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ASIT biotech is confident in the execution of its key priorities for 2019

- gp-ASIT+™ confirmatory phase III study is on track to deliver primary results by end-2019
- First interest shown by potential partners for other assets in the product pipeline
- Cash position of €8.5m at end-2018
- Reduction of planned total 2019 budget by €6.0m by focusing on strategic priorities
- Approval of a planned private placement of convertible notes for a minimum of €9.0m to cover financing requirements until the third quarter of 2020, limiting dilution before the Company reaches several value-creating milestones

Brussels, Belgium, February 25, 2019, 7.00 am (CET) – ASIT biotech (Euronext: ASIT - BE0974289218), a Belgian biopharmaceutical Company specialized in the research and development of innovative allergy immunotherapy products, announces decisions adopted at the meeting of the Board of Directors of February 22, 2019 and a cash position of €8.5m at December 31, 2018¹.

The Board of Directors confirmed and approved the strategy outlined by new CEO, Michel Baijot, including essentially the focus on the ongoing phase III study with gp-ASIT+™, the funding with limited dilution planned for finalizing the clinical development of this lead product candidate and the initiation of discussions for partnering the preclinical product candidates (hdm-ASIT+™ and pnt-ASIT+™).

The confirmatory phase III study with the Company's lead asset, gp-ASIT+™, is on track

At the end of January 2019, the Company announced the treatment of the first patient with gp-ASIT+™ within the framework of this pivotal study that should allow ASIT biotech to file a Marketing Authorization Application (MAA) for gp-ASIT+™ in Germany.

The screening of patients with targeted inclusion criteria is now close to completion, ahead of schedule, while randomization (first treatment or placebo administered) is also continuing, with no major safety issues reported to date.

Taking into account the sustained inclusion rate and the active monitoring of all participating European centers, the Company is confident that it will obtain satisfactory results related to the primary end-points of the study by the end of 2019.

The Company is currently setting up a Scientific Advisory Board of European Key Opinion Leaders to evaluate further clinical development of gp-ASIT+™ that could enhance its future market positioning and differentiation.

Cash position and outlook

At December 31, 2018, ASIT biotech had a cash position of €8.5m compared with €2.1m at December 31, 2017, reflecting:

¹ The 2018 annual financial report is expected to be published on April 26, 2019

- a cash consumption of €13.7m over 2018, including €9.9m spent on the preparation and launch of the confirmatory phase III study with gp-ASIT+™.
- €4.2m in gross proceeds from the drawdowns on the equity line including the conversion of warrants attached.
- €15.4m in gross proceeds from the capital increases over the first quarter of 2018 and the exercise of some of the related warrants.

The Board of Directors approved the budget proposed by the management for 2019, which includes savings of €6.0m thanks to strategic prioritization, under the assumption of successful capital raising. ASIT biotech's activities will be financed by the cash available, the balance of €7.2m on the equity line as of today and a planned private placement of new convertible notes as proposed by the Board of Directors.

The launch of this private placement of a minimum of €9.0m of convertible notes is expected by the end of the second quarter of 2019 with a minimum of €225,000 per note. These notes will be divided into two parts with the aim of minimizing the dilution of existing shareholders and limiting the risks for potential investors:

- the first part will be called at issuance to cover the cash needs by the end of 2019, corresponding to the outcome and first results of the phase III study with gp-ASIT+™
- the second part can be called upon publication of all satisfactory primary endpoints from this ongoing phase III study.

The first part will represent a minimum of one third of the issued notes and will be proposed at a conversion price of €1.2680 per share (corresponding to the VWAP over the 30 trading days preceding the February 22, 2019 Board of Directors meeting to which a discount will be added depending on the final pricing). The second part will represent a maximum of two thirds of the issued notes and will be proposed at a conversion price equivalent to the price that will be set for the capital raising to be closed in 2020 with a discount that will be determined at final pricing. The final pricing of the notes will be validated by the Board of Directors at the closing of the private placement.

These financial resources should allow the Company to continue its developments until the third quarter of 2020.

The Board of Directors also validated an exit indemnity in line with market practice for the former management that will be provisioned in the 2019 financial statements.

Business development strategy

Clear market access strategy for gp-ASIT+™

Considering the strong potential of its lead asset, gp-ASIT+™, to become the first allergy immunotherapy treatment based on natural peptides, the Company has decided to focus its financial and clinical resources on this innovative compound. In terms of market access, as a result of the diversity of the European allergy markets, ASIT biotech will initially focus its development and market entry efforts on Germany, followed by a further country-by-country strategy across Europe.

Regarding the strategic US market, the Company's management is actively looking for a US partner to leverage its local expertise and efficiently allocate ASIT biotech's financial capabilities.

Maximizing the value of the Company's assets through targeted partnerships

For its two product candidates in preclinical stage, pnt-ASIT+™ and hdm-ASIT+™, targeting peanut and house-dust mite allergies respectively, ASIT biotech is currently finalizing their preclinical packages before entering phase I clinical development via partnerships.

The Company also intends to make maximum use of the capacities of its ASIT+™ technological platform: discussions are ongoing to begin other specific allergen formulations, such as birch allergy or allergy to Japanese cedar, to be developed on demand for partners.

ASIT biotech is receiving the first signs of interest and is giving a clear priority to such a partnership strategy for sharing funding and risks.

Michel Baijot, CEO of ASIT biotech, comments: *“First of all, I’m very satisfied with the sustained pace of patient recruitment and randomization in our confirmatory phase III study with gp-ASIT+™ which puts us ahead of initial schedule. It demonstrates substantial interest from all stakeholders – investigators, medical teams and patients – in evaluating the benefits of a short-course treatment based on natural allergen peptides. Secondly, initial feedback from several potential partners confirms considerable interest in our technology.*

Taking into account the quality of production and logistic processes and backed by our highly committed team, ASIT biotech is well on track to confidently execute its structured, ambitious and realistic development plan.

Furthermore, our current cash position combined with a refinancing project will enable ASIT biotech to accelerate its development momentum and extend the Company’s financial visibility until the third quarter of 2020 without any excessive dilution for our shareholders.”

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 allergy immunotherapy (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 contains three novel ASIT+™ product candidates targeting respiratory allergies with the highest prevalence (i.e. grass pollen: gp-ASIT+™ - in ongoing phase III - and house dust mite: hdm-ASIT+™), and food allergies (peanut allergy: pnt-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 26 staff members, at its headquarters in Brussels and its facilities in Liège, Belgium.

Further information can be found at www.asitbiotech.com.

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