Hemispherx Biopharma Reports Low NK Cell Activity in Chronic Fatigue Syndrome (CFS) and Relationship to Disease Symptoms

Ampligen® Increases NK Activity More than 100% In Vitro in a CFS Patient Population

PHILADELPHIA – September 15, 2015 - Hemispherx Biopharma (NYSE MKT: HEB) announced today the publication in the current issue of the peer reviewed Journal of Clinical and Cellular Immunology (Strayer D, et al, J Clin Cell Immunol 2015;6:4 http://doi.org/10.4172/2155-9899.1000348) an article entitled “Low NK Cell Activity in Chronic Fatigue Syndrome (CFS) and Relationship to Symptom Severity” in which 17 studies were reviewed that evaluated NK cell cytotoxicity (NKCC) data and the relationship to different CFS case definitions and CFS disease severity.

NK cells are an important component of the human immune response acting as a surveillance mechanism against invading pathogens and tumor cells. The review includes evidence that there is an association between decreased NK cell activity and increased CFS symptomatology.

New data was also reported in this publication, of in vitro exposure of peripheral blood mononuclear cells (PBMCs) from 15 CFS patients (mean average age 47.5 years and median age 46.1 years, 67% are female). These data indicated than in vitro treatment with Ampligen®, an experimental biotherapeutic, produced a 178% increase in mean NK activity (NKCC) and a 100% increase in median NK activity (NKCC). Patients in the study meet both the 1988 and 1994 case definitions of CFS as advanced by the Centers for Disease Control (CDC).

Further clinical studies are now underway in the U.S. to evaluate the interrelationships between CFS disease severity, dysfunction of NK cells, and therapeutic response to Ampligen®, an experimental biotherapeutic.

About Hemispherx Biopharma
Hemispherx Biopharma, Inc. is a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based disorders. Hemispherx’s flagship products include Alferon N Injection® and the experimental therapeutics Ampligen® and Alferon® LDO. Ampligen® is an experimental RNA nucleic acid being developed for globally important debilitating diseases and disorders of the immune system, including Chronic Fatigue Syndrome. Hemispherx’s platform technology includes components for potential treatment of various
severely debilitating and life threatening diseases including cancers. Because both Ampligen® and Alferon® LDO are experimental in nature, they are not designated safe and effective by a regulatory authority for general use and are legally available only through clinical trials. Hemispherx has patents comprising its core intellectual property estate and a fully commercialized product (Alferon N Injection®), approved for sale in the U.S. and Argentina. The FDA approval of Alferon N Injection® is limited to the treatment of refractory or recurrent external genital warts in patients 18 years of age or older. The Company’s Alferon N Injection® approval in Argentina includes the use of Alferon N Injection® (under the brand name “Naturaferon”) for use in any patients who fail, or become intolerant to recombinant interferon, including patients with chronic active hepatitis C infection. The Company wholly owns and exclusively operates a GMP certified manufacturing facility in the United States for commercial products. For more information please visit www.hemispherx.net.

Disclosure Notice
The information in this press release includes certain “forward-looking” statements including without limitation statements about additional steps which the FDA may require and Hemispherx may take in continuing to seek commercial approval of the Ampligen® NDA for the treatment of Chronic Fatigue Syndrome in the United States. The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete. While the facility is approved by FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. The final results of these and other ongoing activities could vary materially from Hemispherx’s expectations and could adversely affect the chances for approval of the Ampligen® NDA in the United States and other countries. Any failure to satisfy the FDA regulatory requirements or the requirements of other countries could significantly delay, or preclude outright, approval of the Ampligen® NDA in the United States and other countries. The re-launch of Alferon® N as a commercial product cannot commence until all regulatory approvals have been obtained.

Information contained in this news release, other than historical information, should be considered forward-looking and is subject to various risk factors and uncertainties including, but not limited to, general industry conditions and competition; general economic factors; the Company’s ability to adequately fund its projects; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Company’s ability to accurately predict the future market conditions; manufacturing difficulties or delays; dependence on the effectiveness of the Company’s patents and other protections for products; and the exposure to litigation, including patent litigation, and/or regulatory actions; as well as numerous other factors discussed in this release and in the Company’s filings with the Securities and Exchange Commission. The final results of these efforts could vary materially from Hemispherx’s expectations. Finally, the projection of savings above is subject to change based upon operational requirements of the company and the possibility that additional finance and accounting staff may be required to accomplish the Company’s goals and objectives.

Forward-Looking Statements
To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as “intends,” “plans,” and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Hemispherx that any of its plans will be achieved. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond Hemispherx’s control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Examples of such risks and uncertainties include those set forth in the Disclosure Notice, above, as well as the risks described in Hemispherx’s filings with the Securities and Exchange Commission, including the most recent reports on Forms 10-K, 10-Q and 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Hemispherx undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise revise or update this release to reflect events or circumstances after the date hereof.