Impact of baseline disease extent on efficacy of obefazimod in patients with moderately to severely active ulcerative colitis: pooled results from ABTECT-1 and ABTECT-2 phase 3 trials

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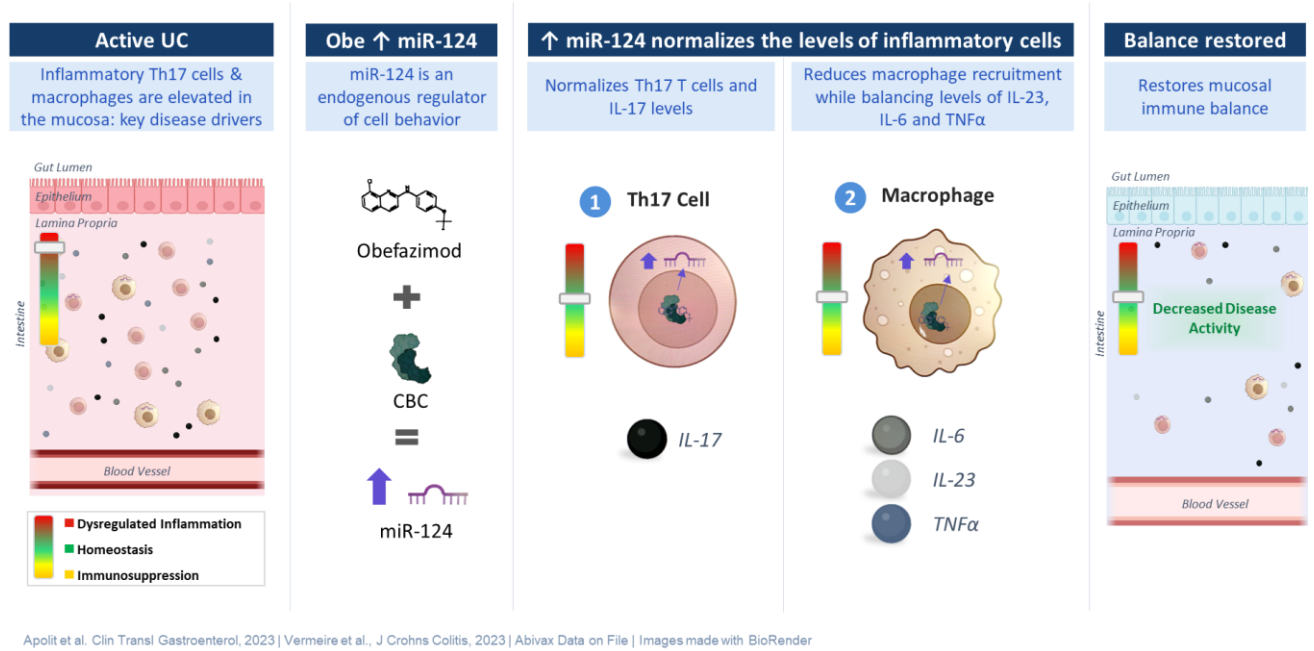
Disclosure of Conflicts of Interest

Consulting and/or speaking fees from:

Abbvie, Alfasigma, Amgen, AstroPharma, MSD, Falk, Ferring, Galapagos, Gilead, Lilly, Janssen, Pfizer, Roche, Shire, Stada, Takeda, Vifor.

Obefazimod MOA

Obefazimod restores immune mucosal balance in ulcerative colitis (UC) through physiologic immunoregulation of Th17 cells and macrophages



