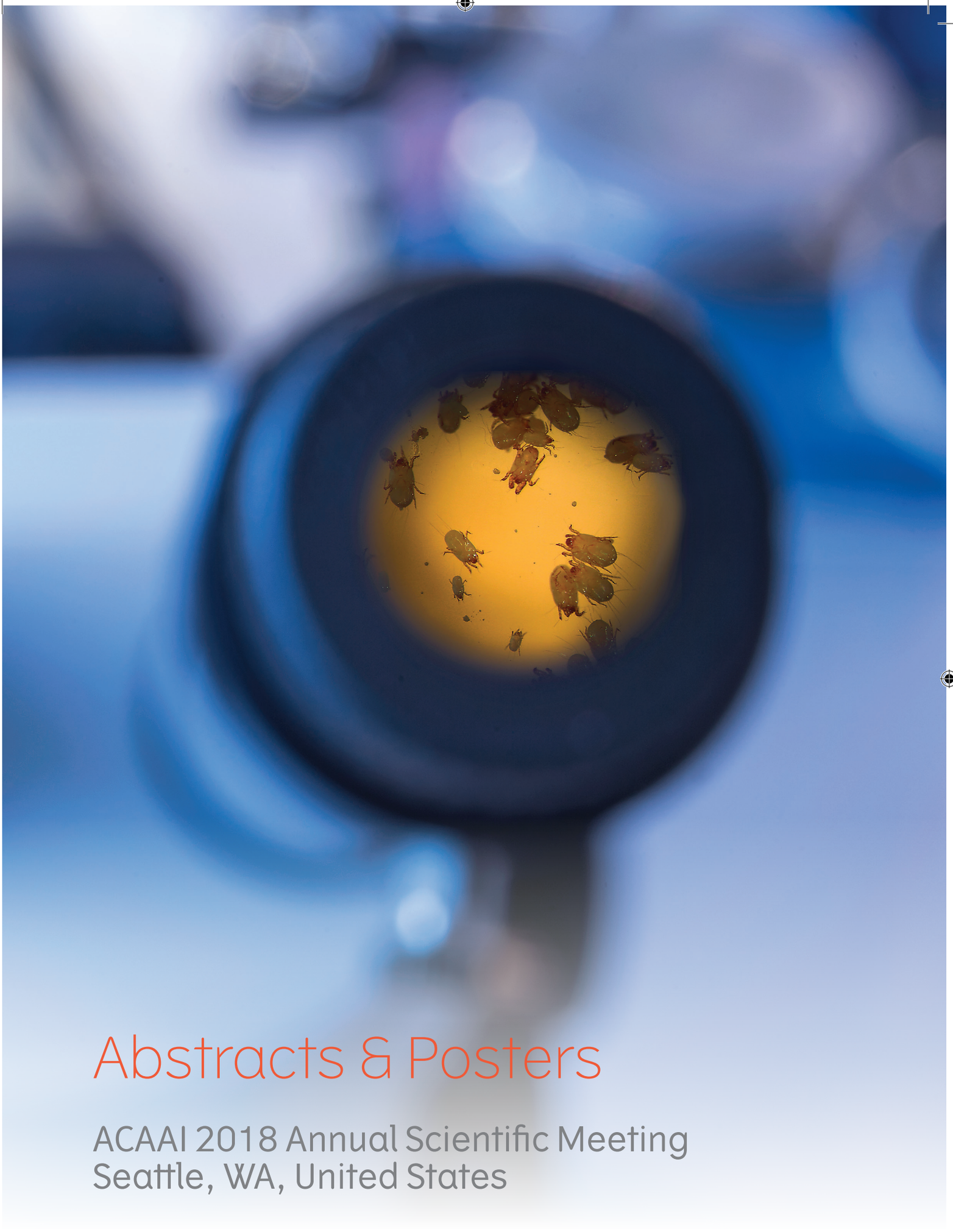

Abstracts & Posters

ACAAI 2018 Annual Scientific Meeting
Seattle, WA, United States

ALK

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Dear ACAAI delegate

ALK welcomes you to the ACAAI 2018 Annual Scientific Meeting in Seattle, WA.

As the world leader in allergy immunotherapy, we are proud to present four abstracts, all concerning house dust mite (HDM) induced respiratory allergic disease.

The first abstract reports that treatment with the SQ HDM SLIT-tablet in patients with well controlled mild to moderate asthma did not increase the risk of asthma events. A second abstract based on 14 trials shows no serious adverse events related to first dose, which must be taken under medical supervision, were observed in relation to the first dose. Other clinically important adverse events were uncommon, occurred within minutes, and were manageable with conventional pharmacotherapy and/or epinephrine. A third abstract indicates that short-term interruption of the treatment does not appear to compromise safety after re-initiation. Finally, a fourth abstract demonstrates that uncontrolled allergic disease is associated with significant productivity loss among working individuals in the United States.

