



Successful pollen season confirms ASIT biotech on track for Phase III results of gp-ASIT+™ in December 2019

- End of pollen season reached in all sites, allowing for last subject visits according to plan
- Vaccine industry veteran Beatrice De Vos, MD, to join ASIT biotech as Chief Medical Officer
- New CMO to focus on gp-ASIT+ Marketing Authorisation Application and launch preparations

Brussels, Belgium, 5 September 2019, 07.00 am (CET) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough allergy immunotherapy products, announces that all sites in its Phase III trial of gp-ASIT+™ in grass pollen rhinitis have reached the end of the grass pollen season, allowing for last patient visits according to plan, and thus confirming the study is on track to deliver results by mid-December.

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 651 patients from 69 centers. A certain level of grass pollen circulation is required during the study period in order for the patients to be exposed in a real-life setting, and thus demonstrate and assess the difference with placebo. The primary objective of the study is a 0.3 absolute reduction in the Combined Symptom and Medication Score (CSMS) in the treated group compared to placebo, equaling a treatment effect of 20% between gp-ASIT+™ and placebo according to protocol hypotheses.

The clinical sites were selected in collaboration with the European Aeroallergen Network (EAN) of the Medical University of Vienna, based on their pollen count history. The EAN has confirmed that all sites have reached their end of 2019 pollen season and experienced grass pollen concentration

The last visit of the protocol can now be scheduled for all patients, putting the study on track for readout, as planned, by mid-December 2019.

ASIT biotech has also appointed Beatrice De Vos, MD, as Chief Medical Officer. Beatrice has an impressive track record in clinical development and regulatory affairs of drugs, vaccines, and cell and immune therapies at leading companies. Most recently she was CMO at Promethera; prior to that she was Vice President Global Scientific and Medical Affairs at Sanofi, and Vice President Medical Affairs at GlaxoSmithKline.

Michel Baijot, CEO of ASIT biotech, said: *“The confirmation of grass pollen circulation around our clinical centers will allow us to generate a solid data set on gp-ASIT+™, enabling the assessment of its effectiveness compared with placebo. gp-ASIT+™ has the potential to be an effective new therapeutic alternative with long-term benefits for the millions of patients with moderate to severe allergic rhino-conjunctivitis due to grass pollen allergy, and I look forward to reporting results from this important study later this year. The appointment of Beatrice De Vos as CMO will further increase our focus on bringing gp-ASIT+™ to market. Beatrice’s extensive experience will be invaluable in driving our MAA filing for European registration and ramping up commercial launch efforts, and I would like to take this opportunity to welcome her to the leadership team”.*

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+™ - 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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