Regulated information

ASIT biotech presents its 2016 annual results and recent updates in clinical developments

- ASIT biotech has obtained positive clinical Phase III data with its **gp-ASIT+™** product candidate for grass pollen induced allergic rhinitis demonstrating for the first time ever the efficacy of allergen peptides in a real-life setting.
- gp-ASIT+™ induced a 15% to 21% reduction in the combined clinical symptom and medication score (CSMS), which is only slightly below the originally defined 20% threshold. As most important next step ASIT biotech will work with German regulatory agency to define a pathway to licensure. In this context the complementary analysis of the immunological readouts of the Phase III trial, which elucidate a clear and consistent mechanism of action of **gp-ASIT+™** even in an atypical 2017 pollen season, are expected to play an important role.
- Furthermore the understanding of the mechanism of action of **gp-ASIT+™** constitutes an outstanding strategic asset of the ASIT+™ technology allowing now a rational design of other pipeline product candidates targeting important allergies.
- The safety and tolerability profile for **hdm-ASIT+™,** the company second most advanced product candidate in house dust mite rhinitis, has been confirmed in a recent Phase I/IIa trial. A slight positive immunological and clinical impact could be observed in a limited number of treated patients, although the study was not powered to show statistically significant results.
- ASIT biotech has received a €6 million grant from the Walloon government to support an ambitious development program to design, develop and clinically test new product candidates targeting various food allergies induced by peanut, egg white and cow's milk. This program is performed in collaboration with Imperial College of London (Prof. Mohamed Shamji) and Guy King's College Hospital (Dr. Stephen Till).
- ASIT biotech's cash position at year end 2016 was €13.4 million.

Brussels, Belgium, 11 April 2017 5:45 pm – 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, today announces its annual results for the year 2016, prepared in accordance with the IFRS standards adopted by the European Union, as well as its recent clinical developments and 2017 outlook.

Thierry Legon, CEO of ASIT biotech, says: *"2016 was a very successful year of transformation for ASIT biotech in several aspects. From a financial perspective, our IPO in May 2016 provided us with the necessary means to effectively advance our various R&D programs. In this context we most importantly finalized the Phase III clinical trial with gp-ASIT+™ in grass pollen rhinitis, the Phase I/IIa clinical trial with hdm-ASIT+™ in house dust mite rhinitis, and the identification of a 3rd drug candidate in ragweed-induced rhinitis in accordance with our commitments. Based on the encouraging results of the Phase III clinical trial with gp-ASIT+™ and the Phase I/IIa with hdm-ASIT+™, we are embarking on 2017 full of confidence. For gp-ASIT+™ we will focus all our efforts to define and execute all necessary steps*

towards a first earliest possible market approval. Furthermore the understanding of the clinical mechanism of action of our lead product will significantly reduce the development risk in our upcoming work for our other product candidates derived from our ASIT+™ technology platform."

Financial results at 31 December, 2016

In thousands of euros - IFRS	31.12.2016	31.12.2015
Revenue	**-**	**4**
Other operating income	**1,667**	**-3**
Research & Development expenses	-12,123	-6,691
General & Administrative expenses	-1,822	-947
Operating profit / loss	**-12,278**	**-7,640**
Financial income / expense	-60	-75
Tax	-1	-
Net profit / loss	**-12,339**	**-7,715**

Operating income, which totaled €1.7 million, consisted of a recoverable advance of €663 thousand from the Walloon government for the hdm-ASIT+™ program and research tax credit of €1,061 thousand. ASIT biotech recorded no revenue in 2016, as the Company is still in its clinical development phase.

Research & Development spending and General & Administrative expenses totaled €13.9 million over the year 2016 (versus €7.6 million at 31 December 2015) given the acceleration in the Company's clinical development; R&D spending, which accounted for 87% of total operating expenses, was entirely devoted to the development of ASIT biotech's R&D programs and was allocated as follows:

- 80% for the most advanced drug candidate, gp-ASIT+™, to treat grass pollen rhinitis;
- 15% for the second drug candidate, hdm-ASIT+™, to treat house dust mite rhinitis;
- 5% for preclinical activities and the discovery of product candidates for other types of allergies.

The operating loss over the year ending 31 December 2016 was thus -€12.3 million, versus -€7.6 million at 31 December 2015.

Financial structure

ASIT biotech had a net cash position of €13.4 million at 31 December 2016, compared with €4.6 million at 31 December 2015. The increase in the figure over the last 12 months was notably the result of:

- the €23.5 million raised by the Company's IPO on the Euronext Brussels and Euronext Paris regulated markets in May 2016;
- the conversion of €4.1 million of convertible bonds on 12 May 2016.

