Regulated information

ASIT biotech presents its 2017 half-year results and provides update on its clinical programs

- The clinical efficacy of gp-ASIT+™ has been demonstrated in the BTT-009 Phase III study.
- The first Phase III clinical efficacy data validates the relevance of the ASIT+™ technology platform.
- The German Regulatory Authorities has requested a second Phase III before considering a Marketing Authorization Application submission in Germany, and a future expansion to other European countries.
- To reduce the operational risks and maximize the chances of success of the next Phase III clinical trial with gp-ASIT+™, the patients screening would start by Q4 2018 in order to treat them prior to the 2019 grass pollen season.
- The identification of the mechanism of action of gp-ASIT+™ paves the way for future developments of other ASIT+™ therapeutic product candidates for house dust mite and food allergies, indications with high unmet medical need.
- This understanding has already resulted into an international collaboration with Imperial College London and King's College Hospital in a rational drug design program for the screening of other ASIT+™ products. This program will reduce the risks and increase the speed of further developments of all ASIT+™ products.
- The first peanut prototype products are currently being tested on blood cells from allergic patients.
- Cash position of €8.2 million at end-June 2017.

Brussels, Belgium, 14 September 2017 - 08:00 am (CEST) – 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, announces today its 2017 half-year results, prepared in accordance with the IFRS standards adopted by the European Union, and also provides an update on its R&D programs.

Thierry Legon, CEO of ASIT biotech, says: *"The first half of 2017 has been very fruitful and productive regarding the corporate and R&D developments at ASIT biotech.*

The key milestone of this period was the disclosure of the first Phase III study results with gp-ASIT+™, our lead product candidate in grass pollen rhinitis. The 15.5% reduction of the CSMS between placebo and treated group during the pollen peak reached statistical significance ($p<0.05$). However, these results did not reach the predefined 20% difference necessary to the registration of gp-ASIT+™ based on one sole compelling clinical study. All clinical results related to the primary and secondary endpoints as well as post-hoc analyses, have highlighted symptom improvement in patients after only 3 weeks of treatment with gp-ASIT+™. Furthermore, the immunologic study results showed for the first time ever a unique mechanism of action supporting the gp-ASIT+™ clinical efficacy. The understanding of the mechanism of action of ASIT+™ product is a key asset for the Company. It confirms and validates the clinical relevance of our technology platform and constitutes the basis of our rational drug design program for the development of new ASIT+™ products targeting other allergy indications.

As requested by the German Regulatory Authorities (Paul Ehrlich Institute - PEI), these results need to be confirmed in a second Phase III study before considering a Marketing Authorization Application (MAA) submission in Germany, and for a future expansion of this MAA to other European countries. To reduce the operational risk and maximize the chances of success, patient recruitment and screening for the next Phase III study is planned to start end of 2018 before the 2019 pollen season.

In parallel to the preparation of the next Phase III with gp-ASIT+™, the Company will focus on the development of its product portfolio in food and house dust mite allergies, very attractive indications with a high unmet medical need in Europe and worldwide. This development remains in the framework of our rational drug design program in collaboration with Dr. Mohamed Shamji, Scientific Advisor at ASIT Biotech and Associate Professor at Imperial College London. The know-how harvested throughout the gp-ASIT+™ preclinical and clinical developments, the understanding of the ASIT+™ mechanism of action and the fruitful collaboration with Dr. Mohamed Shamji significantly reduce the risk of these new developments. The first peanut prototype products have been transferred to Dr. Mohamed Shamji's team and are currently being tested on blood cells from allergic patients. This is the first milestone of the ASIT+™ food allergy product development supported by the €6m non-dilutive funding received from the Walloon government."

FINANCIAL RESULTS AT 30 JUNE 2017

In thousands of euros - IFRS	30.06.2017	30.06.2016
Revenue	**-**	**-**
Other operating income	**300**	**298**
Research & Development expenses	-6,337	-6,757
General & Administrative expenses	-785	-937
Operating profit / loss	**-6,816**	**-7,396**
Financial income / expense	-6	-85
Tax	-1	-
Net profit / loss	**-6,822**	**-7,481**

As of 30 June 2017, ASIT biotech recorded no revenue during the 1st half of 2017, as the Company's pipeline portfolio is still in clinical development. The other operating income of €300 thousand mainly consists of a research tax credit

The operating costs totaled €7.1 million at 30 June 2017 versus €7.7 million at 30 June 2016. Research & Development expenses of €6.3 million accounted for 89% of the total operating cost and were entirely devoted to the development of ASIT biotech's R&D programs.

The operating loss at 30 June 2017 amounted to €6.8 million, versus €7.5 million the previous year.

FINANCIAL STRUCTURE

ASIT biotech had a net cash position of €8.2 million at 30 June 2017, compared to €13.4 million at 31 December 2016. Cash burn from operating and investment activities totaled €6.6 million and was consistent with the Company's development budget over the last 6 months.

In order to continue its full development program, in accordance with the roadmap described in the offering prospectus and in the latest annual report, the Company may look for additional funding before the end of

2017. The company also has the possibility to substantially reduce the scope of its R&D activities and G&A expenses in order to cover its financial obligations within the next 12 months.

