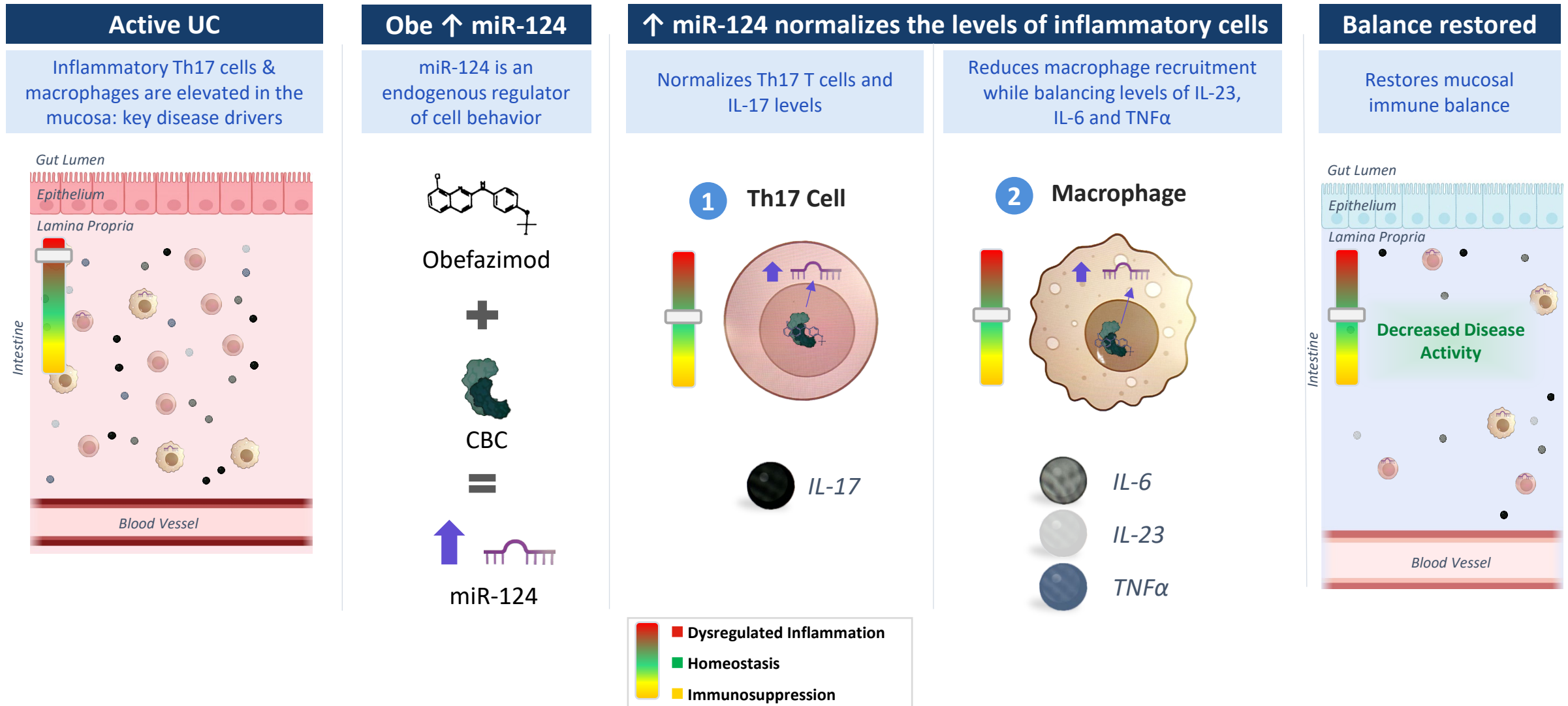


Rapid and Progressive Improvement with Obefazimod in Ulcerative Colitis in the ABTECT Induction Program: Subgroup Analysis by Prior Advanced Therapy Failure Status and Therapeutic Class

