Regulated information

ASIT biotech announces the last patient last visit in the Phase III clinical study with its first product candidate gp-ASIT+™ for grass pollen rhinitis

The study reached a strong patient retention rate of 93%

Brussels, Belgium, 5 October 2016 – ASIT biotech (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, is pleased to announce a patient retention rate of 93% after the last patient last visit in the Phase III clinical study with its first product candidate gp-ASIT+™ for grass pollen rhinitis.

The study was performed in 67 centers in Belgium, the Czech Republic, France, Germany, Italy and Spain. Of the 549 patients enrolled in the study, 512 attended the last visit planned in the study protocol, giving a global retention rate of 93% between enrolment and last visit.

The objective of this first phase III clinical study is to demonstrate the clinical efficacy of gp-ASIT+™ during one grass pollen season when administered subcutaneously prior that season in patients suffering from hay fever. The primary endpoint is the reduction (in the treated group compared with the placebo group) of the Combined Symptom and Medication Score (CSMS) taking into account the daily Rhinoconjunctivitis Total Symptom Score (RTSS) and the daily Rescue Medication Score (RMS) over the peak of the grass pollen season subsequent to treatment.

A significant reduction in combined scores of at least 20% (minimum required for a clinical significance according to current guidelines), would be considered as successful achievement of the primary endpoint.

In this context, the high number of patients who underwent the last visit is considered as very satisfactory with regards to statistical analysis of the clinical data.

Thierry LEGON, CEO of ASIT biotech, commented: *"I am delighted that we have achieved such a high retention rate in our study. This large number of completers would provide ASIT biotech with an ideal set of data to evaluate our product gp-ASIT+™ in a sizeable sample of the relevant population. We are on track to analyse this data and have the results available in Q1 2017. This progress shows our ability to keep to the timelines we announced at the time of our IPO."*

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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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