

News advisory

HEADLINE:

Scientists demonstrate investigational MS drug down regulates the underlying cause believed responsible for multiple sclerosis at the 16th Meeting of the European Neurological Society

DATE OF EVENT: 30 May 2006

PLACE: Lausanne, Switzerland

WHO/WHAT/WHERE:

Bayhill Therapeutics, a Palo Alto, CA-based biotechnology drug development company, will present clinical findings today at the Sixteenth Meeting of the European Neurological Society 27 May – 31 May, 2006, in Lausanne, Switzerland in connection with development of the company's lead drug candidate, BHT-3009, for the treatment of multiple sclerosis.

Co-founder and Vice President of Research, Hideki Garren, MD, PhD, will present clinical data for Bayhill's Phase I/II trial of BHT-3009, and details on the Phase IIb trial of BHT-3009, which is currently being enrolled in Europe. Dr. Garren will make his presentation as follows:

MULTIPLE SCLEROSIS 4 SESSION:

Tuesday, 30 May 2006, 16:15 - 16:30

Phase I/II trial of a MBP encoding DNA plasmid (BHT-3009) alone or combined with atorvastatin for treatment of multiple sclerosis

ROOM: Lausanne, Oral session, 14

ENS ABSTRACT AVAILABLE AT: http://bayhilltx.com/bayhill_ens_2006_abstract.pdf

CONFERENCE INFORMATION: <http://www.akm.ch/ens2006/>

SPECIAL RECOGNITION: Bayhill's abstract has been judged by The Scientific Programme Committee to be among the "top 5 percent of those submitted" and will be highlighted at the conference as "Best of Free Communications" on Wednesday, 31 May, 2006, 12:30 – 13:30.

RESEARCH/PROGRAM HIGHLIGHTS:

1. Bayhill's Phase I/II clinical investigation of BHT-3009 is believed to be the first human trial of an antigen-specific DNA plasmid for multiple sclerosis (MS), an autoimmune disease.
2. BHT-3009 is an antigen-specific treatment for MS. The MS therapeutic has been designed to NOT cause broad-based immunosuppression.
3. Bayhill's experimental MS therapeutic, BHT-3009, has been designed to down-regulate rogue T cells specific for MBP. Left unchecked, these rogue T cells shred the myelin sheath that insulates the nerve cells of the brain and spinal cord, resulting in

MS. BHT-3009 down regulates, or tolerizes, these MBP specific T cells and only these T cells. The remainder of the immune system remains intact to fight infections and cancer.

4. Researchers and clinicians believe that BHT-3009 is distinguished from other antigen-specific approaches attempted in the clinic in several ways: (1) the DNA allows low-level persistence of the antigen for 2-4 weeks, thus allowing for less frequent dosing. (2) BHT-3009 expresses full-length MBP, thereby encompassing all possible target auto-antigens rather than a single auto-antigen, and allowing for a broader possible population of responders to the drug.
5. Bayhill's Phase I/II clinical trial of BHT-3009 is complete. In the Phase I/II trial, clinicians observed that BHT-3009 is safe and reported that "adverse events" were higher in the placebo arm compared to the treated arms.
 - a. Clinicians observed brain MRI trending toward improvement in Gad + lesion count with BHT-3009 versus placebo.
 - b. All patients are clinically stable, or improved with treatment.
 - c. Peripheral T cell assays showing decrease in activity of MBP specific T cells were observed in a number of patients.
 - d. Thus, safety and proof-of-concept were demonstrated in this phase I/II 30-patient trial.

Phase IIb trial:

- o Enrollment in this double-blind, placebo-controlled, multi-center trial has begun.
- o A total of 252 patients are being recruited in the following countries: Bulgaria, Czech Republic, Finland, Poland, Romania, Russia, Serbia, Slovakia, Turkey, Ukraine, UK, and in the US.
- o Over 120 patients have been enrolled and randomized to the study as of 30 May 2006.
- o Dosing will be for one-year with MRI Gad + lesion formation as the primary endpoint.
- o For clinical trial enrollment information, please send an email to: BHT3009@bayhilltx.com

Background resources:

MS overview: <http://www.bayhilltherapeutics.com/ms.html>

Other scientific research findings: <http://www.bayhilltx.com/publications.html>

Bayhill Therapeutics web site: <http://www.bayhilltx.com>

COMPANY CONTACT:

Mark W. Schwartz, Ph.D.
President, CEO
Bayhill Therapeutics Inc.
01-650-320-2801
mwschwartz@bayhilltx.com

CORPORATE COMMUNICATIONS CONTACT:

Lorraine Ruff
01-206-444-0022 office
lorraine@thinkmilestones.com