Regulated information

ASIT biotech announces that it has achieved the primary endpoint of the Phase I/IIa clinical trial with its hdm-ASIT+™ product candidate for house dust mite rhinitis

- Confirmation of hdm-ASIT+™'s safety and tolerability profile
- The conjunctival provocation test showed a slight numerical difference in favour of the treated group compared to the placebo group (not statistically significant). Immunogenicity parameters remained similar in both groups.
- Thanks to the understanding of the mechanism of action in the Phase III trial undertaken with gpASIT+™, these results make it possible to continue the optimization of hdm-ASIT+™ which will be tested in a future trial.

Brussels, Belgium, 4 April, 2017 6:00 pm – 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 the results of its Phase I/IIa (first-in-human) double-blind placebo-controlled clinical trial in house dust mite rhinitis[1].

The study was carried out at the Carl Gustav Carus University Hospital in Dresden, Germany. Of the 36 randomized patients, 27 were treated with hdm-ASIT+™ whilst the other 9 received the placebo.

The trial's primary endpoint was achieved, insofar as hdm-ASIT+™ showed, at this stage, a good safety and tolerability profile for the product candidate. No serious or unexpected adverse treatment-related event was observed during the trial, even at the highest allergen dose of 200 µg, which was 200 times greater than the first dose administered. The two groups were comparable at baseline for all the tested parameters, with the exception of house dust mite allergen-specific IgE antibodies, which were substantially lower in the treated group than the placebo group.

Assessing hdm-ASIT+™'s impact on the immune system and on the reduction in reactivity to a conjunctival provocation test (CPT)[2] were amongst the secondary objectives. An effect was observed on the immune system in a limited number of patients. However, there was no difference overall between the treated group and the placebo group with regard to immunogenicity parameters. Lastly, the trial showed a somewhat stronger reduction in CPT reactivity in the treated group compared to the placebo group. The study was not powered to show statistical significance. The absence of a larger reduction can be explained by a substantial response to placebo (55%), the limited number of patients, the short observation period in this perennial disease and/or the nature of the product.

Thierry Legon, CEO of ASIT biotech, says: "*We are pleased to have achieved the primary endpoint of the trial, which at this stage confirms the safety and tolerability profile of hdm-ASIT+™, even at high allergen doses. Regarding the results relative to the secondary objectives, we will carry out an in-depth analysis of this data in order to learn all the lessons we can from it. Thanks to the understanding of the mechanism of action in*

[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.

the Phase III trial recently completed with gpASIT+™, we are confident that we will be able to rapidly develop an optimized version of hdm-ASIT+™ that will be tested in a future clinical trial."

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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 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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