RWE Observational Study Report –Database Study

Drug Substance	Symbicort
Study Code	000152
Edition Number	V6
Date	V1:

A U.S. Retrospective Database Analysis Evaluating the Comparative Effectiveness of Budesonide/Formoterol (BFC) vs. Fluticasone/Salmeterol (FSC) Combination in Patients with COPD

Product Name: Budesonide/Formoterol (Symbicort™)

RWE Team Members:

Requesting department

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Table 1. PRIMARY OUTCOME: COPD exacerbation rate during the 12- month post-index period

	Adjusted Rate[1]		Rate ratio[1]	95% CI[1]		P-value[1]
	BFC (n=3,697)	FSC (n=3,697)		Lower	Upper	
COPD exacerbation Rate	0.88	0.86	1.02	0.96	1.09	0.5637
Due to COPD-related inpatient hospitalization	0.06	0.07	0.96	0.79	1.16	0.6644
Due to COPD-related ED visit	0.14	0.13	1.11	0.97	1.28	0.1304
Due to COPD outpatient/office visit + OCS and/or antibiotics	0.67	0.66	1.01	0.94	1.09	0.7153

1: Adjusted exacerbation rates and the rate ratio are from a negative binomial regression model. Statistical comparisons are comparing BFC to FSC (reference group), where rate ratio is Rate(BFC) / Rate(FSC).
Model covariates include: Sum of inpatient hospital stays >5 days (0 vs. 1), LTRA use (0, 1, 2+), geographic region, Peripheral vascular disease / atherosclerosis (0 vs. 1), index prescribing physician specialty, and analogous pre-index variable (i.e. when analyzing the number of COPD related hospitalizations in the post-index, the model will control for the number of pre-index COPD related hospitalizations).
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: 1) Exacerbations occurring within 14 days of each other were calculated as one event. 2) ED visits that result in a hospital stay were counted as an inpatient hospitalization only. 3) 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. 4) Multiple OCS and/or antibiotic fills within 10 days of the same outpatient visit were only counted as one event.

Table 2. SECONDARY OUTCOME: COPD exacerbation event during the 12-month post-index period

	BFC		FSC (ref.)			95% CI		
	N/Mean	%/SD	N/Mean	%/SD	Estimate*	Lower	Upper	P-value
Number of patients	3,697	100.0%	3,697	100.0%				
Composite COPD exacerbation event								
Number of patients with ≥1 event (n, %)	1,759	47.6%	1,738	47.0%	1.03	0.94	1.13	0.5111
Patients with 0 event	1,938	52.4%	1,959	53.0%	1.03	0.94	1.12	0.5552
Patients with 1 event	889	24.0%	901	24.4%				
Patients with 2+ events	870	23.5%	837	22.6%				
Number of events (mean,sd)	1.0	1.5	1.0	1.5	0.02	-0.04	0.07	0.5637