ASIT biotech announces the approval by the regulatory authorities of a follow-up study of the Phase I/IIa clinical trial with its hdm-ASIT+™ product candidate for house dust mite rhinitis

A subset of patients treated during the Phase I/IIa clinical trial with its hdm-ASIT+™ product candidate for house dust mite rhinitis will undergo a complementary medical visit to assess potential long-term effect of hdm-ASIT+™

Brussels, Belgium, 16 August 2017, 5.45 pm (CEST) – 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 it has received the approval of the regulatory authorities and ethical committee to start a follow-up study with the patients enrolled during the Phase I/IIa clinical trial of its product candidate for house dust mite rhinitis (see press release from 4 April 2017).

The study is carried out at the Carl Gustav Carus University Hospital in Dresden, Germany. The conjunctival provocation test (CPT)[1] showed a slight numerical difference in favor of the treated group compared to the placebo group in the original study. The objective of this follow-up study is to evaluate whether longer natural exposure to house dust mites may have an impact on immunological and reactivity parameters, and assess a potential long-term effect of hdm-ASIT+™.

A subset of the 36 initially randomized patients (27 treated with hdm-ASIT+™ and 9 with placebo) will undergo a complementary medical visit in order to assess their reactivity score to a CPT and their titles of house dust mite allergen specific antibodies (IgG, IgG4, IgE and blocking antibodies).

Thierry Legon, CEO of ASIT biotech, says: "*The immunogenicity parameters and CPT score that were tested as a secondary endpoint one week after the end of the treatment with hdm-ASIT+™ were improved between the treated group and the placebo. It is clinically and scientifically sound to test a potential long-term effect of our product against house dust mite-induced rhinoconjunctivitis. An increase of the IgG4 and the blocking antibodies associated to a reduction of the CPT score in treated patients would show that a long term natural challenge is needed to allow the treatment clinical efficacy. In parallel to this follow-up study, we are actively working on the design of an optimized version of hdm-ASIT+™ based on our improved understanding of the mechanism of action of our lead product gp-ASIT+™ following the results of the Phase III study in grass pollen rhinitis.*"

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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

[1] 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.

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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