

Contact: Melissa Chefec, MCPR Public Relations, 203-968-6625

For Immediate Release

**LYME DISEASE DIAGNOSTIC PROCEDURES CAN “TEST” THE PATIENCE OF PATIENTS:
*Time for Lyme founders, experts discuss symptoms and importance of early, accurate diagnosis***

Greenwich, CT, June 2007 – Lyme Disease and other tick-borne illnesses are on the rise, particularly here in the Northeast, which is considered a high-risk location for Lyme by the Centers for Disease Control (CDC). Approximately 18,000 cases are diagnosed each year in the United States – a total that’s more than doubled since 1990 – but experts agree that the actual number of people struggling with Lyme and other tick-borne illnesses may be much higher. That’s because there is no diagnostic test that provides a patient with a definitive diagnosis for these diseases.

“A diagnosis of Lyme Disease or another tick-borne illness is usually a ‘process of elimination’ diagnosis, based on both the likelihood of exposure and the ruling out of other conditions that cause the same symptoms,” explains Diane Blanchard, co-president and co-founder of Time for Lyme, Inc. – a research, education and advocacy group. “After this process, a series of blood tests is conducted, and the results can confirm only the probability that the patient has been infected with Lyme or another tick-borne illness,” Blanchard adds. Time For Lyme and the Lyme Disease Association recently lead the way in endowing the first Lyme and Tick-Borne Diseases Research Center at Columbia University Medical in New York City dedicated to the study of chronic Lyme disease.

Symptoms mimic many illnesses

The early stage of Lyme Disease is problematic for doctors, because the symptoms mirror those of hundreds of other illnesses, from fibromyalgia to lupus. “The initial symptoms of Lyme Disease and other tick-borne illnesses include flu-like feelings, headache, stiff neck, fever, muscle aches, and fatigue,” says Dr. Brian A. Fallon, MD, MPH, Associate Professor of Clinical Psychiatry at the Columbia University College of Physicians and Surgeons and director of the newly opened Lyme and Tick-borne Diseases Research Center.. “Even the telltale Lyme Disease rash, called erythema migrans (EM), can differ widely from patient to patient,” Dr. Fallon adds. For example, some may find a large, spreading “bull’s-eye” rash of alternating red and flesh-colored rings, while others may find a small, simple red ring around the bite site. On patients with darker skin, the rash may appear more like a bruise. Complicating matters further, the rash only appears on about 60% of patients, and can take up to a month after infection to appear; the remaining 40% of patients experience little or no skin involvement at all.”

“The irony is that early diagnosis is the key to treating Lyme Disease and other tick-borne illnesses in their ‘acute’ stages, when the disease has not spread throughout the body and antibiotics are most likely to be effective at eradicating the bacteria that causes the illnesses,” Dr. Fallon explains. “Yet, because there is not a definitive diagnostic tool for these diseases, it is difficult to obtain an early medical conclusion in patients who do not present with a clear EM rash or an embedded tick,” he notes.

The next steps to diagnosis

Once doctors have ruled out other causes for early symptoms, the next step is a series of blood tests designed to determine the probability that Lyme Disease is present. However, the tests cannot provide a definitive diagnosis, because medical science has yet to find a way to identify the actual bacteria (*B. burgdorferi*) that causes the disease. In fact, one of the primary goals of the Lyme and Tick-Borne Diseases Research Center is to focus on identifying a gold-standard test for Lyme. Currently, the tests look for antibodies in the bloodstream that indicate the patient's immune system has been fighting off the *B. burgdorferi* infection. Two of these "ELISA" (enzyme-linked immunosorbent assay) tests have been approved to check for these bacteria – the whole cell sonicate ELISA, which has many false positives and negatives, and the C6 Lyme Peptide, which is widely considered the most accurate of the two. "These tests are an important tool for diagnosis," Dr. Fallon says. "However, by the time the patient has built up antibodies, the infection is likely to be in its second disseminated stage, making it a more difficult, often chronic condition to treat."

Once an ELISA test is returned with either a positive or uncertain result, doctors usually perform a second and more accurate blood test called the Western Immunoblot test, or Western blot. In this test, the patient's immune system response is translated to a visual of colored bands and "blots" that indicate whether the *B. burgdorferi* antibodies are present. Again, however, the test cannot definitively confirm a diagnosis of Lyme or other tick-borne illnesses.

Confusion lingers after diagnosis

Even after a Lyme Disease diagnosis, patients are often confronted with a confusing cadre of information, recommendations and prognoses. "Depending upon the stage of the illness, patients may find a short course of antibiotics can effectively eradicate the bacteria, or they may experience long-term, chronic symptoms of the disease," Dr. Fallon explains. These symptoms, though rare, can range from severe arthritis to persistent numbness and tingling, from heart disease to lung and liver problems, and from loss of concentration and short-term memory to mood changes and psychosis.

"The good news is that medical research continues, and there are many more resources than ever before available for patients diagnosed today with Lyme Disease and other tick-borne illnesses," Time for Lyme's Diane Blanchard notes. Many of these resources and links are available through the Time for Lyme web site at www.timeforlyme.org. "The best advice for these patients, as for all patients diagnosed with a serious illness, is that they become their own best health advocates, that they become aware of the treatments and options available, and that they realize the unreliability of the tests," Blanchard concludes.

About Time for Lyme

Time For Lyme is an organization dedicated to eliminating the devastating effects of Lyme disease and other tick-borne illness. Our mission is to prevent the spread of disease, develop definitive diagnostic tools and effective treatments, and to ultimately find a cure for tick-borne illness by supporting research, education, and the acquisition and dissemination of information. In addition, we will continue to act as advocates for Lyme disease sufferers and

their families through support of legislative reform on the federal, state and local levels. For more information on our organization, please visit www.timeforlyme.org.

About Dr. Brian A. Fallon

Brian A. Fallon, MD, MPH, Associate Professor of Clinical Psychiatry at the Columbia University College of Physicians and Surgeons, is the director of the Lyme Disease Research Program at the New York State Psychiatric Institute. A graduate of Harvard College, he obtained his M.D. degree from the Columbia University College of Physicians and Surgeons, as well as a master's degree in public health epidemiology from Columbia University. He did his research training and an NIH fellowship in biological psychiatry at Columbia Presbyterian Medical Center and the New York State Psychiatric Institute. In addition to his work on anxiety, obsessive compulsive disorder, and somatoform disorders, Dr. Fallon has published and lectured widely on the neuropsychiatric effects of Lyme Disease and recently completed a 5 year NIH-Funded study of Brain Imaging and Treatment of Persistent Lyme Encephalopathy.