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

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Introduction

- House dust mite (HDM) sublingual immunotherapy (SLIT)-tablets have been evaluated in large clinical trials of adolescents and adults with allergic rhinoconjunctivitis in North America and Japan[1,2]

- Because of the diversity of participants in the trials and the large sample sizes, it is possible to assess safety and efficacy across age groups and ethnic/world regions

1. Nolte H, et al. *J Allergy Clin Immunol* 2016; 138:1631-1638.
2. Okubo K, et al. *J Allergy Clin Immunol* 2017; 139:1840-1848.e1810.

Methods

- Data from 2 randomized, double-blind, placebo-controlled phase III clinical trials (NCT01700192 [12 SQ-HDM, n=741; placebo, n=742] and JapicCTI-121848 [12 SQ-HDM, n=314; placebo, n=319]) [1,2] with 12 SQ-HDM were analysed by:
  - Age groups: adolescents (12-17 years) and adults (18-64 years)
  - Ethnicity/region (Japan/North America [NA])
- Trials had similar design, medical practice, target population, eligibility criteria, efficacy and safety monitoring
  - Primary endpoint: Total combined rhinitis score (TCRS; sum of rhinitis daily symptom score and daily medication score: max=24) during the 8-week efficacy assessment period

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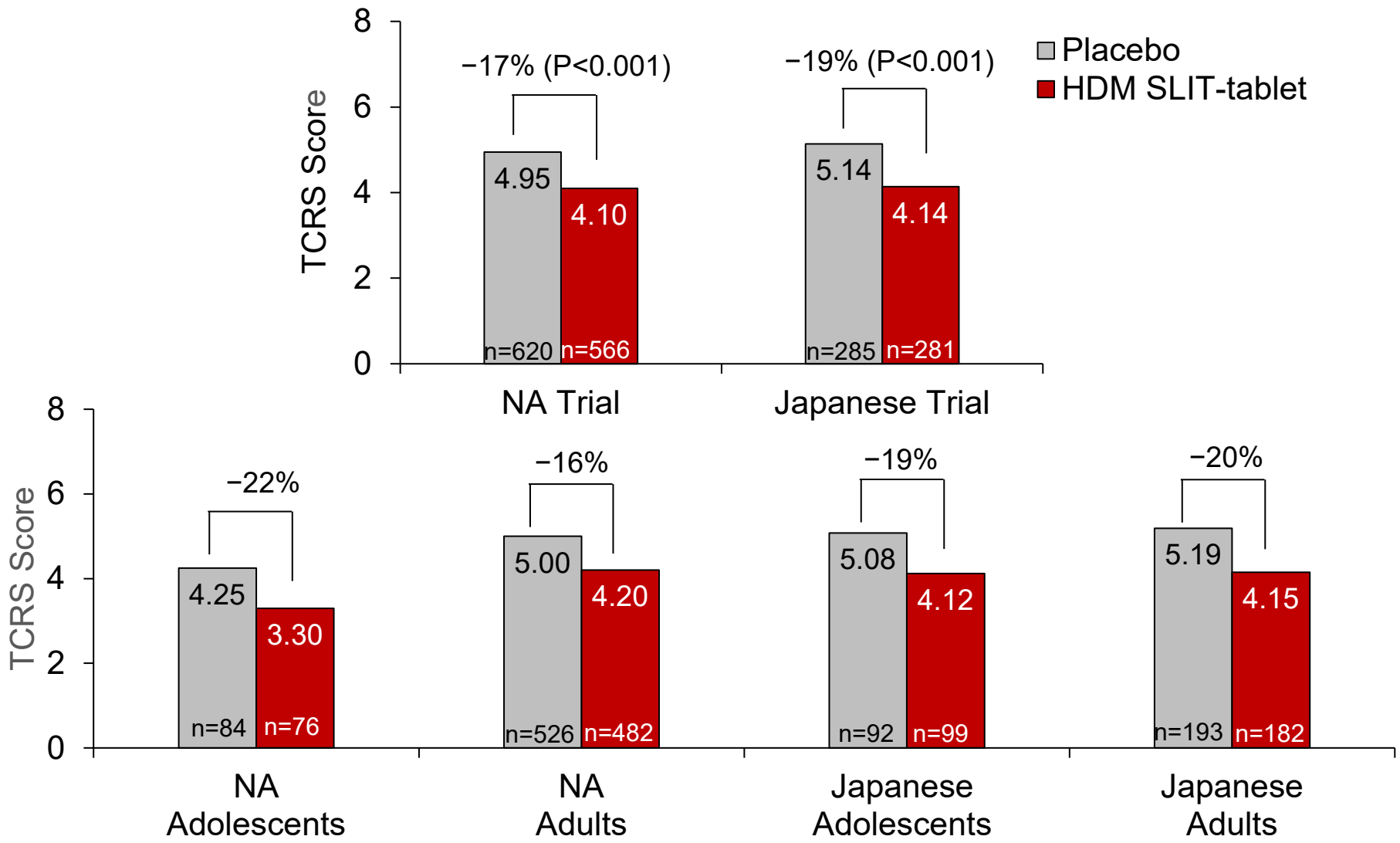
TCRS is comparable across ethnic/world regions and age



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

Safety is comparable across ethnic/world regions and age

- HDM SLIT-tablet was well-tolerated and safety profile was generally similar in NA and Japanese populations
- In total, 4 events of epinephrine use due to treatment-related events – all were in NA adults*

