ALK (ALKB:DC / OMX: ALK B / AKABY / AKBLF) today announced that its house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet ACARIZAX® has had its approval in 12 European countries expanded to include the treatment of adolescent patients with HDM-induced allergic rhinitis.

The expanded approval, which covers patients who are aged 12-17, is based upon data from clinical trials conducted in Japan and North America as part of the global ACARIZAX® clinical development programme. The results confirmed the favourable efficacy, safety and tolerability profile of ACARIZAX® and were in line with previous studies in adults.

Henrik Jacobi, ALK’s Executive Vice President, Research and Development, said: “This expanded approval is important for patients and important to ALK’s strategy for ACARIZAX®. For patients, it means there can now be an earlier intervention to treat a condition that has far-reaching consequences for teenagers whose sleep, education and social lives are blighted by house dust mite allergy.”

He continued: “For ALK, it continues our strategy of widening patient access to evidence-based allergy immunotherapy (AIT) and of addressing unmet medical need.”

As a result of today’s announcement, ACARIZAX® is now approved for use in adolescents in Austria, Czech Republic, Denmark, Finland, Italy, the Netherlands, Norway, Poland, Sweden, Slovakia, and the key European markets of France and Germany.

ACARIZAX® first gained European approval for use in adults in 2015, when it also became the first SLIT product to be approved for use in allergic asthma. In February 2017, clinical data from the ACARIZAX® development programme led the Global Initiative for Asthma (GINA), for the first time, to add allergy immunotherapy as a treatment option in its Global Strategy for Asthma Management and Prevention.

ACARIZAX® is currently approved in 17 countries worldwide and launched in nine. Registration reviews are underway in a further nine countries with further submissions planned.