

## First Potential Lupus-Specific Treatment in Sight

### BENLYSTA – Successful | First of Two Pivotal Clinical Trials

July 20, 2009 is a day which will go down in History. Human Genome Sciences (HGS) and GlaxoSmithKline (GSK) announced positive results from a year-long clinical trial of BENLYSTA for treating lupus. When the 52-week study concluded, the lupus patients who were treated with BENLYSTA had improvement in overall disease activity without clinically significant flare-ups in one or more isolated organs when compared to patients who received the placebo (inactive agent). The patients receiving BENLYSTA also were able to reduce their intake of steroid medications. The study is the largest ever to be completed for lupus and the first Phase III (late stage) trial of a new biologic immune therapy for lupus to succeed in meeting its primary endpoint and most of its secondary endpoints.

Sandra C. Raymond, President and Chief Executive Officer of the Lupus Foundation of America (LFA) issued the following statement.

“For people with lupus and their loved ones, this is an historic day! With no new drugs for more than 50 years, since the Eisenhower Administration the news today indicates that it is possible to develop new, safe, and effective therapies for lupus. We are greatly encouraged by the positive top-line data which shows that HGS’ 52-week BENLYSTA study met its primary endpoints. These results provide hope that this complex chronic autoimmune disease can be brought under control and that, eventually, a cure can be found for the estimated 1.5 million Americans and more than 5 million people worldwide living with lupus.”

“We look forward to hearing the results, this fall, of a longer-term Phase III clinical study of BENLYSTA. The data from both studies will be evaluated by the U.S. Food and Drug Administration (FDA). Should the FDA ultimately approve BENLYSTA, it would become the first drug successfully developed to specifically treat lupus since the disease was discovered more than a century ago.”

“Lupus is a complex disease and not every therapy will be appropriate for all patients. Each person with lupus is unique and it is likely that successful management of lupus will require a number of therapies, perhaps used in combination with each other. The LFA and its Medical-Scientific Advisory Council urge the feral government and industry to greatly step up their research efforts on lupus so that physicians have a complete arsenal of therapies at their disposal to provide the individualized treatment that lupus requires.”

“We are grateful to human Genome Sciences and GlaxoSmithKline for their pioneering efforts to develop a new, safe, effective and tolerable treatment for

lupus, to the physicians who have passionately committed to researching this disease to the companies who continue to invest in finding new treatments, and to the thousands of people with lupus who have volunteered and participated in clinical studies over the years so discoveries such as this one could be possible.”

“Meanwhile, the LFA will continue to implement its initiative entitled, *A New 21<sup>st</sup> Century Approach to Lupus Healthcare*, to ensure the ongoing advancement of the science and medicine of lupus to meet the multi-dimensional needs of people with lupus.

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