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AIT Bulletin

A MONTHLY NEWSLETTER

ALK MEDICAL AFFAIRS

CLINICAL SPOTLIGHT

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A year ago this week almost all of my subcutaneous immunotherapy (SCIT) injection patients made the hard decision to either stop their injections altogether or struggle to find a location willing to see them, which essentially fell to me. While my hospital based clinic remained open, it was to be used for urgent patient assessments only. Enter the opportunity to transition patients to SLIT-tablets because of the requirement for less in person clinic visits. Now SLIT is my first line option posed to patients who have failed pharmacotherapy or desire to use less medication. One initiation visit per tablet is preferable over weekly build up injections when in person assessments are to be minimized.

@DrAnneEllis

AIT FROM ALK

Adverse Event Profile of SQ House Dust Mite Sublingual Immunotherapy Tablet After Treatment Interruption

*Tilles S, Nelson H, Prenner B, Maloney J, Smith I, Nolte H**

The SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet is approved for daily administration for the treatment of HDM-induced allergic rhinitis. In a post-hoc analysis, the adverse event (AE) profile following treatment interruption was evaluated. Safety data from 2 DBRPC trials were pooled and analyzed for AEs reported at any point after a treatment interruption of ≥2 consecutive days for any reason. Data for the Europe/Canada/U.S. approved dose 12 SQ-HDM (n=783) and placebo (n=782) are presented.

Summary of treatment interruptions and AEs after treatment re-initiation

	SQ HDM SLIT-Tablet 12 SQ-HDM n=783	Placebo n=782
Any treatment interruption, n (%)	**476 (61%)**	**501 (64%)**
Duration of treatment interruption, days		
Median (range)	7 (1-142)	8 (1-143)
Mean (SD)	13.4 (16.7)	13.8 (18.3)
Any treatment-emergent AEs after treatment re-initiation, n (%)	**226 (29%)**	**203 (26%)**
Systemic allergic reactions, n (%)	0	0
Epinephrine administrations, n (%)	0	0
Severe local swellings, n (%)	0	0

Most AEs after treatment re-initiation were assessed by the investigator as mild or moderate in severity

In all, 977/1565 subjects reported a treatment interruption for any reason. Median interruption duration was 7 days for 12 SQ-HDM and 8 days for placebo. The proportion of subjects who experienced AEs at any point after treatment re-initiation was similar between 12 SQ-HDM and placebo. Most AEs after treatment re-initiation were assessed by the investigator as mild or moderate in severity. No systemic allergic reactions, epinephrine administrations, or severe local swellings were reported after treatment re-initiation. In the 12 SQ-HDM group, the most frequently reported AEs after re-initiation were oral pruritus (8%), throat irritation (8%), and ear pruritus (7%); the frequencies of these AEs with placebo were 1%, 2%, and 1%, respectively. This AE profile characterized by local application site reactions is consistent with the known safety profile of the SQ-HDM SLIT-tablet.

In this trial, safety data after short-term interruption of SQ-HDM SLIT-tablet treatment do not indicate a safety signal after tablet re-initiation. The safety profile after long-term treatment interruption was not determined.

Tilles S, Nelson H, Prenner B, Maloney J, Smith I, Nolte H. Adverse event profile of SQ house dust mite sublingual immunotherapy tablet after treatment interruption. In: Conference Annals from the ACAAI; November 15-19, 2018; Seattle, WA. https://doi.org/10.1016/j.anai.2018.09.048

*H. Nolte is the SVP of Research and Development at ALK-Abello Americas and International, and also serves the role of CMO.

DID YOU KNOW?

The prevalence of allergic diseases has increased over the past 50 years and affects between 10-30% of the world population.

American Academy of Allergy Asthma & Immunology. Allergy Statistics. https://www.aaaai.org/about-aaaai/newsroom/allergy-statistics. Accessed April 2021.

WHAT'S NEW IN RESEARCH?

New Horizons: ALK ventures into development of AIT targeting food allergy

If ALK's history has proved anything so far, it is that our entrepreneurial spirit and the standard we set in treatment and services translates to real value for people with allergy. Our new strategic focus carries on that spirit, as ALK ventures into new horizons: food.

No allergy company can truly be the allergy company without tackling one of the most common allergies in the world – food allergies. ALK is now looking to leverage almost a century of competences and know-how to develop a new AIT product that seeks to make our product portfolio broader and more robust to ensure long-term growth.

What gaps in research would you like to share with ALK? Let us know:

@US_ALK #ALKMedAffairs

UPCOMING ALK EVENTS

"As we head into Spring allergy season, we appreciate your participation and engagement in our virtual medical roundtable programs and other events that focus on how we can best develop drugs and help improve medical practices for allergy sufferers. Our current calendar of events is available below. Please continue to share your feedback so that we can make these events as valuable as possible; and if you'd like to share a future idea for a Medical Roundtable topic, please reach out to MedicalAffairs@alk.net."

Hendrik Nolte, M.D., Ph.D., Chief Medical Officer and SVP, Research and Development ALK-Abello Americas and International

Click here for ALK Virtual Programs Calendar

U.S. Events

Michigan Asthma and Allergy Society
Wednesday, May 12, 2021

How Does SLIT Fit in Clinical Allergy Practice?
Dr. Hendrik Nolte
Presentation at University of Washington
Tuesday, May 18, 2021

Canada Events

Allergy Asthma & Immunology Society Of Ontario
Wednesday, April 21, 2021
7 – 8 PM EST
Guest Speaker:
Hendrik Nolte, M.D., PhD.

Canadian Society of Allergy & Clinical Immunology: Women in Allergy & Immunology Conference
Saturday, May 8, 2021
11 AM – 4 PM EST

Do you have a suggestion for a future ALK Medical Affairs event? Let us know!

MedicalAffairs@alk.net

AIT NEWS AROUND THE GLOBE

Acute Allergic Reactions to mRNA COVID-19 Vaccines

Blumenthal K, Robinson L, Camargo C

In this prospective cohort of health care employees, 98% did not have any symptoms of an allergic reaction after receiving an mRNA COVID-19 vaccine. The remaining 2% reported some allergic symptoms; however, severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations. All individuals with anaphylaxis cases recovered without shock or endotracheal intubation. The incidence rate of confirmed anaphylaxis in this study is larger than that reported by the CDC based on passive spontaneous reporting methods. However, the overall risk of anaphylaxis to an mRNA COVID-19 vaccine remains extremely low and largely comparable to other common health care exposures.

Blumenthal K, Robinson L, Camargo C. Acute allergic reactions to mRNA COVID-19 vaccines. JAMA. Published online March 08, 2021. doi:10.1001/jama.2021.3976.