

**In line with the business plan presented at the IPO, ASIT biotech prepares an additional fund raising to further develop its products**

- A maximum of 3 million new shares will be issued
- The issue will be structured as a private placement, with no discount to the average share price over the last 30 days before the issue
- Each subscriber will receive two free warrants enabling the subscription to two new shares at the issue price – the first by June 30, 2018, and the second by December 31, 2019, provided that the first warrant has been exercised
- Assuming all 3 million shares are subscribed to and that all the warrants are exercised, the Company would raise approximately 3 x €10 million

**Brussels, Belgium, November 7, 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, announces the submission of a proposal to the General Meeting on December 7, 2017, to issue 3 million new shares, in the framework of a private placement subject to approval by shareholders. The new shares will be issued without a discount on the average share price of the last 30 days preceding the issue of the new shares.

It shall be proposed to the General Shareholders' Meeting that each subscriber will receive two warrants free of charge. The first warrant would expire on June 30, 2018, and the second on December 31, 2019. The second warrant may be exercised solely if the first warrant has already been exercised. If exercised, these warrants will increase the share capital and provide funds to cover the cost of ASIT biotech's research and clinical development activities. The first warrant's expiration date has been timed to coincide with the expenditures associated with the launch of the Phase III trial with gp-ASIT+™.

The Board of Directors believes that this financing structure is best suited, at this stage of the Company's development, to meet the expectations of the different participants, including shareholders, the Company and investors participating to the offering.

The funds raised will be assigned in priority to the preparation of the Phase III trial with gp-ASIT+™ and to the development of products against allergies to dust mites, peanuts, cow's milk and egg white.

**The Company's shareholders will be invited to decide on the issue of shares and warrants during the meeting on December 7, 2017. Arrangements for the subscription will be made after the General Meeting's approval has been secured.**

18 months after the IPO, this fundraising provides the opportunity to review ASIT biotech's key strengths, clinical developments and strategy.

## 1. Meeting an unmet medical need and commercial opportunities

The number of patients suffering from allergies increases every year: 15% of the world's population suffers from allergic rhino-conjunctivitis, and 2% of the world's population has a food allergy. Current commercialized drugs for allergic rhino-conjunctivitis (intranasal antihistamines and corticosteroids) reduce symptoms by no more than 20%<sup>1</sup>. Furthermore, these treatments do not provide any relief to 20%-25% of patients<sup>2</sup>. Sales of symptomatic treatments nonetheless add up to \$10 billion every year. Today, there are no drugs available to treat food allergies.

The only viable alternative to drugs currently commercialized for allergic rhino-conjunctivitis is immunotherapy. Its efficacy is greater than that of symptomatic drugs, but requires a 3-year treatment with a daily drug intake (sublingual route) or a total of 40-60 visits to the doctor (subcutaneous injections). These constraints that are difficult to reconcile with the demands of everyday life, make immunotherapy less attractive. **The limited number of patients under immunotherapy (estimated at 3 million in the United States and approximately 1.4 million in Europe)** and the corresponding annual sales of less than €1 billion support this reality.

## 2. Clinical development of gp-ASIT+™: releasing the potential

**Our gp-ASIT+™ product for the treatment of grass pollen induced rhino-conjunctivitis has reached Phase III in Europe.** It is estimated that one out of every two drugs tested in Phase III is approved (TCSDD, 2014). The results of the first Phase III trial with gp-ASIT+™ obtained in June 2017 increase, in our view, the chances of success:

- the 15% to 21% symptoms reduction depending on the analyzed period (pollen peaks or throughout the entire season) is statistically significant, i.e. there is little chance that the results are merely fortuitous
- the immunology results obtained by Prof. M. Shamji on a sub-group of patients enrolled at the Ghent University Hospital revealed a highly positive and very rapid mechanism of action, these results are supported by a more important symptom reduction in these patients compared to the mean of the study ([link](#) to the presentation)
- following the approval of a Scientific Committee, the results of this first Phase III trial were presented by Prof. R. Mösges of the University of Cologne ([link](#) to the poster) and Prof. M. Shamji of Imperial College London at the European Academy of Allergy and Clinical Immunology (EAAACI 2017) conference in June 2017
- the results of this study were also presented to the German health authority (Paul Ehrlich Institute), which recognized the very high quality, consistency and statistical significance, while stating that a second Phase III study was needed before the submission of an NDA
- the publication of preliminary clinical results obtained with gp-ASIT+™ in a prestigious peer-reviewed journal (Journal of Allergy and Clinical Immunology - JACI) is a recognition of the quality of the drug development by the world's leading immunology experts and allergists.

