

Testimony

Mary McGrory Richardson

My name is Nancy McGrory Richardson and, I am the education and outreach director for Hemispherx Biopharma. I would like to provide an update to the committee on our efforts since the last meeting.

As previously reported, working with the Whittemore Peterson Institute, Hemispherx prospectively monitored blood form patients from our Phase III study, AMP 516. The collaboration was to evaluate for the presence of anti-bodies directed against XMRV in blood samples from Chronic Fatigue Syndrome patients. The results suggest that XMRV antibody positive cohort had a greater relative percent of patients showing a greater than or equal to 25% increase in exercise treadmill duration with Ampligen® treatment compared to placebo, that the XMRV antibody negative cohort.

In order to facilitate our next phase of collaboration with the Whittemore Peterson Institute, the AMP511 protocol was revised to include the monitoring for XMRV to investigate for a possible relationship between the magnitude of response of Ampligen and XMRV viral activity. We currently have a number of new clinical sites opening for the AMP 511 open-label, cost recovery treatment protocol.

We are also expanding the number of virus signatures that we are evaluating including work with Chronix Biomedical where we are using highly sophisticated equipment for Next Generation Sequencing (NGS) of serum DNA. The Chronix team is assessing whether there may be unique serum DNA sequences in the peripheral blood of patients with CFS. In the next several months, we anticipate making a formal presentation.

Hemispherx conducted its 9th Clinical Investigators Conference held March 2011 in, Florida attended by a variety of prominent clinicians and scientists including some whom have served on this committee. While discussions included the progress with Ampligen® as an immune enhancing compound for both cancer and viral vaccines, a large portion of the three day meeting was focused on CFS and Ampligen®, as a potential therapeutic.

Dr. Judy Mikovits, Research Director, Whittemore Peterson Institute for Neuro-Immune Disease presented a detailed review of the discovery of XMRV (“Xenotropic Murine Leukemia Virus”) and MLV (“Murine Leukemia Viruses”) variants found in CFS as well as new data on these variants. The XMRV genome may contain a hormonal response element that may explain the disorder of the adrenal stress response pathway in some

patients with CFS. Dr. Mikovits also discussed a cellular resistance mechanism as a possible human genetic factor in XMRV infection.

Dr. Maureen Hanson, Professor, Department of Molecular Biology & Genetics, Cornell University, presented corroborating results of her analytical work with Dr. David Bell on the presence of XMRV markers in a pediatric CFS cohort. She further provided an analysis of the relative sensitivities of PCR (“Polymerase Chain Reaction”) markers of potential mouse contamination that should be used in PCR assays for XMRV and other related murine retroviruses in human samples.

During the meeting, the Wall Street Journal (March 5, 2011 issue entitled “The Puzzle of Chronic Fatigue”) provided a comprehensive overview of potential retro-viral etiology focusing on CFS patients studied by Drs. Hanson and Bell. The writer of the article attended the meeting.

Hemispherx recently attended the NIH State of Knowledge meeting and will be attending the upcoming IACFSME meeting and NJCFSA. We believe the future holds great promise as we continue with various researchers and examine the patient-unique signatures captured by the Chronix technology.