**Hemispherx Biopharma Announces Major Breakthrough: Approval for Commercial Sale of Rintatolimod (U.S. Tradename: Ampligen®) to Treat Severe Cases of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) in the Argentine Republic**

*First Product Approved for ME/CFS Indication Anywhere in the World*

*Breakthrough Approval Provides Clear Path for Growth in Latin America and the European Union*

PHILADELPHIA, Aug. 23, 2016 (GLOBE NEWSWIRE) -- Hemispherx Biopharma, Inc. (NYSE MKT:HEB) (the "Company" or "Hemispherx"), announced that it has received approval of its New Drug Application (NDA) from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT) for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The product will be marketed by GP Pharm, Hemispherx's commercial partner in Latin America. We believe that rintatolimod is the first drug to receive approval for this indication anywhere in the world. We also believe that there are no other products in the pipeline for approval, worldwide, for this debilitating disease. A copy of the official approval from ANMAT, translated in English, is available on the Company's website at http://ir.hemispherx.net/Events_Presentations.

The approval was based on submission of two pivotal studies, AMP-502 and AMP-516. Safety data also included additional CFS and non-CFS studies for a total of over 800 subjects including over 100 subjects with severe CFS who received Ampligen® for one year or longer. Several post-approval activities are required to be completed before product launch, including manufacturing site inspections and reimbursement evaluation by the Health Services Authority (SSS), the central health authority in Argentina. "*Working closely with our partner in this effort, GP Pharm, our team at Hemispherx addressed all medical and scientific issues presented by ANMAT and deserves great credit for this major success. At Hemispherx, we may be small by big pharma standards, but our commitment to addressing this dire unmet medical need makes us mighty*," stated Hemispherx CEO Tom Equels.

Approval for commercial sale in Argentina provides a platform for potential commercial sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. Hemispherx and GP Pharm are now working to expand the approval of rintatolimod to additional countries with a focus on Latin America. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, adds further validation for the product as the Early Access Program (EAP) is launched in Europe.

"*In Argentina, rintatolimod (Ampligen) has just been commercially approved for the severe disabling form of ME/CFS. The number of patients with ME/CFS is estimated to be over three million worldwide, however, only a portion of these have the severe and disabling form of the disease which we are targeting with this drug,*" stated Tom Equels. "*Until now, there has been no commercially available effective treatment and there are no advanced clinical candidates, other than rintatolimod, that we are aware of. This commercial approval in Argentina will dramatically improve our ability to treat patients suffering from severe ME/CFS in Latin America. We continue to work aggressively to clarify a path toward approval for those with severe ME/CFS in the United States, where we have Orphan Drug status, and therefore seven years of product exclusivity upon approval. We are greatly encouraged by this new regulatory approval in Argentina. This is the most significant accomplishment to date in Hemispherx's plan to bring our drug to severe sufferers of ME/CFS worldwide.*"

"*We have worked diligently with Hemispherx to get to this point, and are now preparing for the commercial launch of rintatolimod for ME/CFS in Argentina*," commented Jorge Braver, chief executive officer of GP Pharm Latin America. "*Looking ahead, we will continue to seek approval in additional Latin American countries.*"

***About Hemispherx Biopharma***

Hemispherx Biopharma, Inc. is an advanced specialty pharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of seriously debilitating disorders. Hemispherx's flagship products include Alferon N Injection® and the experimental therapeutics rintatolimod (tradenames Ampligen® or Rintamod®) and Alferon® LDO. Rintatolimod 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. Because both rintatolimod 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 Company's Alferon N approval in Argentina includes the use of Alferon N Injection (under the pending 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.

***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, below, 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.

***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 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. The clinical studies referenced herein have been previously reviewed by the FDA and are not, in and of themselves, a sufficient basis for approval in the United States. 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.

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; and 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 and/or any other activities could vary materially from Hemispherx's expectations. Approval of Ampligen® for CFS in the Argentine Republic does not in any way suggest that the Ampligen® NDA in the United States will obtain commercial approval. Also, it is noted that ANMAT approval is only an initial, but important, step in the overall successful commercialization. Namely, additional steps required for commercialization in Argentina will require, among others, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch including possible requirements for approval of final manufacturing, etc., and there are no assurances as to whether or when such multiple subsequent steps will be successfully performed to result in an overall successful commercialization and product launch.

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