

Regulated information

Inside information

ASIT biotech discloses next steps following gp-ASIT+™ Phase III results

- To explore strategic options in H1 2020 to retain maximum shareholder value, including refocus on food allergies
- To reduce organization size to minimize cash burn and file request for judicial reorganization to restructure the company's indebtedness and to give time to management to accomplish this mission

Brussels, Belgium, 20 December 2019, 10.30 am (CEST) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focused on the research and development of breakthrough immunotherapy products for the treatment of allergies, strongly reduces the size of its organization and re-focus on developing treatments for food allergies, following the results of the Phase III trial of its gp-ASIT+™ treatment in grass pollen allergy.

Real-life exposure trials required for respiratory programs such as gp-ASIT+™ represent inherent challenges that are difficult to overcome even for big pharma. In the recent Phase III trial (ABT-gpASIT011), gp-ASIT+™ showed a 0.15 (p=0.05) absolute reduction in the Combined Symptom and Medication Score (CSMS) during the peak of the grass pollen (GP) season, and a 0.18 (p=0.005) absolute reduction in the CSMS during the entire GP season, versus the primary endpoint of 0.30. Both groups took an extensive amount of other medication against allergic symptoms during the study period, which potentially masked the efficacy of gp-ASIT+™, and despite this the data show a statistically significant treatment effect over placebo, consistent with the previous Phase III trial (BTT009). Moreover, blood analysis of immunological parameters has confirmed an immune response in gp-ASIT+™ patients, in line with the mechanistic study published in the Journal of Allergy and Clinical Immunology earlier this year, but the persistence of the effect was not long enough, potentially questioning gp-ASIT+™ dosing.

Based on the extensive pre-clinical and clinical data sets across all of its programs, ASIT biotech firmly believes its technological platform can be adapted to any protein-based allergen, and that there is extensive value in further developing a pipeline against food allergens where the unmet need is the highest.

The Board of Directors has mandated the management of ASIT biotech to explore strategic options during H1 2020 to retain maximum shareholder value, supported by current cash position of € 3.7 M. ASIT biotech's assets are its innovative technological platform and pipeline, protected by strong intellectual property (IP); offices, laboratories and a good manufacturing practice (GMP) certified manufacturing site in Belgium; as well as a dual listing on EURONEXT in Brussels and Paris. ASIT biotech believes there could be additional value for ASIT shareholders if a partner can be identified to fund further developments or to acquire ASIT biotech assets.

In order to minimize cash expenses to identify new options and to reach new objectives, the Board of Directors has also decided to reduce the organization to the strict minimum and has filed a request for judicial reorganization*. As a consequence, the gp-ASIT+™ program is placed on hold pending further discussions.

Michel Baijot, CEO of ASIT biotech, said: “ASIT biotech has a strong technology platform which has the potential to change the lives of people living with food allergies. We now have the opportunity to focus the organization on this area of medical need, starting with pnt-ASIT+™ for peanut allergies currently in preclinical phase, while we explore strategic options for the company. In the meantime, we have cut all non-vital expenses to reduce our cash burn to the minimum.”

*Judicial reorganization filing documents are available on the company website

About ASIT biotech

ASIT biotech is a Belgian clinical stage biopharmaceutical company focused on the research and development 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+™ 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.

Further information can be found at www.asitbiotech.com

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