LUPUS™
Foundation of America, Inc.

Frequently Asked Questions
BENLYSTA ™
(Formerly Lymphostat-B)

1. **What is BENLYSTA?**
   BENLYSTA is a human monoclonal antibody that is being investigated as a potential new treatment for lupus. A monoclonal antibody is a type of protein made in the laboratory that is developed to find and attach to only one type of substance in the body.

2. **How does BENLYSTA work?**
   BENLYSTA is a human monoclonal antibody that specifically recognizes and blocks the biological activity of B-lymphocyte stimulator, or BLyS® (pronounced bliss), a naturally occurring protein which was discovered by scientists at Human Genome Sciences (HGS). Elevated levels of BLyS prolong the survival of B cells which can contribute to the production of autoantibodies – antibodies that target the body's own tissues. Previous studies have shown that BENLYSTA can reduce autoantibody levels and help control autoimmune disease activity.

3. **Who developed BENLYSTA?**
   BENLYSTA is being co-developed by Human Genome Sciences (HGS) and GlaxoSmithKline (GSK).

4. **What clinical research has been conducted on BENLYSTA?**
   HGS released Phase II clinical trial results for BENLYSTA in June 2006. The results demonstrated that it significantly reduced disease activity versus a placebo in patients with clinically active lupus, and appeared generally safe and well-tolerated.

   In July 2009, HGS announced positive top-line results from the Phase III clinical trial, BLISS-52, which will continue to be analyzed. Results from the Phase III BLISS-76 clinical trial are expected to be released in November 2009. The design of the two trials is similar, but the duration of therapy in the two trials is different, 52 weeks for BLISS-52, and 76 weeks for BLISS-76.The BLISS-52 study was conducted primarily in Asia, South America, and Eastern Europe, and BLISS-76 is being conducted mostly in North America and Europe.

5. **What are the results of the BLISS-52, Phase III BENLYSTA study?**
   The study demonstrated that 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.

6. **If BENLYSTA is approved by the FDA, what does it mean for people with lupus?**
   While clinical trials are still ongoing, assuming success, BENLYSTA could represent a breakthrough in the treatment of lupus. If approved, BENLYSTA could be the **first drug approved to treat lupus in more than 50 years AND** would be the first drug developed **specifically for lupus** since the disease was discovered **more than a century ago**!

7. **What makes BENLYSTA different from other lupus treatments?**
   BENLYSTA could be the **FIRST** FDA-approved medication specifically designed for the treatment of lupus. Current medications are borrowed from other diseases and conditions and some are used off-label, which means they were never approved by the FDA for lupus. These drugs include high doses of steroids, antimalarial medications, immunosupressive drugs, and organ-rejection drugs – many which have serious and devastating side effects.

8. **When will the drug be available for patients?**
   More information on this issue will be available after the results of BLISS-76, a longer-term Phase III clinical study, are released this fall. **The results from the BLISS-52 study and the BLISS-72 study** will be submitted to the U.S. Food and Drug Administration (FDA) for review. The review process can take anywhere from six months to several years to complete. **ONLY** after receiving FDA approval will the drug be available to patients.

9. **What side effects have been found with BENLYSTA?**
   In earlier Phase II studies, BENLYSTA has shown no increase in overall or serious side effects or infections. More information will be available on this issue as the data continues to be analyzed along with the results for the BLISS-76 clinical study which are expected to be released in November.

10. **Are there other treatments being researched for lupus?**
    There are several promising treatments in the near-term pipeline. More companies are involved in lupus research and there are more potential new therapies being investigated than ever before.

11. **Why has it taken so long to find a treatment for lupus?**
    Lupus is a complex disease. It can affect multiple organ systems and symptoms can range in severity from one day to the next. And it can affect each person differently with varying responses to treatment. The complexity presents challenges in evaluating potential new therapies. With each research study, regardless of the outcome, there are new discoveries that help pave the way for new therapies.