National report shines light on lupus 50-year treatment drought

October 5 2009

Today, The Lewin Group, a national health care consulting firm, issued recommendations on ways to overcome the barriers that have obstructed lupus drug development resulting in no new drug approval for this disease in more than 50 years - since the Eisenhower Administration. The recommendations are included in the report, "Overcoming Barriers to Drug Development in Lupus," which is the outcome of a 9-month study commissioned by the Lupus Foundation of America, Inc. (LFA). The recommendations highlight the need for a national collaborative and coordinated effort among key stakeholders, including the FDA, the National Institutes of Health (NIH), researchers and scientists from academia, the LFA, and industry, to implement a range of initiatives that would create a path forward to develop a robust arsenal of safe, effective, and more tolerable treatments for this difficult to treat and devastating disease.

The report provides recommendations for each of the key stakeholders, which include expanding federal support for medical research on lupus, assessing the existing standard of care used in clinical trials, examining the interpretation of regulations pertaining to clinical trial design and related standards of evidence used to evaluate investigational drugs for lupus, expediting the discovery and validation of lupus biomarkers, and more.

As part of the research conducted to prepare this independent report, in June 2009 more than 40 international lupus experts and thought leaders from government, industry, and the scientific community convened in

Washington, DC to discuss the barriers to lupus drug development. This groundbreaking effort represents the first time leaders from all sectors with a broad range of informed opinions were brought together to address the unique challenges of lupus drug development and ways to overcome them.

Lupus is a chronic, severe autoimmune disease that affects approximately 1.5 million Americans – primarily women in their childbearing years. In its more severe form lupus can lead to kidney failure, heart attack, atherosclerosis, or even death. According to the report, lupus "stands apart" from other chronic autoimmune diseases because the majority of therapies currently used to effectively manage lupus have not been approved by the FDA for the disease. Many of these medications often have side effects that can be worse than the primary disease, including osteoporosis, weight gain, high blood pressure, diabetes, sterility, liver damage, and the increased risk of infection.

"The recommendations are a call to action requiring the efforts of all key stakeholders," said Sandra C. Raymond, LFA President and CEO. "They provide the foundation for developing and obtaining approval for the arsenal of therapies and personalized treatment that people with this perilous disease require."

The report states that the persistent lack of success of lupus clinical trials has consequences for the willingness of drug manufacturers to pursue FDA approval and indicates "some in industry perceive no clear pathway or system in place for the development of lupus therapies."

"The report findings demonstrate that the pharmaceutical and biotechnology industries cannot develop lupus treatments in a vacuum," said Rick Goulburn, Executive Vice President - Global Autoimmune Therapy Area at Vifor Pharma. "We need more collaboration and partnership across all sectors of the field, greater investment by the

federal government in basic lupus research, and continued leadership from the LFA and the entire scientific community."

Lupus drug development has had many setbacks in recent years including the failure of several promising new treatments. However, much has been learned from these trials and potentially greater insight can be gained if the data is evaluated collectively.

An immediate outgrowth of the expert panel meeting held in June is the LFA Collective Data Analysis Initiative (LFA CDAI), chaired by Kenneth Kalunian, M.D., Professor of Medicine, Division of Rheumatology, Allergy and Immunology, at the University of California, San Diego, to advance the knowledge of lupus and optimize clinical trial design by researching data from previous and existing lupus clinical trials.

"The lupus community certainly recognizes the urgent need for collaboration," said Dr. Kalunian. "Following the expert panel meeting, working groups were immediately established to begin tackling the recommendations that were identified. When fully implemented, these initiatives will help gain needed insight on the issues which have plagued lupus clinical trials and develop more effective ways to design them, so ultimately lupus trials can be completed successfully."

Source: Lupus Foundation of America