



GENELABS TECHNOLOGIES, INC.

NEWS RELEASE

Investor Contact:

Debra Catz Bannister
Genelabs Technologies, Inc.
(650) 562-1424

Media Contact:

Kathy Lauri
Porter Novelli
(212) 601-8121

FOR IMMEDIATE RELEASE

**GENELABS REPORTS STATISTICALLY SIGNIFICANT PHASE III TRIAL RESULTS
FOR GL701 IN LUPUS AT AUTOIMMUNITY CONFERENCE
– Benefits Extend to Bone Density –**

Redwood City, Calif. – February 14, 2000 – Genelabs Technologies, Inc. (NASDAQ: GNLB) reported today statistically significant results from its Phase III clinical trial of GL701 (prasterone, dehydroepiandrosterone), its investigational drug for systemic lupus erythematosus (SLE), or lupus. Patients in the group treated with GL701 had a statistically significant greater rate of response than the group that received placebo. Response to treatment was defined as improvement or stabilization of SLE disease activity and symptoms, the study's primary endpoint.

In addition, patients who received GL701 experienced fewer disease flares and noted improved quality of life, according to results of a pivotal Phase III study. Treatment with GL701 demonstrated a consistent pattern of efficacy across a number of primary and secondary variables, including fewer lupus-related signs and symptoms reported as adverse events. Further evidence from the trial demonstrated that GL701 significantly increased bone density in patients receiving chronic corticosteroid therapy, compared to placebo. Genelabs also reported that GL701 appears to be well tolerated.

Study results were presented by Philip J. Mease, M.D., Associate Clinical Professor, University of Washington and Director of Clinical Research, Minor and James Medical Center, Seattle, at the Eighth International Scientific Conference on Lymphocyte Activation and Immune Regulation in Newport Beach, California. The February 11-13 scientific conference was sponsored by the University of California at Irvine.

The Phase III trial evaluated disease activity; organ damage; quality of life, such as severity of fatigue and the ability to conduct daily activities; depression; and bouts of heightened disease symptoms, called flares.

-more-

"The study showed that treatment with GL701 resulted in meaningful improvements in important clinical and quality of life measures for patients with lupus," said Dr. Mease. "No other drug currently being used for the treatment of lupus is both anti-inflammatory and capable of increasing bone density. We are enormously gratified to see such positive and compelling results for patients who suffer from this devastating disease yet have no adequate therapies."

GL701: Efficacy For Lupus Patients

The objective of this Phase III study was to determine whether GL701 would improve SLE disease activity and/or its symptoms in women with clinically active disease, which was principally measured by response to treatment. Patients treated with GL701 showed a 35 percent greater response rate than the placebo group ($p=0.005$): 66 percent of patients (87/132) responded to treatment with GL701 compared to 49 percent (65/133) for patients who received placebo. Incidence of flares, a serious manifestation of lupus, were more than 24 percent lower in the GL701 patient group (31/132) compared to patients who received placebo (41/133) ($p=0.201$).

Some ailments commonly associated with lupus and reported as adverse events were less frequent in patients who were treated with GL701 compared with patients who received placebo. These included muscle pain; nasal and mouth ulcers; and hair loss. Patients on placebo experienced significantly ($p<0.05$) more frequent muscle pain (36 percent placebo vs. 22 percent GL701) and nasal and mouth ulcers (23 percent placebo vs. 15 percent GL701). Hair loss was experienced in 20 percent of patients receiving placebo vs. 15 percent of GL701 patients.

If cleared for marketing by the U.S. Food and Drug Administration (FDA), GL701 will be the first drug in 40 years indicated for the treatment of lupus, and will be available only by prescription. SLE is a life-long, devastating autoimmune disease that primarily affects women. Common signs and symptoms include severe fatigue, arthritis, facial rash, unusual sensitivity to sunlight, as well as inflammation of the lungs and heart. More serious, life-threatening organ damage can lead to poor quality of life and ultimately death. There is no cure for lupus. Current treatment is primarily with chronic use of steroids, such as prednisone, which have many serious adverse consequences.

