

Regulated information

## ASIT Biotech has completed the recruitment of its phase IIa clinical study with hdm-ASIT+™ in house dust mite rhinitis

**Brussels, Belgium, 30 November 2016 – ASIT biotech (ASIT - BE0974289218)**, a Belgian clinical-stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough immunotherapy products for the treatment of allergies, announced today the recruitment of the last patient in its phase IIa trial with hdm-ASIT+™, its product candidate for house dust mite rhinitis.

The Company's first house dust mite clinical study "hdmASIT-001" was started at the Carl-Gustav-Carus University Hospital in Dresden in September, following the approval of the German Competent Authority (Paul Ehrlich Institute) and the Ethical Committee of the Technical University of Dresden. The patients' recruitment is now successfully completed as per the planned schedule. A total of 40 patients have been screened, out of whom 37 were eligible to enter the study.

The study's main objectives are to assess the safety and the highest tolerated cumulative dose of hdmASIT+™ in patients diagnosed with house mite allergy. The study protocol requires patients to undergo eight treatment. Other study's objectives include assessment of the impact of hdm-ASIT+™ on:

- the immune system and
- the reactivity to a conjunctival provocation test.

To date, the first four patients have completed the full study course of eight treatment visits, and 25 patients have reached the fifth treatment visit. The safety of the participating patients is monitored by a Data Safety Monitoring Board composed of independent German experts who have not expressed any concern about the safety of the patients so far.

The Company anticipates the last patient last visit in January 2017, followed by database cleaning and publication of the preliminary Results, which should provide a first insight on immunogenicity and potential clinical effect of this second ASIT+™ product candidate.

**Thierry LEGON, CEO of ASIT biotech, commented:** *"I am delighted with the fast progression of the first clinical study with hdm-ASIT+™. This development in house dust mite rhinitis is particularly important for ASIT biotech as positive results would confirm the applicability of our technology to allergens other than grass pollen. We are confident in bringing a relevant solution to patients suffering from this widespread allergy."*

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### About hdm-ASIT+™

hdm-ASIT+™ product candidate for the treatment of house dust mite allergy consists of a mixture of natural allergen fragments obtained from a purified specific proteinic extract from house dust mite (*dermatophagoides pteronyssinus*). In contrast to the synthesized 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 should be of short duration compared with currently commercialised treatments. This should constitute 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).

### About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the development and future commercialisation 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 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 entails two novel ASIT+™ product candidates targeting respiratory allergy with the highest prevalence (i.e. grass pollen: gp-ASIT+™ and house dust mite: hdm-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 22 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).

### Contact

#### Company

Thierry Legon, CEO  
ASIT biotech  
Tel. +32 2 264 03 90  
[investors@asitbiotech.com](mailto:investors@asitbiotech.com)



#### Media and Investor Relations - France

NewCap  
Dusan Oresansky / Pierre Laurent  
Tel.: +33 1 44 71 94 92  
[asitbiotech@newcap.eu](mailto:asitbiotech@newcap.eu)

#### Media Relations - Belgium

Laure-Eve Monfort  
Tel.: +32 2 290 90 93  
[monfort@comfi.be](mailto:monfort@comfi.be)

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