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



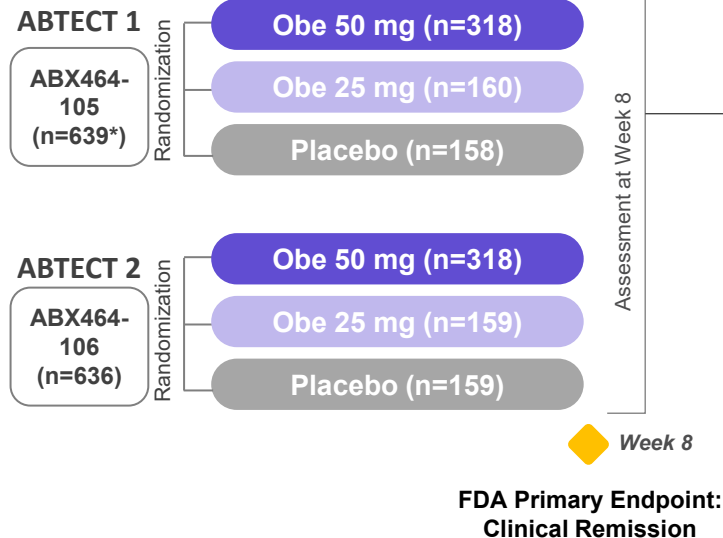
ABTECT Phase 3 Program: Obefazimod in Ulcerative Colitis

2 Induction Trials and 1 Maintenance Trial

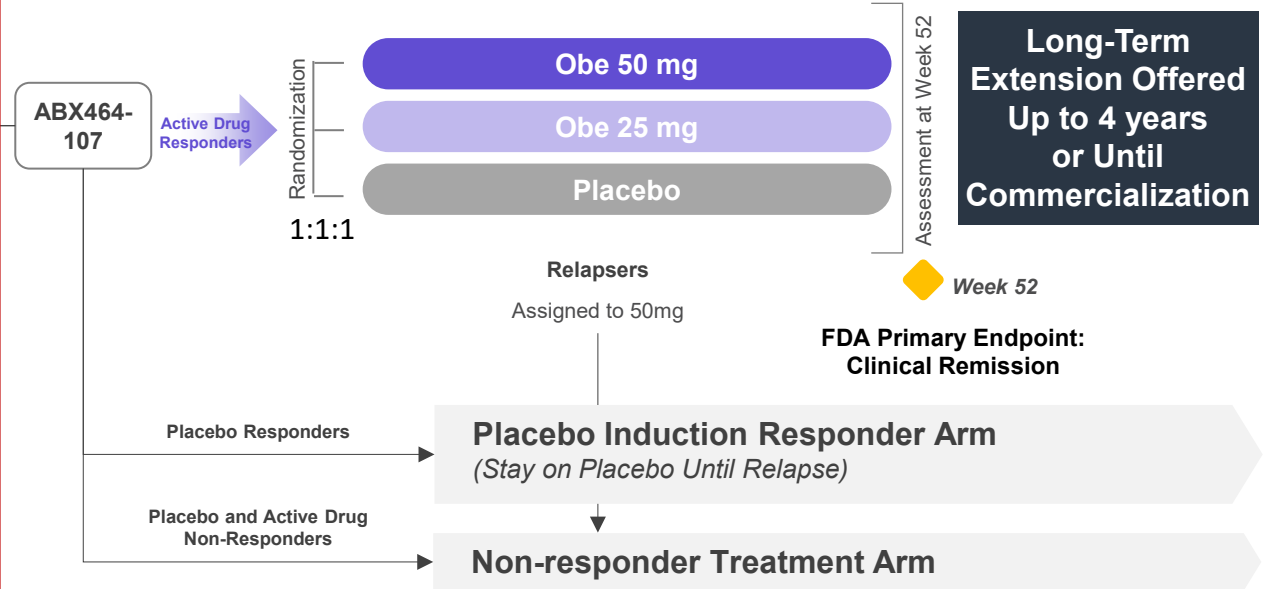
Screening

- ☐ Moderately to severely active UC defined by:
 - MMS 5-9, ES $\geq$ 2, RB $\geq$ 1
- ☐ Prior failure of conventional and/or biologic/JAKi/S1P
- ☐ No limit on number of prior treatment failures

Induction Trials



Maintenance Trial



This presentation will focus on the time to onset of symptomatic improvement and the impact of prior inadequate response to advanced therapy (AT-IR) by AT-IR status and AT class in patients from ABTECT induction trials