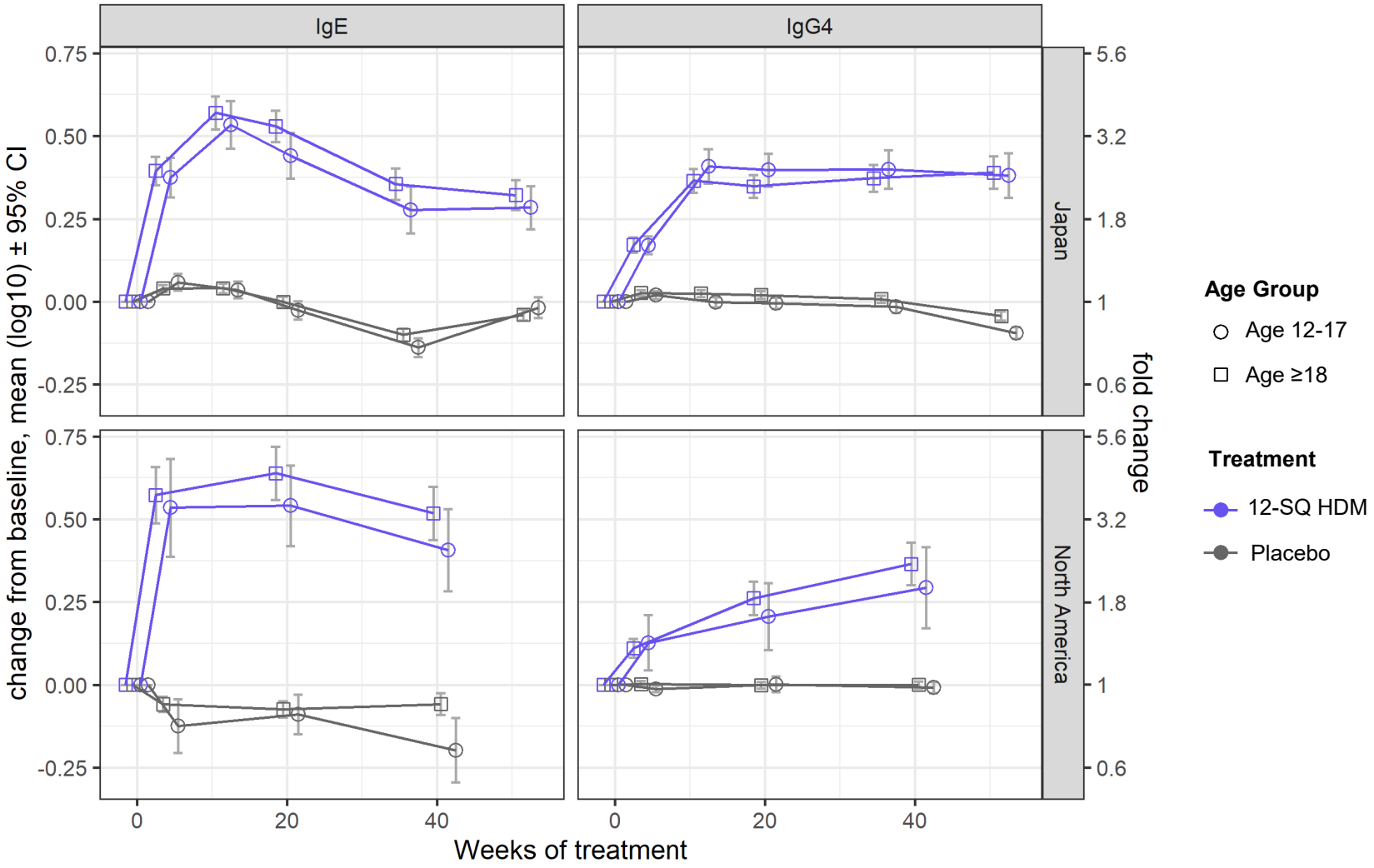
	NA Population					
	Adolescents			Adults		
	12 SQ-HDM (n=94)	PBO (n=95)	PBO-subtracted Rate†, %	12 SQ-HDM (n=649)	PBO (n=643)	PBO-subtracted Rate†, %
Any TEAE	95%	79%	16%	89%	74%	15%
Any TRAE	93%	47%	45%	80%	39%	41%
Any TRAE leading to study discontinuation	10%	0%	10%	6%	1%	5%
	Japanese Population					
	Adolescents			Adults		
	12 SQ-HDM (n=107)	PBO (n=99)	PBO-subtracted Rate†, %	12 SQ-HDM (n=207)	PBO (n=220)	PBO-subtracted Rate†, %
Any TEAE	93%	83%	10%	89%	79%	10%
Any TRAE	66%	19%	47%	62%	16%	46%
Any TRAE leading to study discontinuation	2%	2%	0%	1%	2%	0%

PBO, placebo; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event

*Epinephrine co-prescription was required by the FDA in the North American trial. The Japanese trial had no requirement for epinephrine co-prescription.

†Placebo-subtracted rate = proportion of subjects in 12 SQ-HDM group minus proportion of subjects in placebo group

HDM IgE and IgG_4 responses are comparable across ethnic/world regions and age



Conclusions

- The HDM SLIT-tablet is insensitive to ethnic, age or regional differences with a similar safety, efficacy, and immunologic profile