



ASIT biotech has installed and qualified a pilot unit to produce clinical batches for the Phase I/II studies in house dust mite and peanut allergies expected to start in H2 2019

- The active pharmaceutical ingredients (API) will be produced according to GMP requirements in a clean room rented from Accessia Pharma, a provider of high-quality pharmaceutical infrastructures
- The deployment of the overall quality system and associated documentation system is completed and a GMP certification request has been filed with the Belgian Regulatory Authorities
- The granting of the GMP certification, the manufacturing of the first clinical batches and their release are expected H1 2019

Brussels, Belgium, November 26, 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 has installed and qualified in a clean room the equipment to produce, in compliance with GMP requirements, the API for the Phase I/II studies in house dust mite and peanut allergies treatment.

The availability of a dedicated GMP manufacturing unit reduces the technology transfer duration and improves the flexibility and the agility of such transfer from the R&D to production thanks to the “real-time” fine-tuning opportunities. It also lifts the constraints related to third party CMO capacity scheduling and secures manufacturing as well as the overall development planning.

ASIT biotech expects the grant of the GMP certification by the Belgian Regulatory Authorities, as well as the release of the first clinical batch of pnt-ASIT+™ for the first-in-man study in peanut allergy, in H1 2019.

Thierry Legon, CEO of ASIT biotech, commented: *"The establishing of our own GMP manufacturing unit is key for the development of all our allergy-immunotherapy programs, especially in food allergies where we aim to submit the first clinical trial authorization for pnt-ASIT+™ in peanut allergy as early as the end of H1 2019. We then plan to immediately seek a clinical trial application for hdm ASIT+™ in house dust mite allergy. Thanks to this GMP infrastructure for the manufacturing of Phase I/II clinical batches, ASIT biotech is taking a major step towards the deployment of its ASIT+™ product portfolio designed to offer short course allergy immunotherapy to patients unsatisfied with current symptomatic treatments. I would like to thank our CMC teams, as well as those of our partner Accessia Pharma, for the smooth implementation of this unique site."*

Benoit Verjans, CEO of Accessia Pharma, commented: *"We have been extremely satisfied about our mutual collaboration with ASIT Biotech, notably in aligning our respective processes, infrastructure and quality requirements with the aim of setting up a fully validated production environment. We hope to*

obtain the approval of the pharmaceutical authorities shortly to produce the first clinical batches for ASIT biotech's clinical studies."

Vincent Bille, Vice-President CMC of ASIT biotech, concluded: *"I am proud of our team for having quickly achieved this important milestone. We can now benefit from a state-of-the art CMC environment that will enable us to produce the API for our upcoming clinical trials in peanut and house dust mite allergies according to the required industrial standards."*

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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