Baseline Characteristics: Generally well balanced

	Pooled ABTECT 1 & 2		
	Placebo (N=317)	Obe 25 mg (N=319)	Obe 50 mg (N=636)
Age (years), mean (SD)	42.3 (14.1)	41.4 (13.2)	42.1 (14.0)
Baseline MMS, mean (SD)	6.9 (1.0)	6.9 (1.0)	6.9 (1.1)
Endoscopic subscore 3, n (%)	189 (59.6)	194 (60.8)	378 (59.4)
Extensive Colitis	130 (41.0)	131 (41.1)	236 (37.1)
Fecal Calprotectin (µg/g), median	1902	1762	1564
Concomitant Corticosteroids	126 (39.7)	120 (37.6)	262 (41.2)
AT-IR Yes	148 (46.7)	146 (45.8)	308 (48.4)
Number of prior JAK-IR (% of AT-IR Yes Patients)	35 (23.6)	34 (23.3)	55 (17.9)
Number of prior AT-IR by medication name [†] , n (%)			
1	62 (19.6)	45 (14.1)	150 (23.6)
2	34 (10.7)	45 (14.1)	64 (10.1)
3	28 (8.8)	33 (10.3)	52 (8.2)
4+	24 (7.6)	23 (7.2)	42 (6.6)

Highly refractory population with ~21% of AT-IR failing a JAK inhibitor

[†] Medication name results in each individual advanced therapy being counted as a unique medication; e.g. infliximab + adalimumab would be counted as 2
Data on File ABX464-105 & ABX464-106

Pooled ABTECT 1 & 2: Both doses achieved clinically meaningful improvements across all efficacy endpoints

