ASIT biotech firmly on course for readout of Phase III clinical study in grass pollen allergy

- The Company has passed the Last Patient Last Visit (LPLV) milestone in the pivotal gp-ASIT+™ Phase III trial and remains on track to deliver primary efficacy results in December 2019.
- ASIT biotech is collaborating with ICON plc (CRO) to finalize the data collection before database lock and statistical analyses.

Brussels, Belgium, 26 September 2019, 07.00 am (CEST) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough allergy immunotherapy products, today provided an update on the phase III clinical study with gp-ASIT+™ and confirms next steps.

ASIT biotech’s focus remains firmly on the second Phase III study with gp-ASIT+™ in grass pollen allergy, involving 651 patients from 6 countries treated prior to the pollen season, with no major safety issues. The Last Patient Last Visit (LPLV) has now been completed following the 2019 grass pollen season. More than 600 patients went to the clinical sites for follow up after treatment, indicating that the target of 470 evaluable patients required for the planned statistical analyses should be reached.

ASIT biotech is collaborating with ICON plc (CRO) to finalize the data collection before database lock and statistical analyses. The Company remains on track to deliver top-line efficacy results on gp-ASIT+™ in December 2019.

Michel Baijot, CEO of ASIT biotech, stated: “We continue to gather momentum towards our clinical and commercial objectives. This pivotal study has benefited from a robust design, the careful selection of study centers in regions that are the most exposed to grass pollen, and the commitment of those clinical study centers to treat and follow up significant numbers of patients. As a result, the Company is poised to deliver primary efficacy results by the end of this year as planned”.

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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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