UPDATE ON R&D PROGRAMS

gp-ASIT+™ product candidate in grass pollen induced allergic rhinitis

- **BTT-009 phase III study results**

At the end of February 2017, ASIT biotech presented the results of the BTT-009 study, a Phase III international multicenter clinical study evaluating the effect of the Company's lead product candidate, gp-ASIT+™, in 516 patients suffering from grass pollen induced allergic rhinitis. The results show a 15% to 21% reduction in the combined clinical symptom and medication score (CSMS). Even though the 20% CSMS reduction threshold was not reached, this phase III study was considered positive and supportive due to the statistically significant in CSMS reduction, the very good consistency between the different symptoms scores and the immunogenicity results and the atypical pollen season. In the framework of a scientific advice, the Paul Ehrlich Institute (PEI) considered the BTT009 study supportive and requested an additional compelling pivotal study before considering a Marketing Authorization Application (MAA) in Germany, and a future expansion of this MAA to other European countries based on international guidelines.

- **Preliminary design of the next phase III study with gp-ASIT+™ (ABT-011)**

The next Phase III study with gp-ASIT+™ (ABT-011) will be a randomized, double-blinded, placebo-controlled, international multi-centric confirmatory phase III study aiming to enroll approximately 600 patients suffering from grass pollen-related allergic rhinoconjunctivitis.

To reduce the operational risk and maximize the chances of success, ABT-011 Phase III study is expected to start in H2 2018 prior to the 2019 grass pollen season.

- **Development of gp-ASIT+™ in the United States**

In July 2017, ASIT biotech replied to the FDA's initial comments by filing an updated Master file with the results of the phase III study. Depending on the FDA's first feedback, expected in Q4 2017, a pre-IND meeting will be requested to discuss the remaining clinical issues to be solved before the launch of a first US clinical trial with a Phase IIb or a Phase III depending on the FDA's feedback.

hdm-ASIT+™ product candidate in allergic rhinitis to house dust mites

- **Primary endpoint of the Phase I/IIa clinical study achieved**

In early April 2017, the Company announced the achievement of the primary endpoint of its first in-human trial, confirming the good safety and tolerability profile of this second product candidate. A slight positive immunological and clinical impact was observed in a limited number of treated patients (not statistically significant), although the study was not designed to show statistically significant results.

- **A two-pronged strategy for further development of hdm-ASIT+™**

The first strategy is to perform a follow-up of the first study to assess the impact of a prolonged (six-month) natural exposure to house dust mites on the immunogenicity parameters and the reactivity to the conjunctival provocation test. The Company has received the approval from the regulatory authorities and

ethical committee to conduct this follow-up study with 36 patients initially randomized in the Phase I/IIa clinical trial. The results of this follow-up are expected in Q4 2017.

The second strategy consists of designing several ASIT products derived from natural source of house dust mite allergens that will be tested *ex vivo* on blood cells from allergic patients in the framework of the rational drug design program in collaboration with Dr. M. Shamji from Imperial College London. Complementary *in vivo* preclinical developments would be performed to support the *ex vivo* immunogenicity tests. An improved hdm-ASIT+™ product candidate is expected to be selected out of the *ex vivo* tests by Q1 2018.

rag-ASIT+™ product candidate in ragweed allergies

The first phase of the preclinical development of rag-ASIT+™, the Company's third product candidate, was completed at the end of 2016. The clinical development of rag-ASIT+™ is postponed.

ASIT+™ product candidates in food allergies

The Company has recently launched a rational drug design program to develop new ASIT+™ drugs for the main food allergies (peanut, cow's milk and egg white) in close collaboration with Dr. M. Shamji (Senior Lecturer in Immunology and Allergy at Imperial College London) and Dr. S. Thill (consultant Allergist at Guy's & St Thomas' Hospitals and Reader at King's College London). Dr. S. Thill is one of the few specialist doctors accredited in Adult Allergy by the General Medical Council. This program includes *ex vivo* studies on allergic patient blood cells up to the end of the first in man clinical study. The Company has received a recoverable cash advance of approximately €6 million from the Walloon Region to co-finance on a 55% basis the food allergy drug development program.

The *ex vivo* tests would be performed in Q4 2017 and Q2 2018 on blood cells from patients suffering from food allergy. The first in man clinical trial with peanut ASIT+™ is expected to be conducted during the second half of 2018 and until the end of 2019.

OUTLOOK AND UPCOMING MILESTONES

In function of its financial futures resources, ASIT biotech intends to concentrate its activities on the preparation of next Phase III study with gp-ASIT+™ as well as on the development of new product candidates targeting indications with high unmet medical needs like house dust mites and food allergies:

- FDA's feedback on the clinical development of gp-ASIT+™ in the US is expected in Q4 2017.
- Results from the follow-up study with hdm-ASIT+™ are expected in Q4 2017. An improved hdm-ASIT+™ product is expected to be selected out of the *ex vivo* tests in Q1 2018.
- The *ex vivo* tests with peanut ASIT+™ products on blood cells from allergic patients would be performed in Q4 2017 with results available Q1 2018.
- The first in-human clinical trial with peanut ASIT+™ is expected to be started in the second half of 2018 with results available end 2019.
- ABT-011 Phase III study with gp-ASIT+™ is expected to start in H2 2018 with patient treatment prior to the 2019 grass pollen season.

To finance the above-mentioned activities until the end of 2018, the Company is considering to prepare a financing round including only the preparation costs of the gp-ASIT+™ Phase III clinical study that would be performed in 2019.

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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+™ 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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