

### *Statistical Analysis*

FEV<sub>1</sub> in the OCS dependent and non-OCS dependent subgroups was examined using two repeated measures analyses. The models had covariates for treatment group, region, number of exacerbations in the year prior to the study (on the basis of patient recall and case-note review), visit, and baseline pre-bronchodilator FEV<sub>1</sub>, visit by baseline pre-bronchodilator FEV<sub>1</sub> and visit by treatment group interactions we also included. All data up to the time of study discontinuation were included for patients who withdrew prematurely.

As described previously, the number of exacerbations per year in the OCS dependent and non-OCS dependent populations were analysed with separate negative binomial generalized linear models with log-link functions.<sup>3</sup> The models had covariates for treatment group, region, exacerbations in the year prior to the study (on the basis of patient recall and case-note review), and baseline percentage of predicted pre-bronchodilator FEV<sub>1</sub>, time on treatment was included as an offset variable. A separate model was used to assess the interaction between treatment and baseline OCS therapy, this model included the same covariates as the subgroup models plus covariates for baseline maintenance OCS therapy and an interaction term between baseline maintenance OCS therapy and treatment group. All analysis were conducted with SAS (versions 9.1.3 and 9.2; SAS Institute, Cary, NC, USA).

**Table 3: Exacerbation History and Related Healthcare Utilization Events**

	Non-OCS dependent	OCS dependent
% population with history in the past 12 months of:		
2 exacerbations	55	25
>2 exacerbations	44	75
% population reporting 1 or more prior hospitalization for an exacerbation	22	25
% population reporting prior intubation(s) for exacerbation	3	7
% population reporting prior near fatal event for exacerbation	8	17

\* one subject in the non-OCS dependent population had reported only one exacerbation at baseline and was considered a protocol violator