ALK is committed to sustain, develop and disseminate allergy immunotherapy and anaphylaxis management worldwide.

Enjoy the congress and please join us at our stand in the exhibition area to learn more about our concepts and ongoing research activities at ALK.

Hendrik Nolte, MD, PhD
Senior Vice President
Research & Development

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Safety of first dose of SQ house dust mite sublingual immunotherapy tablet in clinical trials

Bernstein DI[1], Maloney J[2], Mosbech Smith I[3], Nolte H[2]
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Introduction

Supervision in the physician's office for 30 minutes following the first dose of SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet (ALK, Denmark) is required to monitor for potential adverse reactions. Clinically important adverse events (AEs) occurring in connection to administration of the first dose were evaluated.

Methods

Safety data from 14 DBPC trials (N=6784) of SQ HDM SLIT-tablet were analyzed for clinically important treatment-related AEs associated with the first dose. IRB approval was obtained. Data for the Europe/US approved dose of 12 SQ-HDM (N=2139) are presented.

Results

The majority of treatment-related AEs with the first dose were mild or moderate local allergic reactions. In all, 2/2139 (0.09%) subjects experienced AEs requiring treatment with epinephrine within minutes of administration of the first dose. One subject developed laryngeal edema assessed as mild by the investigator, which was treated with epinephrine and resolved after 30 minutes; the subject completed the trial. The other subject discontinued treatment after experiencing a systemic allergic reaction (reported as moderate hypersensitivity), which was treated with epinephrine and resolved after 1 hour. Four additional subjects discontinued treatment on day 1 due to AEs, mainly mild/moderate local allergic reactions, all of which resolved within 2 hours. No late-phase allergic reactions occurred. No serious AEs related to first dose were observed.

Conclusion

Clinically important AEs related to the first dose of SQ HDM SLIT-tablet occurred within minutes and were manageable with conventional allergy pharmacotherapy.

Abstract ID: 8032
ePoster Session: 1
Session Code: P452
Poster Hall Location: Room 4ABCDE on Monitor 3
Presentation Date: Friday, November 16
Presentation Time: 5:20 PM

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Safety of first dose of SQ house dust mite sublingual immunotherapy tablet in clinical trials

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Introduction

The SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet (ALK, Denmark) has obtained regulatory approval in North America and Europe, as well as other countries. In the United States, SQ HDM SLIT-tablet is approved for the treatment of HDM-induced allergic rhinitis with or without conjunctivitis (AR/C). Supervision in the physician's office for 30 minutes following the first dose of SQ HDM SLIT-tablet is required to monitor for potential adverse reactions.[1] Clinically important adverse events (AEs) occurring in connection to administration of the first dose were evaluated.

Methods

Safety data from 14 randomized, double-blind, placebo-controlled trials (N=6784) of SQ HDM SLIT-tablet in subjects with HDM-induced AR/C and/or asthma were analyzed for clinically important treatment-related AEs associated with the first dose. Clinically important treatment-related AEs were defined as AEs treated with epinephrine, leading to discontinuation, or assessed as serious. Institutional review board approval was obtained for all trials. Data for the North American and European approved dose of 12 SQ-HDM (N=2139) are presented.

Results

The majority of treatment-related AEs with the first dose were mild or moderate local allergic reactions. Approximately 20% of all treatment-related AEs occurred with the first dose and approximately 60% of subjects who experienced a treatment-related AE at any point during the trials reported a treatment-related AE on day 1.

Table 1. Epinephrine administrations associated with the first dose of SQ-HDM SLIT-tablet

Epinephrine Administration	Symptoms	Severity*	Duration of Symptoms	Treatment	Outcome
Administration 1	Laryngeal edema	Mild	30 min	Antihistamine, OCS, epinephrine	Resolved and completed trial
Administration 2	Systemic allergic reaction	Moderate	1 hour	Epinephrine	Resolved and discontinued trial

OCS, oral corticosteroid.
*Severity assessed by the investigator.

Table 2. Trial discontinuations associated with AEs after the first dose of SQ-HDM SLIT-tablet.

Discontinuations	Symptoms	Severity*	Duration of Symptoms	Treatment	Outcome
Discontinuation 1	Swollen tongue, oral paraesthesia, dyspnea, hyperhidrosis	Moderate	2 hours	Antihistamine, IV steroids, ICS	Resolved and discontinued trial
Discontinuation 2	Palatal swelling	Mild	32 min	None	Resolved and discontinued trial
Discontinuation 3	Abdominal discomfort, dyspepsia, nausea, laryngeal discomfort	Moderate, except laryngeal discomfort was severe	1-2 hours	Antihistamine	Resolved and discontinued trial
Discontinuation 4	Throat irritation	Mild	30 min	None	Resolved and discontinued trial

ICS, inhaled corticosteroid; IV, intravenous.
*Severity assessed by the investigator.

