Regulated information

ASIT biotech reports positive results in its Phase III clinical trial with gp-ASIT+™ for grass pollen induced allergic rhinitis

- First ever clinical study to demonstrate the clinical efficacy of allergen peptides in a real-life setting
- gp-ASIT+™ induced a 15% to 21% reduction in the combined clinical symptom and medication score (CSMS) which is considered as satisfactory despite an atypical pollen season
- Identification of a novel mechanism of action for gp-ASIT+TM allows further development and optimization of the ASIT+™ portfolio of product candidates
- Results allow further discussions with regulatory agencies in Germany and the US regarding gp-ASIT+™ clinical development

Brussels, Belgium, 28 February, 2017, 6 PM (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, reports positive results for its Phase III clinical trial in grass pollen rhinitis.

The study was conducted in 67 clinical centers in Belgium, the Czech Republic, France, Germany, Italy and Spain, and involved 554 randomized patients.

gp-ASIT+™ consistently improved clinical symptoms and reduced medication use in allergic rhinitis patients by between 15 and 21% compared to placebo, depending on the type of analyses performed (peak vs. entire pollen season, intention-to-treat (ITT) vs. per protocol (PP) population). More specifically, the statistical significance of the primary endpoint, the mean combined clinical symptom and medication (CSMS) score during the peak pollen period, reached $p<0.041$ using non-parametric testing (Mann-Whitney) and $p<0.078$ using parametric testing (ANOVA using square root transformation of the scores) on the ITT population. Similar results were obtained when assessing the entire pollen period.

These results confirm:

- the use of the Conjunctival Provocation Test (CPT) as a surrogate marker of clinical efficacy and the reduction in the reactivity score to this test induced by gp-ASIT+™ ($p<0.01$);
- the induction by gp-ASIT+™ of grass pollen allergen-specific IgG4 and blocking antibodies (assessed on a subset of 32 patients);
- the overall good tolerability of gp-ASIT+™, as demonstrated by the occurrence of mostly mild adverse reactions and the absence of new or unexpected safety findings.

Following additional analyses, full results will be presented at upcoming scientific meetings.

Dr. Mohamed Shamji, Scientific Advisor at ASIT Biotech and Associate Professor at Imperial College London, states: *"These positive results are consistent with previous studies performed with gp-ASIT+™ in grass pollen rhinitis, and confirm the efficacy and safety of gp-ASIT+™ in this patient population by activating the regulatory mechanisms of the patient's immune system. I am delighted to have identified for the first time a*

novel mechanism of action of gp-ASIT+™. These findings will be reported in a research article which will be published in a high impact factor scientific journal."

Thierry Legon, ASIT biotech's CEO says: *"We are pleased to report the first ever clinical study to demonstrate the clinical efficacy of allergen peptides in a real-life setting. This study confirms the effectiveness of our gp-ASIT+™ grass pollen product, and we are looking forward to discussing the detailed results with regulatory agencies in Germany and the US to determine a clear pathway to further clinical development and marketing authorization. Furthermore, the finding of the mechanism of action further supports the development of the ASIT+™ product portfolio targeting house dust mite, ragweed and food allergies. As described in the IPO prospectus, we will explore additional financial opportunities to develop new ASIT+™ products."*

Conference call on 1st March, 2017 at 10:30 AM (CET)

ASIT biotech's senior management, accompanied by Dr. Mohamed Shamji, Scientific Advisor at ASIT Biotech and Associate Professor at Imperial College London, will hold a conference call in English 1st March, 2017 at 10:30 AM (CET) in order to present its results and answer your questions. To access this conference call, please dial the applicable number:

From France: +33 1 70 77 09 44
From Belgium: +32 2 4040629
From UK: +44 2 033679453
From the United States: +1 6467224908

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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 is investigated in the current first phase III clinical study with gp-ASIT+™, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

As a result, the Company believes that gp-ASIT+™ is the only short course treatment AIT product without adjuvant that is currently in phase III clinical studies with positive and statistically significant efficacy and immunogenicity results obtained during the phase IIa and phase IIb clinical studies.

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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