Neuroscience Pharma (NPI) Initiates Phase II/III Clinical Trial for Neurosteroid Program

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SAN DIEGO, Calif., June 6 /PRNewswire/ -- Neuroscience Pharma, Inc. (NPI), a subsidiary of Neurocrine Biosciences (Nasdaq: NBIX) has initiated a Phase II/III double-blind, placebo-controlled clinical trial in Canada to evaluate the neurosteroid compound dehydroepiandrosterone (DHEA) for the treatment of memory deficits associated with Alzheimer's disease. The study was designed in collaboration with, and will be conducted by, the Consortium of Canadian Centres for Clinical Cognitive Research (C5R) in 18 Canadian Alzheimer's research centers. NPI expects to expand the trial to Europe later in the year to supplement enrollment. If successful, this trial represents one of two pivotal trials required for regulatory approval.

The clinical trial plans to evaluate efficacy parameters in 300 patients with a single dose of DHEA vs. placebo administered twice daily. The primary endpoints include the evaluation of standard cognitive measures used in the approvals of currently available therapeutic treatments for Alzheimer's disease including the Alzheimer's Disease Assessment Scale (ADAS-Cog) and the Alzheimer's Disease Cooperative Study-Global Impression of Change (ADCS-CGIC).

NPI was formed in March, 1996 to conduct research and development. Neurocrine Biosciences licensed certain technology and Canadian marketing rights of the neurosteroid program to NPI.

"This program is part of Neurocrine's business model to develop proprietary in-licensed products for the treatment of neurologic diseases while retaining commercial rights and participation," said Gary Lyons, President and Chief Executive Officer of Neurocrine Biosciences. The company expects to develop a sustained delivery system to enhance patient compliance and further build upon our proprietary position with this compound.

NPI is currently supporting a double-blind, placebo-controlled, physician- IND Phase II clinical trial in the U.S. to treat memory deficits associated with Alzheimer's disease. This trial is being conducted by clinical investigators from the Langley Porter Psychiatric Institute at the University of California, San Francisco (UCSF) and involves 8 additional U.S. centers. The trial has been designed to assess the safety, tolerability, and cognition- enhancing effects of DHEA in 60 mild to moderate Alzheimer's patients.

Several outside preclinical and clinical studies have demonstrated that DHEA exhibits a wide range of effects in the central nervous system. Clinical studies conducted by the Max Planck Institute of Psychiatry have shown that DHEA administration increases rapid eye movement (REM) sleep. Because REM sleep has been implicated in memory storage, these findings support the potential clinical usefulness of DHEA in age-related dementia including the enhancement of memory.

DHEA is a naturally occurring hormone. Scientific literature has also shown evidence in preclinical and clinical trials that DHEA may protect neurons from death by increasing growth factor levels in the brain, such as insulin-line growth factor-1, which is known to have neuroprotective activity. DHEA also appears to modulate several cytokines involved in inflammation, which are believed to be involved in the pathology of Alzheimer's disease. DHEA levels are reduced in aging and further decreases are seen in Alzheimer's
disease. In addition, in preclinical and clinical studies, low levels of DHEA correlate with memory and functional deficits.

Alzheimer's disease is a neurodegenerative brain disorder which leads to progressive memory loss and dementia. According to the National Alzheimer's Association, in 1994 over four million individuals in the United States and Canada suffered from Alzheimer's disease. Alzheimer's disease is the fourth leading cause of death for adults, responsible of over 100,000 deaths in 1994.

Neurocrine Biosciences is a leading neuroimmunology company focused on the discovery and development of novel therapeutics to treat diseases and disorders of the central nervous and immune system such as anxiety, depression, Alzheimer's disease, obesity and multiple sclerosis.

The statements in this press release related to the continuation and expansion of clinical trials, the development of future delivery systems for DHEA, and the potential regulatory approval and potential commercialization of DHEA as a therapeutic for Alzheimer's disease are forward looking statements. Such forward looking statements involve risks and uncertainties, including the expense and difficulty in successfully conducting clinical trials, the uncertainty that DHEA will prove effective for therapeutic treatment of Alzheimer's disease, the risks inherent in the pharmaceutical industry with regard to obtaining regulatory approval for therapeutic products, the potential difficulty in enforcing use patents and successfully commercializing products such as DHEA, and the other risks factors set forth in Neurocrine's Form 10-K dated December 31, 1997 filed with the SEC. Actual results and the timing of certain events may vary materially from those indicated in the forward-looking statements as a result of these and other factors.
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