ALK acts on French injunction by accelerating investments in its quality system at the French manufacturing facility

ALK's 2017 full-year guidance remains unchanged.

ALK (*ALKB:DC / OMX: ALK B / AKABY / AKBLF*) today announced that the French National Agency for Medicines and Health Products Safety (ANSM) has issued an injunction against ALK, linked to needed upgrades of the quality system at its manufactoring facility in Vandeuil, France.

The injunction follows the identification by ALK of an environmental contamination (not a product contamination) in the facility's sterile production area where injectable SCIT products and skin prick tests for the French market are manufactured. As a result, ALK has temporarily stopped production in the sterile area and halted the release of all products manufactured there.

ALK and ANSM have been in close dialogue, with the authority carrying out an inspection of the facility in September. In its injunction, the ANSM instructs ALK to make a series of quality improvements to the entire facility, predominantly a strengthening of the environmental monitoring and deviation handling. Furthermore, as a precautionary measure, and in agreement with ANSM, ALK has initiated a recall of all injectable SCIT products released from the affected area since March 2017, regardless of the fact that routine testing of product quality did not reveal any effect from the environmental contamination. The SCIT products that are recalled were only distributed in France. The manufacturing facility in France also produces SLIT-drops, mainly for the French market. SLIT-drops are not affected by the recall.

ALK's President and CEO, Carsten Hellmann, says: *"We are already investing heavily in equipment upgrades, new systems, digitalisation, and a strengthening of Quality Assurance and Quality Control efforts at our production sites, and the injunction shows that we need to continue these investments. We are committed to rigorously improving the systems and ensuring that we have meticulous training and education in place for our people."*

A plan of action to address ANSM's instructions is now being put in place and manufacturing in the sterile area will restart once adequate corrective measures have been implemented and verified by the authority. The temporary halt in production will lead to SCIT products and skin prick tests being in short supply until the situation is fully remedied. ALK has informed patients and prescribers in France accordingly.

The products that are affected by the temporary production suspension represent less than 0.5 percent of ALK's total, global revenue. At this stage, ALK expects only a limited, negative spill-over effect on sales of other products. Hence, ALK expects that the suspension will have a slightly negative effect on its full-year revenue. Furthermore, ALK expects extra costs associated with the needed upgrade of the quality system. However, ALK's 2017 full-year guidance remains unchanged.

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About ALK

ALK is a research-driven global pharmaceutical company focusing on allergy prevention, diagnosis and treatment. ALK is a world leader in allergy immunotherapy – a treatment of the underlying cause of allergy. The company has approximately 2,300 employees, with subsidiaries, production facilities and distributors worldwide. ALK has entered into partnership agreements with Torii, Abbott, and Seqirus to commercialise sublingual allergy immunotherapy tablets in Japan, Russia, and South-East Asia, and Australia and New Zealand, respectively. The company is headquartered in Hørsholm, Denmark, and listed on Nasdaq Copenhagen. Find more information at www.alk.net.