

ALK secures approval in Germany for shorter up dosing of Alutard SQ®

- ▶ **ALK advances strategy of investing in competitiveness of key legacy products**
- ▶ **Amended approval shortens up dosing period from 11 or 16 injections to seven injections for house dust mite, grass and tree allergies**
- ▶ **Positions Alutard SQ® to continue benefiting from market shift to documented, registered products**

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that it has secured an amended regulatory approval in Germany for its subcutaneous allergy immunotherapy (SCIT) product Alutard SQ®, sold in Germany under the brand name ALK-depot SQ®, allowing a shortened up dosing regimen for the product.

Henrik Jacobi, ALK's Executive Vice President, Research and Development, said: *"The shorter up dosing of Alutard SQ® means that allergy patients and doctors can avoid four to nine injections in the doctor's clinic without compromising the efficacy of the product."*

Alutard SQ® is a SCIT treatment (also known as allergy shots) that involves regular injections of tiny doses of allergen under the skin. In Germany, the treatment is administered by a doctor and, when treatment first begins, doses are gradually increased to build up immune system tolerance until a maintenance dose is achieved – a process known as 'up dosing'.

Patients with house dust mite, grass or tree allergies now only require seven injections with Alutard SQ® before reaching a maintenance dose, versus a previous requirement for 11 or 16 injections. The approval is based upon new data from a recent clinical trial involving 340 adults and adolescents, which documented the safety and tolerability of the shortened up dosing regimen.

Henrik Jacobi said: *"Alongside the commercialisation of our tablets, the optimisation of our legacy portfolio is a key part of ALK's strategy for the future. Many older, unviable products are being phased out. However, for products that remain relevant, such as Alutard SQ®, we are investing to ensure their continued competitiveness, to maintain patient choice, and to meet the needs of prescribers."*

In recent years, the SCIT market in Germany has seen a growing preference among patients and prescribers for products with shorter up dosing periods. This approval is designed to enhance the competitiveness of Alutard SQ® so that it can continue to benefit from the increasing shift towards documented products currently taking place in Germany – a trend replicated in multiple markets around the world.

Alutard SQ® was first approved in Germany in 1990. It has since become one of the most documented SCIT treatments on the market, and has been the subject of more than 150 scientific publications. Today, the product is authorised in 25 countries worldwide. This amended approval, which covers product variants for house dust mite, grass pollen and tree pollen allergies, is specific to Germany, however ALK has similar applications pending in other markets.

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For further information please contact:

Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525

Media: Jeppe Ilkjær, mobile +45 3050 2014

About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,400 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net