

June 2015, EAACI 2015 Congress in Barcelona

Biotech Tools disclosed Phase IIb results of its grass pollen immunotherapy product gpASIT+™ at the 2015 EAACI congress in Barcelona

Phase IIb clinical results with gpASIT+™ in the treatment of grass pollen allergic rhinitis were presented at the International Congress organized by the European Academy of Allergy and Clinical Immunology (EAACI) in Barcelona, June 6-10, 2015:

1. Hydrolyzed *Lolium perenne* peptide fragments administered subcutaneously to hay fever patients induce allergen-specific IgG4 and blocking antibodies after two or more weeks of treatment: Prof. Mohamed Shamji et al, Imperial College of London (poster session LB TPS 12, Immunotherapy).

See attached file: [Prof M Shamji EAACI 2015 Poster LB TPS 12.pdf](#)

2. A prospective, randomized, double-blind placebo-controlled multi-centre dose-finding study of 3 different regimens of gpASIT+™ administered subcutaneously to adult patients with grass pollen-induced allergic rhinoconjunctivitis, Dr. Gregor Zadoyan et al, Institute of Medical Statistics, Informatics and Epidemiology (IMSIE) of the University of Cologne (poster session OAS 14, Innovations in immunotherapy).

See attached file: [Dr G Zadoyan EAACI 2015 Poster OAS 14.pdf](#)

About allergic rhinitis

Allergic rhinitis is a common inflammatory condition affecting the upper airways and the membranes of the nose and eyes, caused by an allergic reaction to an allergen. Conjunctivitis often accompanies this condition. Blocked or running nose, sneezing, itching and watering eyes and inflamed eyelids are its most common symptoms, which may be seasonal (hay fever) or permanent. Allergic rhinitis is often associated with asthma.

Allergic rhinitis has a significant socio-economic impact on the patient, the patient's family and the society. It affects multiple parameters including quality of life, physical, psychological and social functioning and has important financial consequences (Pawankar et al. WAO White Book on Allergy, 2013).

In 2010, Americans with allergic rhinitis spent approximately USD 17.5 billion on health-related costs, lost more than 6 million work and school-days and made 16 million doctor office visits (Lindner. Fortune, July 26 2010). Out-of-pocket patient costs of USD 1,000 to 2,000 each year are not uncommon. On any given day, about ten thousand children are absent from school in the United States because of allergic rhinitis (WAO, White Book on Allergy: Update 2013).

Despite abundant treatment options, 60% of all allergic rhinitis patients responded in an Asthma and Allergy Foundation of America survey that they are "very interested" in finding a new medication and 25% are "constantly" trying different medications to find one that "works" (Marple, Otolaryngol Head Neck Surgery, 2007; June; 136 (6 Suppl): S107-24).

About allergy immunotherapy

Desensitisation or allergy immunotherapy is the only treatment that seeks to restore the normal functioning of the immune system, switching the immune response against allergens from “abnormal” to “normal”. This treatment consists of the administration of multiple doses of allergens in an effort to build tolerance of the immune system and to reduce the severity of allergy symptoms over time.

In 1998, the World Health Organisation recognised immunotherapy as being of therapeutic value and issued the first position paper on immunotherapy (Bousquet et al, J Allergy Clin Immunol. 1998 102:558-62). Currently, AIT is well established, and its indications, contraindications, limits and practical aspects are well defined in numerous guidelines.

About Biotech Tools

The Company is a clinical-stage biopharmaceutical company, focused on the development and future commercialisation of a range of immunotherapy products for the treatment of allergies. The Company believes that its breakthrough immunotherapy product candidates, based on the Company’s innovative technology, ASIT+™, have the potential to address the risks and limitations of current allergy immunotherapy treatments. Whole allergen immunotherapy is the only current therapy available on the market that targets the cause of allergy. However, it causes significant side-effects and requires a lengthy and inconvenient course of treatment resulting in limited efficacy. The Company therefore believes that there is a large and attractive market for its immunotherapy product candidates.

About ASIT+™ technology platform

The ASIT+™ platform allows the production, characterisation and quality control of truly new active ingredients consisting of highly purified natural allergen fragments, in an optimal size selection and without adjuvant.

About gp-ASIT+™

In the framework of phase I and phase II clinical studies, gp- ASIT+™ for grass pollen rhinitis immunotherapy has been demonstrated to:

- trigger a rapid immune response without the need for an adjuvant, leading to the potential for at least one-year protection;
- induce minimal side-effects;
- reduces the reactivity to an artificial allergen challenge; and
- allow for a faster injection regimen of higher doses, compared to treatments with whole allergens, resulting in a reduced course of treatment with four doctor visits over 3 weeks.

About Univ.-Prof. Mohamed Shamji, Imperial College of London

Dr. Shamji completed his clinical scientist fellowship training in clinical immunology at the Chelsea & Westminster Hospital NHS Foundation Trust in London, United Kingdom (UK) in 2004. He then pursued his interest in translational research and completed my PhD studies in allergy and clinical immunology at the National Heart & Lung Institute, Imperial College London, UK in 2010. He has recently established his research group (Immunomodulation and Tolerance group) within Allergy and Clinical Immunology at Imperial College lead by Professor Stephen Durham.

He is an American Academy Asthma Allergy and Immunology (AAAAI) international Fellow since 2014 and a committee member for Immunotherapy, Allergen Standardization and Allergy Diagnostic interest section (IASAD) (since 2011) and Immunotherapy, Rhinitis, Sinusitis, Ocular allergy and Cough (IRSOC) (since 2015). He represents basic science at the British Society of Allergy and Clinical Immunology (BSACI) annual meeting programme planning committee.

About Dr. Gregor Zadoyan, Institute of Medical Statistics, Informatics and Epidemiology (IMSIE) of the University of Cologne

Dr. Zadoyan graduated from the Medical University of Cologne. After finishing the PhD studies at the same university, he held several positions in medical science management. He is currently Lead Project Manager at the Institute of Medical Statistics, Informatics and Epidemiology (IMSIE) of the University of Cologne.

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