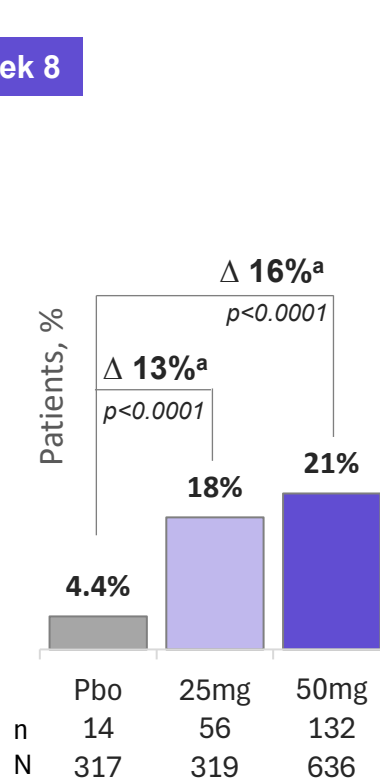
ABTECT-1

ABTECT-2

All p-values are nominal

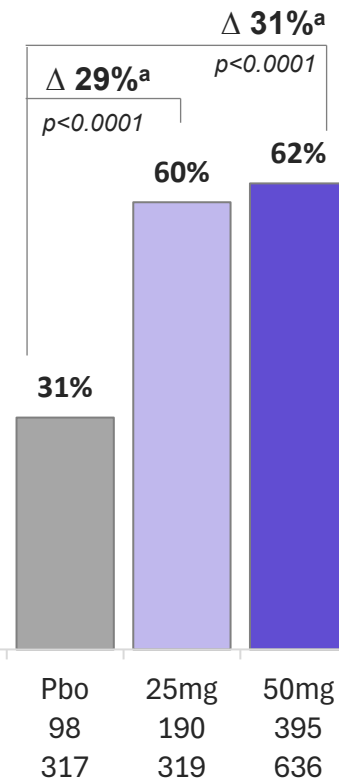
Primary Endpoint

At Week 8

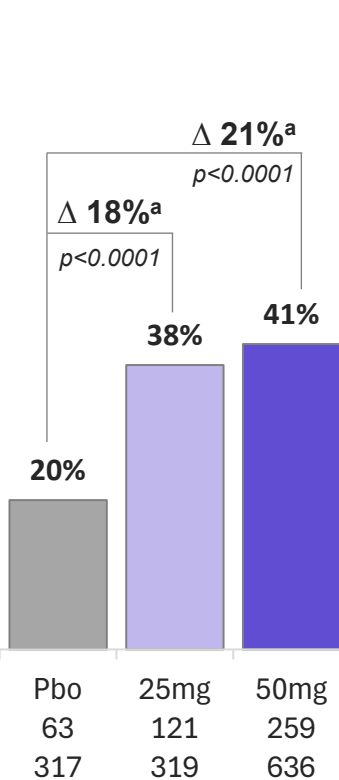


Clinical Remission

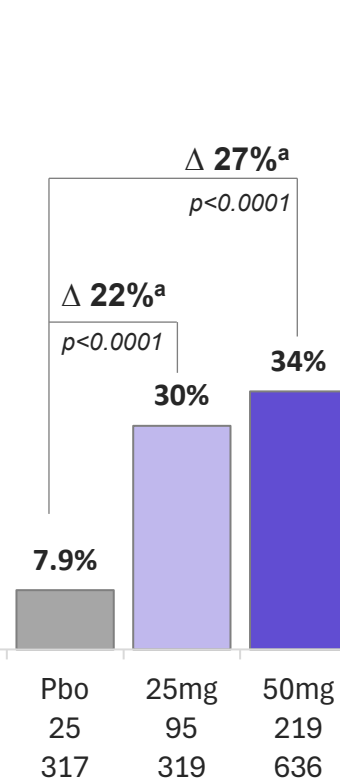
Key Secondary Endpoints



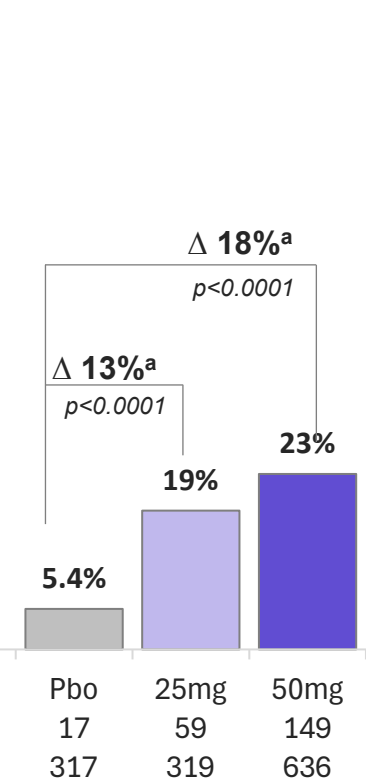
Clinical Response



Symptomatic Remission



Endoscopic Improvement



HEMI

Data on File ABX464-105 & ABX464-106;

[a] % Difference is for ABX464 minus placebo 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). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability). **Endoscopic improvement** is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).

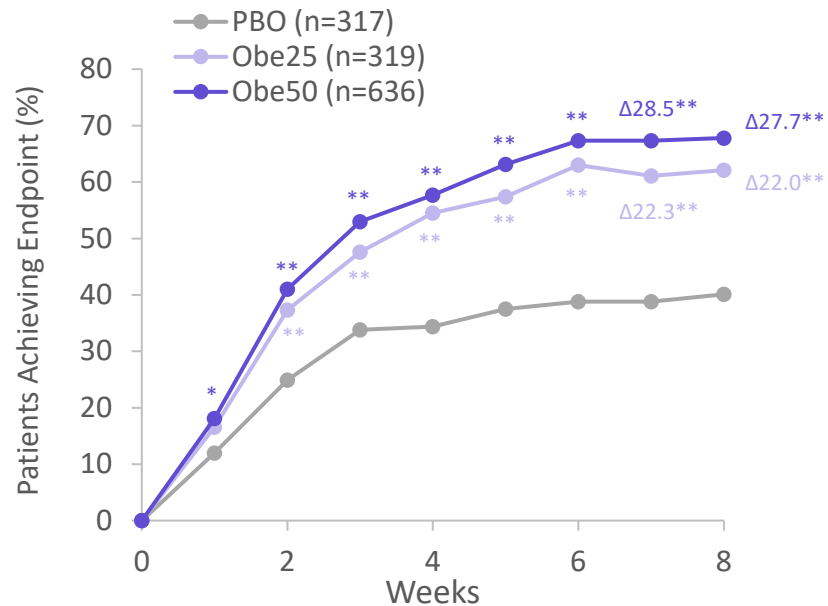
Clinical response is defined as a reduction from Baseline in MMS ≥ 2 points and a relative reduction from Baseline in MMS $\geq 30\%$, and a reduction from Baseline in RBS ≥ 1 point and/or RBS = 0 or 1.

