ALK gains paediatric approval for its ragweed SLIT-tablet in the USA

ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF):

- The US Food and Drug Administration has approved extending the current product labelling of RAGWITEK® to include paediatric allergic rhinitis patients
- The approval is based on data from one of the largest-ever paediatric SLIT-tablet trials, involving over 1,000 children 5 through 17 years of age in North America and Europe
- This label extension advances ALK's efforts to expand the coverage of its tablet portfolio to all relevant ages

ALK today announced that it has gained approval from the US Food and Drug Administration (FDA), to expand the use of ALK's ragweed sublingual allergy immunotherapy (SLIT) tablet RAGWITEK® (RAGWIZAX® in Europe) to include paediatric patients, down to the age of 5, with ragweed-induced allergic rhinitis.

Ragweed is a common cause of seasonal, airborne allergy in North America and in certain parts of Europe, as well as international markets. RAGWITEK® was first launched for adult use in the USA and Canada in 2014 and was approved in nine European countries and Russia in late 2017. In addition, ALK recently received European and Canadian regulatory approval for paediatric use of the ragweed tablet.

ALK's Executive Vice President of Research and Development, Henrik Jacobi, says: "Ragweed is a major cause of allergy in North America. This expanded approval means there can now be an earlier intervention to treat what can be a distressing condition. It also advances ALK's commitment to address unmet medical need by expanding the coverage of its tablet portfolio to cover patients of all relevant ages."

The application for paediatric use drew upon clinical data from a Phase III safety and efficacy trial involving 1,022 patients 5 through 17 years of age with a history of ragweed-induced allergic rhinitis. The randomised, multi-centre, placebo-controlled, double-blind, comparative trial met its primary endpoint, with a major reduction in the average total combined score (TCS) during the peak ragweed season of 38%. Moreover, efficacy in children was consistent with that seen for its sister product, GRAZAX® (GRASTEK® in the USA) for grass pollen allergies.

Since RAGWITEK® is already on the market in the USA for patients 18 through 65 years of age, the product becomes available for paediatric use with immediate effect.

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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 2,500 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.