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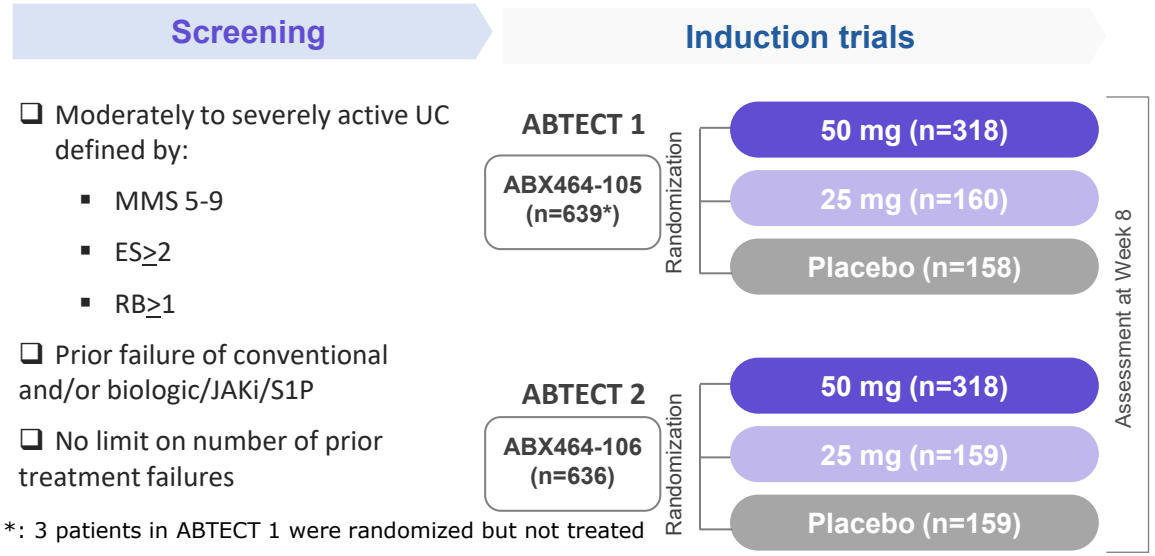
Design of ABTECT induction trials

pts categorized by baseline disease extent as designated by investigator:

- proctosigmoiditis
- left-sided colitis
- extensive colitis



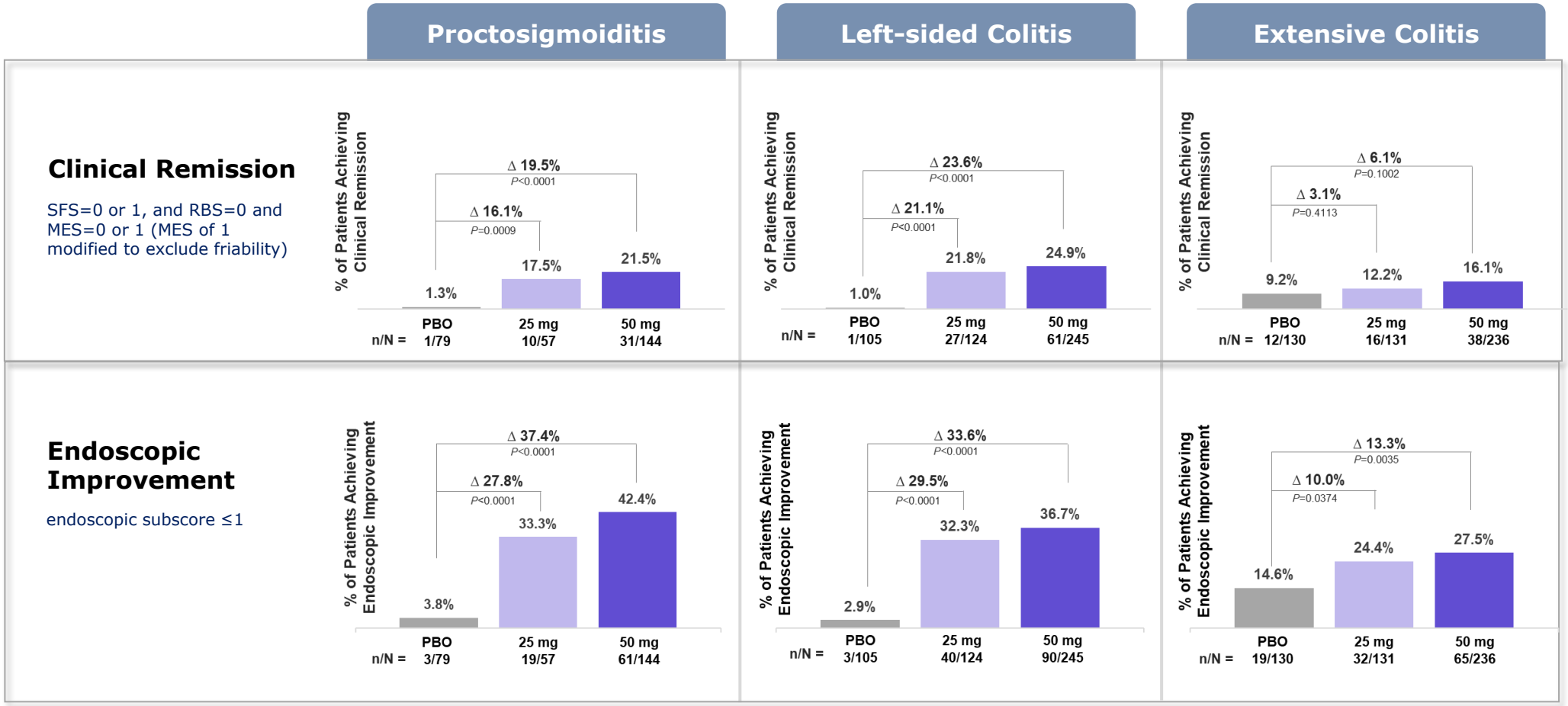
*: 3 patients in ABTECT 1 were randomized but not treated

