First vaccine developed against grass pollen allergy

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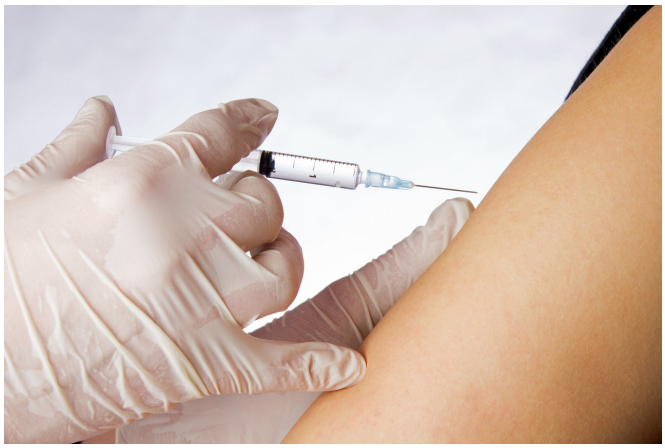

Approval of the vaccine scheduled for 2021. Credit: Medical University of Vienna

Around 400 million people worldwide suffer in some form or other from a grass pollen allergy (rhinitis), with the usual symptoms of runny nose, cough and severe breathing problems. In collaboration with the Viennese firm Biomay AG, MedUni Vienna researchers at the Institute of Pathophysiology and *Allergy* Research have now shown in a Phase II-b study with 180 patients in 11 European centres, that four injections of the synthetically manufactured vaccine BM32 in the first year and a top-up in the second year of treatment relieve the sufferers' symptoms by at least 25 percent.

Immunotherapy with BM32 is based on an innovative recombinant peptide-carrier technology, which requires far fewer injections and has fewer side-effects than other immunotherapies for allergy sufferers. This technology was developed at the Christian Doppler Laboratory for Allergy Research at MedUni Vienna, under the direction of Rudolf Valenta, in collaboration with Viennese partner company Biomay AG (CEO: Rainer Henning). This company specialises in discovering and developing innovative allergy therapeutics.

Revolutionary Viennese product

The vaccine that is used and the requisite antibodies can be synthetically manufactured. This involves extracting the B-cell-reactive peptides from the allergen using a technology developed in Vienna. These peptides are modified so that they lose their bonding properties for allergen-specific IgE and serve as carrier proteins for the necessary support from T-cells. "This process can be repeated an infinite number of times but the vaccine retains its efficacy, is always of equal quality and safe," explains Valenta. "This is a Viennese product that will revolutionise the treatment of grass pollen allergies." The Medical University of Vienna has transferred the patent for production to Biomay AG.

On average, there was a 25 percent improvement in symptoms. "The more severely the allergy sufferer is affected by grass pollen, the greater the beneficial effect following vaccination," explains Verena Niederberger-Leppin from MedUni Vienna's Department of Ear, Nose and Throat Diseases and lead author of the study, which has now appeared in the *Journal of Allergy and Clinical Immunology*. The researchers are assuming that the symptoms will diminish even further if the vaccination is topped up for a period of years (the available data relates to a study period of two years). Moreover, it could potentially also be used preventatively.

Approval of the vaccine scheduled for 2021

A follow-on Phase III study and a simultaneous child vaccination study in compliance with all applicable guidelines is scheduled to start in 2019, to create the pre-requisites for general approval of the vaccine from 2021.

At the same time, the investigations into the efficacy of BM32 have shown that the vaccine might also be an effective treatment for hepatitis B

and could also bring relief to asthma patients. The MedUni Vienna researchers and experts at Biomay AG believe that other potential applications of BM32 are the treatment of allergies to dust mites, cats and ragweed pollen.

More information: Verena Niederberger et al. Safety and efficacy of immunotherapy with the recombinant B-cell epitope–based grass pollen vaccine BM32, *Journal of Allergy and Clinical Immunology* (2018). DOI: 10.1016/j.jaci.2017.09.052

Provided by Medical University of Vienna