To further increase the chances of success of the next Phase III trial in Europe, ASIT biotech has decided to implement the following measures:

- the study will be managed by a single CRO with an international network
- the inclusion criteria for patients will be more selective to enroll a more allergic and more homogenous group
- all patients will be given an electronic journal to record daily symptoms and drug intake
- the number of clinical centers will be increased to obtain a consistent enrollment of a limited number of patients per center leading to an increased results consistency

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<sup>1</sup> *Canonica GW et al Allergy 2007; 62:317–324; Pfaar O et al Allergo J Int 2014;23:282–319*

<sup>2</sup> *Marple BF Otolaryngol Head Neck Surg. 2007; 136(6 Suppl):S107-24; Didier A et al Rev. Fr Allergol. 1999; 39:171-185*

The Company recently hired Dr. Marie-Etienne Pinelli, an expert in the clinical developments of anti-allergic drugs (Zyrtec and Xyzal) to optimize the management of clinical developments and oversee the upcoming Phase III trial of gp-ASIT+™.

### **3. Continue the clinical development of hdm-ASIT+™**

The hdm-ASIT+™ drug candidate for dust mite-induced rhinitis is in an early clinical development stage. The Phase I results confirmed that the drug was well tolerated and that it could be tested in a Phase II trial.

The good tolerance of this second product supports the great safety of other active compounds issued from the ASIT+™ technology platform. Using this platform, ASIT biotech is also able to assess the clinical potential of a new drug at the end of a Phase I trial by comparing its properties with those of gp-ASIT+™. This early-stage assessment of clinical properties helps to lower the risk of upcoming clinical developments and increase cost-efficiency given that the cost of a Phase II trial is between three and five times higher than that of a Phase I.

Since the results obtained with hdm-ASIT+™ in the first trial were different than those obtained at the same stage with gp-ASIT+™, the Company made the strategic decision to postpone by several months the next clinical developments of the drug in order to:

- assess a possible increase of the initial effect after an 8-month exposure to natural dust mite allergens
- select a new product candidate better suited to the targeted profile

Since the follow-up study has not shown a complementary effect, the Company has decided to focus its resources on the selection of a new product and hopes to resume clinical developments in this indication in early 2019.

### **4. Develop ASIT+™ products to fight food allergies**

ASIT biotech received a €6 million research grant from the Walloon Region to develop immunotherapy products for food allergies to peanut, egg white and cow's milk. This grant, in the form of refundable advances, covers 55% of the investments – from product conception through to the end of the first trial in allergic patients (Phase I). The award of this research grant is the positive result of an independent evaluation process of our projects by the scientific experts from the Walloon Region. This project is a collaboration between Imperial College London, the Guy's Hospital (King's College London) and ASIT biotech. This partnership with highly prestigious research institutions is a recognition of the scientific caliber of our development work. The first *ex vivo* tests (on blood cells of food allergies patients) to select a product candidate per indication will be carried out to the end of the second quarter of 2018. The first clinical trials with an ASIT+™ product for peanut allergy are expected to take place in the second half of 2018 to the end of 2019.

Thierry Legon, CEO of ASIT biotech CEO, commented: *“The last 18 months have brought ASIT biotech strong clinical insights and advances. Despite the delay, we are happy with the scientific results obtained since our IPO in May 2016. The results of the Phase III trial with gp-ASIT+™ have enabled the identification of its unique mechanism of action, confirming the relevance of short-term subcutaneous immunotherapy with linear peptides. Although the safety of hdm-ASIT+™ in humans has been proven, three new products for dust mite-induced rhinitis have been sent to the Prof. M. Shamji laboratory to compare their immunological profile with the one of gp-ASIT+™ and select the best one. Preclinical development of a new series of products has started for the highly attractive indications of allergy to peanuts, cow's milk and egg white. The first drug candidates for these food allergies are due to be identified in the summer 2018. Given our expertise and the scientific*

*information acquired during the development of gp-ASIT+™, we would be able to accelerate the development of our product portfolio and consolidate our leadership in the development of short and effective immunotherapy treatments to meet the strong market demand.”*

#### **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](http://www.asitbiotech.com).

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