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FDA Grants Orphan Drug Status to Creatine for Amyotrophic Lateral Sclerosis

SAN FRANCISCO, CA -- March 26, 2002 -- The Avicena Group, Inc. announced that it has received Orphan Drug Designation from the United States Food and Drug Administration (FDA) for creatine to treat patients with amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig's Disease.

The company plans to submit an investigative new drug application this year.

Creatine is a critical element in cellular energy production and modulation. It is the substrate of the creatine kinase system, which helps prolong cellular life and protect against cell injury and death.

Avicena is supporting three clinical studies on the effects of creatine among ALS patients. A pilot study was conducted at Cornell Medical Center in 1999. Ongoing Phase II/III studies, started in 1999, are being conducted at multiple centers coordinated by the Carolinas Neuromuscular ALS/MDA Center in Charlotte North Carolina and the North East ALS Consortium, consisting of over 300 patients at 29 sites. Preliminary data from three centers in the Carolinas Neuromuscular/ALS study are very encouraging.

Dr. Jeffrey Rosenfeld, director of the Carolinas Neuromuscular ALS/MDA Center and lead investigator of the Carolinas Neuromuscular ALS study, commented, "We have seen, and continue to see, encouraging results among ALS patients, as measured by muscle strength and a decreased rate of deterioration. Additionally, creatine has a long history of safe use, and is well tolerated by patients in the study."

These clinical studies build on Avicena's extensive pre-clinical studies, 14 of which have been published, which demonstrate that creatine, in transgenic mouse models, has a neuroprotective effect in ALS, Huntington's disease, and Parkinson's disease.

ALS is a progressive and fatal disease that attacks motor neurons, the components of the nervous system that connect the brain with the skeletal muscles. More than 5000 people in the U.S. are diagnosed with ALS each year, with about 30,000 having the disease at any given time. Worldwide, ALS occurs in one out of every 100,000 people across racial, socioeconomic and ethnic boundaries.

SOURCE: The Avicena Group