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## News Release

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**EMBARGOED UNTIL 4 P.M. ET, WEDNESDAY, OCT. 10, 2007**

### **Columbia University Medical Center Leads First Placebo-Controlled Study of Cognitive Impairment Due to Chronic Lyme Disease**

*Findings Show Severe Physical Dysfunction Among Patients & Benefit of Repeat IV Antibiotic Therapy to Provide Long-Term Symptom Relief*

NEW YORK – Findings from the first placebo-controlled study of chronic cognitive impairment after treated Lyme disease (also known as chronic Lyme encephalopathy) demonstrate that patients report moderate cognitive impairment, physical dysfunction comparable to patients with congestive heart failure, and fatigue comparable to patients with multiple sclerosis. In the study, repeated intravenous (IV) antibiotic therapy was shown to be effective in treating cognitive dysfunction and the debilitating pain, fatigue and physical dysfunction associated with this disease.

The study, titled “A Randomized, Placebo-Controlled Trial of Repeated IV Antibiotic Therapy for Lyme Encephalopathy,” will be published on-line by the journal *Neurology* on Oct. 10, 2007. The study was led by Principal Investigator Brian Fallon, M.D., M.P.H., director of the recently established Lyme and Tick-borne Disease Research Center at Columbia University Medical Center ([http://www.cumc.columbia.edu/news/press\\_releases/fallon\\_lyme\\_center.html](http://www.cumc.columbia.edu/news/press_releases/fallon_lyme_center.html)). The research was conducted jointly at the Columbia University Medical Center and New York State Psychiatric Institute and was funded by the National Institute of Neurological Disorders and Stroke (NINDS).

“These findings replicate results from a prior placebo-controlled trial of post-Lyme fatigue, which found positive treatment results from repeated antibiotic therapy. They also replicate the degree of physical impairment results demonstrated in another prior study of chronic Lyme disease,” said Dr. Fallon ([\\*see citations below](#)). “The door should be left open for physicians to prescribe medications as warranted, after a careful discussion with the patient of the potential risks and benefits.”

Dr. Fallon and his research team identified patients with cognitive problems that developed after being diagnosed with Lyme disease and which persisted or relapsed despite prior treatment, in order to determine whether patients who have already received the “standard” course of antibiotic treatment (three weeks of IV antibiotic therapy), would benefit from an additional 10 weeks of antibiotic therapy. They also set out to determine whether patients relapse when taken off antibiotics or whether the alleviation of symptoms is sustained or enhanced with time.

Study participants (57 subjects: 37 patients with a history of Lyme disease and 20 controls) were divided into three subject groups: patients with a history of treated Lyme disease who were randomized to IV treatment with an antibiotic called ceftriaxone for 10 weeks; patients with a history of treated Lyme disease who were randomized to IV placebo for 10 weeks; and, healthy controls who were tested at the same time points as the patients to help to control for the practice effect on neuropsychological testing. All patients had to meet criteria for memory impairment at the start of the study and they were also required to have a positive IgG Western blot for Lyme disease at study entry.

### **Key findings from the *Neurology* paper are as follows:**

#### Cognition

- There was significantly greater improvement in cognition in the antibiotic treated sample at the primary end point for efficacy (week 12).
- When patients were retested three months after antibiotic treatment, the initial gains in cognition for the ceftriaxone-randomized sample were no longer present.
- Patients lose their cognitive improvement when IV antibiotic therapy is stopped.

#### Pain, Fatigue and Physical Dysfunction

- Among patients with greater severity at the start of the study, those randomized to ceftriaxone had more significant symptom relief of pain, fatigue, and physical dysfunction at week 12, as compared to those patients who did not receive ceftriaxone.
- Patients initially randomized to IV ceftriaxone who had greater severity of symptoms at baseline continued to show reduced pain and improved physical functioning at week 24. Improvement in fatigue continued, but was no longer statistically different from placebo at week 24.
- Repeated IV antibiotic therapy is effective in improving cognition, and among the more impaired, in improving pain, fatigue, and physical dysfunction.

#### Safety

- 18.9 percent of the 37 patients had serious adverse effects associated with either the IV line or a reaction to the antibiotic itself. Although all fully recovered, IV antibiotic therapy has the potential for serious risks, such as systemic infection, thrombus formation, or allergic reactions.

#### Clinical Recommendations

- Repeated IV antibiotic therapy should be considered a valuable option with long-term benefit for managing the disabling symptoms associated with chronic Lyme disease.
- Given the risks and benefits associated with IV antibiotic therapy, physicians and patients need to have a thoughtful discussion prior to initiating treatment.

#### \*Citations from Recently Published Research

- The percentage of patients with meaningful improvement in fatigue noted at six months in this *Neurology* study (66.7 percent for patients treated with ceftriaxone vs. 25 percent for placebo) was comparable to the improvement in fatigue noted after repeated IV ceftriaxone therapy in a prior placebo controlled study (64 percent for drug vs. 18.5 percent for placebo) (Krupp et al., *Neurology*, 2003).
- The degree of physical impairment (comparable to congestive heart failure) was comparable to the impairment noted in another chronic Lyme study (Klempner et al., *NEJM*, 2001).

“Future research needs to focus on identifying a treatment approach that either allows not only for acute efficacy, but also long-term cognitive improvement; or, a treatment that could be given after the

IV antibiotic therapy that would allow for sustained or enhanced cognitive improvement over time. Our Lyme and Tick-borne Disease Research Center continues to work towards finding these solutions,” said Dr. Fallon. “The most important lesson of this study is that physicians and patients need to collaborate openly to design an individual treatment plan to manage the long-term and complex suffering from symptoms of chronic Lyme disease.”

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**Columbia University Medical Center** provides international leadership in basic, pre-clinical and clinical research, in medical and health sciences education, and in patient care. The medical center trains future leaders and includes the dedicated work of many physicians, public health professionals, dentists, nurses, and scientists at the College of Physicians & Surgeons, the Mailman School of Public Health, the College of Dental Medicine, the School of Nursing, the biomedical departments of the Graduate School of Arts and Sciences, and allied research centers and institutions. [www.cumc.columbia.edu](http://www.cumc.columbia.edu)

**PATIENT QUERIES:**

- To schedule a clinical evaluation for patients with neurocognitive or neuropsychiatric problems from Lyme disease, please call 212-543-6508.
- To schedule a research evaluation for possible participation in a diagnostic study, please call 212-543-6510.
- Please note: As of June 4, 2007, the center is not currently conducting any active treatment trials.