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GREER® Reports Positive Findings from Large Phase III Clinical Trial
Evaluating Sublingual Immunotherapy for Ragweed Allergies

Trial reaches objectives of significantly reducing allergy symptom scores and anti-allergy medication use during ragweed pollen season

LENOIR, N.C. – June 12, 2012 – GREER®, a leading developer and provider of allergy immunotherapy products and services, announced the initial results from its investigational pivotal Phase III clinical trial that studied the effectiveness of sublingual immunotherapy (SLIT) as a treatment for adults with allergic rhinoconjunctivitis caused by short ragweed pollen. The primary objective of the randomized, multi-centered, double-blind, placebo controlled, parallel group trial was to evaluate the efficacy and safety of GREER Sublingual (standardized short ragweed extract) Allergy Immunotherapy Liquid (SAIL)™. The trial was conducted prior to and during the ragweed pollen season of 2011. The intent-to-treat (ITT) analysis met its primary endpoint with a 43% reduction in the total combined (symptom + medication use) score relative to placebo (p=0.0032).

Peter Socrates Creticos, M.D., lead principal investigator for the trial remarked, “In this clinical trial, ragweed sublingual immunotherapy demonstrated statistically significant clinical improvement as compared to placebo in highly allergic ragweed-sensitive patients. These findings potentially represent an important advancement for immunotherapy treatment options.”

The trial included 429 participants, ages 18-55 years, across 27 centers. Participants had a minimum 2 year history of moderate to severe allergic rhinoconjunctivitis attributable to ragweed pollen, and they normally required anti-allergy medications. These 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 ITT analysis included 389 participants.

Ragweed sublingual therapy was generally well-tolerated in the trial. Of the 4 reported serious adverse events, 2 participants received placebo, and none of the serious adverse events were judged by the investigators as attributable to study treatment. There were no reported cases of anaphylaxis and no reported epinephrine injection use. Nine participants’ study medication was permanently discontinued for adverse experiences. Of the 9 participants, 6 received active drug. The investigator 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 pruritus, edema, or swelling, urticaria or rash and diarrhea.
“We often hear allergy specialists state that patients are interested in immunotherapy but are often intimidated by the commitment it entails. Our investigational program in sublingual-oral immunotherapy may ultimately provide them an additional option to consider that fits in their busy lifestyles,” said Terrance C. Coyne, M.D., Chief Medical Officer at GREER.

“This trial is a major advance in GREER’s ongoing mission to develop and provide innovative allergy therapies,” said John G. Roby, President and CEO of GREER. “We are moving forward with the preparation of a complete dossier for submission to the appropriate regulatory authorities.”

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 when improperly administered, 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 if improperly used and be capable of handling such reactions.

Patients receiving 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 utilizing GREER standardized short ragweed extract that is administered orally.

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.

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