



Testimony to HHS CFSAC
May 10, 2010
as given by
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As has been previously communicated, the FDA has issued a completed response letter regarding our New Drug Application (NDA) for the use of Ampligen® to treat chronic fatigue syndrome (CFS). In this letter, the FDA has recommends at least one additional clinical study which shows a convincing effect and confirms safety in the target population. Hemisphere Biopharma remains committed to the development of Ampligen as a treatment options for patients suffering from debilitating CFS.

Hemisphere has instituted a new clinical study protocol to retrospectively monitor blood from patients enrolled in the key pivotal study (AMP 516). The primary purpose of this study is to identify target subsets of patients who are most likely to benefit from active treatment with Ampligen. This study specifically is monitoring patients for evidence of xenotropic murine leukemia virus-related virus (XMRV) which has recently been implicated as having a strong association with CFS. One of the key research organizations, The Whittmore Peterson Institute, is performing the analysis for this on-going study. We anticipate that this data will be available for analysis by late summer.

The information gained from this study and the recommendations made by the FDA in the complete response letter along with their review of the new subgroup analysis will guide the design of the next clinical study using Ampligen to treat CFS.

The company has provided a grant to IACFS to conduct a clinical guidelines workshop which is set to begin this month and has also made significant investment to expand and enhance its biopharmaceutical manufacturing facility in New Brunswick, New Jersey where Ampligen is produced.

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