

ASIT biotech reaches a key milestone in the development of a new drug for peanut allergy by finalizing the industrialization process for the manufacture of clinical batches of its pnt-ASIT+™ product candidate

- With the completion of this crucial stage, the Company initiated the final preclinical developments required by the authorities ahead of a clinical trial
- The technology required for the GMP¹-compliant manufacture of batches for an initial phase I/II trial is currently being transferred
- 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, November 12, 2018 – 6.00 pm (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 pnt-ASIT+™ product candidate. They will be used in its initial Phase I/II clinical trials as a treatment for patients with peanut allergy.

pnt-ASIT+™ is the first product candidate of ASIT biotech against food allergies specifically targeting peanut allergy. It was selected in June 2018 through *in vitro* testing conducted by Dr. Mohamed Shamji (Imperial College, London) and his team on the blood cells of allergic patients enrolled by the team led by Dr. Stephen Till (King's College London). It is the first potential treatment for a food allergy based on peptides developed on the ASIT+™ technology platform. The first *in vitro* tests showed 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 pnt-ASIT+™ manufacturing process is a crucial stage required by the regulatory authorities, as it ensures all clinical batches are homogeneous throughout the product's development, until its final approval.

Thierry Legon, CEO of ASIT biotech, commented: "Our development strategy in food allergies is progressing, and the finalization of industrialization procedures for the manufacture of pnt-ASIT+ $^{\text{TM}}$, our first product candidate for peanut allergy, represents a major step towards the start of clinical development. We are in the final stages of preclinical development and the GMP-compliant manufacture of the first clinical batches. We are in the home stretch before the launch of the first-in-man clinical trial and expect to submit an application for its authorization by the end of the first half of 2019."

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,

¹ GMP - Good Manufacturing Practices

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 <u>www.asitbiotech.com</u>

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