News

Dec 2014, Positive results of Phase IIb with gp-ASIT+^{TM}, allowing for fast launch of Phase III.

Statistically significant positive results with gp-ASIT+^{TM} in phase IIb clinical trial for the treatment of seasonal grass pollen allergic rhinitis.

BioTech Tools is proud to announce the positive results of a Phase IIb clinical trial with gp-ASIT+TM for the treatment of the seasonal grass pollen allergic rhinitis (BTT008): in this trial, this novel short-course allergy immunotherapy product reached the primary endpoint in a statistically significant manner.

BTT008 was a double-blind multicenter, dose-finding study conducted in 198 allergic adult patients. The gp-ASIT+^{TM} treatment was safe and well tolerated by patients. It has a positive impact on the immune system leading to a clinical benefit demonstrated by a statistically significant higher reduction of the reactivity to a conjunctival provocation test (CPT) in treated patients compared to placebo. This clinical benefit was observed after only 4 treatment visits in 3 weeks.

Univ.-Prof. Dr. med. Dipl.-Ing. Ralph Mösges, the principal investigator of the trial, and the Head of the Institute of Medical Statistics, Epidemiology and Computer Science at the University of Cologne, commented that "*Immunotherapy is the only treatment targeting the causes of the allergic disease. Despite this unique advantage, this type of treatment has currently limited patient acceptance and poor compliance due to the associated risks and a cumbersome duration of 3 to 5 years. The results of the Phase IIb confirm that a short course treatment with gp-ASIT+^{TM} at the end of the winter could reduce the rhinitis symptoms during the pollen season. These very promising results allow the selection of the dose and treatment schedule which will be tested in pivotal Phase III efficacy clinical trial".*

Thierry Legon, the Chief Executive Officer of BioTech Tools, commented that "*gp-ASIT+^{TM} is the first product generated from our innovative ASIT+^{TM} technology platform. The ASIT+^{TM} active principles are allergens with optimal size distribution improving safety and allowing a faster administration schedule. These characteristics allow for a short course of therapy: 4 doctor visits over 3 weeks. Such short course treatment should constitute a very attractive therapeutic option, with the potential to improve patient acceptance and compliance. In addition, the successful Phase IIb trial confirms the proof of concept of our technology platform, reinforcing the attractiveness of the BioTech Tools pipeline.*"

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, Otolarynol 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. Dr. med. Dipl.-Ing. Ralph Mösges, Head of the Institute of Medical Statistics, Epidemiology and Computer Science at the University of Cologne

Professor Ralph Mösges, is otorhinolaryngologist and allergist and since 1996 has been Professor for Medical Informatics and Deputy Chairman of the Institute of Medical Statistics, Informatics and Epidemiology at the University of Cologne in Germany. His current major research fields are allergology, epidemiology and clinical pharmacology. He is the author and editor of 7 books and has published more than 150 articles in prominent journals. He holds several editorial positions for such journals.

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