HEMI is defined as MES = 0 or 1 and Geboes Index score ≤ 3.1 . **Symptomatic remission** is defined as RBS=0 and SFS=0 or 1

Pooled ABTECT trials: Proportion of patients achieving symptomatic response/remission over time (week 1 to week 8)

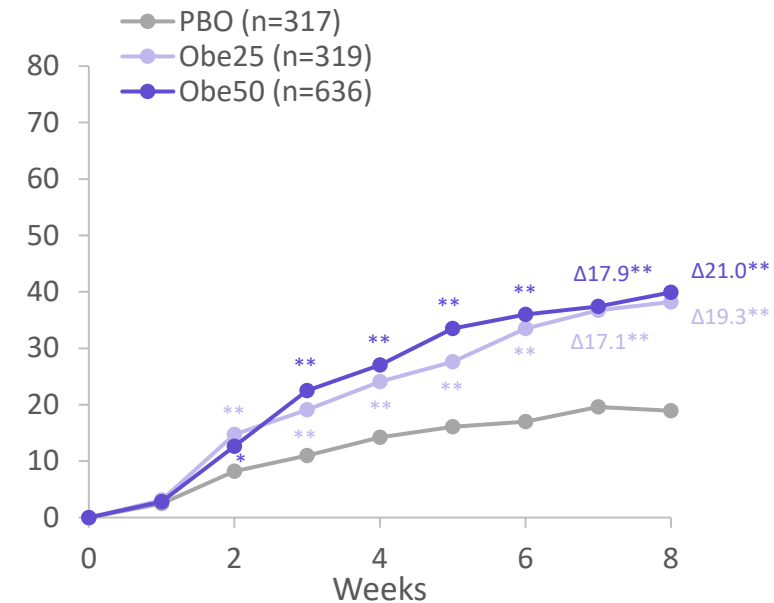
All p-values are nominal

Symptomatic Response



Symptomatic response by week 1

Symptomatic Remission

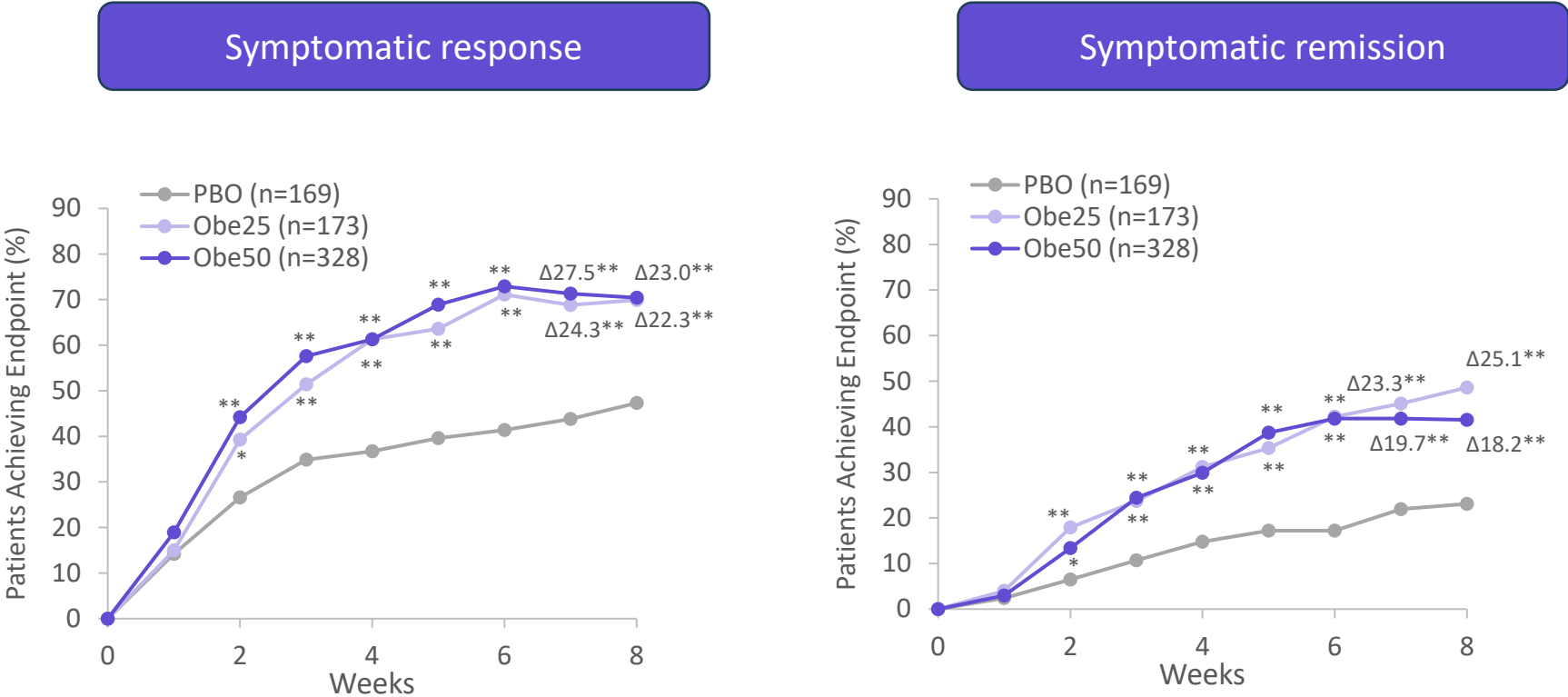


Symptomatic remission by week 2

Non-responder imputation (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 placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies, ATIR (yes/no), baseline oral corticosteroids usage (yes/no). Symptomatic response: a reduction from baseline in pMMS of ≥ 1 point and a relative reduction from baseline in pMMS of $\geq 30\%$, and a reduction from baseline in RBS of ≥ 1 point and/or RBS ≤ 1 . Symptomatic remission: RBS=0, SFS ≤ 1 ; IE, investigator event; NRI,; Obe, obefazimod; PBO, placebo. * $P < 0.05$; ** $P < 0.01$.

