Erratum to the FDA Briefing Package

Please note the following corrections to the FDA Briefing Package. Deletions are marked by a strikethrough. Corrections are highlighted.

1. Page 7:
    a. "Cipro DPI was evaluated in two Phase 3 randomized, double-blind, placebo-controlled trials of ~~933~~ 937 subjects with non-cystic fibrosis bronchiectasis (NCFB) in the full analysis set (FAS). Of these, 933 were treated (safety analysis set): 622 subjects received at least one dose of Cipro DPI…"

2. Page 10:
    a. "RESPIRE 1 randomized 416 subjects and RESPIRE 2 randomized 521 subjects. The sample size in RESPIRE 2 was increased to 521 subjects due to a ~~higher~~ lower than expected ~~dropout~~ exacerbation rate with respect to ~~observed in~~ RESPIRE 1."

3. Page 12:
    a. In Table 2, the value for "Chronic Macrolide Use", "No" for RESPIRE 2 Cipro 28, should be changed from 9.8 to 91.8.

4. Page 13:
    a. Four changes as noted in the following table.

Table 1: NCFB history for subjects in RESPIRE 1 and 2– integrated analysis (FAS)

	RESPIRE 1			RESPIRE 2		
NCFB, n (%)	**Cipro 28 (N=141)**	**Cipro 14 (N=137)**	**Pooled Placebo (N=138)**	**Cipro 28 (N=171)**	**Cipro 14 (N=176)**	**Pooled Placebo (N=174)**
Etiology						
Idiopathic	70 (49.6)	81 (59.1)	75 (54.3)	43 (25.1)	62 (35.2)	68 (39.1)
Post-Infective	68 (48.2)	59 (39.4)	62 (44.9)	126 (73.7)	113 (64.2)	106 (60.9)
Other	3 (2.1)	2 (1.5)	1 (0.7)	2 (1.2)	1 (0.6)	0
Number of acute exacerbations in the previous 12 months						
1	0	1 (0.7)	0	0	0	0
2	79 (56.0)	72 (52.6)	76 (55.1)	136 (79.5)	134 (76.1)	136 (78.2)
3	34 (24.1)	36 (26.3)	29 (21.0)	22 (12.9)	26 (14.8)	25 (14.4)
4	10 (7.1)	8 (5.8)	21 (15.2)	9 (5.3)	10 (5.7)	7 (4.0)
> 4	18 (12.8)	19 (13.9)	12 (8.6)	4 (2.3)	6 (3.4)	6 (3.4)
Number of exacerbation episodes with sputum culture performed						
0	60 (42.6)	65 (47.4)	60 (43.5)	83 (48.5)	83 (47.2)	71 (40.8)
1	52 (36.9)	43 (31.4)	47 (34.1)	52 (30.4)	60 (34.1)	63 (36.2)
2	18 (12.8)	18 (13.1)	24 (17.4)	32 (18.7)	25 (14.2)	35 (20.1)
3	7 (5.0)	5 (3.6)	5 (3.6)	3 (1.8)	6 (3.4)	4 (2.3)
> 3	4 (2.8)	5 (3.6)	2 (1.4)	~~4 (2.3)~~ 1 (0.6)	~~8 (4.5)~~ 2 (1.1)	~~5 (2.9)~~ 1 (0.6)

Number of exacerbation episodes with systemic antibiotic treatment						
0	9 (6.4)	7 (5.1)	7 (5.1)	3 (1.8)	6 (3.4)	4 (2.3)
1	11 (7.8)	9 (6.6)	10 (7.2)	14 (8.2)	9 (5.1)	12 (6.9)
2	64 (45.4)	62 (45.3)	63 (45.7)	121 (70.8)	131 (74.4)	123 (70.7)
3	30 (21.3)	32 (23.4)	25 (18.1)	20 (11.7)	17 (9.7)	22 (12.6)
> 3	27 (19.2)	24 (17.5)	33 (23.8)	13 (7.6)	13 (7.4)	13 (7.5)
Number of exacerbation episodes with hospitalization						
0	113 (80.1)	106 (77.4)	105 (76.1)	106 (62.0)	96 (54.5)	100 (57.5)
1	20 (14.2)	23 (16.8)	24 (17.4)	38 (22.0)	36 (21.0)	40 (23.0)
2	7 (5.0)	4 (2.9)	5 (3.6)	24 (14.0)	35 (19.9)	29 (16.7)
3	1 (0.7)	0	3 (2.2)	3 (1.8)	7 (4.0)	4 (2.3)
> 3	0	3 (2.2)	1 (0.7)	0	1 (0.6)	1 (0.6)
Scan compatible with BE						
No	4 (2.8)	3 (2.2)	0	0	0	0
Yes	137 (97.2)	134 (97.8)	138 (100)	171 (100)	176 (100)	174 (100)
Type of CT scan						
CT Scan	30 (21.3)	26 (19.0)	27 (19.6)	93 (54.4)	84 (47.7)	85 (48.9)
HRCT	111 (78.7)	111 (81.0)	111 (80.4)	78 (45.6)	92 (52.3)	89 (51.1)

5. Page 14:
    a. Three changes as noted in the following table.

Table 2: Number of subjects with baseline pathogens in sputum culture – (FAS)

	RESPIRE 1			**RESPIRE 2**		
Organisms Identified, n (%)	**Cipro 28 (N=141)**	**Cipro 14 (N=137)**	**Pooled Placebo (N=138)**	**Cipro 28 (N=171)**	**Cipro 14 (N=176)**	**Pooled Placebo (N=174)**
Number of subjects (denominator)	**141 (100)**	**137 (100)**	**138 (100)**	**~~129~~170 (100)**	**~~113~~176 (100)**	**~~112~~173 (100)**
H. influenzae	34 (24.1)	34 (24.8)	42 (30.4)	38 (22.4)	25 (14.2)	27 (15.6)
M. catarrhalis	9 (6.4)	7 (5.1)	9 (6.5)	8 (4.7)	11 (6.3)	11 (6.4)
P. aeruginosa	83 (58.9)	83 (60.6)	86 (62.3)	99 (58.2)	107 (60.8)	109 (63.0)
S. maltophilia	2 (1.4)	9 (6.6)	0	7 (4.1)	8 (4.5)	5 (2.9)
B. cepacia	0	0	0	1 (0.6)	0	3 (1.7)
S. aureus	34 (24.1)	26 (19.0)	29 (21.0)	42 (24.7)	43 (24.4)	47 (27.2)
S. pneumoniae	11 (7.8)	11 (8.0)	12 (8.7)	14 (8.2)	11 (6.3)	10 (5.8)
Other	3 (2.1)	1 (0.7)	5 (3.6)	0	0	0

6. Pages 22 and 34:
    a. Table 8 footnote #2 (p. 22) and Table 14 footnote #4 (p. 34): the confidence intervals used for RESPIRE 1&2 Combined analyses should be changed from 95% to 97.5%.

7. Page 32:
    a. Table 13, Ciprofloxacin-14, RESPIRE 1, the Hazard Ratio should be changed from 0.58 to 0.75.