

FOR IMMEDIATE RELEASE

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FDA to Rule on Testing New Drug for Chronic Lyme

STAMFORD, CT March 30th, 2012—Researchers led by Time for Lyme grantee, M. Karen Newell-Rogers, Ph.D, have submitted a pre-IND briefing document to the US Food and Drug Administration, a preliminary step toward developing proposals for clinical testing of a new drug that could one day end the suffering of those with chronic, or long-term Lyme disease.

“To our knowledge this is the first novel drug candidate that has been proposed for study in the treatment of chronic Lyme Disease post-infection in some time,” said a representative of Viral Genetics, that submitted the proposal for its drug candidate, VGV-L, to the FDA. A response is expected in April.

Tests led by Dr. Newell-Rogers, a professor at Texas A&M Health Science Center College of Medicine and Scott & White Hospital, and a scientific advisor to Viral Genetics, have been conducted for over two and a half years. The results were submitted this month to the FDA, along with a protocol for a proposed human clinical trial designed under the guidance of a leading Lyme clinician at one of the nation’s top medical centers. Testing to date was conducted by Dr. Newell-Rogers with significant contributions from other clinicians at the University of Colorado, Texas A&M Health Science Center and Scott & White Hospital in Texas.

Prior research had established the insight that certain immune characteristics may contribute to whether a person is susceptible or resistant to the development of chronic inflammation as a result of infection. Dr. Newell-Rogers theory proposes a “targeted” peptide to replace or remove the self-peptides and restore a healthy immune response in patients.

Much of the funding for the pre-clinical studies leading to the FDA filing was provided by Time for Lyme, acting in concert with Richard Gerstner, the ex-IBM Executive VP who saw the potential applicability of Dr. Newell’s work, to Lyme disease.

Time for Lyme has raised over \$5 million since its founding in 1998 to fund research on Lyme and other tick-borne diseases at esteemed institutions across the U.S., including the establishment and endowment of Columbia University Medical Center's Lyme and Tick-borne Disease Research Center.

"Time for Lyme is focused on its clear and single mission of promoting research into Lyme and tick borne diseases," said Peter Wild, executive director of the organization. "At present there is no recognized treatment for Lyme once it has developed into its chronic, long-term state. We are hopeful that Dr. Newell-Roger's work will provide the solution that long-term Lyme disease sufferers have been hoping for, for decades."

About Time for Lyme

Time for Lyme, Inc. is a Connecticut-based 501(c)(3) non-profit organization dedicated to funding and promoting research about Lyme Disease and other tick-borne diseases, with a primary focus on accelerating the development of more effective methods of diagnosis and treatment of Lyme Disease. Time for Lyme has raised over \$5 million since its founding in 1998 to fund research on Lyme and other tick-borne diseases at esteemed institutions across the U.S., including the establishment and endowment of the Columbia University Medical Center's Lyme and Tick-borne Disease Research Center. Time for Lyme has also reached thousands of people in Connecticut and beyond with Lyme and tick-borne disease educational materials and support groups.

For information contact Peter Wild, Executive Director: pwild@timeforlyme.org; TEL (203)-348-5963.

Time for Lyme plans to hold its first annual Race Against Lyme 5K Walk/Run on April 29 at Cove Island Park in Stamford. For information, go to www.timeforlyme.org/race.htm

About Viral Genetics, Inc.

San Marino, California-based Viral Genetics discovers drug therapies from two platform technologies based on over 60 patents: Metabolic Disruption (MDT) and Targeted Peptides (TPT). Founded in 1994, the biotech company is researching treatments for Lyme Disease, HIV/AIDS, Strep, Staph and drug resistant cancer. For more information, visit www.viralgenetics.com.