In all, 2/2139 (0.09%) subjects that experienced AEs received treatment with epinephrine within minutes of administration of the first dose (**Table 1**). One subject developed laryngeal edema assessed as mild by the investigator. The event was treated with epinephrine and resolved after 30 minutes; the subject subsequently tolerated the trial medication and completed the trial. The other subject discontinued treatment after experiencing a systemic allergic reaction reported as moderate hypersensitivity characterized by itchy palms, facial flushing, dyspnea, pre-syncope, and throat swelling which began approximately 10 minutes after dosing of 12 SQ-HDM. The subject was treated with epinephrine and the symptoms resolved after 1 hour. Four additional subjects discontinued treatment on day 1 due to AEs. These AEs were predominantly characterized by local symptoms; all of these AEs resolved within 2 hours (**Table 2**). No late-phase allergic reactions (up to 24 hours after the 30 minute observation period) occurred.

No serious AEs related to first dose were observed. One adult subject with a recent history of pneumonia and viral infection experienced treatment-related moderate asthma on day 1, but the asthma symptoms did not meet the criteria for a serious AE. Asthma continued over the next 6 days. The subject was treated with inhaled corticosteroids and discontinued trial medication. After discontinuation, the subject was treated with oral corticosteroids with no improvement and was hospitalized on day 8, thereby categorizing the event as a serious AE. The subject was discharged from the hospital on day 12 and recovered from the event.

Reference

1. ODACTRA (House dust mite allergen extract tablet for sublingual use). Full Prescribing Information, ALK-Abelló A/S, Hørsholm, Denmark, 2017.

Funding: Support for this analysis was funded by ALK, Hørsholm, Denmark.
Disclosure of presenting author: Dr. Bernstein has served as a speaker, advisory committee member, and clinical investigator for ALK.

Conclusion

Clinically important AEs related to the first dose of SQ HDM SLIT-tablet were uncommon, occurred within minutes, and were manageable with conventional pharmacotherapy and/or epinephrine.

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SQ house dust mite sublingual immunotherapy tablet is well tolerated in subjects with allergic asthma

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Introduction

Asthma is a risk factor for systemic allergic reactions to subcutaneous immunotherapy. The safety of SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet (ALK, Denmark) in subjects with or without asthma was evaluated.

Methods

Safety data from 6 phase II/III double-blind, placebo-controlled trials of SQ HDM SLIT-tablet for the treatment of allergic rhinitis or mild-to-moderate asthma were pooled and compared between subjects with and without reported asthma. IRB approval was obtained. Data for the 12 SQ-HDM dose approved in Europe/US are presented.

Results

In all, 3473 subjects were randomized to 12 SQ-HDM (n=1663) or placebo (n=1810), 2036 (59%) of whom had reported asthma. Most asthma was moderate according to GINA criteria (66%, 12 SQ-HDM; 70%, placebo).

The proportion of subjects reporting treatment-emergent adverse events (AEs) was similar between subjects with and without asthma (86% vs 85%, respectively) in the 12 SQ-HDM group and in the placebo group (70% vs 64%, respectively). The frequencies of treatment-related AEs, discontinuations due to AEs, severe AEs, and serious AEs were generally similar for subjects with and without asthma. One treatment-related systemic allergic reaction was reported; this event occurred in a subject without asthma. The frequency of asthma events in subjects with asthma was 11% with 12 SQ-HDM and 10% with placebo; in subjects without asthma the frequency was <1% in both treatment groups.

Conclusion

SQ HDM SLIT-tablet was well tolerated and did not appear to increase asthma events in patients with mild-to-moderate asthma. The safety profile was comparable for subjects with HDM-induced respiratory allergy irrespective of asthma status.

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Presentation Time: 5:10 PM

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SQ house dust mite sublingual immunotherapy tablet is well tolerated in subjects with allergic asthma

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[1]ALK, Bedminster, NJ; [2]ALK, Hørsholm, Denmark

Introduction

Asthma is a risk factor for systemic allergic reactions to subcutaneous immunotherapy.[1] The safety of SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet (ALK, Denmark) in subjects with or without asthma was evaluated.

Methods

Safety data from 6 phase II/III double-blind, placebo-controlled trials of SQ HDM SLIT-tablet for the treatment of allergic rhinitis or mild-to-moderate asthma were pooled and compared between subjects with and without reported asthma (**Table 1**). Institutional review board approval was obtained for all trials. Asthma events were defined by the standardized MedDRA query "Asthma/Bronchospasm" (version 19.0). Data for the 12 SQ-HDM dose approved in the US and Europe are presented.

