



Press Release

Contact: Andrea Moody

Phone: 919-457-0743

Email: andrea.moody@fleishman.com

GREER[®] Investigational Sublingual Allergy Immunotherapy Liquid (SAIL)[™] for Short Ragweed Allergies Phase III Data Published in *Journal of Allergy and Clinical Immunology*

LENOIR, N.C. – March 10, 2014 – GREER[®], a leading developer and provider of allergy immunotherapy products and services, announces that data from its pivotal Phase III investigational clinical trial for GREER[®] Sublingual (standardized short ragweed extract) Allergy Immunotherapy Liquid (SAIL)[™] is published in the March issue of the *Journal of Allergy and Clinical Immunology*. The study marks the first successful North American Phase III clinical trial to demonstrate the safety and efficacy of a sublingual standardized ragweed allergen immunotherapy liquid extract.

Dr. Peter Socrates Creticos, lead investigator and author, notes, “Sublingual immunotherapy is an alternate form of treatment that is often administered to pollen allergic patients in Europe. However, the few previously performed U.S. studies of liquid allergenic extracts were either early safety and preliminary dose-ranging studies or were unsuccessful. This study provides the first conclusive evidence that this form of treatment can be safely tolerated at effective doses.”

The objective of the study was to determine the efficacy and tolerability of GREER[®] SAIL[™] Standardized Short Ragweed extract in subjects with ragweed-related allergic rhinoconjunctivitis. The 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. During the entire season, there was a 43% decrease in the total combined (symptom + medication use) score (TCS) relative to placebo ($p=0.0005$). Similar decreases were observed in the secondary endpoints in TCS between the two groups during peak season (42%) and in daily symptom scores during the entire (42%) and peak (41%) seasons.

The occurrence of adverse events was similar, except for local application site events, between the treatment groups; most were mild in severity, or mild to moderate in severity for the local application site events which were more frequent in the active treatment group. Overall, there were no serious adverse events related to the study drug and there was no occurrence of anaphylaxis in the study. 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. 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 permanently discontinued the study 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.

“We are pleased with the publishing of this data which demonstrate that the once-daily administration of GREER® SAIL™ Standardized Short Ragweed extract was well-tolerated and clinically effective,” said Terrance C. Coyne, M.D., Chief Medical Officer at GREER. “Our goal is that this study will provide the additional data needed to support a positive action by the FDA for GREER® SAIL™ Standardized Short Ragweed extract and provide another allergy immunotherapy treatment option for allergy specialists and patients to consider.”

GREER President and CEO John G. Roby added, “We are committed to advancing allergy immunotherapy, and GREER continues to make progress in our efforts to gain the necessary governmental agency approvals for GREER® SAIL™. We look forward to taking the next steps in this process.”

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®

GREER® is a leading developer and provider of allergy immunotherapy products and services for treating humans and animals. As part of its commitment to allergy immunotherapy innovation, GREER’s clinical development programs are primarily focused on sublingual allergy immunotherapy liquid (SAIL)™. GREER also plans to bring ORALAIR®, an investigational sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts, to the United States through its partnership with STALLERGENES. Sublingual immunotherapy would be an extension of GREER’s allergy immunotherapy products and would provide another treatment option for allergy specialists to offer patients.

GREER was founded in 1904 and is located in Lenoir, North Carolina. For more information, visit www.greerlabs.com.

MPN 030514H1024