VHC (reference device) and made with an Andersen 8-stage cascade impactor operated at 28.3 L/min with Ventolin®-HFA pMDIs. The EMA guideline requires comparisons to be performed by justified groupings of stages and recommends at least 4 groups based on physiological relevance. Since a traditional t-test is inappropriate to demonstrate true equivalence a two-one-sided test (TOST) was used.
Results: The values for each of the 5 test devices at each of the 4 particle size groupings were outside acceptance criteria for equivalence, thus clearly demonstrating non-equivalence to the reference device.
Conclusions: The drug delivery performance from AeroChamber Plus* Flow-Vu* AVHC was significantly different to all test VHCs, none of which passed a test for equivalence. Interchanging of such VHCs with the reference VHC may therefore result in safety and/or efficacy implications unless otherwise proven via in vivo studies.

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Omalizumab treatment response after dose step-up in patients with chronic diopathic/spontaneous urticaria (CIU/CSU): results from the OPTIMA study

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Background: A key secondary objective of the Phase 3b, randomized, open-label, non-comparator OPTIMA study (NCT02161562) was to evaluate omalizumab response in patients with CIU/CSU who step up therapy from 150 to 300 mg.
Methods: Patients with CIU/CSU and symptomatic despite H1-antagonists were randomized 4:3 to omalizumab 150 or 300 mg for 24 weeks (1st dosing period). All well-controlled patients (UAS7 $\leq$ 6) were then subjected to treatment withdrawal for up to 8 weeks. The patients whose symptoms came back (UAS7 $\geq$ 16) within this timeframe were retreated at the same dose. The patients who did not achieve remission during the 1st dosing period were either: (1) stepped-up (150–300 mg) if symptoms were not controlled after $\geq$ 8 and $\leq$ 24 weeks; or (2) had treatment extension if symptoms were not well-controlled with 300 mg at 24 weeks.
Results: A total of 314 patients (73% female, 79% white, mean age 46 years, mean baseline UAS7 score 29.8) were randomized to either 150 mg (n = 178) or 300 mg (n = 136) omalizumab. After initial treatment, 64.7% treated with 300 mg were well-controlled (UAS7 $\leq$ 6). In the 150 mg arm, 27 (15.2%) were well-controlled (UAS7 $\leq$ 6) and 141 stepped-up to 300 mg between week 8–24 as their symptoms were not controlled (UAS7 > 6). Most patients (115/141; 81.5%) up-dosed after 2.150 mg omalizumab doses (8 weeks), and the remaining 26 lost symptom control (UAS7 > 6) and up-dosed later during the initial dosing. One hundred and thirty (130) of the stepped-up patients completed the 3-dose step-up period. Of these, 59/130 (45.4%) patients achieved symptom control (UAS7 $\leq$ 6) and 33/130 (25.4%) had complete response (UAS7 = 0). In contrast, 55.9% of patients initially randomized to 300 mg achieved UAS7 $\leq$ 6 after three doses.
Conclusions: Most CIU/CSU patients treated with 150 mg omalizumab had to up-dose to 300 mg because of insufficient symptom control. About half of up-dosed patients achieved symptom control following 3 doses of 300 mg omalizumab.

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Omalizumab retreatment of patients with chronic idiopathic/spontaneous urticaria (CIU/CSU) after initial response and relapse: primary results of the OPTIMA Study

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Background: The primary objective of the Phase 3b, randomized, open-label, non-comparator OPTIMA study (NCT02161562) was to assess omalizumab retreatment of patients with CIU/CSU.
Methods: Patients with CIU/CSU and symptomatic despite H1-antagonists were randomized 4:3 to Omalizumab 150 or 300 mg for 24 weeks (1st dosing period). All well-controlled patients (UAS7 $\leq$ 6) were then subjected to treatment withdrawal for up to 8 weeks: Patients whose symptoms came back (UAS7 $\geq$ 16) within this timeframe were retreated at the same dose as in the 1st dosing period. The patients who did not achieve remission during the 1st dosing period were either: (1) stepped-up (150–300 mg) if symptoms were not controlled after $\geq$ 8 and $\leq$ 24 weeks; or (2) had treatment extension if symptoms were not well-controlled with 300 mg at 24 weeks.
Results: There were 314 patients (73% female, 79% white, mean age 46 years, mean baseline UAS7 score 29.8) randomized to either 150 mg (n = 178) or 300 mg (n = 136) Omalizumab. After 1st dosing period, 15.2% (150 mg dose) and 64.7% (300 mg dose) of patients were well-controlled. After withdrawal, 44% of patients on 150 mg and 50% on 300 mg relapsed within 8 weeks. Mean time to relapse was 4.8 (150 mg) and 4.7 (300 mg) weeks. Upon retreatment, most patients achieved UAS7 $\leq$ 6 (150 mg: 83.3% [95% CI, 62.2 – 100%]; 300 mg: 89.2% [95% CI, 79.2 – 99.2%]). In responders, mean time to response was similar between the 1st and 2nd dosing periods (3.5 vs 3.1 weeks). Of all retreated patients (n = 56), 80% (1st period) and 85% (2nd period) achieved symptom control (UAS7 $\leq$ 6) and 63% (1st period) and 56% (2nd period) achieved complete response (UAS7 = 0) after two doses. Omalizumab was well-tolerated throughout.
Conclusions: Omalizumab retreatment is safe and effective in patients with CIU/CSU who respond to initial treatment and later relapse; most patients regain symptom control after a 2nd course.

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Design and rationale of OPTIMA, a study to evaluate retreatment, extension, or step-up therapy with omalizumab in patients with chronic idiopathic/spontaneous urticaria (CIU/CSU)

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