

# Newly published Phase IIb clinical results with gp-ASIT+™ in the ALLERGY journal highlight outstanding clinical and remarkable immunological effects

- Publication of our results in the high impact factor journal ALLERGY confirms the importance, the validity and the treatment impact in allergic patients of gp-ASIT+™. Our clinical and scientific results:
  - were peer-reviewed and accepted as meeting the highest scientific quality standards,
  - make alert the world's largest scientific community in the field of Allergy and Clinical Immunology i.e. more than 10,000 members worldwide, about the outstanding clinical and remarkable effects of gp-ASIT+™ making allergy immunotherapy much more attractive for the patients.
- Results of the dose-ranging Phase IIb clinical trial with gp-ASIT+™ distinctly differentiate gp-ASIT+™ treatment for grass pollen allergy from available therapies. An optimal dose of 170 µg of gp-ASIT+™ administered during 4 visits to the doctor within 3 weeks reduced allergic reaction and induced anti-inflammatory, allergen neutralizing antibodies in patients with grass pollen rhinitis.
- The outstanding clinical and remarkable immunological effects observed in this Phase IIb
  have been confirmed in the first Phase III which has showed a convincing reduction of the
  combined symptoms and medication scores in real life grass pollen exposure. The results of
  this Phase III trial will be published soon in a peer-reviewed journal.

Brussels, Belgium, November 30, 2017, 19 am (CET) – ASIT biotech (Euronext: ASIT - BE0974289218), a Belgian clinical-stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough immunotherapy products for the treatment of allergies, announces the publication of its Phase IIb dose-finding clinical trial results with gp-ASIT+™, the company's lead product candidate for grass pollen rhinitis, in ALLERGY, a high impact scientific journal (impact Factor 7.36). ALLERGY is the official journal of the European Academy of Allergy and Clinical Immunology (EAACI) the world's largest scientific community in the field of Allergy and Clinical Immunology with over 10,000 members worldwide. All members, among which allergists, receive this journal on a monthly basis, informing them about the last scientific results in their field.

The results were obtained from a state of the art randomized double-blind, placebo-controlled dose finding study in 198 grass pollen allergic patients. It demonstrated that 170  $\mu$ g of gp-ASIT+<sup>TM</sup> administered during 4 visits to the doctor over 3 weeks is the optimal dosage to reduce the reactivity to a challenge test and to induce antibodies capable of blocking and preventing the allergic reaction in patients with grass pollen rhinitis. The study results also confirmed that gp-ASIT+<sup>TM</sup> is safe and well tolerated.

Thierry Legon, CEO of ASIT Biotech, commented: "The publication of our data in ALLERGY is a strong signal to the largest community of allergists in the world supporting our lead product gp-ASIT+ $^{\text{TM}}$  and its remarkable immunogenicity allowing allergic patients desensitization in only 3 weeks when other products

take several years to achieve the same objective. These results have been confirmed by our first Phase III results which showed a convincing reduction of the combined symptoms and medication score in real life grass pollen exposure."

Prof. Ralph Mösges, University of Köln, a member of the Scientific Committee of ASIT biotech and principal clinical investigator of the study added: "I am extremely delighted that we have been able to identify a clinically relevant optimal dose of gp-ASIT+™ which clearly showed efficacy and safety in this large Phase IIb trial conducted in the framework of our German Rhinitis Study Group. The selected dose showed a clear superiority to placebo in a clinically meaningful parameter of efficacy. These findings confirm that gp-ASIT+™ could improve patient treatment acceptance and compliance which are major concerns with other immunotherapy treatments."

Prof Mohamed Shamji, Associate Professor at Imperial College London and co-investigator of the study who performed the immunological tests added: "The immunological findings of the Phase IIb trial with only 4 visits to the doctor over a 3-week period showed a rapid and impressive allergen neutralizing antibody response correlated with the treatment dose. We know that allergen neutralizing antibody responses are of major relevance to ensure clinical benefit. This is clearly seen with  $gp-ASIT+^{TM}$ . Such properties clearly differentiate  $gp-ASIT+^{TM}$  from currently available therapies."

#### References:

Article in ALLERGY (click here)

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#### **About ALLERGY**

ALLERGY is the official journal of the European Academy of Allergy and Clinical Immunology (EAACI), the world's largest scientific community in the field of Allergy and Clinical Immunology with over 10,000 members worldwide. Each member, including allergists, receives this journal monthly and is informed on the last scientific results in their field of professional activities.

## About Ralph Mösges & Mohamed Shamji

https://www.asitbiotech.com/company/scientific-committee

# **About ASIT biotech**

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the development and future commercialisation of a range of breakthrough immunotherapy products for the treatment of allergies. Thanks to its innovative ASIT+™ technology platform, ASIT biotech is currently the only developer of AIT product candidates consisting of a unique mixture of highly purified natural allergen fragments in an optimal size selection. This innovation results in a short treatment, expected to improve patient compliance and real-life effectiveness. ASIT biotech's product pipeline entails two novel ASIT+™ product candidates targeting respiratory allergy with the highest prevalence (i.e. grass pollen: gp-ASIT+™ and house dust mite: hdm-ASIT+™), that could significantly expand the current immunotherapy market. The Company believes that its innovative ASIT+™ platform is flexible and would be applicable across a range of allergies.

ASIT biotech has a headcount of 22 staff members, at its headquarters in Brussels and a laboratory in Liège, Belgium.

Further information can be found at: www.asitbiotech.com.

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