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.

## A74

### 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.

## A75

### 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.

## A76

### 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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**Background:** In Phase 3 studies, subcutaneous Omalizumab (150 or 300 mg every 4 weeks for 24 weeks) was safe and effective in treating symptoms associated with CIU/CSU. OPTIMA (NCT02161562) is a novel study addressing remaining gaps in knowledge of optimal CIU/CSU treatment.
**Design:** 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 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. The entire study was 53 weeks. To observe a sufficient number of relapses after initial dosing with 150 or 300 mg, 314 patients were enrolled.
**Analysis:** The primary endpoint was the proportion of patients who were clinically well controlled (UAS7 $\leq$ 6) after the initial dosing phase, relapsed (UAS7 $\geq$ 16) upon withdrawal, and who achieved a UAS7 score $\leq$ 6 at the end of the second dosing phase. Key secondary endpoints include: change in UAS7 score and proportion of patients UAS7 $\leq$ 6 in those who step-up from 150 to 300 mg; change in UAS7 score in patients who extend 300 mg treatment; time to relapse in both doses.
**Conclusions:** This study helps identify appropriate Omalizumab treatment in CIU/CSU patients who relapse or are not well controlled after initial treatment.

## A77

### Assessing the validity and reliability of a penicillin allergy de-labeling questionnaire in pediatric patients

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**Background:** Among patients who report a penicillin allergy, more than 80% have negative testing. Patients can be erroneously labeled with a penicillin allergy due to a misclassification of the suspected reaction. This study seeks to validate a questionnaire and assessment tool that will guide physicians in identifying penicillin allergy risk groups among pediatric patients.
**Methods:** The questionnaire was developed by pediatric allergists to assess history of possible penicillin allergy. Subjects are recruited from referrals to the allergy clinic for penicillin allergy assessment. Pharmacists and allergists administer the questionnaire to participants during the visit. The questionnaire answers will be assessed for inter-rater reliability. The allergist assessment and outcome from the clinic visit will be compared with follow up clinical assessment and decision forms (completed by allergy and non-allergy physicians) to assess validity.
**Results:** We report the results of a preliminary analysis from the first 24 patients recruited between November 2016 and March 2017. 46% were male and the median age was 7 years. 79% received amoxicillin. 71% subjects reported a maculopapular rash, 42% of subjects reported urticaria. Symptoms lasted > 48 h in 55% of cases. 96% of subjects had consulted medical advice. Skin testing was not indicated in 66%. 19 subjects received amoxicillin oral challenge, and none reacted. Of 24 subjects assessed, 22 (91%) were found not to be allergic, one was deemed allergic to penicillin and one was diagnosed with severe adverse drug reaction.
**Conclusions:** Most patients received amoxicillin and presented with prolonged maculopapular rashes or urticaria. The majority of subjects referred were deemed not allergic after an allergist assessment. Most patients are not deemed allergic based on history alone and pass drug challenges, without need for skin testing. The availability of a clinical tool to guide physicians in assessing risk level for possible penicillin allergy would decrease risk of erroneous penicillin allergy labels.