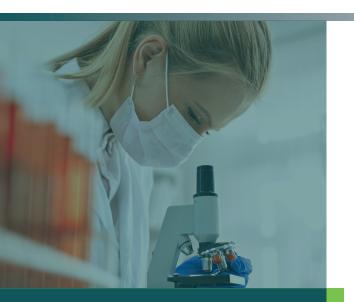
AIT Bulletin





A MONTHLY NEWSLETTER



CLINICAL SPOTLIGHT

David I. Bernstein FAAAAI, FACAAI, FACP, M.D. Cincinnati, OH

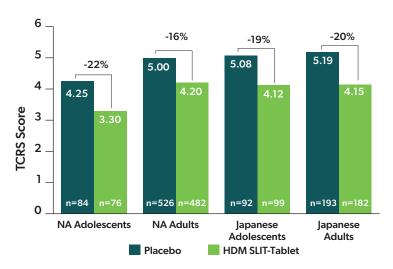
SLIT-tablets for pollen or house dust mite (HDM) tablets can be self-administered conveniently for those patients with demanding work schedules, unable to comply with SCIT injection build-up protocols. Severe rhinoconjunctival symptoms are often triggered at work in atopic patients with jobs involving high exposure to indoor HDM allergens in home environments (e.g., cleaning workers, construction workers, plumbers) or those seasonal workers with substantial outdoor exposure to pollen (e.g., landscapers, construction workers). I have been impressed by the deleterious impact of allergic rhinitis symptoms experienced by patients in a variety of occupational settings. Clearly, an unmet need exists to better understand the potential impact of allergen immunotherapy on improving work related symptoms as well as QOL outcome measures specifically related to work productivity and performance.

AIT FROM ALK

The 12-SQ HDM SLIT-Tablet Shows Similar Safety and Efficacy Across Geographies, Ethnic and Age Groups

H. Nolte, T. Matsuoka, D. Bernstein, V. Hulstrøm

ouse dust mite (HDM) sublingual immunotherapy (SLIT)-tablets have been evaluated in large clinical trials of adolescents and adults in North America and Japan. In a post-hoc study, efficacy and safety data from two randomized, double-blind, placebo-controlled phase III clinical trials with 12-SQ HDM were analysed by age (12–17 years/18–64 years) and ethnicity/region (Japan/North America [NA]). Trials were desiågned similarly with respect to medical practice, target population, eligibility criteria, efficacy and safety monitoring.



NA, North America; TCRS=sum of rhinitis daily symptom score and daily medication score $\,$

The treatment effect on the primary endpoint of total combined rhinitis score (TCRS) in Japanese (N=633) and NA (N=1482) subjects were comparable both for the overall trial populations and the adolescent and adult subgroups, ranging between 17%-22% relative to placebo. HDM SLIT-tablet was well tolerated, and in general, the safety profile was similar in Japanese and NA populations. The placebo-subtracted treatment-related adverse event (AE) rate in NA adolescents/adults was 45%/44% and in Japanese adolescents/adults was 47%/46%. In these trials, there was no epinephrine use due to treatment-related events in adolescent subjects in either trial. The HDM IgE and ${\rm IgG_4}$ responses were comparable between Japanese and NA subjects and between age groups.

In conclusion, the analysis shows that SQ HDM SLIT-tablet is insensitive to ethnic, age or regional differences with a similar safety, efficacy and immunologic profile.





Allergy is rarely a lifethreatening condition, but it can often be life-changing.



WHAT'S NEW IN RESEARCH?

Tablets for the Big Five

ALK has been at the leading edge of scientific innovations focusing on allergy and its treatment for 98 years. Since 2006, we have leveraged our scientific expertise to develop a portfolio of SLIT-tablets covering five of the most common global allergies. In the U.S., house dust mite (age 18–65 yrs), grass (age 5–65 yrs) and ragweed (age 18-65 yrs) SLIT-tablets are approved by the FDA for allergic rhinoconjunctivitis. In Canada, house dust mite (age 18-65 yrs), grass (age 5-65 yrs), ragweed (age 5-65 yrs) and tree (age 18-65 yrs) SLITtablets are approved by Health Canada for allergic rhinoconjunctivitis. All SLIT-tablets are standardized, well-characterized and have proven safety and efficacy in DBRPC trials.

Today, our R&D focus is on completing this portfolio and gaining approval for its use in all relevant agesadults, adolescents and children.

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



@US_ALK #ALKMedAffairs



medicalaffairs@alk.net

ALK EVENTS MARCH 2021

"Thank you to all who attended our February and Early March virtual medical roundtable programs. We are so pleased to hear the positive feedback and value these events are bringing. In our social-distancing world of COVID-19, these face-to-face virtual connections are vital to our continued learning and collaborations. If you'd like to share a future idea for a Medical Roundtable topic or view our current calendar of events, please reach out to MedicalAffairs@alk.net."

> Karen Rance DNP, CPNP Director of Medical Affairs, North America



Clinical Data on Ragweed SLIT-tablet for Pediatrics

Thursday, March 18, 2021 7:00 PM - 8:15 PM ET

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



MedicalAffairs@alk.net

AIT NEWS AROUND THE GLOBE

The role of circulating eosinophils on COVID-19 mortality varies by race/ethnicity

Jacob W. Glickman, Ana B. Pavel, Emma Guttman-Yassky, Rachel L. Miller

During this rapidly moving international health crisis, varying and seemingly contrasting reports indicate both a protective and exacerbating contribution of atopy to the severity of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The authors performed a retrospective analysis of reported demographics, medical history, medication and baseline laboratory values from 4252 hospitalized patients with a positive SARS-CoV-2 polymerase chain reaction test between 03/01/20 to 06/07/20in the Mount Sinai Health System. These data reveal the potentially protective role of eosinophils in systemic circulation on mortality and hospital duration. This protection varied across racial/ethnic groups. The findings may have implications for the management of COVID-19 patients.

EAACI Allergy Journal, Dec. 2020 https://doi.org/10.1111/all.14708