Table 1. The six phase 2 and phase 3 randomized, double-blind, placebo-controlled trials pooled and analyzed for subjects with and without asthma.

		With Asthma, N		Without Asthma, N	
Trial ID Trial registry	Population	12 SQ-HDM	Placebo	12 SQ-HDM	Placebo
MT-02/P012 EudraCT 2006-001795-20	Moderate AA + AR	-*	143	-	-
MT-04/P014** EudraCT 2010-018621-19	Moderate AA + AR	282	277	-	-
MT-06/P015 EudraCT 2011-002277-38	AR ± mild AA	153	151	166	186
P001 clinicaltrials.gov NCT01700192	AR/C ± mild/moderate AA***	229	231	514	507
P003 EudraCT 2012-001855-38	AR/C ± mild AA	10	9	32	32
TO-203-3-1** JapicCTI-121847	Moderate AA ± AR	277	274	-	-
Total		951	1,085	712	725

AA, allergic asthma; AR, allergic rhinitis; AR/C, allergic rhinitis with or without conjunctivitis.
*Only doses 1, 3, and 6 SQ-HDM were included in the trial.
**Asthma exacerbations were efficacy endpoints and therefore not assessed as adverse events unless categorized as a serious event during the efficacy period.
***Asthma without inhaled corticosteroid use was classified as mild and asthma with inhaled corticosteroid use was classified as moderate.

References

1. Iglesias-Cadarso A and Hernandez-Weigand P. *Curr Opin Allergy Clin Immunol*. 2011;11(6):579-585.
2. Global strategy for asthma management and prevention, Global Initiative for Asthma (GINA) 2018 report. Available at: http://www.ginasthma.org/. Accessed September 11, 2018.

Funding: Support for this analysis was funded by ALK, Hørsholm, Denmark.
Disclosure of presenting author: J. Maloney is an employee of ALK, Bedminster, NJ.

Results

In all, 3473 subjects were randomized to 12 SQ-HDM (n=1663) or placebo (n=1810), 2036 (59%) of whom had reported asthma (**Table 1**). Asthma was of moderate intensity in most subjects according to baseline inhaled corticosteroid (ICS) use and/or GINA[2] criteria (66%, 12 SQ-HDM; 70%, placebo). All subjects with asthma had a forced expiratory volume in 1 second of ≥70% of predicted at baseline.

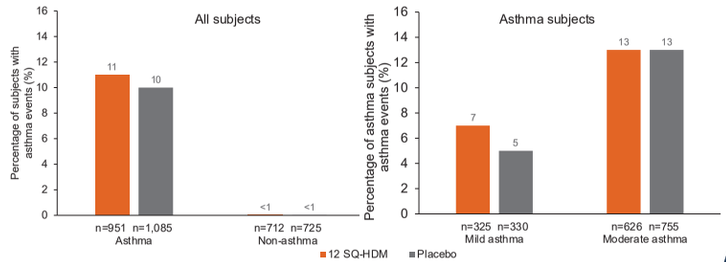
The proportion of subjects reporting treatment-emergent adverse events (AEs) was similar between subjects with and without asthma (86% vs 85%, respectively) in the 12 SQ-HDM group and in the placebo group (70% vs 64%, respectively; **Table 2**). The frequencies of treatment-related AEs, discontinuations due to AEs, severe AEs, and serious AEs were generally similar for subjects with and without asthma (**Table 2**). One treatment-related systemic allergic reaction occurred on Day 1; this event occurred in a subject without asthma. The frequency of asthma events in subjects with asthma was 11% with 12 SQ-HDM and 10% with placebo; in subjects without asthma the frequency was <1% in both treatment groups (**Figure 1**). A higher proportion of subjects with moderate asthma experienced asthma events (13% with both 12 SQ-HDM and placebo) compared with subjects with mild asthma (7% with 12 SQ-HDM and 5% with placebo; **Figure 1**).

Table 2. Summary of adverse events in subjects with or without asthma.

	With Asthma		Without Asthma	
	12 SQ-HDM (N=951)	Placebo (N=1,085)	12 SQ-HDM (N=712)	Placebo (N=725)
Any TEAEs, % of n	86	70	85	64
Severity of TEAEs, % of n				
Mild	78	60	79	51
Moderate	38	29	36	29
Severe	5	4	6	6
Treatment-related AEs, % of n	63	24	75	32
Serious TEAEs, % of n	2	3	1	1
TEAEs leading to treatment discontinuation, % of n	8	3	7	2

AE, adverse event; n, number of subjects with events, TEAE, treatment-emergent adverse event

Figure 1. Percentage of subjects with asthma events.