Demographic and baseline characteristics

Baseline disease extent:		Pts with proctosigmoiditis (N1=280)			Pts with left-sided colitis (N1=474)			Pts with extensive colitis (N1=497)		
		Obe-25 (N=57)	**Obe-50 (N=144)**	**PBO (N=79)**	**Obe-25 (N=124)**	**Obe-50 (N=245)**	**PBO (N=105)**	**Obe-25 (N=131)**	**Obe-50 (N=236)**	**PBO (N=130)**
Age (yr), mean (SD)		44.5 (11.7)	43.3 (14.5)	45.9 (14.0)	41.9 (13.1)	42.4 (13.3)	43.3 (14.2)	39.5 (13.9)	41.3 (14.2)	39.0 (13.5)
Baseline MMS, mean (SD)		6.9 (1.0)	6.8 (1.2)	6.9 (1.0)	6.9 (1.1)	7.0 (1.1)	6.9 (1.1)	6.9 (1.0)	6.9 (1.0)	6.8 (1.0)
Endoscopic subscore 3, n (%)		33 (57.9)	78 (54.2)	53 (67.1)	69 (55.6)	143 (58.4)	63 (60)	88 (67.2)	149 (63.1)	70 (53.8)
Fecal Calprotectin (mg/g), median		1149.280	996.255	1052.505	1356.830	1422.900	1957.995	2137.850	1882.935	2340.705
Concomitant Corticosteroids, n (%)		17 (29.8)	69 (47.9)	26 (32.9)	55 (44.4)	97 (39.6)	47 (44.8)	47 (35.9)	92 (39)	52 (40)
ATIR-No, n (%)		38 (66.7)	81 (56.3)	45 (57)	71 (57.3)	138 (56.3)	59 (56.2)	60 (45.8)	103 (43.6)	64 (49.2)
ATIR-Yes, n (%)		19 (33.3)	63 (43.8)	34 (43)	53 (42.7)	107 (43.7)	46 (43.8)	71 (54.2)	133 (56.4)	66 (50.8)
Number of prior JAK-IR (% ATIR-Yes pts), n (%)		5 (26.3)	13 (20.6)	6 (17.6)	17 (32.1)	17 (15.9)	6 (13)	11 (15.5)	22 (16.5)	23 (34.8)
Number of prior AT-IR†, n (%)	0	38 (66.7)	81 (56.3)	45 (57)	71 (57.3)	138 (56.3)	59 (56.2)	60 (45.8)	103 (43.6)	64 (49.2)
	1	8 (14)	28 (19.4)	17 (21.5)	17 (13.7)	61 (24.9)	24 (22.9)	19 (14.5)	60 (25.4)	19 (14.6)
	2	2 (3.5)	15 (10.4)	8 (10.1)	18 (14.5)	20 (8.2)	10 (9.5)	24 (18.3)	29 (12.3)	16 (12.3)
	3	6 (10.5)	6 (4.2)	7 (8.9)	9 (7.3)	16 (6.5)	9 (8.6)	18 (13.7)	29 (12.3)	12 (9.2)
	4+	3 (5.3)	14 (9.7)	2 (2.5)	9 (7.3)	10 (4.1)	3 (2.9)	10 (7.6)	15 (6.4)	19 (14.6)

