

Embargoed for release:  
Thursday, February 23, 2006 10:00 a.m. EST

For more information:  
Marian Emr or Margo Warren  
WPC Press Office, 202-249-4186;  
after 2/26/06: 301-496-5924

### **Preliminary Results Shows Creatine and Minocycline May Warrant Further Study in Parkinson's Disease**

Washington, DC – Feb. 23 – A National Institutes of Health-sponsored clinical trial with 200 Parkinson's disease patients has shown that creatine and minocycline may warrant further consideration for study in a large trial, according to Karl Kieburtz, M.D., M.P.H., University of Rochester, who spoke today at the World Parkinson Congress on behalf of the trial investigators. Study investigators caution that while the news is encouraging, the results do not demonstrate that these agents are effective in Parkinson's disease. Before these interventions can be recommended as a treatment they must be tested in a larger trial with hundreds of patients. Study findings are available online and will be published in the March 14 issue of *Neurology*.<sup>1</sup>

Parkinson's disease is a degenerative disorder of the brain in which patients may develop progressive tremor, slowness of movements, and stiffness of muscles. It affects approximately 1 percent of Americans over the age of 65. Although certain drugs, such as levodopa, can reduce the symptoms of Parkinson's, no treatment has been shown to slow the progressive deterioration in function.

The National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH) has organized a nationwide multi-center effort called NET-PD (Neuroprotection Exploratory Trials in Parkinson's Disease), a randomized, double-blind futility trial, to study compounds that may slow the clinical decline of Parkinson's disease. As the initial step in these efforts, creatine and the antibiotic minocycline were identified as agents worthy of preliminary study. Patients very early in the disease course who did not yet need medications typically used to treat their Parkinson's symptoms were included in the study.

---

<sup>1</sup> The NINDS NET-PD Investigators. "A randomized, double-blind, futility clinical trial of creatine and minocycline in early Parkinson disease." *Neurology*, March 14, 2006; 66: 664.

“We are encouraged not only by these preliminary results, but also by the level of collaboration in the Parkinson’s community. These findings represent the efforts of pharmacologists, clinicians, statisticians, and clinical trial experts – including NINDS staff – who have come together with academia, industry, patients, and foundation groups to advance the development of innovative therapies for Parkinson’s. The exceptional speed of patient recruitment allowed us to finish this study in record time,” said Story Landis, Ph.D., NINDS director.

Patients were randomly assigned to receive minocycline, 200 mg per day; creatine, 10 grams per day; or placebo. The study participants were then followed for 12 months. Researchers examined the safety and tolerability of taking these medications as well as the severity of Parkinson’s. Although neither agent caused major side effects, minocycline was not as well tolerated. Both creatine and minocycline appeared to modify the disease features as measured by a decline in the clinical signs of Parkinson’s disease. However, it is important to note that the study was not designed nor intended to determine whether creatine or minocycline was effective as a treatment for Parkinson’s. The study was primarily designed to determine whether it would be worthwhile to invest the resources necessary to determine if creatine and minocycline are effective treatments. Studies to determine the effectiveness of a drug typically require hundreds of patients followed for many years.

Based on the initial analyses of the pilot studies, creatine and minocycline have passed the first hurdle. Additionally, the NINDS has supported a pilot study of two other compounds, Coenzyme Q10 and GPI-1485, and the investigators are currently analyzing the data. The NINDS and the consortium are already planning a large long-term study of neuroprotection in Parkinson’s disease.

The trial investigators note that while encouraging, this pilot study does not have sufficient numbers of patients or duration of follow-up to recommend that patients with Parkinson’s take either agent. In fact, the investigators caution Parkinson’s patients and their physicians not to interpret the results of this study as suggesting such a course of treatment. Further study is required before the researchers can conclude whether creatine or minocycline is in fact helpful, harmful or has no significant impact.

The NINDS is a component of the National Institutes of Health (NIH) in Bethesda, Maryland, and is the nation’s primary supporter of biomedical research on the brain and nervous system. For more information, visit the NINDS website at <http://www.ninds.nih.gov> or the NET-PD website, <http://www.parkinsontrial.org>.

The NIH is comprised of 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is the primary Federal agency for conducting and supporting basic, clinical, and translational medical research, and investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov>.

###

