Regulated information

ASIT biotech significantly moves forward in the preparation of the clinical development plan of gp-ASIT+™ in the US

Brussels, Belgium, December 6, 2017, 7 am (CET) – 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, has made significant progress in the preparation of the clinical development, in the United States, of gp-ASIT+™, its lead drug candidate for the treatment of grass pollen rhinitis.

ASIT biotech has received positive feedback from the US Food and Drug Administration (FDA) on the preparation of the clinical development plan for gp-ASIT+™ in the United States, with only a few comments and the request for some clarification on the Master File. In July 2017, ASIT biotech filed its answers to the initial comments from the FDA, together with an updated Master File including the results of the first Phase III conducted in Europe between 2015 and 2017.

Once ASIT biotech has answered the final questions and updated the Master File, it will request a pre-IND meeting. The main objective of this meeting with the FDA is to receive its validation that the drug development plan and future clinical trials are acceptable to the US Agency.

Thierry Legon, CEO of ASIT biotech, comments: *"We are very satisfied with the significant progress that we have made in the preparation of the clinical development plan of gp-ASIT+™ in the US, the biggest market worldwide for our lead product candidate with 3 million patients allergic to grass pollen treated with immunotherapy. As soon as we will have answered the FDA's last questions, we will request a pre-IND meeting to discuss the design of our first clinical trial in the US."*

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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.

Contact

Company
Thierry Legon, CEO
ASIT biotech
Tel. +32 2 264 03 90
investors@asitbiotech.com

Media and Investor Relations - France
NewCap
Dusan Oresansky / Pierre Laurent
Tel.: +33 1 44 71 94 92
asitbiotech@newcap.eu

Media Relations - Belgium
Laure-Eve Monfort
Tel.: +32 2 290 90 93
monfort@comfi.be

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