Phase III Study Design

The double-blind, randomized study enrolled 381 women with SLE to receive either 200 mg orally of GL701 or placebo once a day for 12 months. Concomitant (background) medications were allowed in both groups, including prednisone and immunosuppressives; however, baseline doses were required to be maintained throughout the 12-month study. The study was conducted at 27 sites nationwide; 8 of the sites were equipped to perform bone density measurements. The study was

designed to determine whether GL701 improves disease activity and/or lupus symptoms in female patients with clinically active disease. Efficacy was measured by the patients' response to treatment as defined by improvement or stabilization in each of four scoring instruments.

Lupus has been a very difficult disease to study because of its many diverse manifestations. Because of the complexity of lupus, this groundbreaking study utilized a responder endpoint, which was designed to identify those patients who demonstrated improvement or stabilization in disease activity and quality of life. Patient assessments were taken at baseline and every 13 weeks during the study. Responders were patients with improvement or stabilization for each of four scoring instruments – Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) and Systemic Lupus Activity Measure (SLAM), which measure disease activity; and the Krupp Fatigue Severity Score (KFSS) and Patient Visual Analog Scale (VAS), which measure quality of life parameters. A patient who had improvement in three scores and deterioration in the fourth would not be a responder by this definition. Because of the inherent variability in the scoring instruments, the classification of a patient as a responder allowed for a slight deterioration in any of the four scores from baseline. The primary analysis of efficacy was based on patients who received study drug for at least 60 days and had at least one efficacy assessment after 60 days (per protocol).

Benefits Extend to Bone Density

In Genelabs' earlier Phase III study, GL701 was shown to enable reduction of steroid doses among SLE patients with active disease. Long-term use of corticosteroids, common treatment for lupus patients, can result in premature osteoporosis, which can lead to incapacitating bone fractures. This debilitating side effect of chronic steroid therapy provided the rationale to study the effect of GL701 on steroid-induced osteoporosis in lupus patients in this Phase III study.

Bone density measurements were taken at eight investigator sites using the Dual X-ray Absorptiometry (DXA) test. Thirty-seven SLE patients who had been on steroids for at least six months prior to entry in the study were evaluated for mean changes in bone density of both the lumbar spine and hip. In this study, 18 lupus patients on chronic steroid therapy who received GL701 demonstrated a statistically significant increase ($p=0.004$) in mean bone density in lumbar spine, compared to 19 patients receiving placebo. Mean bone density in the spine increased 1.83 percent in patients on GL701 vs. a decrease of 1.78 percent in placebo patients. There were similar findings in changes in mean bone density of the hip. Total hip mean bone density increased 2.08 percent in patients receiving GL701 and decreased 0.16 percent in placebo patients ($p=0.080$).

"GL701 is a promising medication for people with lupus," said James A.D. Smith, Genelabs President. "In addition to the beneficial effect that has been observed on SLE disease activity and symptoms, GL701 may have an important role in reversing steroid-induced osteoporosis, according to the changes in bone density seen in this study. Such increases in bone density are especially encouraging given the widespread, chronic administration of corticosteroid therapy for lupus. In addition, due to the positive efficacy results seen in both Phase III clinical trials of GL701 in SLE, Genelabs intends to evaluate the use of GL701 in other indications."

Tolerability Benefits

GL701 appears to be well tolerated. Adverse events of this androgenic hormone were mild and expected, and included acne, facial hair growth and hormonal changes. In patients receiving GL701, there was a statistically significant reduction in triglycerides, a lipid which increases risk of heart disease; however, there was also a statistically significant decrease in high-density lipoprotein (HDL) cholesterol ("good" cholesterol). The findings from this study confirmed both the tolerability of GL701 seen in other studies in patients with lupus as well as the necessity of physician supervision for patients receiving hormone therapy.

