RWE Observational Study Report –Database Study

Drug Substance	Budesonide/Formoterol
Study Code	000202
Edition Number	V4
Date	V4:

A U.S. Retrospective Database Analysis Evaluating the Comparative Effectiveness of Budesonide/Formoterol (BFC) and Tiotropium Bromide among COPD Patients

Product Name: BFC

RWE Team Members:

Requesting department

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Table 12. PRIMARY OUTCOME: Time to first COPD exacerbation during the 12-month post-index period

	BFC (n=1,198)			Tiotropium (n=1,198)			Hazard ratio[1]	95% CI[1]		P-value[1]
	N	%	Median	N	%	Median		Lower	Upper	
Number of patients	1,198			1,198			0.78	0.70	0.87	<.0001
Primary outcome: time to first COPD exacerbation * Median time (days) to first COPD exacerbation for all patients (from Kaplan-Meier analysis)			351.5			243.0				
Number of patients with ≥ 1 COPD exacerbation (n, %)	607	50.7%		710	59.3%					
Additional statistics	Mean	SD	Median	Mean	SD	Median				
Time (days) to first COPD exacerbation (mean, sd, median) within patients having at least one exacerbation	127	105	95	119	101	92				

* A COPD exacerbation is defined as any of the following:
(1) COPD related inpatient hospitalization (inpatient hospitalization with a primary diagnosis for COPD) ;
(2) COPD related emergency department (ED) visit (an ED visit with a diagnosis in any position for COPD);
(3) A pharmacy claim for OCS and/or antibiotics on the same day as or within 10 days after an office/outpatient visit with a diagnosis for COPD.

Note: ED visits that result in a hospital stay were counted as an inpatient hospitalization only. Any OCS or antibiotic prescription fill occurring within 14 days of an ED/inpatient hospitalization was counted as the hospitalization only and not a separate event. Multiple OCS and/or antibiotic fills within 10 days of the same outpatient visit were only counted as one event.
1: Hazard ratios are from Cox Proportional Hazards models. Statistical comparisons are comparing BFC to tiotropium (reference group), where the hazard ratio is Hazard (BFC) / Hazard (tiotropium). Model covariates were selected using forward selection from all the following variables that were not balanced: prescribing physician type (cardiologist), comorbid conditions (Allergic rhinitis, Sinusitis, and Obesity). However, no covariates met the selection criteria to enter the final model.

Table 14. SECONDARY OUTCOME: COPD exacerbation rate during the 12-month post-index period

	Exacerbation Rate[1]		Rate ratio[2]	95% CI[2]		P-value[2]
	BFC	Tiotropium		Lower	Upper	
Number of patients	1,198	1,198				
COPD exacerbation Rate	1.23	1.50	0.82	0.73	0.91	0.0004
Due to COPD-related inpatient hospitalization	0.11	0.13	0.80	0.59	1.09	0.1649
Due to COPD-related ED visit	0.19	0.25	0.76	0.60	0.95	0.0141
Due to COPD outpatient/office visit + OCS and/or antibiotics	0.93	1.12	0.83	0.73	0.94	0.0038

1: The total number of exacerbations in the study population divided by total person years. Because all persons contribute exactly one year this rate is simply (# of exacerbations) /(# of patients)only and not a separate event. Multiple OCS and/or antibiotic fills within 10 days of the same outpatient visit were only counted as one event.

2: The rate ratio is from a negative binomial regression model. Statistical comparisons are comparing BFC to tiotropium (reference group), where the rate ratio is ExacerbationRate(BFC) / ExacerbationRate(tiotropium). No covariates were adjusted in the model.