Approximately 1% of subjects with asthma discontinued treatment due to asthma events (**Table 3**). The proportion of subjects with asthma who experienced a serious asthma event was <1% in both 12 SQ-HDM and placebo groups (**Table 3**). One of the serious asthma events was related to 12 SQ-HDM treatment. This event occurred in an adult subject who had moderate asthma and a recent viral infection. This subject experienced asthma on day 1 of treatment, which worsened over the next 6 days. The subject was treated with ICS and β-agonist, but did not improve and he discontinued treatment on day 6. On day 7 the subject was given oral corticosteroids and he was hospitalized on day 8. The subject was discharged from the hospital on day 12 and fully recovered from the event.

Table 3. Summary of asthma events in subjects with and without asthma.

	With Asthma		Without Asthma	
	12 SQ-HDM (N=951)	Placebo (N=1,085)	12 SQ-HDM (N=712)	Placebo (N=725)
Any asthma event, n (%)	104 (11)	112 (10)	2 (<1)	6 (<1)
Asthma	99 (10)	103 (9)	2 (<1)	3 (<1)
Bronchospasm	1 (<1)	0	0	0
Hyperventilation	1 (<1)	2 (<1)	0	0
Wheezing	3 (<1)	8 (<1)	0	2 (<1)
Bronchial hyperreactivity	0	0	0	1 (<1)
Serious asthma events, n (%)	3 (<1)	3 (<1)	0	0
Serious treatment-related asthma events, n (%)	1* (<1)	0	0	0
Asthma events leading to treatment discontinuation, n (%)	13 (1)	9 (<1)	0	0

n, number of subjects with events.
*Following a week of asthma worsening, the subject was hospitalized, treated, and recovered.

Conclusion

SQ HDM SLIT-tablet was well tolerated and did not appear to increase asthma events in patients with mild-to-moderate asthma. The safety profile was comparable for subjects with HDM-induced respiratory allergy irrespective of asthma status.

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Adverse event profile of SQ house dust mite sublingual immunotherapy tablet after treatment interruption

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Introduction

The SQ house dust mite (HDM) sublingual immunotherapy (SLIT)-tablet (ALK, Denmark) is approved for daily administration for the treatment of HDM-induced allergic rhinitis. The adverse event (AE) profile following treatment interruption was evaluated.

Methods

Safety data from 2 DBPC 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/US approved dose 12 SQ-HDM (n=783) and placebo (n=782) are presented. IRB approval was obtained.

Results

In all, 977/1565 subjects (62%; 476/783, 12 SQ-HDM; 501/782, placebo) 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 (226/783 [29%]) and placebo (203/782 [26%]). 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.

Conclusions

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.

Abstract ID: 8029
Oral Abstracts Session 3B: Rhinitis & Other Upper Airway Disorders
Session Code: A450
Poster Hall Location: Room 615-617
Presentation Date: Monday, November 19
Presentation Time: 9:45-10:00 AM

