Merck’s Investigational Allergy Immunotherapy Tablet (AIT) Significantly Reduced the Combination of Ragweed Allergy Symptoms and Medication Use in Phase III Trial

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Company Plans to File NDAs for Ragweed and Grass AITs in 2013

WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the results from a Phase III clinical study of its investigational allergy immunotherapy tablet (AIT) for ragweed pollen. The study results showed that the use of ragweed AIT significantly reduced the total combined score that measured nasal and eye symptoms and use of rescue allergy medicines, compared to placebo, in ragweed-allergic adults with or without asthma. The study was conducted during peak ragweed pollen season. These data were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Orlando.

Merck’s AIT is an investigational, dissolvable oral tablet designed to treat the underlying cause of allergies, and is being studied to determine whether AIT may help to prevent allergy symptoms by generating an immune response to protect against targeted allergens. The company is investigating disease-modifying AITs for the treatment of allergies caused by ragweed pollen, grass pollen and house dust mites. Merck has partnered with ALK-Abello to develop AITs to treat these allergens in North America and plans to file New Drug Applications (NDAs) for its ragweed and grass AITs with the U.S. Food and Drug Administration (FDA) in 2013.

“Merck is pleased that patients who took its AIT in this study experienced a significant reduction in the nasal and eye symptoms caused by ragweed allergies, and these positive results are an important step in the development of this investigational therapy,” said Rupert Vessey, M.D., Ph.D, senior vice president and franchise head, Respiratory & Immunology, Merck Research Laboratories. “We are committed to providing physicians and patients with a broad range of treatment options for allergies and other respiratory diseases.”

Additional results from this Phase III study will be presented at the AAAAI meeting in an oral presentation titled, “Ragweed Allergy Immunotherapy Tablet Reduces Nasal and Ocular Symptoms of Allergic Rhinoconjunctivitis Over the Peak Ragweed Pollen Season in North America” on March 6, 2012, 2 p.m. EST. A second, pivotal Phase III study of similar design with ragweed AIT in 784 patients was also presented at AAAAI.

Study Design

This multicenter, double-blind, randomized, placebo-controlled, parallel group Phase III trial was designed to assess the efficacy and safety of two doses of ragweed AIT. The study involved 565 adults who were 18 to 50 years old with ragweed-induced allergic rhinoconjunctivitis, with or without asthma. The majority of these patients (85 percent) were sensitive to multiple allergens. Patients were randomized to receive a once-daily tablet of Ambrosia artemisiifolia (ragweed) allergen extract at a dose of 6 Amb a 1-U or 12 Amb a 1-U or placebo for approximately 16 weeks prior to and throughout the ragweed pollen season, for a total treatment period of 52 weeks.

During ragweed pollen season, patients recorded their symptoms and rescue medication use daily in electronic diaries. The primary efficacy assessment was total combined score, which was the sum of the daily symptom score and the daily medication score averaged over the peak ragweed pollen season (peak season was defined as the 15 consecutive days with the highest 15-day moving average pollen count). The daily symptom score consisted of daily ratings of four nasal symptoms (runny nose, blocked nose, sneezing, and itchy nose) and two eye symptoms (gritty eyes and watery eyes) on a scale from zero (no symptoms) to three (severe symptoms), and the daily medication score assigned a score based upon the type and amount of rescue medication used each day. The safety profile of the study drug was monitored via adverse event (AE) reporting, as well as by an external data and safety monitoring committee.

Study Results

During peak ragweed season, patients treated with ragweed AIT 12 Amb a 1-U or AIT 6 Amb a 1-U showed 27 percent and 21 percent reductions in total combined score, respectively, relative to placebo (p=.0002 and p=.0039). Specifically, both
doses of ragweed AIT resulted in significant reductions in daily symptom score relative to placebo during peak ragweed season (17 percent for AIT 12 Amb a 1-U, p=.0144; and 14 percent for AIT 6 Amb a 1-U, p=.0472). Ragweed AIT 12 Amb a 1-U and AIT 6 Amb a 1-U also yielded 45 percent and 34 percent reductions in daily medication score, respectively, relative to placebo (p=.0001 and p=.0039) during peak ragweed pollen season, a time when rescue medications are expected to be utilized most.

The most frequently reported treatment-related AEs were itchiness of the mouth and ear and throat irritation. Two patients received epinephrine during the course of the study. There were no reports of death, systemic allergic reactions or life-threatening events over 52 weeks.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company’s plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck’s ability to accurately predict future market conditions; dependence on the effectiveness of Merck’s patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2011 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

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