The Company also benefited from repayable advances from the Walloon government:

- €1.3 million granted in December 2015 for the development of the hdm-ASIT+™ drug candidate, of which €125 thousand is still to be gradually received as this program progresses;

- approximately €6.0 million granted in January 2017 to co-finance the research and development of product candidates to treat food allergies.

Cash burn from operating and investment activities totaled €14.1 million, a level consistent with the Company's development budget over the last 12 months.

The statutory auditors are currently still auditing the Company's consolidated financial statements to 31 December 2016. These auditors have already indicated that their report will include an emphasis-of-matter paragraph relative to continuity assumptions, which will be detailed in the financial statements. The annual financial report (regulated information) will be available in the Investors / Documentation section of the Company's website from April 21 2017.

Recent clinical and preclinical developments

- gp-ASIT+™ (grass pollen induced allergic rhinitis): at the end of February 2017, the Company presented the results of the Phase III international clinical trial involving 516 patients suffering from grass pollen induced allergic rhinitis. gp-ASIT+™ induced a 15% to 21% reduction in the combined clinical symptom and medication score (CSMS), which is only slightly below a originally defined 20% threshold. The complementary analysis of the immunological readouts of the Phase III trial elucidates a clear and consistent mechanism of action of gp-ASIT+™ even in an atypical 2017 pollen season. This and the very good consistency of the overall results of the Company's lead product will allow further discussions with German authorities towards regulatory approval and with US authorities regarding the clinical development strategy for this important market.

- hdm-ASIT+™ (allergic rhinitis to house dust mites): at the end of November 2016, the Company completed the enrollment of patients for its Phase I/IIa trial in allergic rhinitis to house dust mites undertaken in Germany. A total of 40 patients were successfully selected, of whom 36 were eligible and began the treatment with hdm-ASIT+™. The results, published on 4 April, confirmed a good safety and tolerance profile. The trial showed a somewhat higher numerical reduction in the Conjungtivitis Provocation Test (CPT) reactivity in the treated group compared to the placebo group, although the study was not powered to demonstrate statistical significance. The absence of a larger reduction can be explained, at least in part, by a substantial response to placebo (55%), the limited number of patients and the short observation period in this perennial disease. An optimization of the product candidate will now be performed based on the mechanism of action obtained from the gp-ASIT+™ Phase III results.

Organization and governance

In 2016, the Company strengthened its governance and continued to put together its teams with a view to the ramping up of its R&D programs with the appointment of two world-renowned experts:

- Dr. Vincent Bille as Vice President of Manufacturing & Controls;
- Dr. Mohamed Shamji of Imperial College of London as Scientific Advisor for the discovery of new drug candidates and for preclinical activities.

With the positive results of the Phase III with gp-ASIT+™ in grass pollen rhinitis, ASIT biotech has reached a very important clinical development milestones under the presidency of Béatrice De Vos MD, PhD, BCPM. To face the new strategic challenges in regulatory affairs and business development,

the Board of Directors has appointed **Gerd Zettlmeissl, who is already serving on the Board of the Company since 2011,** as Chairman in March 2017.

To secure its development in the United States, ASIT biotech has signed an agreement with SynteractHCR, a CRO (Contract Research Organization) acknowledged for its expertise in running clinical trials in the field of respiratory disorders. Aside the strategic agreement, the Company has also set up a Key Opinion Leader Committee composed by:

- **Dr. Linda Cox**, former 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);
- **Dr. Peter Creticos**, former Director of the Division of Allergy and Clinical Immunology of the Johns Hopkins University School of Medicine.

Outlook and upcoming milestones

In 2017, ASIT biotech intends to continue the preclinical and clinical development of its drug candidates in accordance with the planned timeline:

gp-ASIT+™ in grass pollen rhinitis

- Scientific Advise Meeting with Paul Ehrlich Institute (Q2/Q3) to discuss Phase III data and to define route to German licensure;
- Preparation of a 2nd Phase III in Europe in adults or in children depending on Paul Ehrlich Institute outcome (potential study start Q1-2018);
- Scientific Advise Meeting with FDA (Q3/Q4) to define the clinical development strategy towards licensure in the US.

hdm-ASIT+™ in house dust mite allergy

- Compare immunogenicity profile of hdm-ASIT+TM to gp-ASIT+TM by ex vivo test on house dust mite allergic patients by Q3 to further confirm the product design and to define further clinical development program.

food-ASIT in food allergy

Assess immunogenicity profile of ASIT+™ by ex vivo test on:

- peanut allergic patients by Q3;
- cow's milk allergic patients by Q4;
- egg white allergic patients by Q4.

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About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the development and future commercialization of a range of breakthrough immunotherapy products for the treatment of allergies. Thanks to its innovative ASIT+TM 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+TM and house dust mite: hdm-ASIT+TM), 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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