Regulated information

ASIT biotech takes important steps in US clinical development of gp-ASIT+™, its lead drug candidate for grass pollen rhinitis

- Constructive recommendations from the FDA regarding the gp-ASIT+™ file for the preparation of a first clinical trial

- Partnership with SynteractHCR, a North American CRO specialized in running clinical trials in the field of respiratory disorders

- Two internationally renowned allergy experts, Dr. Linda Cox and Dr. Peter Creticos, are joining the opinion leaders Committee for the clinical development in the United States

Brussels, Belgium, 14 November 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, presents its recent breakthroughs in the preparation of the clinical development in the United States of its first drug candidate designed to treat grass pollen rhinitis, gp-ASIT+™.

gp-ASIT+™, the Company's most advanced drug candidate, is currently being assessed via a phase III clinical trial in Europe whose results should be available during the first quarter of 2017.

ASIT biotech has received the FDA's initial comments regarding the gp-ASIT+™ Master File. These include very useful recommendations regarding the product's quality and the launch of a first clinical trial in the United States. ASIT biotech will interact with the FDA over the coming weeks to submit, during the first half of 2017, an approval application for a clinical trial whose phase will depend on the conclusion of the Company's interaction with the FDA.

Moreover, ASIT biotech has reached an agreement with SynteractHCR, a CRO (Contract Research Organization) acknowledged for its expertise in running clinical trials in the field of respiratory disorders. This agreement foresees, in compliance with the budget presented at the time of the IPO, the preparation and execution of the next clinical trials, from the choice and auditing of sites through to the analysis of clinical data. ASIT biotech is therefore ready – subject to the FDA's definitive approval – to initiate its first clinical trials in the United States.

Lastly, in order to address the specificities of North American clinical developments, ASIT biotech has set up a Committee of experts notably comprising Dr. Linda Cox, Past President of the American Academy of Allergy, Asthma & Immunology (AAAAI) and of the immunotherapy and allergy diagnostics committees of both the AAAAI and the ACAAI (American College of Allergy, Asthma & Immunology), and Dr. Peter Creticos, former Director of the Division of Allergy and Clinical Immunology of the Johns Hopkins University School of Medicine, and now clinical Director of research for his own entity and who has worked with governmental agencies and industry to design, develop, and conduct clinical research on the therapeutic efficacy of new drugs or underlying mechanisms of allergen immunotherapy. These recognized leaders in the field of allergy and immunology will contribute their extensive expertise to the preparation and monitoring of the clinical trials undertaken by ASIT biotech in the United States.

Thierry Legon, CEO of ASIT biotech, comments: "*With a view to continuing our discussions with the American health authorities, we are delighted to be able to cooperate with world-renowned experts such as Dr. Linda Cox and Dr. Peter Creticos, and to be able to call on the support of a very solid CRO like SynteractHCR, to prepare the launch of our clinical activities. The next major step will consist in responding to the FDA's comments so that we can launch the first clinical trial as soon as possible*."

***

About Linda Cox, MD, FAAAI, FACAAI ACP

Linda S. Cox, MD runs an adult and paediatric allergy and immunology practice since 1992 in Fort Lauderdale, Florida (USA). She is also Assistant Clinical Professor of Medicine at University of Miami School of Medicine and Nova South-eastern University School of Osteopathic Medicine. She is a past president of the Broward County Medical Association and of the Florida Allergy Asthma and Immunology Society. Dr Cox is a past president of the American Academy of Allergy, Asthma & Immunology (AAAAI) and has been chair of the immunotherapy and allergy diagnostics committees of both the AAAAI and the ACAAI's (American College of Allergy, Asthma & Immunology). She was recognized as one of "The Best Doctors in America" (Woodward/White - 1998) and named one of "Best Physicians in the U.S" in the Consumer's Guide to Best Physicians in the U.S (Centre for the Study of Services - 1997, 1998, 1999 and 2001). She has over 63 publications in peer-reviewed journals and has given numerous presentations at local, national and international medical scientific meetings.