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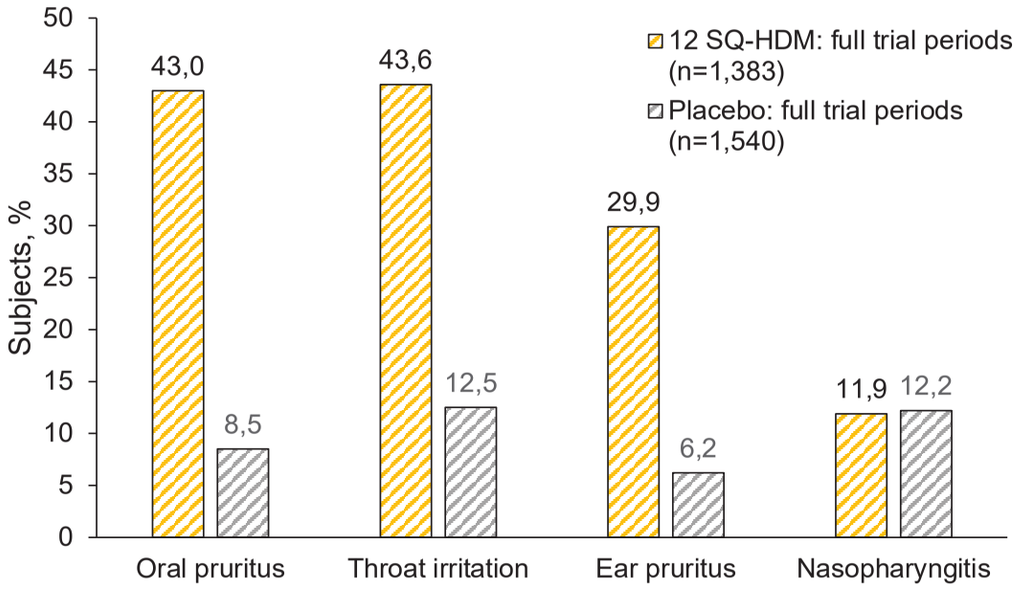
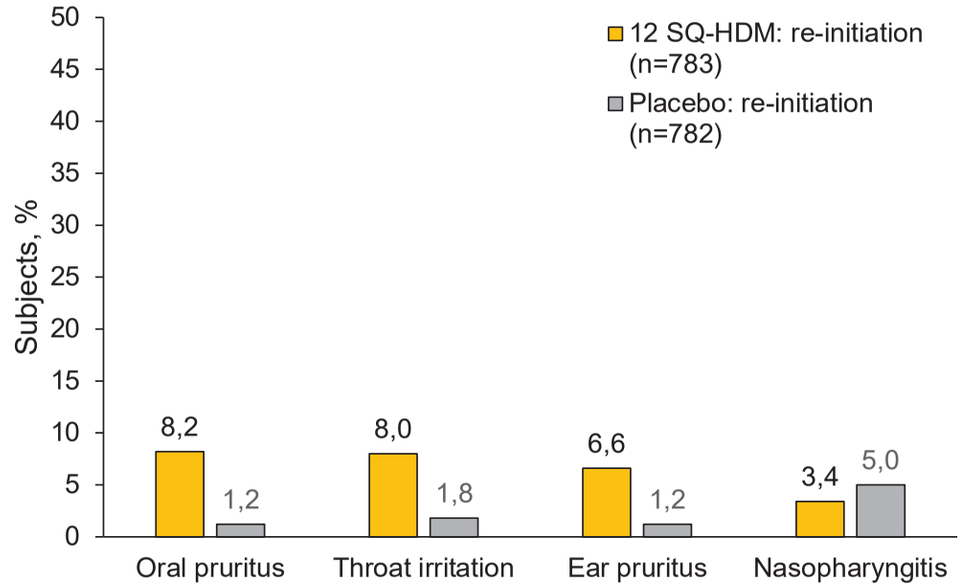
AE profile after treatment re-initiation vs known AE profile

- The AE profile after re-initiation was consistent with the known AE profile of SQ HDM-SLIT-tablet, characterized mainly by local application site reactions
- The most common treatment-emergent AEs after treatment re-initiation were the same most common AEs as the full trial periods*





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*AE frequencies from pooled data of five phase 2 and phase 3 trials of SQ HDM SLIT-tablet

31/10/2018 15:55

Uncontrolled allergy is associated with significant productivity loss among working Americans

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Introduction

Uncontrolled allergic rhinitis negatively impacts workplace productivity. House dust mite (HDM) is the most prevalent perennial allergy, but it can be effectively treated with allergy immunotherapy (AIT). Subcutaneous injection (SCIT) is the most common route of HDM AIT, however SCIT itself can adversely affect workplace productivity when the travel time required to receive the injections overlaps the workday.

Methods

This is an assessment, using an economic model, of the productivity impact of uncontrolled allergy in the US and an evaluation of the productivity impact of SCIT versus a new FDA-approved form of AIT, sublingual immunotherapy tablet (SLIT-tablet). The productivity impact is split into absenteeism and presenteeism.

Results

For the average employee with uncontrolled allergy, the estimated annual productivity loss is $4,500, where presenteeism accounts for 81% of that total. In the pivotal North American placebo-controlled trial with HDM SLIT-tablet, statistical significant improvement was demonstrated by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) in the activities domain (p=0.0001 vs placebo), which includes work-related actions. The HDM SLIT-tablet is home-administered and associated with considerably fewer doctor's office visits, contributing to less workplace productivity loss versus SCIT. The additional productivity loss of SCIT and SLIT-tablet due to related doctor visits are $1,147 and $80, respectively.

Conclusions

Uncontrolled allergic rhinitis is associated with workplace productivity loss. HDM SLIT-tablet offers an AIT treatment option that demonstrates improved RQLQ and contributes to decreased productivity loss. Furthermore, the home-administration of SLIT-tablet optimizes productivity versus SCIT because of fewer visits to the doctor.

