

## Study demonstrates that once-a-day pill offers relief from ragweed allergy symptoms

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An international team of researchers, led by physician-scientists at Johns Hopkins, reports that a once-daily tablet containing a high dose of a key ragweed pollen protein effectively blocks the runny noses, sneezes, nasal congestion and itchy eyes experienced by ragweed allergy sufferers.

Tests showed that treatment with the pill, which contains the protein Ambrosia artemisiifolia major allergen 1, and is placed under the tongue to be absorbed, also reduced the need for anti-allergy drugs to get relief. More than 80 million Americans are allergic to ragweed.

The study is believed to be the first and largest, multicenter, double-blind, randomized controlled trial of its kind to investigate the use of sublingual immunotherapy against ragweed allergy. Begun in April 2010, it was funded by the drug's manufacturer, Merck of Whitehouse Station, N.J.

Results of the trial, published today in the *Journal of Allergy and Clinical Immunology*, showed that overall symptoms and need for such allergy medications as antihistamines and nasal steroids fell by 27 percent in people who took a pill containing 12 units of the allergen. During peak ragweed season, the roughly two-week period between August and October when pollen counts are highest, symptoms and medication use dropped 24 percent.

Researchers say that if the pill wins approval from the U.S. <u>Food and Drug Administration</u>, it could serve as a more convenient, less painful



option than weekly or monthly allergy shots. The pill also presents fewer potential side effects than allergen injections.

"Our results show this oral tablet for ragweed allergy is highly effective and well-tolerated, and offers considerable relief from what many allergy sufferers consider the most agonizing part of the year," says allergist and lead study investigator Peter Creticos, M.D.

Some 784 men and women from the United States, Canada, Hungary, Russia and the Ukraine volunteered to take part in the year-long study, in which participants were randomly assigned to take either a high-, medium-, or low-dose tablet, or placebo. Neither researchers nor study participants were aware of which dose of the pill or placebo they were taking. Patients kept track of their symptoms and medication use through detailed and daily diaries, which were later scored by researchers for analysis.

"Physicians treating ragweed <u>allergy sufferers</u> may soon have an alternative to the current approach to managing ragweed allergy, which usually involves weekly or monthly visits to the doctor's office for allergy shots and carries the risk of swelling and pain at the injection site, plus risk of anaphylactic shock," says Creticos, an associate professor at the Johns Hopkins University School of Medicine.

Creticos says that no adverse events occurred during the study. The only side effects observed were mild throat irritation, itchy tongue and swollen lips.

Creticos says his team has also begun studies of other non-injectible forms of immunotherapy, including ragweed allergy drops, and treatment applications where the allergen is lightly pricked or inserted into the middle layers of the skin.



## Provided by Johns Hopkins University School of Medicine

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