

## **2010: Moving Toward a New Era of Hope and Optimism in Lupus Research, Treatment and Awareness** *Lupus Foundation of America Highlights the Year's Top Ten Achievements*

(December 23, 2010) WASHINGTON, DC – Events of 2010 represented the beginning of the long anticipated transition to a new era in which the 1.5 million Americans and the more than five million individuals worldwide living with the autoimmune disease lupus can look forward to an improved quality of life. Potential new treatments for lupus passed several milestones on the road toward approval, public and private investment in lupus research continued to grow, awareness of lupus received a boost from celebrity involvement, and several new LFA initiatives fueled efforts to improve future lupus clinical trials. The Lupus Foundation of America (LFA) has compiled a list of the *2010 Top Ten Achievements in Lupus*.

One of the most anticipated achievements of 2010 was the vote by a U.S. Food and Drug Administration (FDA) advisory committee to recommend approval of the investigational medicine, Benlysta<sup>®</sup>, for the treatment of systemic lupus. Top achievements this past year also included continued growth of public and private funding for lupus. For example, the Department of Defense (DoD) Medical Research Program and the Centers for Disease Control and Prevention (CDC) provided nearly \$7 million in additional research support. Additional pharmaceutical and biotechnology companies announced positive clinical trial data, initiated studies on new compounds, or acquired new technologies to develop potential treatments for lupus.

A growing list of celebrities helped shine a spotlight on lupus by announcing their support or speaking publicly about the disease. In an article in the September issue of *Vanity Fair* magazine, entertainer Lady Gaga listed the LFA as one of her 'two favorite' charities. Previously she announced on CNN's *Larry King Live* that she had undergone testing for lupus, greatly swelling public interest in the disease. Musician and philanthropist Julian Lennon and singer James Scott Cook generated thousands of dollars for lupus research through sales of their song, "LUCY." Long-time LFA supporters Will Smith and Jada Pinkett Smith were on hand for the inaugural LFA Butterfly Gala in New York City to honor their aunt, Karen B. Evans, who serves as the executive director of their family foundation and is the former chair of LFA's National Board of Directors. Eduardo Xol, a landscape designer for ABC's *Extreme Makeover: Home Edition*, served as Chair of LFA's observance of Lupus Awareness Month held annually in May. Also in 2010, the LFA launched an online portal to train clinical investigators on instruments used to measure lupus disease activity (LFA POINT<sup>™</sup>), enhanced its web-based *Center for Clinical Trials Education*<sup>™</sup> to better inform people about lupus clinical trials, and established the *Lupus Research Registry*<sup>™</sup> to allow individuals to indicate their interest in participating in future lupus clinical studies. The LFA also began the Collective Data Analysis Initiative (CDAI), the first project of its kind in lupus to mine and analyze data from previously failed trials of potential new lupus treatments in order to determine the impact of background therapies on trial outcomes and improve future trial design. These initiatives are part of the LFA's National Research Program: *Bringing Down the Barriers*<sup>™</sup>, which seeks to advance the science and medicine of lupus.

These 2010 achievements were the result of combined efforts of many people. Through the ongoing support of the lupus community, other stakeholders and the public, the LFA will continue its efforts in 2011 to find the causes of and cure for lupus while providing support, services and hope to all people affected by lupus – **From Care to Cure**<sup>™</sup>.

**The Top Ten Achievements in Lupus for 2010 are:**

**1. FDA Advisory Panel voted 13-2 to recommend approval of Benlysta<sup>®</sup>** as the first new treatment for lupus in more than 52 years, and the first potential FDA-approved treatment ever developed specifically for lupus. The FDA announced that it plans to make a final decision on approval of Benlysta by March 10, 2011.

**2. Global pharmaceutical and biotechnology companies moved to late stage treatment trials of investigational medicines for lupus.** UCB began a Phase III study of epratuzamab in late 2010 after earlier releasing positive data from a small Phase II study that showed a significant reduction in disease activity among patients with moderate to severe active systemic lupus (SLE) who received epratuzamab. Other companies that have either launched or were preparing to launch new clinical trials of potential new lupus therapies include Bristol-Myers Squibb, MedImmune, and Eli Lilly and Company.

**3. Well-known celebrities bring greater attention and interest to lupus.** Entertainer Lady Gaga's comments in *Vanity Fair* and on CNN's *Larry King Live* generated record traffic to LFA's website, nearly tripling the normal daily number of visitors. Musician and philanthropist Julian Lennon and singer James Scott Cook generated thousands of dollars for lupus research through sales of their song, "LUCY." Long-time LFA supporters Will Smith and Jada Pinkett Smith helped secure significant media coverage for the inaugural LFA *Butterfly Gala™* in New York City. ABC's *Extreme Makeover: Home Edition* designer Eduardo Xol raised awareness of lupus by serving as spokesperson for LFA's Lupus Awareness Month observance held annually in May.

