

ASIT biotech presents its recent corporate developments

- Grass pollen peptide manufacturing supply chain secured through solid partnerships
- Appointment of Dr. Vincent Bille as Vice President of Manufacturing & Controls

Brussels, Belgium, 21 June 2016 – 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 latest corporate developments.

Completion of the grass pollen peptide manufacturing supply chain

ASIT biotech has established a streamlined network of industrial manufacturing partners to whom the elements of the ASIT+™ technology platform have been successfully transferred in full compliance with international GMP requirements.

In particular, the industrial process development of the gp-ASIT+™ drug substance and drug product have been established and secured. The final drug product manufacturing process validation has now been successfully completed at a leading CMO (Contract Manufacturing Organization) who is approved by international health authorities including EMA (European Medicines Agency) and the US FDA (Food and Drug Administration). In this respect, the final gp-ASIT+™ drug product should be suitable for Phase III clinical studies in the US as well as for registration purposes in Germany upon delivery of positive results of the current pan European Phase III clinical study.

These developments secure the future clinical development of the gp-ASIT+™ product candidate in the US, that should begin in 2017 as presented during the Company's IPO.

Appointment of Dr Vincent Bille as Vice President of Manufacturing & Controls

Dr Vincent Bille is the founder and Managing Director of Marble Pharma Consult sprl, an independent firm offering expert consultancy services to pharmaceutical and biopharmaceutical companies covering all aspects of externalized process and analytical development as well as manufacturing operations.

Prior to founding Marble Pharma Consult in 2007, Vincent served as Director Sales and Business Development for Lonza (Basel Switzerland), a global contract manufacturing organization. Before joining Lonza, Vincent held various operational and senior management positions with UCB-Bioproducts, a subsidiary of the biopharmaceutical company UCB (Brussels, Belgium) including the positions of General Manger of the US subsidiary, Director Global Commercial Operations, Peptides and Formulation BU Manager and Operations and Development Manager.

Vincent Bille holds a Doctorate in Biochemistry (1987) and a Master's Degree in Administration and Management (1994).

Thierry Legon, Chief Executive Officer of ASIT biotech, commented: *“Our clinical development is on track and the completion of our manufacturing supply chain with the support of our CMO partners is an important step towards the execution of our strategy presented during the IPO. We are also pleased to welcome Vincent within our team. His strong track record in international, cross-cultural projects and relationship management will provide ASIT biotech with sound expertise in the areas of GMP-regulated pharmaceutical operations as well as regulatory activities.”*

About gp-ASIT+™

gp-ASIT+™ product candidate for the treatment of grass pollen rhinitis consists of a mixture of natural allergen fragments obtained from a purified specific proteinic extract from *Lolium perenne* pollen. In contrast to the synthesized peptides, the natural peptides (70% of the fragments ranging from 1,000<MW<10,000) include a wide range of epitopes that stimulate the immune system with optimal complexity.

The administration schedule of the treatment is of short duration compared with currently commercialised treatments. This constitutes a major competitive advantage to improve the acceptance and the compliance of the patients. In addition, the administration schedule includes successive injections with half of the visit dose in both arms, an innovative solution that enables the delivery of the total dose necessary for the therapeutic effect in a faster and safer way. Finally, the product candidate is formulated without adjuvant, which increases the long-term safety of the product by decreasing the local and general reactogenicity as well as the frequency of the adverse events, which represents a further advantage in markets less permissive to adjuvanted formulations (e.g. US).

Except for the clinical efficacy during natural grass pollen exposure that is investigated in the current first phase III clinical study with gp-ASIT+™, all the above-mentioned characteristics have been demonstrated in the already conducted clinical studies.

As a result, the Company believes that gp-ASIT+™ is the only short course treatment AIT product without adjuvant that is currently in phase III clinical studies with positive and statistically significant efficacy and immunogenicity results obtained during the phase IIa and phase IIb clinical studies.

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.

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