
ALK announces Health Canada approval of ITULATEK SLIT-tablets for the treatment of tree pollen allergy

- ▶ Over 20 percent of Canadians with allergies are impacted by tree pollenⁱ
- ▶ With this approval, ALK now provides four SLIT-tablet options in Canada, treating some of the most prevalent allergies

MISSISSAUGA, Ontario, Apr. 20, 2020 – ALK, a global, research-driven pharmaceutical company that focuses on the prevention, diagnosis and treatment of allergies, today announced that Health Canada has approved once-daily ITULATEK™ (standardised allergen extract, white birch (*betula verrucosa*) sublingual tablet) for the treatment of tree pollen allergy.

ITULATEK™, the fourth once-daily sublingual allergy immunotherapy (SLIT) tablet available in Canada from ALK, is indicated as an allergy immunotherapy for the treatment of moderate to severe seasonal allergic rhinitis, with or without conjunctivitis, induced by pollen from birch, alder, and/or hazel in adults 18 to 65 years of age who have a clinical history of symptoms of allergic rhinitis, despite use of symptom-relieving medication, and a positive test of sensitisation to one or more of the pollen of birch, alder, or hazel (skin prick test and/or specific IgE). Treatment with ITULATEK™ should only be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.

“We are committed to exploring innovative treatments to improve the lives of people who suffer from the most common allergies and may benefit from a more convenient, long-term solution,” said Jorge Alderete, President ALK, Inc. “The approval of ITULATEK™ brings an important option to the many patients in Canada with tree pollen allergy. Further, this approval complements our existing SLIT-tablet portfolio which includes treatments for house dust mite, grass and ragweed allergies.”

The approval was based, in part, on data from a pivotal Phase III trial that evaluated the efficacy and safety of ITULATEK™ in adult and adolescent patients with birch pollen allergic rhinitis and/or conjunctivitis. The randomised, placebo-controlled, double-blind, multi-centre trial was conducted with 634 patients age 12-65 in eight European countries. The primary endpoint of the trial was the daily total combined score, which is the sum of the allergy symptom score and the use of symptom-relieving medication, measured during the birch pollen season.

In the trial, treatment with ITULATEK™ reduced the total combined score by 39.6 percent compared to placebo. The results were highly statistically significant ($p < 0.0001$). The efficacy was similar when analysing data for the entire tree pollen season (i.e., including the alder and hazel pollen seasons). The trial also showed that the treatment was well-tolerated by patients, with no new or unexpected adverse events reported compared to previous clinical trials with SLIT-tablets.ⁱⁱ

Full results were published in *The Journal of Allergy and Clinical Immunology* in March 2019 and can be found [here](#).

“About one in five Canadians are allergic to tree pollen specifically,” said Dr Paul Keith, associate professor of medicine in the Division of Allergy and Clinical Immunology at McMaster University in Hamilton, Ontario. “Many patients are not able to achieve adequate symptom control from their current treatments. Sublingual immunotherapy options like ITULATEK™ can provide long term relief by addressing the underlying cause of the allergic response with convenient at-home administration after an initial visit with an allergist.”

About Sublingual Allergy Immunotherapy (SLIT) Tablets

Allergy immunotherapy, or AIT, treats the underlying cause of environmental allergies using a person's own immune system. Small amounts of allergens are introduced into the body so the immune system can gradually learn to tolerate them better. SLIT-tablets are prescription medication taken daily that offers flexible daily dosing. Subcutaneous immunotherapy (SCIT), also known as allergy shots, is another form of allergy immunotherapy administered in a doctor's office.

Important Safety Information for ITULATEK™

- ▶ Treatment with ITULATEK™ should only be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
- ▶ Systemic allergic reactions, including severe local allergic reactions, are known risks in patients receiving allergy immunotherapy and may require emergency administration of epinephrine, antihistamines, bronchodilators or systemic corticosteroids (see 8 WARNINGS AND PRECAUTIONS / Immune).
- ▶ The first tablet of ITULATEK™ must be taken at the physician's office under medical supervision and the patient must be monitored for at least 30 minutes.

ALK-Abelló A/S

For further information please contact:

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

Media: Jeppe Ilkjær, tel. +45 7877 4532, 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.

ⁱ Keith, P.K.; Desrosiers, M.; Laister, T.; Schellenberg, R.R.; Wasserman, S. The burden of allergic rhinitis (AR) in Canada: Perspectives of physicians and patients. *Allergy Asthma Clin. Immunol.* 2012, 8, 7.

ⁱⁱ Biedermann, Tilo et al. The SQ tree SLIT-tablet is highly effective and well tolerated: Results from a randomized, double-blind, placebo-controlled phase III trial. *Journal of Allergy and Clinical Immunology*, Volume 143, Issue 3, 1058 - 1066.e6. Available at <https://www.jacionline.org/action/showCitFormats?pii=S0091-6749%2819%2930018-1&doi=10.1016%2Fj.jaci.2018.12.1001>. Accessed April 14, 2020.