**4. LFA spurred nearly \$7 million in new federal funding for lupus during 2010.** LFA advocacy efforts generated a significant return for lupus research in 2010. The Department of Defense (DoD) Medical Research Program provided another \$2.3 million in 2010 to fund studies on lupus and lupus biomarkers, bringing the program's total support for lupus over the past five years to \$9.5 million. The Centers for Disease Control and Prevention (CDC) provided another \$4.5 million in 2010, for a total of \$16.6 million, to support the first comprehensive study to determine the incidence and prevalence of lupus. Study sites now underway are located in California, Georgia, Michigan, and New York, and also in Alaska through the Indian Health Services.

**5. \$50 million in donated media helped to elevate awareness of lupus through the National Lupus Public Awareness Campaign, "Could I Have Lupus"** The Ad Council and the U.S. Department of Health and Human Services Office on Women's Health (OWH) released data that showed the campaign increased awareness of lupus among women ages 18-44. The LFA was the Founding Partner with OWH on the campaign, which began in March 2009 and included lupus messages in print publications and on billboards, broadcast stations, mass transit and the Internet.

**6. LFA's direct funding for research studies on lupus surpassed \$23 million.** As part of its national research program, *Bringing Down the Barriers™*, the LFA provided grants to lupus investigators in 2010 for studies of neuropsychiatric lupus, pediatric lupus, lupus nephritis, male lupus, as well as studies on stem cells for treating lupus, reproductive issues relevant to lupus, and animal models of lupus.

**7. New research findings offered potential for improved lupus diagnosis and management.** Studies reported in 2010, both in the U.S. and abroad, provided insight into better ways to diagnose and manage different manifestations of lupus. Researchers at the University of Pittsburgh have developed a laboratory test that may enable doctors to more accurately assess lupus disease activity. Investigators from Spain found that cognitive behavioral therapy (CBT), a form of psychotherapy, significantly reduced

the degree of psychological disorders associated with lupus and improved patients' quality of life. Researchers in China discovered that disease activity decreased significantly in a small group of lupus patients who received infusions of stem cells taken from umbilical cords. And a team of researchers at Albert Einstein College of Medicine in Bronx, New York found a protein in urine that was able to accurately diagnose lupus nephritis, opening the possibility that one day patients will no longer have to undergo invasive kidney biopsies.

**8. 2010 LFA initiatives strengthened clinical trials in lupus.** The LFA established the *Lupus Research Registry™*, enabling individuals to indicate their interest in participating in lupus clinical studies in their area. Additionally, the organization launched the LFA POINT™ Program (Professional Online Instrument Training) to provide training and certification to clinical investigators using instruments to monitor disease activity and assess response to treatment in clinical trials of potential new therapies. Also in 2010, the LFA launched the Collective Data Analysis Initiative™ (CDAI), the first project of its kind in lupus, which will mine and analyze data from past failed lupus drug trials to determine the impact that background medicines have on clinical trial outcomes and help improve the design of future clinical studies.

**9. The largest lupus walk, LFA's Walk For Lupus Now®, attracted 35,000 participants and raised \$3.5 million.** There were 68 LFA-sponsored lupus walks in 2010 to bring additional attention and resources to fund lupus research, education programs, and support services. The LFA walks also provided opportunities for people with lupus to connect with each other and learn more about the disease through presentations made in conjunction with the events. *Walk for Lupus Now®* events also helped increase the visibility of lupus and its impact on individuals and families through extensive local media coverage secured about the event and its participants.

**10. LFA cosponsored major national and international scientific meetings to further expand lupus research and education.** The LFA collaborated with the National Cancer Institute (NCI), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Allergy and Infectious Diseases (NIAID) and the Office of Research on Women's Health (ORWH) to conduct a major scientific meeting on mouse models used in lupus research. The program brought together basic, clinical and translational researchers to discuss clinical markers and their use in assessing the relevance of mouse models and the efficacy of treatment. The LFA also co-sponsored the Ninth International Congress on Lupus in Vancouver, Canada, which is conducted every three years for lupus investigators and clinicians from around the world. At the same meeting, the LFA helped organize a parallel program for leaders of international lupus advocacy and support groups to discuss developments in research and ways to enhance awareness and services to people with lupus. Additionally, LFA led international efforts to boost awareness of lupus by coordinating the annual World Lupus Day observance and securing signatures from lupus advocates in 81 countries for an online pledge to *Band Together for Lupus™* and raise awareness of the disease.