

Regulated information

ASIT biotech announces the initiation of a phase 2a clinical study of its second product candidate hdm-ASIT+™ for house dust mite rhinitis

Brussels, Belgium, 22 September, 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, is pleased to announce that its phase 2a trial with hdm-ASIT+™ for house dust mite rhinitis has been approved by the German Competent Authority (Paul Ehrlich Institut) and the Ethic Committee of the Technical University Dresden.

This clinical trial is performed at the Carl Gustav Carus University Hospital of Dresden in collaboration with Prof. B. Hauswald. The Investigators Meeting – which gives the required training to all the trial contributors - already took place on 8 September 2016.

About 45 house dust mite allergic patients are expected to be included in a 2-to-1 ratio of active-treated to placebo-treated patients.

This clinical trial aims to assess the safety and clinical tolerability of this ASIT+™ product candidate in house dust mite allergic patients. The impact of the product candidate on the immune system and the reactivity to a conjunctival provocation test are set as secondary endpoints. Preliminary study results are foreseen by the end of this year.

Thierry LEGON, CEO of ASIT biotech, commented: *“The initiation of this first clinical trial for our second product candidate marks a very important milestone for our company. It shows our ability to keep the timelines we have announced at the time of the IPO and is the first step of the expansion of our product pipeline to treat a broad range of respiratory and food allergies. I know how much efforts and dedication the achievement of this milestone has represented for the ASIT biotech team that I warmly thank.”*

Next press release:

- Results for the first half of 2016: 23 September 2016 after market

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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