer. "This program was successfully advanced within our projected timeline by combining the initial discovery of a novel mechanism and selective chemistries with an efficient lead optimization effort and an accelerated preclinical development program. It is especially exciting that ACADIA may participate in late-stage development and commercialization of ACP-103 for the initially targeted indication."

ACP-103 is a proprietary small molecule that acts as a selective inverse agonist at the 5-HT2A receptor. Studies of established drugs and preclinical studies with ACP-103 have strongly suggested that this mechanism of action will be effective in preventing treatment-induced dysfunction in Parkinson's disease as well as treating a range of neuropsychiatric disorders.
Parkinson's disease is a progressive neurodegenerative disease that afflicts more than one million people in the United States and over four million people worldwide. The disease is currently treated by various drugs that enhance dopaminergic activity in the brain. Unfortunately, nearly all patients using these therapies develop treatment-induced dysfunctions, which may include hallucinosis, psychosis, and dyskinesias. There are currently no approved treatments for these disorders and clinicians often must compromise between treating Parkinson's disease itself and accepting the range of the hallucinations and dyskinesias elicited by the drugs used to treat this disease.

"The initial focus of our clinical program, treatment-induced dysfunction in Parkinson's disease, represents an ideal clinical indication and an attractive commercial opportunity for ACADIA," said Robert E. Davis, Ph.D., ACADIA's Executive Vice President of Drug Discovery and Development. "These are very well defined clinical indications with clear and robust end points. Our clinical program is based on a strong scientific rationale and will provide the opportunity to rapidly obtain safety and efficacy data on ACP-103. Due to its unique profile, ACP-103 and other development stage compounds in ACADIA's 5-HT2A inverse agonist drug discovery program also may have broad utility in a range of other important indications including general anxiety disorders, other psychoses, and normalization of sleep architecture in the elderly. We intend to expand into these larger clinical indications with ACP-103 in conjunction with a pharmaceutical partner."

The Phase I safety studies for ACP-103 are being conducted in the United Kingdom. ACADIA plans to incorporate the results from these initial clinical studies into an Investigational New Drug (IND) application that it will file later this year to initiate phase IIa efficacy trials in Parkinson's patients.
ACADIA Pharmaceuticals is a drug discovery and development company that efficiently discovers small molecule drug candidates using its proprietary chemical-genomics platform. ACADIA has successfully applied its platform to generate a broad discovery pipeline directed at major diseases including Parkinson's disease, psychosis, chronic pain, and glaucoma. Two of ACADIA's small molecules have been successfully advanced from initial discovery to clinical development. ACADIA's corporate headquarters as well as its genomics and biological research facilities are located in San Diego, California and its chemistry research facilities are located in Copenhagen, Denmark.

Contact:

ACADIA Pharmaceuticals
United States:
Uli Hacksell, Ph.D.,CEO
+1 858-558-2871

Europe:
Bo-Ragnar Tolf, Ph.D., VP of Chemistry and
Managing Director of ACADIA Pharmaceuticals A/S
+45 4329-3000