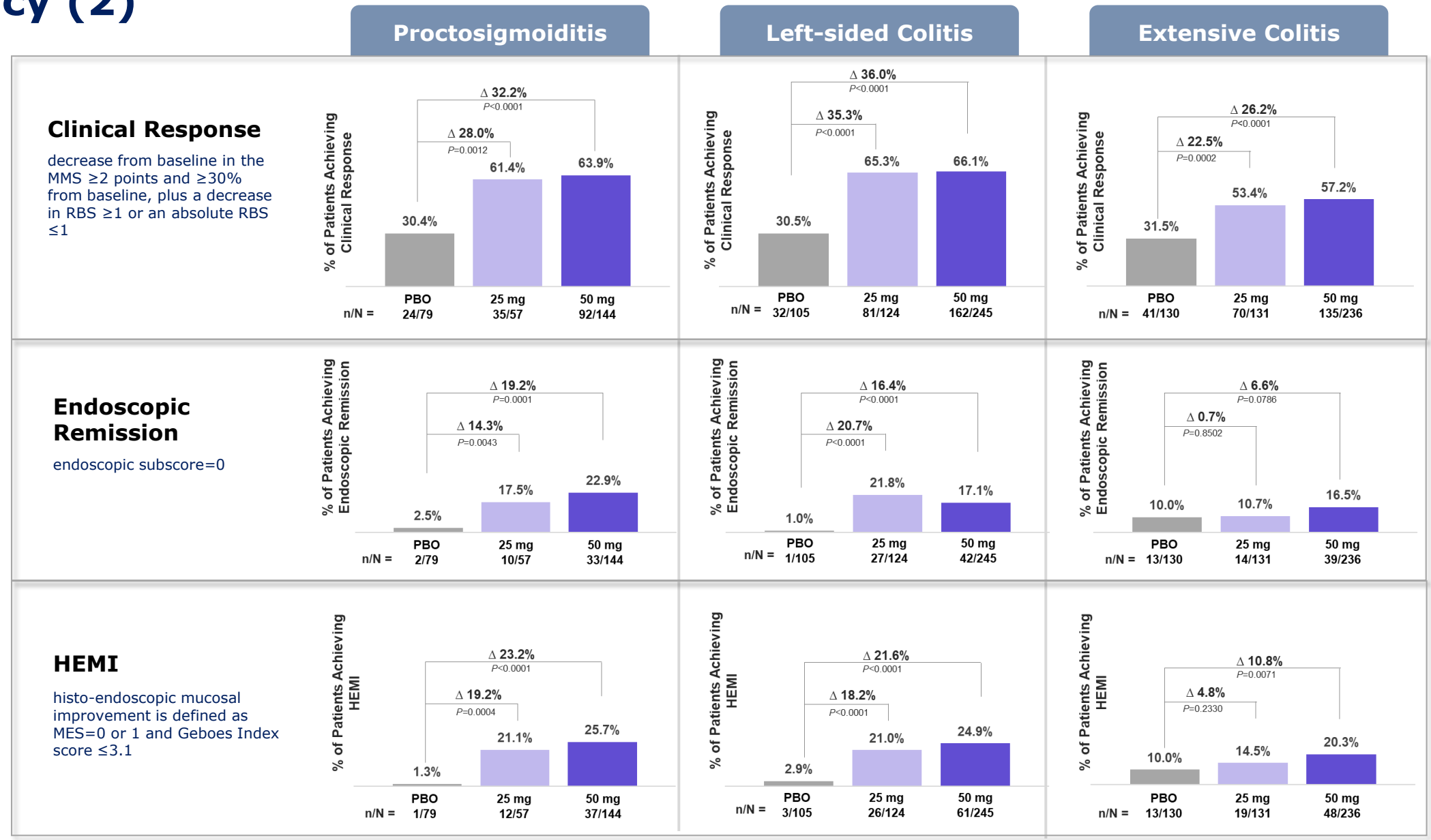
ATIR: inadequate response to advanced therapies; JAK: janus kinase; MMS: modified Mayo score; SD: standard deviation; %: n/N*100; N1 represents number of pts in each subgroup; †: ATIRs are counted by unique medication name (e.g. infliximab and adalimumab would be counted as 2 ATIRs)

Efficacy



Pooled analyses were not powered for statistical comparisons between subgroups; Statistical inferences are exploratory and all P values are nominal and 2-sided. NRI is used for subjects with missing outcome at week 8 and subjects reporting any IE prior to week 8; % difference is for Obe minus PBO and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), baseline oral corticosteroids usage (yes/no).

Efficacy (2)



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Conclusions

- In the ABTECT induction trials, obefazimod demonstrated consistent efficacy at week 8 across all baseline disease extents including proctosigmoiditis, left-sided, and extensive colitis.