ASIT biotech announces the publication of its first clinical data with gp-ASIT+™ in the Journal of Allergy and Clinical Immunology (JACI)

- Results of this first-in-human clinical trial (Phase I/II) with gp-ASIT+™ formed the basis for further clinical development of the company's lead product candidate for grass pollen allergic rhinitis up to Phase III

- For the first time, allergy immunotherapy clinical results obtained from a short-course treatment with allergen peptide injections are published in a renowned peer reviewed journal in allergology

- This scientific publication is a strong recognition by the immunology and allergology experts of the quality of ASIT biotech's clinical development programs with gp-ASIT+™

Brussels, Belgium, 12 October 2017, 5.45 pm (CEST) – 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 the first clinical trial data with gp-ASIT+™, its lead product candidate for grass pollen rhinitis, in the *Journal of Allergy and Clinical Immunology* (JACI), the official scientific journal of the American Academy of Allergy, Asthma and Immunology (AAAAI). Respected worldwide, JACI is a prestigious peer reviewed journal with an impact factor as high as 13.081. With 46,218 citations in 2016, it is the most cited in the field of allergy and clinical immunology.

The results are established on a state of the art double-blind, placebo-controlled, study design and demonstrated that:

- 5 consecutive injections of gp-ASIT+™ in patients with grass pollen rhinitis, are safe and well tolerated,
- the treatment was associated with the induction of grass pollen specific antibodies capable of blocking the allergic reactions responsible for grass pollen rhinitis in human.

The authors conclude that gp-ASIT+™ is a potential candidate for Allergen Immunotherapy (AIT) and is to be further validated in AIT trials. All the clinical studies conducted with gp-ASIT+™ since then and up to Phase III have confirmed and validated the results of this first clinical study.

Thierry Legon, CEO of ASIT Biotech, commented: "*The publication of our data in a renowned peer-reviewed journal such as JACI confirms the quality of our work. For the first time, we have shown in collaboration with Dr. Mohamed Shamji, Associate Professor at Imperial College London, that gp-ASIT+™ has a reduced allergenicity while keeping the necessary immunogenicity to treat the allergic patients. These results constituted a reliable basis for the further clinical developments of our lead product candidate up to the end of the first Phase III.*"

Dr. Mohamed Shamji added: *"I am delighted that our first clinical study has been accepted by the allergy scientific community and that the data characterizing gp-ASIT+™ has been accepted for publication in JACI. This publication emphasizes the validity of the short-course injections formulation of gp-ASIT+™ as a promising treatment for seasonal allergic rhinitis*."

References:

Article in JACI (click here)
News on the Imperial College London website (click here)

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About the Journal of Allergy and Clinical Immunology (JACI)

JACI is the official scientific journal of the American Academy of Allergy, Asthma and Immunology (AAAAI). Respected worldwide with 46,218 citations in 2016, it is the most cited journal in the field of allergy and clinical immunology. Each monthly issue features the very latest and best research in the allergy / immunology specialty, with a special interest in clinical medicine and basic science as it translates into optimal patient care. JACI is one of the most prestigious journals in the field of allergy and immunology (ranked 6 out of 150), with an impact factor of 13.081 (the impact factor is a measure of scientific prestige and influence based on the frequency with which that journal is cited by other publications).

About gp-ASIT+™

gp-ASIT+™ product candidate for the treatment of grass pollen rhinitis consists of a mixture of natural allergen fragments obtained from a purified specific proteinic extract from *Lolium perenne* pollen. In contrast to the synthetized peptides, the natural peptides (70% of the fragments ranging from 1,000<MW<10,000) include a wide range of epitopes that stimulate the immune system with optimal complexity.

The administration schedule of the treatment is of short duration compared with currently commercialized treatments. This constitutes a major competitive advantage to improve the acceptance and the compliance of the patients. In addition, the administration schedule includes successive injections with half of the visit dose in both arms, an innovative solution that enables the delivery of the total dose necessary for the therapeutic effect in a faster and safer way. Finally, the product candidate is formulated without adjuvant, which increases the long-term safety of the product by decreasing the local and general reactogenicity as well as the frequency of the adverse events, which represents a further advantage in markets less permissive to adjuvanted formulations (e.g. US).

Except for the clinical efficacy during natural grass pollen exposure that was investigated in the first phase III clinical study with gp-ASIT+™, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

The phase III clinical study of gp-ASIT+™ was conducted in 67 clinical centers in Belgium, the Czech Republic, France, Germany, Italy and Spain, and involved 554 randomized patients suffering from grass pollen rhinoconjunctivitis.

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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