Regulated information
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First patient treated with gp-ASIT+™ within the framework of the confirmatory Phase III study in grass pollen rhinitis

- The first treatment in this final study prior to the application for marketing authorization for the gp-ASIT+™ product candidate on the German market was undertaken on schedule at the Memmingen medical center in Germany
- More than 450 patients have already had their first visit before treatment in accordance with the new more selective inclusion criteria in 73 active European centers
- This inclusion rate is in line with the objective of treating 624 patients across 6 European countries before the start of the pollen season

Brussels, Belgium, January 31, 2019 – 07:00 am CET – ASIT biotech (ASIT - BE0974289218), a Belgian biopharmaceutical company specialized in the research and development of innovative allergy immunotherapy products, today announces the treatment of the first patient in the confirmatory Phase III study with gp-ASIT+™ in grass pollen rhinitis at the Memmingen medical center in Germany.

The patients in this study are being enrolled in accordance with an improved protocol based on the lessons learned from the first Phase III study, which has already demonstrated the efficacy of gp-ASIT+™ compared to the placebo, to target the most allergic patients, who respond better to treatment, with more accurate monitoring thanks to the use of an electronic diary.

The study foresees the inclusion of a total of 624 patients, in 79 centers in 6 European countries, who have a regular history of high pollen exposure. All of the patients should be treated before the start of the next pollen season. The last-patient-last-visit is scheduled for the third quarter of 2019, and the results could be available by December 2019.

The primary objective of this study is a 20% reduction in the Combined Symptom and Medication Score (CSMS) in the treated group compared to placebo (i.e. an absolute score difference versus placebo of at least -0.30).

The German health authority, the Paul Ehrlich Institute (PEI), has confirmed that this confirmatory Phase III study should, assuming the primary objective is met, allow the Company to file a Marketing Authorization Application (MAA) for gp-ASIT+™ in Germany, with the possibility of extending this authorization to other European countries in line with international guidelines.

gp-ASIT+™ is an innovative compound of natural allergen fragments, without adjuvant, administered by subcutaneous injection. A three-week treatment (4 visits to the doctor) should enable allergic patients to be protected for the entire grass pollen season.

Michel Baijot, CEO of ASIT biotech, comments: "*The treatment of the study's first patient with gp-ASIT+™ has been undertaken in accordance with the improved clinical protocol and in line with our roadmap, which foresees the inclusion of all patients in the study before the start of the next pollen season. We believe that the qualities of gp-ASIT+™, whose efficacy and safety profile were confirmed during previous clinical trials on several hundred patients, make it a product candidate that could meet the clearly-expressed needs of allergic patients, i.e. shorter and better-tolerated treatments. This is why we have decided to focus our resources and development efforts on this unique compound. If the results are conclusive, and subject to the approval of the PEI, gp-ASIT+™ could become the first peptide-based allergen immunotherapy product registered on the German market, one of the largest markets in terms of the prevalence of grass pollen rhinitis*".

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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 commercialization 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 allergy immunotherapy (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 contains three novel ASIT+™ product candidates targeting respiratory allergies with the highest prevalence (i.e. grass pollen: gp-ASIT+™ and house dust mite: hdm-ASIT+™), and food allergies (peanut allergy: pnt-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 26 staff members, at its headquarters in Brussels and a laboratory in Liège, Belgium.

Further information can be found at www.asitbiotech.com

Contacts

Company
Philippe Ghem
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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