

PRESS RELEASE



Inside information
Regulated information

ASIT biotech gp-ASIT+™ Phase III trial in grass pollen allergy did not meet the primary endpoint

Liège, Belgium, 25 November 2019, 7.00 am (CEST) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focusing on the research and development of breakthrough immunotherapy products for the treatment of allergies, announces results from a Phase III trial of its gp-ASIT+™ treatment in grass pollen allergy (gpASIT011).

The Phase III trial of gp-ASIT+™, an innovative immunotherapy treatment for grass pollen allergies which is administered in only three weeks prior to the grass pollen season, has randomized 650 patients from Belgium, Czech Republic, France, Germany, Hungary and Poland. The primary objective of the study is a 0.30 absolute reduction in the Combined Symptom and Medication Score (CSMS) in the treated group compared to placebo during the peak of the GP season. The study results showed a 0.15 ($p=0.05$) absolute reduction in the CSMS, during the peak of the GP season, and a 0.18 ($p=0.005$) absolute reduction in the CSMS during the entire GP season, translating into a treatment effect of 7.4% and 9.8% respectively vs. 20% expected.

Michel Bajot, CEO of ASIT biotech, stated: “Although the execution of the study was flawless and despite a good safety profile in line with previous results, these efficacy results are disappointing. As of 24th November 2019, the Company had a cash position of 3,8 Million Euro. We will analyze the data further and assess best options for the company on which we will communicate by year end.”

About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the research and development 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+™ - in ongoing phase III - 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.

Further information can be found at www.asitbiotech.com.

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Forward-looking statements

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