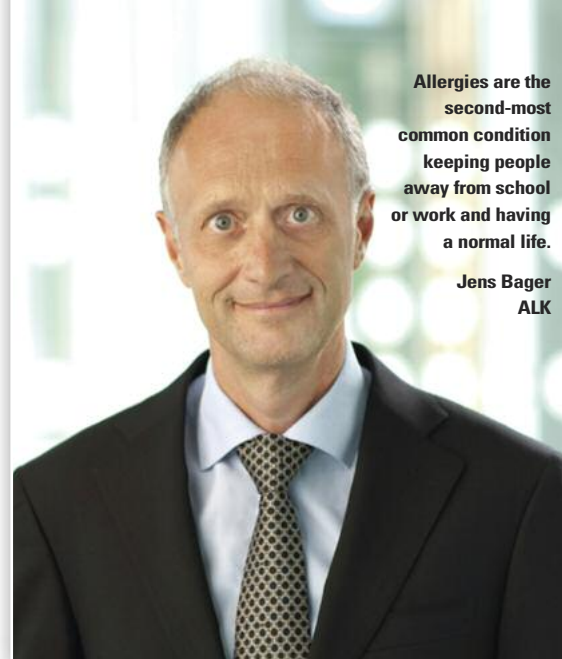


### ▶ Allergy Immunotherapy Without the Shots

Jens Bager of ALK talks about the company's allergy tablet, which addresses the specific substance causing the immune system to overreact.



Allergies are the second-most common condition keeping people away from school or work and having a normal life.

Jens Bager  
ALK

Allergies have become increasingly common worldwide and have a tendency to aggravate with time. Currently, more than 20% of the population suffers from respiratory allergies, which is an abnormal response of the immune system.

People who have allergies have an immune system that reacts to a usually harmless substance — such as pollen, mold, and animal dander — in the environment.

Prescription and over-the-counter medications treat the symptoms of allergy — itchy watery eyes

and nose, sneezing, rashes, hives — and these often work in people who have mild or moderate symptoms. For those with more serious symptoms, immunology, so-called “allergy shots,” can help the person adjust to the specific allergen. This is the only treatment that addresses the underlying cause of allergy.

Allergy immunotherapy involves treatment with doses of the specific allergen that causes the allergic reaction to gradually expose and desensitize the reaction. Gradually desensitizing the body to the allergens reduces the immune system's response when it encounters the allergens naturally, thus treating the actual cause of the allergy.

Allergy immunotherapy is the only documented treatment that targets the underlying cause of the allergy while reducing the risk of the allergy developing.

It is also the only treatment with the potential to prevent allergy sufferers from developing asthma. But fewer than 5% of allergic patients are currently treated with immunotherapy.

“Allergy immunotherapy treats a defect in the immune defenses, which makes an allergic patient overreact to substances that normally wouldn't be recognized,” says Jens Bager, president and CEO of ALK.

Up until recently, immunology therapy in the United States has only been given through injections in a doctor's office. Now Denmark-based ALK and U.S. partner Merck have developed a new immunotherapy in a tablet form that dissolves under the tongue. The FDA approved two products in April: Grastek to treat grass allergy and Ragwitek to treat ragweed allergy. They are being marketed by Merck. Both products were launched in Europe in 2006.

The companies have also initiated a Phase III program in North America with the new allergy immunotherapy tablet for the treatment of house dust mite-induced respiratory diseases. The trial is expected to include about 1,500 subjects and will investigate safety and efficacy of the tablet in the treatment of dust mite-induced allergic rhinitis in

North American patients. The dust mite product has the potential to become a first-in-class, disease-modifying allergy immunotherapy tablet aimed at the most common cause of allergy and allergic asthma in the world.

In 2013, ALK successfully completed two Phase III clinical trials in Europe investigating the efficacy and safety of the tablet in the treatment of dust-mite induced allergic rhinitis and allergic asthma.

One study found that both doses of active treatment significantly reduced the average total nasal symptom score compared with placebo in adults with house dust mite-induced allergic rhinitis. The other trial demonstrated that the treatment significantly reduces patients' risks of moderate to severe asthma exacerbations.

In Japan, ALK's strategic partner, Torii, is undertaking a similar development program and has recently announced the successful outcome of a Phase II/III clinical trial into allergic rhinitis.

In the United States, Merck plans to continue development with a Phase II/III clinical trial for allergic asthma expected to be completed in 2014.

“Of the 60 million allergic patients in the United States, 25% are not in adequate control of their allergy,” Mr. Bager says. “This is 12 million to 13 million people. They are heavily affected and may have allergic asthma symptoms from the house dust mite allergy. We are targeting the more severe patients.”

Up to 20% of patients have symptoms classified as severe. Up to 28% of those with allergies to pollen also suffer from allergic asthma, which is a form of asthma caused by exposure to a specific allergen.

Additionally, it is estimated that allergic rhinitis in children is associated with a two to seven times increased incidence of asthma.

ALK manufactures allergen extracts for allergy diagnosis such as a skin prick test.

In conjunction with the patient's medical history, a skin prick test can easily and simply show whether the patient is allergic and to what the patient is allergic. **PV**

#### Allergy Facts

- » Allergic rhinitis is estimated to affect about 50 million people in the United States, and its prevalence is increasingly affecting as many as 30% of adults and up to 40% of children.
- » 16.9 million adults and 6.7 million children have been diagnosed with hay fever in the last year.
- » More than 13.4 million visits to physician offices, hospital outpatient departments, and emergency departments were due to allergic rhinitis.
- » People with perennial allergic rhinitis experience symptoms year-round. It is generally caused by sensitivity to house dust mites, animal dander, cockroaches, and/or mold spores. Underlying or hidden food allergies rarely cause perennial nasal symptoms.
- » Allergic diseases, which include asthma, are the fifth most prevalent chronic diseases in all ages, and the third most common in children.
- » 8.3 million American children have respiratory allergies.

Source: American College of Allergy, Asthma, & Immunology

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