

Hemispher Biopharma, Inc.

My name is Nancy McGrory Richardson. I am the Education and Outreach Director at Hemispherx Biopharma. On behalf of the management of Hemispherx, we appreciate the opportunity to provide an update for the committee.

As previously, Hemispherx instituted a new clinical study to retrospectively monitor blood from patients enrolled in the key pivotal study (AMP 516). The study included 208 subjects who meet the original (1988) and (1994) Centers for Disease Control criteria. Baseline (or earliest specimen) serum samples from all subjects were analyzed for antibodies directed against XMRV. Recently, Dr. David Strayer, Medical Director for Hemispherx presented the results of this initial study at the 1st International Workshop on XMRV at the National Institutes of Health. Hemispherx has since submitted the findings for publication so we will not be commenting today on the specific results of that study.

To continue research in this critical area, Hemispherx has recently amended its Open-Label Study of Ampligen® (AMP 511) to include XMRV testing and will be expanding this study; recruitment of new clinical sites is underway. Hemispherx will, of course, keep the community informed on the addition of new sites and look forward to working with the advocacy groups for the recruitment of patients.

The information collected on XMRV will be needed in the development and implementation of the final phase III study to obtain FDA approval of Ampligen® as a treatment for Chronic Fatigue Syndrome.