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**Title:** Sublingual tablets of house dust mite allergen extracts: Results of a phase I study in adults with mite-associated allergic asthma

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**Body:** Background: Efficacy and safety of sublingual immunotherapy tablets (SLIT) of house dust mite (HDM) allergen extracts have been demonstrated in patients with HDM allergic rhinitis. Aims and objectives: Here we report their safety and tolerability in patients with HDM-associated allergic asthma. Methods: Adults with a history of HDM allergic asthma ( $\geq 1$  year) controlled with therapies consistent with GINA treatment step 2, 3 or 4, a positive skin prick test to HDM, and HDM-specific serum IgE  $\geq 0.7$  kU/L were eligible for this DBPC study. Participants, stratified according to GINA treatment step at screening, were randomised 3:1 within dose-regimen groups to receive either increasing doses of SLIT tablets of HDM allergen extracts or placebo for 10 consecutive days. Four dose regimens with progressive incremental dosing from 300IR to 1000IR (IR=Index of Reactivity) were studied sequentially. Adverse events (AEs), physical examination, vital signs, spirometry, ECG and laboratory tests were analysed descriptively. Results: 63 patients received either 300IR (n=11), 500IR (n=12), 800IR (n=12), 1000IR (n=12) or Placebo (n=16). No deaths, serious AEs, anaphylaxis, epinephrine use, or treatment-related asthma exacerbation were reported. The most common AEs were mild oropharyngeal reactions which resolved without treatment. A similar safety profile was observed in patients regardless of asthma treatment step at screening or the dose administered. Conclusion: Sublingual tablets of HDM allergen extracts administered with ascending doses up to 1000IR were well tolerated in patients with HDM-associated allergic asthma and are suitable for further clinical evaluation.