Regulated information

ASIT biotech reviews the efficacy results of gp-ASIT+™ observed during the phase III trial completed in 2016

	Pollen peak				Whole season			
	Number of patients		Clinical efficacy		Number of patients		Clinical efficacy	
	Placebo	Treated	Reduction in CSMS[3]	P value	Placebo	Treated	Reduction in CSMS[3]	P value
All patients[1]	136	264	-15.5%	0.04	95	201	-17.9%	0.03
The most allergic patients (50% total population)[1]	67	136	-19.8%	0.05	46	108	-24.4%	0.05
Patients recruited in Belgium[2]	13	24	-35.1%	0.03	8	12	-53.7%	ns[4]

1 R. Mösges et al EAACI 2017
2 M. Shamji et al EAACI 2017
3 CSMS: Combined Symptom and Medication Score
4 ns: non significant

Brussels, Belgium 14 December 2017, 6.00 pm (CET) – ASIT biotech (ASIT - BE0974289218), a Belgian biopharmaceutical company specialising in allergen immunotherapy, reviews and details the results of the first Phase III trial with gp-ASIT+™ presented by Professor R. Mösges (University of Cologne) and Professor M. Shamji (Imperial College London) at the 2017 Annual EAACI Congress (European Academy of Allergy and Clinical Immunology).

The efficacy of gp-ASIT+™ is measured by the reduction in symptoms and the intake of common rescue medications like antihistamines or intranasal corticosteroids during the pollen season. This is referred to as a reduction in the Combined Symptom and Medication Score (CSMS). This score is calculated on the basis of data on symptoms and medication use recorded every day in a diary by each patient.

The results presented to the EAACI show that over the course of the whole pollen season, gp-ASIT+™ resulted in an average reduction in the combined score of 17.9% for the entire study population, close to the threshold of 20% required by the registration authorities. The effects of gp-ASIT+™ were greater and exceeded this threshold of 20% (24.4%) for the most allergic group of patients (representing 50% of the total population). These effects were even more marked (53.7%) for patients recruited in Belgium

The differences in efficacy between these groups of patients are linked to variability in the severity of their allergy as well as differences in pollen levels between the regions of Europe in which the study was conducted. The exceptional results achieved in Belgium can be explained by the optimum combination of patients who were severely allergic and a normal season in terms of grass pollen exposure.

This optimum combination in Belgium created the best possible conditions for conducting the study into the immunological mechanism of gp-ASIT+™ as initially planned. This study showed that gp-ASIT+™ was capable of achieving development of an optimal immune tolerance in only 3 weeks, whereas competing products take months, or even years, of treatment to achieve comparable results.

The results of this first study in Phase III confirm that gp-ASIT+™ is capable of achieving a reduction in the combined score above the threshold of 20% demanded by the registration authorities. In view of this, for its next clinical trials with gp-ASIT+™, ASIT biotech has decided to maximize chances of success, in particular by using electronic diaries to significantly improve patient monitoring and by recruiting more patients with a severe allergy.

Within this context, the latest response from the FDA, which focuses on a limited number of clarifications on the gp-ASIT+™ master file, can be seen as a positive, significant advance in the definition of the clinical development plan in the United States. This development plan will be discussed at a meeting with the FDA.

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About Ralph Mösges & Mohamed Shamji

https://www.asitbiotech.com/company/scientific-committee

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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