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# ASIT biotech will publish the results of the phase 3 clinical trial with its gp-ASIT+™ product candidate for treating grass pollen rhinitis on 28 February, 2017

Brussels, Belgium, 27 February, 2017, 8:30am (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, announces that it will publish the results of the phase 3 clinical trial in grass pollen rhinitis on 28 February, 2017 after the Euronext Brussels and Euronext Paris markets close.

This study was conducted in 67 clinical centers in Belgium, the Czech Republic, France, Germany, Italy and Spain. 512 patients attended the last visit to the allergist, giving a retention rate of 93% (see the press release of 5 October 2016).

The objective of this first phase 3 clinical trial is to demonstrate the clinical efficacy of gp-ASIT+™ when administered subcutaneously in patients suffering from hay fever before the grass pollen season. The study's primary endpoint is to assess the reduction of the Combined Symptom and Medication Score (CSMS) during the peak of the grass pollen season subsequent to treatment.

The Company today received the results of the phase 3 clinical trial. These results are currently being analyzed and will be made available to the public after market on 28 February, 2017. In the meantime, ASIT biotech has asked the FSMA to suspend trading of the Company's shares with immediate effect until these clinical results are published.

If the results are positive, the Company is planning to file for marketing approval for gp-ASIT+™ in Germany with a view to marketing the product in 2018. The development plans and associated financing requirements are in line with the forecasts announced within the framework of the Company's IPO.

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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 commercialised 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+TM, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

As a result, the Company believes that gp-ASIT+ $^{\text{TM}}$  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.

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