Regulated information

ASIT biotech announces Last Patient Last Visit in the phase IIa clinical study with its hdm-ASIT+™ product candidate for treating house dust mite rhinitis

- 89% of patients who began the treatment attended the study's last visit
- No major adverse event has been observed
- The clinical data is currently being verified
- Results should be published before the end of the first quarter of 2017

Brussels, Belgium, 24 January 2017 – ASIT biotech (Euronext: 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, announces that its Phase IIa double-blind placebo-controlled clinical study in house dust mite-induced rhinoconjunctivitis[1] has completed its clinical phase.

This first clinical trial in house dust mite rhinitis was undertaken by the team led by Professor Bettina Hauswald, principal investigator, at the Carl Gustav Carus University Hospital in Dresden, Germany. Of the 37 patients who began the treatment with hdm-ASIT+™, 33 attended the last visit to the allergist, giving a retention rate of 89%.

The main objectives of this study are to evaluate the drug candidate's safety and tolerability profile and to determine the maximum cumulative dose tolerated by house dust mite allergic patients. The secondary objectives of this study are the assessment of the impact of hdm-ASIT+™ on the immune system and on the reduction of the reactivity to a conjunctival provocation test[2].

During the trial, no major treatment-related adverse event was observed, even at the highest allergen dose, which is 200 times greater than the first dose administered.

ASIT biotech is currently cleaning the clinical database. This first step will be followed by the statistical analysis of the data and the publication of the clinical results by the end of the first quarter of 2017.

Thierry Legon, CEO of ASIT biotech, comments: "*We are happy because the retention rate of 89% constitutes the first evidence that our second product candidate, hdm-ASIT+™, is safe and well tolerated, even at high allergen doses. We are eager to get the results related to the immunogenicity and the potential clinical effect of this product candidate targeting the worldwide-spread house dust mite allergy.*"

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[1] This research program is partly funded by the Walloon region in the form of recoverable advances, in accordance with the agreement signed at the beginning of 2016.

[2] A test enabling both the diagnosis of a patient's allergy and the determination of their level of hypersensitivity at various times during the desensitization process.

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 synthetized 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.

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