GL701 New Drug Application in 2000

If approved for marketing by the FDA, GL701 will be the first drug indicated for lupus in four decades, and will be dispensed only by prescription. GL701 is a pharmaceutical preparation that contains prasterone, the pharmaceutical generic designation for dehydroepiandrosterone (DHEA) as the active ingredient. DHEA is a naturally occurring hormone that is produced by the adrenal glands. People with SLE generally have abnormally low levels of DHEA and studies have shown that hormonal influences may play a role in the development and progression of SLE.

"GL701 has been studied in rigorous, controlled trials under FDA standards for developing investigational new drugs, and has demonstrated a favorable risk/benefit ratio," stated Marc Gurwith, M.D., Genelabs Vice President, Drug Development and Chief Medical Officer. "Because it is a potent hormone with anabolic and androgenic effects, we believe DHEA should be administered only under medical supervision."

Based on the positive results of its two Phase III clinical trials and its pre-NDA meeting with the FDA in November 1999, the company will submit a New Drug Application (NDA) to the FDA. The FDA has designated GL701 for SLE as a Fast Track drug which, among other benefits, allows for submission of the NDA utilizing a rolling process. Genelabs plans to begin submission of a rolling NDA in the first half of this year and complete the submission in the second half of the year.

About Lupus

SLE is a life-long, devastating autoimmune disease that primarily affects women, many of whom experience the initial onset of disease in their late teens and early twenties. Approximately 200,000 people in the U.S. and more than one million worldwide have lupus, according to various government and private sector statistics. Lupus causes the immune system to attack the body's own tissue, which can lead to discomforting inflammation, arthritis pain, tissue injury and major organ damage. Common signs and symptoms of disease that lupus sufferers experience – severe fatigue, arthritis, facial rash and photosensitivity – can lead to a poor quality of life. More serious, life-threatening symptoms include inflammation of the lungs, heart and brain tissue, and organ damage, most often involving the kidneys.

Genelabs Technologies, Inc.

Genelabs Technologies, Inc. is a biopharmaceutical company engaged in the discovery of small molecule drugs that bind to DNA or RNA to regulate gene expression or inactivate pathogens. The company's drug discovery program is based on an integrated platform of technologies that encompasses genomics, transcription biology, structure-biased combinatorial chemistry, high-throughput screening and several proprietary validation and characterization assays. The company's development efforts are focused on its drug candidate, GL701, which has completed two Phase III clinical trials as a new therapy for systemic lupus erythematosus.

NOTE: Except for historical information, the statements in this news release are forward-looking and are subject to uncertainties and risks that could cause actual results to differ materially from the statements made. Uncertainties and risks include, without limitation, the adequacy of the company's GL701 clinical trial processes and whether the results of those clinical trials and other supporting information will be sufficient to support regulatory submissions and/or approvals; delays regarding the regulatory approval process including the timing and scope of approval received, if any; uncertainties and risks regarding market acceptance of GL701 as a treatment for SLE; the company's limited manufacturing and marketing experience; the validity, scope and enforceability of patents related to GL701; the company's capital requirements and history of operating losses; and uncertainties and risks regarding the company's ability to raise needed additional capital or consummate strategic or corporate partner transactions on favorable terms or at all. The company has not submitted applications for regulatory review in the US or other countries, and the regulatory authorities have not yet made a determination as to the safety or efficacy of GL701 for SLE. Please see the information appearing in the company's filings with the Securities and Exchange Commission, in particular information under the caption "Risk Factors" in the company's 1998 Form 10-K, for more discussion regarding these uncertainties and risks and those associated with the company's research programs, early stage of development and other risks which may affect the company. The company does not undertake any obligation to update these forward-looking statements to reflect events or circumstances after the date of this release.

Genelabs' press releases are available by fax 24 hours a day at no charge by calling PR Newswire's Company News On-Call at 800-758-5804, extension 115-419. They are also posted on the Internet at <http://www.genelabs.com> and <http://www.prnewswire.com>