Regulated information

ASIT biotech discloses comments from the Paul Ehrlich Institute and presents detailed results on the phase III clinical study of gp-ASIT+™ at EAACI 2017

- PEI regards the first Phase III with gp-ASIT+™ in grass pollen rhinitis (BTT009) as supportive and requires an additional compelling pivotal study before considering a Marketing Authorization Application
- PEI agreed that CPT[1] reactivity at baseline may be used to characterize and identify the most appropriate patients in a future Phase III study
- Post-hoc analysis of BTT009 points out that the combined clinical symptom and medication score (CSMS) improved by up to 24% during the entire pollen season in patient subgroup with the highest CPT reactivity at baseline (score 3 and 4) representing more than half of all the BTT009 patients

Brussels, Belgium, 19 June 2017, 7 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, reports comments from the Paul Ehrlich Institute (PEI, the German health authority) and presents detailed results on the phase III clinical study of gp-ASIT+™ today at the European Academy of Allergy and Clinical Immunology congress (EAACI 2017) in Helsinki.

The PEI granted a scientific advice session to ASIT biotech to review the results of BTT009 and agree on further clinical and regulatory developments. At that session, the PEI acknowledged that the results of the primary endpoint analyzed and in the patient group as presented in the meeting documentation reached statistical significance ($p<0.05$). However, these results cannot be regarded as a confirmatory (pivotal) study, because they missed the predefined 20% difference of CSMS between placebo and treated group (i.e. an absolute score difference versus placebo of -0.31) for a clinically relevant effect.

All the data (primary, secondary endpoints and post-hoc analyses) point to symptom improvement in patients after a short course treatment with gp-ASIT+™. Furthermore, the immunologic study results showed a clear effect of gp-ASIT+™ on the immune system which supports CSMS improvement.

PEI considers BTT009 study as supportive and states that an additional compelling pivotal study is needed before considering a Marketing Authorization Application (MAA) submission for Germany, and for a future expansion of this MA to other European countries based on international guidelines. The PEI agreed that CPT reactivity at baseline may be used to characterize and identify the most appropriate patients in a future Phase III study.

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Pr. Dr. Ralph Mösges, University of Köln, member of the Scientific Committee of ASIT biotech and principal investigator of the BTT009 study, presents today the clinical data at EAACI 2017 (see abstract). gp-ASIT+™

[1] Conjunctival Provocation Test (CPT) is a test enabling both the diagnosis of a patient's allergy and the determination of their level of hypersensitivity at various times during the desensitization process.

consistently improved CSMS in allergic rhinitis patients from 15.5% (at peak pollen period, p=0.04) to 17.9% (during the entire pollen season, p=0.03) compared to placebo. The treatment was overall well tolerated and elicited mostly mild adverse reactions.

The observed responses to the Clinical Provocation Test (CPT) further support the clinical efficacy findings:

- in a patient subgroup with the highest CPT reactivity at baseline (reactivity score 3 and 4) representing more than half of all the Phase III patients, the symptoms improvement compared to placebo reached 20% during the peak pollen period (p=0.05) and 24% over the entire season (p=0.05);
- CPT reactivity observed at baseline was predictive of later clinical response;
- improvement in quality of life was in line with efficacy endpoints.

Pr. Dr. Ralph Mösges says: *"These results confirm the efficacy and safety of short course treatment with gp-ASIT+™, an adjuvant free peptide mixture, in patients suffering from grass pollen-induced allergic rhinitis. It further supports the efficacy and safety data of gp-ASIT+™ shown in previous studies."*

Thierry Legon, CEO of ASIT Biotech, added: *"We are satisfied that the PEI has acknowledged the quality of the BTT009 data obtained with gp-ASIT+™. As previously discussed, for this phase III study, we had to deal with an atypical pollen season. The feedback states that an additional compelling pivotal study is needed ahead of submitting an MAA in Germany. The results presented at EAACI demonstrate that the CSMS score was improved by up to 24% in a patient subgroup during the entire pollen season and we will most likely focus on this highly reactive patient population for an additional trial. We are already performing the feasibility study of the next Phase III and we hope that we will be able to treat the patients before the next pollen season."*

EAACI is the most important event of the European Academy, and one of the biggest international meetings dedicated to Allergology and Clinical Immunology. It gathers thousands of delegates from all around the world, and offers simultaneous sessions covering all aspects of the Academy's specialty.

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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.

Contact

Company
Thierry Legon, CEO
ASIT biotech
Tel. +32 2 264 03 90
investors@asitbiotech.com

Media and Investor Relations - France
NewCap
Dusan Oresansky / Pierre Laurent
Tel.: +33 1 44 71 94 92
asitbiotech@newcap.eu

Media Relations - Belgium
Laure-Eve Monfort
Tel.: +32 2 290 90 93
monfort@comfi.be

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