ASIT biotech launches its confirmatory Phase III clinical study with gp-ASIT+™ in grass pollen rhinitis prevention following the investigator meeting hosted in Prague (Czech Republic) on November 16-17, 2018

- Clinical trial authorizations received in all 6 participating countries
- Investigators from 82 participating centers have been trained and patient enrollment is expected to start as early as January 2019
- Based on the learnings from the first Phase III study, major improvements have been successfully implemented to maximize the probability of success of this confirmatory Phase III study
- Study results expected in December 2019

Brussels, Belgium, November 19, 2018 – 7.00 am (CET) – ASIT biotech (ASIT - BE0974289218), a Belgian biopharmaceutical company specialized in the research and development of innovative allergy immunotherapy products, today announced that it hosted the investigator meeting in Prague (Czech Republic) on November 16-17, 2018 ahead of the launch of its confirmatory Phase III clinical study with gp-ASIT+™ in grass pollen rhinitis prevention.

The investigator meeting was attended by 142 participants including the investigators team, the ASIT biotech clinical operations team, the team of the CRO (*Contract Research Organization*) that will coordinate the trial, ICON plc, and different vendors. The objectives of the meeting consisted mainly in establishing rules for effective communication, defining precisely each participant's role and responsibilities and communicating detailed information about the clinical study to ensure it is managed efficiently.

In order to overcome the challenges related to the clinical development in this indication such as overweighting of a center or a country, a lack of pollen or malfunctioning pollen traps, the selection of weakly allergic patients, and poor-quality medication use and symptom data due to poor reporting by patients, ASIT biotech has successfully implemented 9 major improvements following the first Phase III performed in this indication:

- The new Phase III study has been subcontracted to a single CRO, ICON plc, with leading experience in allergy studies.
- Oversight is executed internally by a well-staffed clinical operations team, including a Team Leader with 30 years' clinical development experience, a Chief Medical Officer with 30 years' clinical development experience and two Clinical Project Managers with 10 years' clinical development experience each.
- High pollen count and high-quality data recording history has been used to select the relevant clinical centers.

- To avoid recruitment issues and prevent a single center or country from being overweighted, 82 clinical centers across 6 countries (Germany, Belgium, France, the Czech Republic, Hungary and Poland) are involved in the current Phase III clinical study, and each center is limited to a maximum number of randomized patients.
- A medical history of moderate to severe pollen allergy over the last two years is required for each patient in order to randomize the most allergic ones.
- Patient recruitment at each clinical site is monitored online in line with a provisional schedule established using historical regional grass pollen data for the last 5 pollen seasons.
- Electronic rather than paper diaries are used to significantly improve patient commitment to better data recording and quality.
- Pollen count monitoring is centralized by the European Aeroallergen Network from the University of Vienna to guarantee the reliability of the pollen count data used for statistical analysis.
- The launch date is earlier than for the first Phase III study, allowing for a longer randomization and treatment period prior to the grass pollen season.

In total, 624 patients with grass pollen allergy are due to be enrolled in the study, compared to 554 in the initial phase III study. The first patient first visit is expected in January 2019 and the last patient last visit in September 2019, which should allow the Company to obtain the study results in December 2019.

The primary objective of the study is a 20% reduction in the combined clinical symptom and medication score (CSMS) in the treated group compared to placebo (i.e. an absolute score difference versus placebo of at least -0.30).

As discussed with the German health authority, Paul-Ehrlich-Institut (PEI), within the framework of a scientific advice session held in June 2017, in case of compelling new phase III results, PEI could allow ASIT biotech to file a Marketing Authorization Application (MAA) for Germany, with this marketing authorization then being extended to other European countries in line with international guidelines.

Thierry Legon, CEO of ASIT biotech, commented*: "I would like to congratulate our clinical team on this successful investigator meeting that marks the launch of our confirmatory Phase III study with gp-ASIT+™ in grass pollen rhinitis prevention. The clinical teams across all 82 participating centers are now fully focused on the preparatory work for the recruitment of first patients, expected to begin in January 2019. Our objective is to treat all patients before the 2019 pollen season starts, so we can obtain the full data set by the end of 2019. I would also like to emphasize that our other allergy-immunotherapy programs, in food and house dust mite allergy, are progressing on schedule, with the first clinical trial authorization submission for pnt-ASIT+™ in peanut allergy expected by the end of H1 2019. Thanks to this expanded pipeline, ASIT biotech's profile has never been so strong since its introduction on the stock market"*

Pr Claus Bachert, **Head of Clinics at the Oto-Rhino-Laryngology department of the University Hospital Ghent (Belgium) and Principal Investigator of the study, explained:** *"In the previous Phase III study, we were slightly below the threshold for registration, but the results obtained in our Clinical Center at the University Hospital Ghent on a subset of 32 patients (21 treated/11 placebo) pre-selected to study the mechanisms of action were really encouraging. One week after the end of the three-week treatment all the immunoregulatory mechanisms needed to control the allergic reaction were in place, leading to a symptom and symptomatic drug intake score reduction well above the threshold required by the study*

protocol. The improvements implemented for this new phase III trial make us confident that the study will proceed as smoothly as possible, and we are thrilled that patient recruitment will begin shortly."

Rémy von Frenckell, Head of Clinical Development of ASIT biotech, concluded: *"After a 20-year career as Vice President Biostatics at UCB, I am proud to be taking over as Head of ASIT biotech's clinical operations team. In the last few months, we have assembled a very robust team, including Gilles Della Corte as Chief Medical Officer and Florence Lair and Sabine Pirotton as Clinical Project Managers. With their outstanding careers in clinical development, our team is perfectly placed to conduct this crucial clinical trial with gp-ASIT+™."*

Upcoming event

- **Open Day for shareholders at ASIT biotech:** November 26, 2018 (10:00 am - 12:00 am) - Rue des Chasseurs Ardennais 7, 4031 Angleur (Belgium) - If you wish to participate, you can register by sending an e-mail to asitbiotech@newcap.eu with your contact information.

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About ICON plc

ICON plc is a global provider of outsourced drug development and commercialisation solutions and services to pharmaceutical, biotechnology, medical device, and government and public health organisations. The company specializes in the strategic development, management and analysis of programs that support clinical development from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 93 locations in 37 countries and has approximately 13,675 employees.

Further information is available at https://www.iconplc.com

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 commercialized 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 was investigated in the first phase III clinical study with gp-ASIT+™, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

The phase III clinical study of gp-ASIT+™ was conducted in 67 clinical centers in Belgium, the Czech Republic, France, Germany, Italy and Spain, and involved 554 randomized patients suffering from grass pollen rhinoconjunctivitis.

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+™ 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.

ASIT biotech has a headcount of 26 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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Forward-looking statements

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