

HEMISPHERX BIOPHARMA COMPLETES FULL ENROLLMENT OF ITS PHASE III CLINICAL TRIAL FOR CHRONIC FATIGUE SYNDROME (CFS)

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First Ever Completely Enrolled Phase III Clinical Trial for Disorder Affecting Over 500,000 Americans Surpasses Enrollment Target; Data Analysis Expected in 2003.

Philadelphia, PA, Monday, December 09, 2002: Hemispherx Biopharma, Inc. (AMEX: HEB), a leading company in the experimental stage development of immune based therapies primarily addressing the diseases of HIV/AIDS and Chronic Fatigue Syndrome, announced today that its Phase III, pivotal study in Chronic Fatigue Syndrome (CFS) is now fully enrolled.

CFS represents one of the last major chronic diseases, which has repeatedly defied pharmaceutical efforts to design a safe and effective therapy. According to the Centers for Disease Control (CDC), more than 500,000 Americans are afflicted with this severely debilitating condition which can ultimately lead to a bed-ridden state, dementia and, subsequently, a high incidence of cancer.

First Ever Clinical Development Milestone in CFS Therapy

The phase III pivotal study is rigorous in design and includes multi-center, randomized, double-blind and placebo-controlled components. As a fully enrolled program, it is the first Phase III clinical study ever successfully implemented in CFS, either in North America or Europe. The experimental immunotherapeutic, Ampligen[®], is being given to more than 230 severely debilitating patients who have enrolled in the experimental program at multiple sites across the U.S. (described more fully at www.hemispherx.net). All 230 patients must meet rigorous medical and laboratory criteria in order to qualify.

Historically, four (4) other multinational pharma companies, and two internationally recognized research institutes, including the National Institutes of Health (NIH), ceased product development at an earlier or Phase II level, because their experimental drugs were not shown to be statistically different from placebo in terms of improving physical performance or quality of life.

Hemispherx is also the first biopharmaceutical company to receive treatment IND status for its experimental CFS treatment. Within the framework of this regulatory authorization, the Company is permitted to sell Ampligen[®] on a cost recovery basis in various parts of the world to severely incapacitated patients without any other therapeutic options available to them. This program is expected to expand in year 2003 now that the pivotal Phase III trial is fully enrolled.

Year 2003 CFS Clinical Events Timetable

By establishing full enrollment in the Phase III study, the company plans to conduct a statistically-based data analysis of the double-blind, placebo-controlled portion of the study during year 2003. In addition, new data from an ongoing open-label, Phase II study – conducted in parallel with the Phase III study at similar medical centers and utilizing demographically matched CFS patients – will be presented at the January, 2003, International CFS Conference in Chantilly, Virginia. This conference brings together world-renowned researchers on various aspects of CFS diagnosis and potential treatments.

Research Platform In CFS

For more than ten (10) years, Hemispherx has supported continued study of CFS via clinical and basic research grants to a community of internationally recognized researchers in CFS. This platform positioned the Company to design and execute the Phase III trial, now ongoing with its emphasis on both clinical and molecular insights into CFS therapy.

About Hemispherx

Hemispherx Biopharma, based in Philadelphia, is a bio-pharmaceutical company engaged in the manufacture and global clinical development of new drug entities in the nucleic acid (NA) class for chronic viral diseases and disorders of the immune system including, HIV, CFS and Hepatitis. Its platform technology includes large and small agent components for potential treatment of various chronic viral infections. For more information, including the full text of the abstract described in this press release, please visit the company's Web site at www.hemispherx.net.

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