

## ASIT biotech reaches another key milestone by finalizing the industrialization process for the manufacture of clinical batches of its hdm-ASIT+™ product candidate for house dust mite allergy

- This crucial step has allowed the Company to launch the final preclinical developments required by the authorities ahead of a clinical trial
- A first batch of hdm-ASIT+™ was manufactured on ASIT biotech's new unit for producing GMP<sup>1</sup>-compliant clinical batches for Phase I and II studies
- The Company plans to submit an application for a first-in-man clinical trial authorization by the end of the first half of 2019

**Brussels, Belgium, December 17, 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 finalized the industrialization process for the manufacture of clinical batches of its hdm-ASIT+™ product candidate. They will be used in its initial Phase I/II clinical trials as a treatment for patients with house dust mite allergy.

After gp-ASIT+™, its flagship product for treating grass pollen-induced rhinitis currently in Phase III, hdm-ASIT+™ is ASIT biotech's second product candidate for respiratory allergies, and more specifically for house dust mite allergy. It was selected in June 2018 on the basis of *in vitro* tests undertaken by the team led by Professor Mohamed Shamji (Imperial College London) on the blood cells of allergic patients. The initial *in vitro* tests revealed that these peptides trigger less of an allergic reaction than full allergens while rapidly stimulating the appropriate immune system regulating mechanisms.

The industrialization of the hdm-ASIT+™ manufacturing process is a crucial stage in the development process, as it guarantees the homogeneity of all batches manufactured for clinical trials on the product through to its market approval.

**Thierry Legon, CEO of ASIT biotech, commented:** *“Our development strategy in respiratory allergies is progressing well. The finalization of the industrialization process for manufacturing our new hdm-ASIT+™ product candidate for treating house dust mite allergy represents a major milestone prior to launching clinical trials. A first batch of hdm-ASIT+™ has been successfully obtained in our new pilot unit. We are confident that in coming months we will be able to use these new premises to produce the first clinical batches of house dust mite and peanut peptides. The final preclinical stages are underway prior to the launch of a first clinical trial for which we hope to submit an application for authorization by the end of the first half of 2019”.*

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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

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<sup>1</sup> GMP - Good Manufacturing Practices

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](http://www.asitbiotech.com)

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