About Peter Creticos, MD

Dr. Creticos completed his fellowship in Allergy & Clinical Immunology at the Johns Hopkins School of Medicine under the tutelage of Philip S. Norman and Lawrence Lichtenstein, and joined the faculty in 1983. He remained a member of the full-time faculty during this tenure and served as Clinical Director of the Division for the period 2000-2010. In 2010, he became a part-time member of the Division in order to set up a clinical research group in the mid-Atlantic region of the U.S., and in this capacity, he is Director of Clinical Research for his own private entity, Creticos Research Group. He also consults to the pharmaceutical industry, foundations, and government entities, and is specifically focused on providing innovative solutions to clinical trial design. He lectures widely, both nationally and internationally, on allergen immunotherapy, has published extensively in the field, and has been recognized for his endeavours by Best Doctors in America, the Asthma and Allergy Foundation of America, Top Doctors-Baltimore Magazine, and Who's Who in America & International.

About SyntheractHCR

SynteractHCR is a full-service contract research organization with a successful two-decade track record supporting biotechnology, medical device and pharmaceutical companies in all phases of clinical development. SynteractHCR has conducted Phase I-IV studies on six continents and 60 countries, offering expertise across multiple therapeutic areas, with notable depth in oncology, immunotherapy, CNS, infectious disease, endocrinology, cardiovascular and respiratory, among other indications. With its "Shared Work – Shared Vision" philosophy, SynteractHCR provides customized services collaboratively and cost effectively, ensuring on-time delivery of quality data to help bring tomorrow's treatments to patients.

About gp-ASIT+™

gp-ASIT+™ product candidate for the treatment of grass pollen rhinitis consists of a mixture of natural allergen fragments obtained from a purified specific proteinic extract from *Lolium perenne* pollen. 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 is of short duration compared with currently commercialised treatments. This constitutes 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).

Except for the clinical efficacy during natural grass pollen exposure that is investigated in the current first phase III clinical study with gp-ASIT+™, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

As a result, the Company believes that gp-ASIT+™ is the only short course treatment AIT product without adjuvant that is currently in phase III clinical studies with positive and statistically significant efficacy and immunogenicity results obtained during the phase IIa and phase IIb clinical studies.

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

ASIT
LISTED
EURONEXT

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

Forward Looking Statements

All statements in this announcement that do not relate to historical facts and events are "forward-looking statements". In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes," "estimates," "anticipates," "expects," "intends," "may," "will," "plans," "continue," "ongoing," "potential," "predict," "project," "target," "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. Forward-looking statements include statements regarding the Company's intentions, beliefs or current expectations. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. Given these risks and uncertainties, you should not rely on forward-looking statements as a prediction of actual results. Any forward-looking statements are made only as of the date of this announcement and, without prejudice to the Company's obligations under applicable law in relation to disclosure and ongoing information, the Company does not intend, and does not assume any obligation, to update the forward-looking statements set forth in this announcement.

Important Legal Notice

This announcement does not constitute, or form part of, an offer or invitation to sell or issue, or any solicitation of an offer to purchase or subscribe for shares of ASIT biotech SA (the "Company" and the "Shares"). Any purchase of, subscription for or application for, Shares to be issued in connection with the intended offering should only be made on the basis of information contained in the prospectus and any supplements thereto, as the case may be. This announcement does not constitute a prospectus and the information contained herein is for information purposes only and does not purport to be full or complete. Investors should not subscribe for any Shares except on the basis of the information contained in the prospectus that the Company expects to publish after its approval by the Belgian Financial Services and Markets Authority, and which can then be obtained at the Company's registered office and on www.asitbiotech.com.

This announcement is not for distribution, directly or indirectly, in or into the United States or to any U.S. person within the meaning of the U.S. Securities Act of 1933, as amended (the "Securities Act"). The Shares have not been and will not be registered under the Securities Act and may not be offered or sold in the United States, except pursuant to an exemption from the registration requirements of the Securities Act. The Company has not registered, and does not intend to register, any portion of the intended offering of Shares in the United States, and does not intend to conduct a public offering of Shares in the United States.

This announcement and the information contained herein are not for publication, distribution or release in or into the United States, Australia, Canada, Japan or any jurisdiction where to do so would constitute a violation of the relevant laws of such jurisdiction.

The Company is responsible for the information contained in this press release.