Abstract ID: 8122
ePoster Session: 2
Session Code: P111
Poster Hall Location: Room 4ABCDE on Monitor 1
Presentation Date: Saturday, November 17
Presentation Time: 11:40 AM

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Uncontrolled allergy is associated with significant productivity loss among working individuals in the United States

M. Aagren and E. Hammerby

ALK, Hørsholm, Denmark

Introduction

Uncontrolled, ie, not adequately treated, allergic rhinitis (AR) negatively impacts workplace productivity.[1-3] Approximately 28% of the general population in the United States are sensitized to house dust mite (HDM).[4] HDM allergy can be effectively treated with allergy immunotherapy (AIT).[5,6] In the United States, subcutaneous injection (SCIT) is the most common route of AIT,[7] however, SCIT itself can adversely affect workplace productivity when the travel time required to receive the injections overlaps the workday.[8]

Methods

An economic model was developed to assess the productivity impact of uncontrolled AR in the US and evaluate the productivity impact of SCIT versus a new FDA-approved form of AIT, sublingual immunotherapy tablet (SLIT-tablet). Productivity was defined as paid hourly salary.

The productivity impact is split into absenteeism and presenteeism. Assumptions used in the model were:

- AR-associated absenteeism = 3.6 days/year[1]
- AR-associated presenteeism = 15.1 days/year[1]
- Mean annual salary in 2016 the US = $60,154[9]
- Number of annual work days = 250
- Number of hours per work day = 8
- Average number of annual allergist office visits for SCIT = 29
  - Year 1: Weekly injections = 52 visits[8]
  - Years 2-3: Injections every 3 weeks = 17 visits/year[8]
  - Total injections over 3 years = 86 visits/3 years = 29 visits/year
- Number of annual allergist office visits for SLIT-tablets = 2
  - One initiation visit[10] and 1 annual follow-up visit
- Mean time spent on each allergist office visit = 80 minutes (1.33 hours), includes travel to and from visit[8]

Formulas

- Productivity loss for uncontrolled AR = (annual salary/annual work days) x days lost to absenteeism or presenteeism
- Productivity loss due to allergist office visits = (annual salary/annual work days/daily hours) x (hours lost to allergist office visits x number of office visits)

Funding: Support for this analysis was funded by ALK, Hørsholm, Denmark.
Disclosure of presenting author: M. Aagren is an employee of ALK, Hørsholm, Denmark.

Results

For the average employee with uncontrolled AR the estimated annual productivity loss is $4,500, where presenteeism accounts for 81% of that total (**Figure 1**). Annual productivity loss increases incrementally by approximately $1,496 for each $20,000 increase in annual salary (**Figure 2**).

Figure 1. Estimated annual productivity loss (defined as paid salary) associated with uncontrolled allergic rhinitis in the United States.

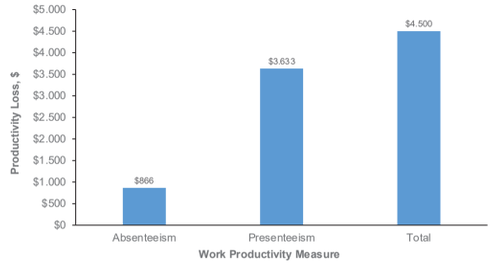
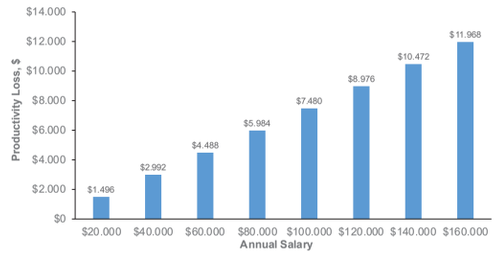
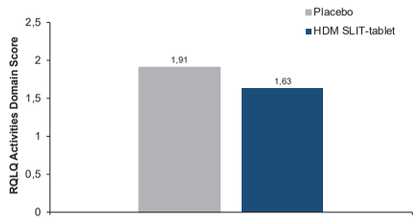


Figure 2. Estimated annual productivity loss associated with uncontrolled allergic rhinitis in the United States by annual salary.



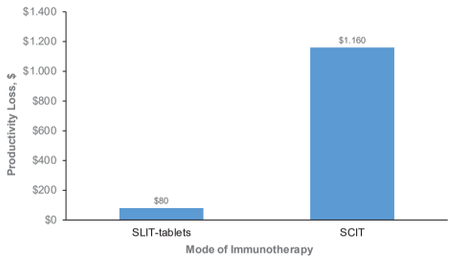
In the pivotal North American placebo-controlled trial with HDM SLIT-tablet, the overall score for the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) was significantly improved after 1 year of treatment with HDM SLIT-tablet vs placebo (p<0.001). The *activities* domain of the RQLQ, which includes work-related activities, was significantly lower after 1 year of treatment with HDM SLIT-tablet vs placebo (p=0.0001; **Figure 3**). Although the minimal important difference of 0.5 was not met,[11] the difference in RQLQ indicates less impairment in daily activities (including work-related activities) for subjects receiving HDM SLIT-tablet vs placebo.

Figure 3. Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) activities domain score with house dust mite sublingual immunotherapy tablet (HDM SLIT-tablet) vs placebo at the end of 1 year of treatment.



