ACADIA Pharmaceuticals Announces Positive Clinical Trial Results Demonstrating That ACP-103 Increases Slow Wave Sleep

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SAN DIEGO, April 19 /PRNewswire-FirstCall/ -- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today reported top-line results from a proof-of-concept clinical study that assessed the effect of ACP-103 on deep, or slow wave, sleep in healthy older volunteers using polysomnography (PSG). Results of the study demonstrated that ACP-103 induced a robust and statistically significant increase in slow wave sleep that was dose-related. ACP-103 treatment also had a positive impact on measures for sleep maintenance, including decreases in the number of awakenings after sleep onset and in the time awake after sleep onset. ACP-103 is ACADIA's proprietary serotonin 5-HT2A inverse agonist that blocks the activity of this key receptor.

"These data provide a proof-of-concept of the ability of ACP-103 to improve the quality of sleep by increasing slow wave sleep," said Uli Hacksell, Ph.D., Chief Executive Officer of ACADIA. "This suggests that ACP-103 has potential as a novel treatment for sleep maintenance insomnia. ACADIA is currently in Phase II clinical development with ACP-103 for use in schizophrenia and treatment-induced dysfunctions in Parkinson's disease, two indications with patients who frequently suffer from sleep disturbances. The trial results provide an excellent demonstration of the relationship between doses of ACP-103, plasma levels and effects of 5-HT2A-receptor antagonism on slow wave sleep, and, therefore, these data also will be helpful in the design of future ACP-103 clinical trials."

Clinical Trial Design

The clinical trial was a double-blind, placebo-controlled study involving 45 healthy volunteers ranging in age from 40 to 64. The subjects were randomized to one of five treatment arms, including placebo and four different doses (1 mg, 2.5 mg, 5 mg, and 20 mg) of ACP-103. Each group was administered placebo or the specified dose of ACP-103 once-daily each morning for 14 consecutive days. All subjects underwent a two-night screening and baseline PSG evaluation. Additional PSG measurements were performed on the evening of study days 1 and 13. The subjects also completed a Continuous Performance Test (CPT) to assess the potential impact on daytime functioning. Blood samples were collected at the beginning and end of the 14-day period to determine ACP-103 levels in plasma. Of the 45 subjects, 20 of them also underwent a positron emission tomography (PET) study to measure 5-HT2A brain receptor occupancy. The PET data are currently being analyzed.

Clinical Trial Results

The PSG data demonstrated that once-daily administration of 5 mg and 20 mg of ACP-103, the two highest doses used in this study, induced statistically significant increases in slow wave sleep (p