Patients Need Access to Treatments, Including Ampligen® and Rituxan®

GRAND RAPIDS, Mich., Oct. 3, 2013 /PRNewswire-USNewswire/ -- PANDORA Org and other patient organizations say a recent report from the U.S. Food and Drug Administration (FDA) shows the agency must take further action to open up opportunities for ME/CFS drug development. Titled "The Voice of the Patient," this report is a detailed summary of an April 25
FDA Patient-Focused Drug Development meeting, the first of its kind, where patients explained the reality of Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS).

"The report reveals the personal and professional devastation caused by the cognitive and energy dysfunctions of ME/CFS," said Lori Chapo-Kroger, RN, president of PANDORA Org, an ME/CFS Advocacy organization.

The FDA's Patient-Focused Drug Development initiative is a commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) that aims to more systematically gather patient perspectives on their condition and available therapies to treat their condition. As part of this commitment, FDA is holding at least 20 public meetings over the next five years, each focused on a specific disease area. ME/CFS was the first among the 20 diseases being addressed.

The meeting was the result of a year-long patient campaign targeted at the FDA and asking for a stakeholders' meeting. They not only sent letters to the FDA but also to key congressional members. The effort secured letters from U.S. Senators Robert P. Casey (D-PA), Kay Hagan (D-NC) and
Richard Blumenthal

(D-CT.).

"We appreciate the response of Dr. Margaret A. Hamburg, FDA Commissioner of Food and Drugs, and Dr. Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research," said Chapo-Kroger. "However, there is still no FDA drug development guidance or clarified endpoints and outcome measures for this disease after two decades, and the
April 25-26
meeting failed to focus on that topic. Therefore, more action is needed to remove these roadblocks and further facilitate drug development for this disease that is causing tremendous suffering and even death."

At this time, no FDA-approved drug is labeled for ME/CS. In the last 20 years, at least eight drugs have been in the pipeline and with one remaining stuck. The patient organizations know that once one treatment is approved, additional research and treatments will follow; 13 drugs were approved in the nine years following the approval of AZT for HIV/AIDS.

"The FDA has considerable latitude in determining what burden of proof a drug must meet, including the legal authority to waive well-controlled and adequate studies particularly for disorders such as ME/CFS that have no FDA-approved drugs," said Chapo-Kroger. "We expect the FDA to provide considerable creativity and flexibility."

Approximately 17 million people worldwide, at least one million in the United States, have ME/CFS. A quarter of all patients are entirely house-, bed- or wheelchair bound. One in ten dies prematurely due to major organ failure, cancer, heart disease or suicide. (http://www.youtube.com/watch?v=7ea1GV0SZEg) The Centers for Disease Control and Prevention estimates the ME/CFS economic impact to be more than
$14 billion
per year in healthcare costs; an 84% increase over the average American per year in medical costs.

For any additional questions or clarification of efforts by the CFS patient advocacy team, please review the information posted at PANDORAorg.net.

About PANDORA OrgPANDORA Org is a national nonprofit organization seeking to alleviate the suffering caused by neuro-endocrine-immune diseases (ME/CFS, fibromyalgia, chronic Lyme disease and Gulf War illnesses) through the following efforts:

- Advocating for improving patient quality of life
- Community awareness projects
- Patient education programs and conferences
- Physician education programs
- Research grants
- Partnerships with other patient organizations
- Collaborations with academia and biotech industry

PANDORA Org advocates for and works toward establishing centers of excellence for research, clinical care, physician education and government services assistance for patients and their families. For more information visit: www.pandoraorg.net .

Additional Links/Background

The Voice of the Patient Report can be found at: http://www.fda.gov/Drugs/NewsEvents/ucm369563.htm

Information on Ampligen® can be found at: www.hemispherx.net

Information on Rituxan® can be found at: www.genentech.com

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