

Once-Daily Triple Therapy in Patients with Advanced COPD: Healthcare Resource Utilization Data and Associated Costs from the FULFIL trial

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Online Data Supplement

METHODS

FULFIL Inclusion/Exclusion Criteria

Patients were required to be receiving daily maintenance therapy for COPD for ≥ 3 months, with medications at screening that continued unchanged during the 2-week run-in period. Patients were excluded if they had a current diagnosis of asthma, COPD caused by $\alpha 1$ -antitrypsin deficiency, other respiratory disorders, lung resection within 12 months of screening, or any other clinically significant diseases. Patients who had pneumonia or a severe COPD exacerbation that had not resolved within 14 days of screening, a respiratory tract infection that had not resolved within 7 days of screening, or an abnormal chest X-ray were also excluded.

Table S1 Patient characteristics at baseline, in the ITT and EXT populations

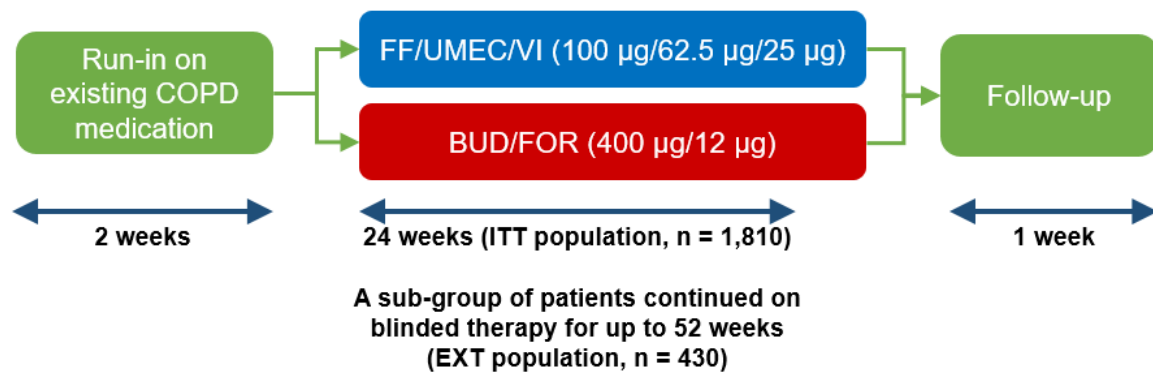
Baseline characteristic	ITT population		EXT population	
	FF/UMEC/VI		FF/UMEC/VI	
	100/62.5/25	BUD/FOR	100/62.5/25	BUD/FOR
	µg	400/12 µg	100/62.5/25 µg	400/12 µg
	(n = 911)	(n = 899)	(n = 210)	(n = 220)
Age, mean years (SD)	64.2 (8.56)	63.7 (8.71)	63.7 (7.76)	63.3 (8.43)
Female, n (%)	233 (26)	236 (26)	53 (25)	58 (26)
Current smokers, n (%)	400 (44)	394 (44)	95 (45)	97 (44)
Smoking pack-years, mean (SD)	39.5 (21.87)	39.2 (22.15)	39.8 (19.92)	39.6 (23.12)
Moderate COPD exacerbations in previous 12 months, n (%)				
0	475 (52)	488 (54)	115 (55)	125 (57)
1	125 (14)	125 (14)	33 (16)	34 (15)
≥2	311 (34)	286 (32)	62 (30)	61 (28)
Severe COPD exacerbations in previous 12 months, n (%)				
0	726 (80)	699 (78)	152 (72)	163 (74)
1	167 (18)	177 (20)	53 (25)	52 (24)
≥2	18 (2)	23 (3)	5 (2)	5 (2)
FEV ₁ , mean (SD)	1.28 (0.46)	1.27 (0.47)	1.33 (0.50)	1.28 (0.48)
% predicted FEV ₁ , mean (SD)	42.5 (13.01)	41.8 (13.48)	44.1 (13.36)	41.7 (14.07)
CAT score ^a , mean (SD)	17.6 (6.43)	17.8 (6.24)	18.1 (6.29)	17.7 (5.93)
Number of occasions of rescue medication use per day, mean (SD)	1.8 (2.07)	1.8 (2.04)	1.6 (1.95)	1.5 (1.87)

BUD/FOR budesonide/formoterol; *CAT* COPD Assessment Test; *COPD* chronic obstructive

pulmonary disease; *EXT* extension; *FEV₁* forced expiratory volume in 1 second; *FF/UMEC/VI*

fluticasone furoate/umeclidinium/vilanterol; *ITT* intent-to-treat; *SD* standard deviation. ^aScale: mild, 0–9; moderate, 10–19; severe, 20–29; very severe, ≥30

Figure S1. FULFIL study design.



BUD/FOR = budesonide/formoterol; COPD = chronic obstructive pulmonary disease;
EXT = extension; FF/UMEC/VI = fluticasone furoate/umeclidinium/vilanterol; ITT =
intent-to-treat.