Large-scale paediatric SLIT-tablet trial meets primary endpoint, confirming potential in children

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

- Phase III efficacy and safety trial of ragweed SLIT-tablet involved over 1,000 children aged 5 to 17 in North America and Europe
- Primary endpoint was met, with a major reduction in the average total combined score (TCS) during the peak ragweed season of 38%. Results were highly statistically significant (p<0.001)
- One of the largest ever paediatric SLIT-tablet trials which advances ALK's strategy of expanding SLIT-tablet labelling to cover all relevant age groups

ALK today announced top-line results from a Phase III paediatric clinical trial of its sublingual allergy immunotherapy (SLIT) tablet for the treatment of ragweed-induced allergic rhinitis.

The trial, which lasted three years and involved 1,022 participants in North America and Europe, was a Phase III, randomised, placebo-controlled trial to study the efficacy and safety of ALK's ragweed SLIT-tablet in children aged 5 to 17 with a history of ragweed-induced allergic rhinitis (also known as hay fever). The trial was conducted by MSD (known as Merck in the USA and Canada), under the terms of its former partnership agreement with ALK.

The trial was designed to assess whether treatment with SLIT-tablets would result in a significant reduction in symptoms and medicine use during the peak ragweed season. The primary endpoint was a reduced total combined score (TCS) covering symptoms and medication use. The trial achieved its primary endpoint with a TCS reduction of 38% compared to placebo treated patients, which was highly statistically significant (p<0.001), with a lower bound of the 95%-confidence interval of 30%, versus a threshold of 10% as required by the US Food and Drug Administration. The trial also demonstrated that the treatment was well tolerated and had a favourable safety profile. Moreover, the findings of clinically relevant efficacy in children are consistent with what has previously been demonstrated for its sister product, GRAZAX® for grass pollen allergies.

ALK's Executive Vice President of Research and Development, Henrik Jacobi, said: " *These results are among the most compelling ever seen in large-scale AIT clinical research and demonstrate the potential benefit of treating childhood allergies with these tablets. Commercialisation of the tablet portfolio for all relevant ages is a central part of ALK's growth strategy, and we have recently seen the importance of a paediatric indication for other SLIT-tablets in Japan, where families and doctors have embraced what was a new treatment option for children with allergies."*

ALK will now begin dialogue with relevant regulatory authorities about extending the current product labelling. Furthermore, ALK expects to present the further details from the trial at a scientific congress later in 2019.

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.

ALK-Abelló A/S

For further information please contact:

Carsten Hellmann, President & CEO, tel. +45 4574 7576
Investor Relations: Per Plotnikof, tel. +45 4574 7527, mobile +45 2261 2525
Media: Jeppe Ilkjær, tel. +45 7877 4532, mobile +45 3050 2014

This information is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

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 2,300 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Attachment

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