



Press Release

EMBARGOED UNTIL
SUNDAY, FEB. 24 AT 6:30 P.M. CT

Contact: Andrea Moody
Phone: 919-457-0743
Email: andrea.moody@fleishman.com

GREER® Investigational Sublingual Allergy Immunotherapy Liquid (SAIL)™ for Short Ragweed Allergies Data From Phase III Trial Featured at Allergy Meeting

First Positive Findings from a Phase III Trial Evaluating Sublingual-Liquid Ragweed Pollen Extract in North America Presented at a Featured Poster Session at Prominent Allergy Meeting

SAN ANTONIO, TEXAS – Feb. 24, 2013 – GREER®, a leading developer and provider of allergy immunotherapy products and services, announces the release of new data from its pivotal Phase III investigational clinical trial evaluating the efficacy and safety of GREER Sublingual (standardized short ragweed extract) Allergy Immunotherapy Liquid (SAIL)™, as a treatment for adults with allergic rhinoconjunctivitis caused by short ragweed pollen. Study findings were presented during a Featured Poster Session presentation on Feb. 24, 2013 at the 2013 American Academy of Allergy Asthma & Immunology (AAAAI) annual meeting in San Antonio, Texas.

Dr. Peter Socrates Creticos, lead investigator of the study, notes “*Millions of Americans suffer from seasonal allergies. Some patients are treated but not well-controlled on pharmacotherapy. Our goal in this study was to further evaluate the safety and tolerability, and define the therapeutic efficacy, of sublingual immunotherapy with a standardized liquid ragweed allergen extract as a potential method of treatment for patients burdened by ragweed-induced allergic rhinoconjunctivitis. We are pleased that the Academy chose to highlight the study’s positive findings during its featured poster session, thereby allowing us to reach a large number of our peers in the allergy community.*”

Study Overview

This randomized, multi-center, double-blind, placebo-controlled, parallel group Phase III trial included 429 participants, ages 18-55 years, across 26 centers in North America. Participants had a minimum 2-year history of moderate to severe allergic rhinoconjunctivitis attributable to ragweed pollen that normally required anti-allergy medications. Participants were randomized to self-administer a metered dose of SAIL Standardized Short Ragweed extract or placebo for 8-16 weeks pre-seasonally and during the entire 2011 ragweed pollen season. The maximum tolerated high dose was a mean of 50 Amb a 1 units and the low dose was a mean of 18 Amb a 1 units. Study participants maintained daily symptom and rescue medication electronic diaries.

Study Results

The primary endpoint of the trial was the change from baseline in average total combined daily rhinoconjunctivitis symptom and medication scores for the entire pollen season. The intent-to-treat analysis met its primary endpoint with a 43% reduction in the total combined (symptom + medication use) score (TCS) relative to placebo ($p=0.0005$). Similar results were demonstrated with all secondary endpoints: TCS during the 3 peak weeks of the short ragweed season 42% reduction compared to placebo ($p=0.0007$); the average daily symptom score (DSS) over the entire ragweed pollen season, 42% reduction vs placebo ($p=0.0022$) and the average DSS over the 3 peak weeks of the ragweed pollen season, 41% reduction vs placebo ($p=0.0022$). Additionally, 94% of subjects achieved the maximum tolerated high dose; 3% of subjects remained on the low dose and 3% of subjects stepped-down from the high dose to the low dose.

Overall, there were no serious adverse events related to study drug and there was no occurrence of anaphylaxis or use of epinephrine in the study. Eight serious adverse events occurred in the study, none judged by the investigators as attributable to study drug (6 in 3 subjects in the placebo group and 2 in 2 subjects in the SLIT group). Nine participants' study medication was permanently discontinued for adverse experiences. Of the 9 participants, 6 received active drug. The investigators deemed 2 discontinuations were not related to the study drug and the remaining discontinuations were for throat/mouth swelling/itching, difficulty swallowing, and sore throat. The most common adverse experiences reported in the trial were similar to what has been found in other SLIT trials, *e.g.*, mild to moderate oral/throat itching, edema, or swelling, hives or rash and diarrhea. Researchers concluded that the study provides evidence that the once-daily administration of SAIL Standardized Short Ragweed extract was well-tolerated and clinically effective.

“GREER SAIL demonstrated statistically significant and clinically meaningful results that met the study’s endpoints” said Terrance C. Coyne, M.D., Chief Medical Officer at GREER. *“This provides further evidence supporting the potential impact we believe sublingual immunotherapy may have on treating short ragweed allergies in the U.S. and Canada.”*

“The results from this study are a critical outcome of our clinical development program for SLIT that we launched seven years ago,” said John G. Roby, GREER President and CEO. *“GREER is committed to advancing allergy immunotherapy and we look forward to taking the next steps in the process to gain the necessary governmental agency approvals for GREER SAIL.”*

About Standardized Short Ragweed Pollen Allergenic Extract

Standardized short ragweed pollen allergenic extract is indicated for the skin-test diagnosis of allergy and subcutaneous immunotherapy treatment of patients with a history of allergy to short ragweed pollen.

Allergenic extracts can elicit severe adverse reactions including anaphylaxis, particularly if the initial dosage or rate of dosage increase is too high. Any person administering a biological product should be aware of the risk of local or systemic reactions and be capable of handling such reactions. Patients receiving subcutaneous allergenic extracts should be kept under

observation a minimum of thirty minutes so that any adverse reaction can be observed and properly handled.

GREER[®] SAIL[™] is an investigational liquid form of allergy immunotherapy using the same GREER Standardized Short Ragweed Extract currently approved for subcutaneous allergy immunotherapy (SCIT) but administered under the tongue.

About GREER[®] — In Touch. Within Reach[®].

GREER[®] is a leading developer and provider of allergy immunotherapy products and services for treating humans and animals. GREER's clinical development programs are focused on sublingual allergy immunotherapy liquid (SAIL)[™]. GREER was founded in 1904 and is located in Lenoir, North Carolina. For more information, visit www.greerlabs.com.
