Regulated information

ASIT biotech presented the immunogenicity data of the gp-ASIT+™ phase III clinical study for the treatment of grass pollen rhinitis at EAACI 2017

- Striking immunogenicity results in a subset of grass pollen allergic patients reveal, for the first time ever, the induction by gp-ASIT+™ of a sound and groundbreaking immunoregulatory mechanism of action.
- This mechanism of action is associated with impressive clinical effect of gp-ASIT+™ observed in this subset of patients who were exposed to high grass pollen concentration.
- The knowledge of the mechanism of action constitutes the basis for rational design of future ASIT+™ products. It reduces the risk of further developments of gp-ASIT+™ as well as of the product portfolio.
- Preparation of the next phase III study of gp-ASIT+™ is underway.

Brussels, Belgium, 3 July 2017, 7.00 am (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, presented the immunogenicity data of its phase III clinical study with gp-ASIT+™, a product candidate for the treatment of grass pollen rhinitis, during the late-breaking oral session entitled "Allergen Immunotherapy – mechanisms and vaccines" at the European Academy of Allergy and Clinical Immunology (EAACI) Congress in Helsinki, June 17-21. This oral communication, which further confirms the clinical results presented earlier at the Congress by Prof. Ralph Mösges, is available on the company website (www.asitbiotech.com).

As planned prior to the start of the Phase III study, all the patients enrolled at the University Hospital in Ghent provided blood samples to allow the study of the mechanism of action of gp-ASIT+™ by Dr. Shamji, Scientific Advisor at ASIT Biotech and Associate Professor at Imperial College London.

Dr. Shamji disclosed striking immunological results supporting a sound and groundbreaking immunoregulatory mechanism of action induced by gp-ASIT+™. Short-course treatment with gp-ASIT+™ significantly inhibits 2 mechanisms leading to allergic reactions: (1) the increase of grass pollen specific IgE antibodies; (2) grass pollen-induced basophil activation. Additionally, a short-course treatment with gp-ASIT+™ induced protective allergen blocking antibodies produced by regulatory B cells which were associated with an impressive clinical effect during the pollen season.

In this subgroup of patients (n=21 gp-ASIT+™; n=11 placebo) a substantial reduction was observed in both the Combined Clinical Symptom and Medication Score (-35.1% during the peak period and -53.7% during the entire pollen season) and Rhinoconjunctivitis Total Symptom

Score (-27.4% during the peak period and -56.9% during the entire pollen season) during a high pollen count season in Belgium.

Dr. Mohamed Shamji comments: *"I am very excited by the data of our phase III study as it revealed a novel mechanism of action of gp-ASIT+™. This observed immunogenicity further supports the clinical efficacy and benefits of immune-regulation mediated by gp-ASIT+™. I strongly believe that short-course treatment with gp-ASIT+™ will have an important impact on how allergic patients could be well managed in the future."*

Thierry Legon, CEO of ASIT Biotech, added: *"We believe that this phase III data confirms that a short-course subcutaneous treatment with gp-ASIT+™ is the future of allergen immunotherapy for grass pollen rhinitis. Our commitment to bring gp-ASIT+™ to the market remains unchanged and we are already working on the preparation of the next phase III study with the aim to launch the trial before the next pollen season. The discovery of the mechanism of action of gp-ASIT+™ is a major milestone for the company that strongly confirms for the first time ever the relevance of allergen peptide immunotherapy. The knowledge of the mechanism of action constitutes the basis for a rational drug design of future ASIT+™ products. It reduces the risk of further developments of gp-ASIT+™ as well as of our product portfolio with a strong emphasis on our food allergy program currently in preclinical development and well-funded thanks to the €6 million financing received from the Walloon government."*

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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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