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ASIT biotech receives GMP certification for its manufacturing site in Liège, Belgium

Brussels, Belgium, 7 October 2019, 07.00 am (CEST) – ASIT biotech (ASIT - BE0974289218), a clinical stage biopharmaceutical company focused on the research, development and future commercialization of breakthrough allergy immunotherapy products, received the Good Manufacturing Practices (GMP) certification for its manufacturing site in Liège, Belgium, from the Federal Agency for Medicines and Health Products (FAMHP).

The certification follows a 2-day site inspection from the FAMHP and the constructive dialogue with the Agency. It allows ASIT biotech to manufacture in-house the active pharmaceutical ingredient of its leading product for grass pollen allergies (gp-ASIT+™) under GMP-compliant conditions for future clinical and commercial use.

Further to the site certification, ASIT biotech is preparing the production of gp-ASIT+™ active pharmaceutical ingredient validation batches in order to support the anticipated regulatory filings in 2020, pending the positive outcome of the ongoing phase III clinical trial expected in December 2019.

Michel Baijot, CEO of ASIT biotech, stated: “The GMP certification is the result of an outstanding team effort and is part of the industrial strategy initiated at the beginning of the year with the new management. We want the ability to control the entire value chain associated with the ASIT+™ technology platform for gp-ASIT+™ active pharmaceutical ingredient as well as for other future immunotherapy product candidates we have in the pipeline. Internalization of our manufacturing process within 8 months with GMP certification at the end reflects the capacity of our organization to stay focused, to execute and to deliver in due time. I am very proud of the team, and I am confident in our capacity to continue the transformation of ASIT biotech in a development and marketing organization focused on bringing innovative therapies to patients suffering from allergies.”

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.

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

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