The HDM SLIT-tablet is home-administered and associated with considerably fewer doctor's office visits, contributing to less workplace productivity loss versus SCIT. The additional productivity loss of SCIT and SLIT-tablet due to related doctor visits are $1,160 and $80, respectively (**Figure 4**).

Figure 4. Estimated annual productivity loss due to allergist office visits for sublingual immunotherapy tablet (SLIT-tablet) and subcutaneous immunotherapy (SCIT).



Conclusion

Uncontrolled AR is associated with workplace productivity loss. HDM SLIT-tablet offers an AIT treatment option that reduces AR-related impairment in daily activities and contributes to decreased productivity loss. Furthermore, the home-administration of SLIT-tablet optimizes productivity versus SCIT because of fewer visits to the doctor.

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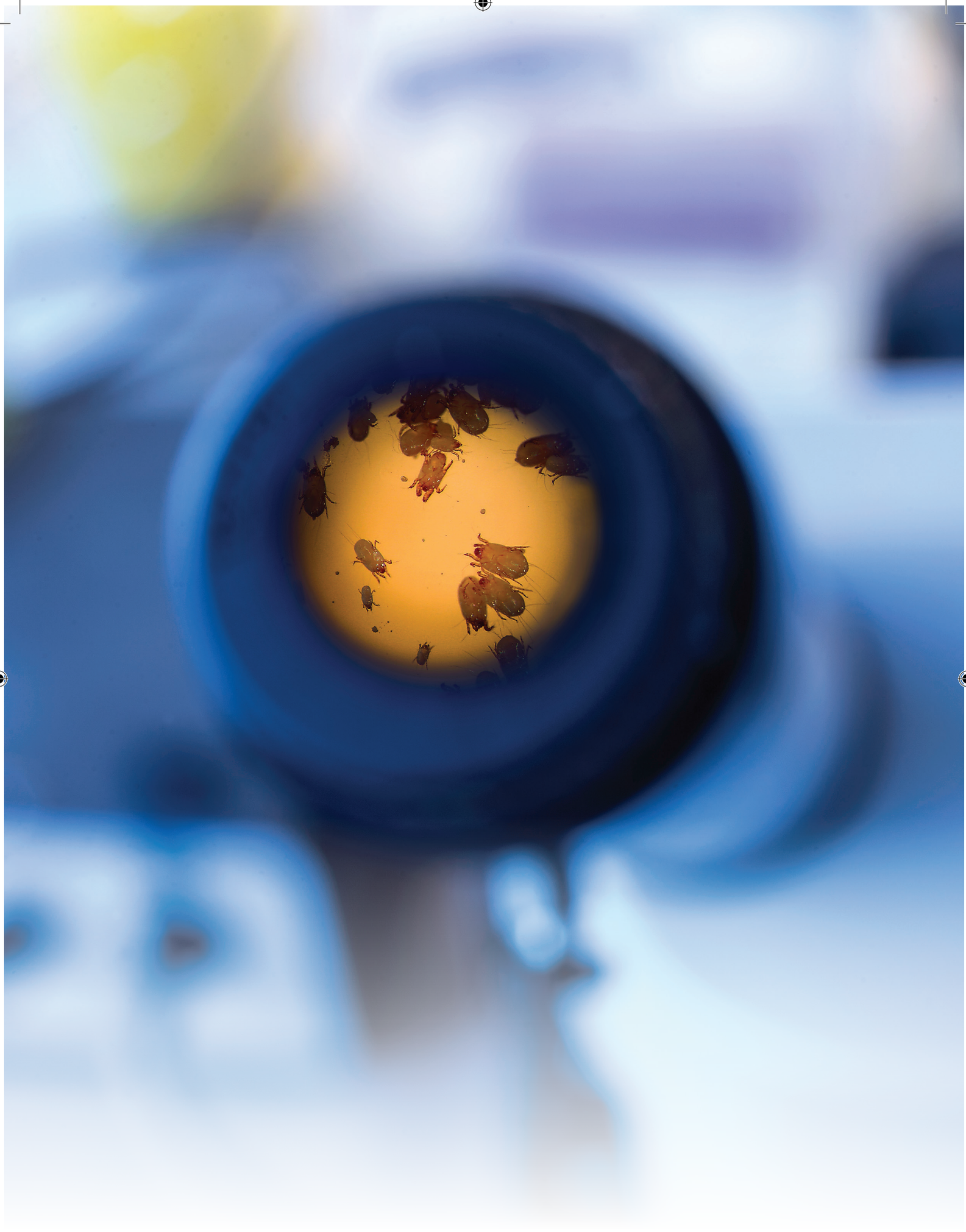

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