Pooled ABTECT trials: Proportion of patients without AT-IR (N=670) achieving symptomatic response/remission over time (week 1 to week 8)

All p-values are nominal



Non-responder imputation (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 placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies, ATIR (yes/no), baseline oral corticosteroids usage (yes/no). Symptomatic response: a reduction from baseline in pMMS of ≥ 1 point and a relative reduction from baseline in pMMS of $\geq 30\%$, and a reduction from baseline in RBS of ≥ 1 point and/or RBS ≤ 1 . Symptomatic remission: RBS=0, SFS ≤ 1 ; IE, investigator event; NRI,; Obe, obefazimod; PBO, placebo. * $P < 0.05$; ** $P < 0.01$.

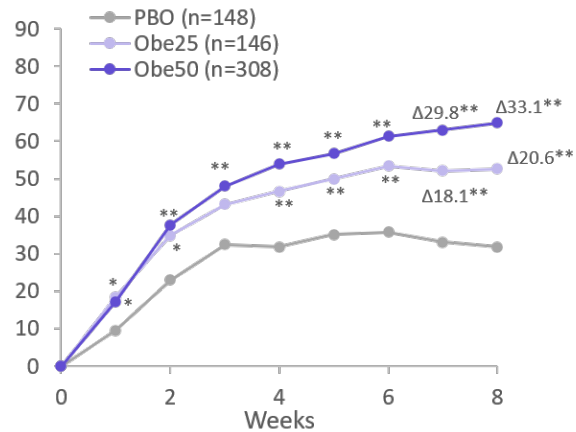
Pooled ABTECT trials: Proportion of patients at AT-IR achieving symptomatic response over time (week 1 to week 8), categorized by AT class

ABTECT-1

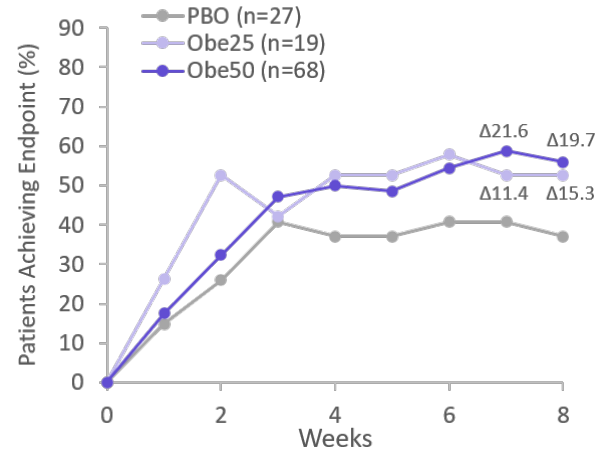
ABTECT-2

All p-values are nominal

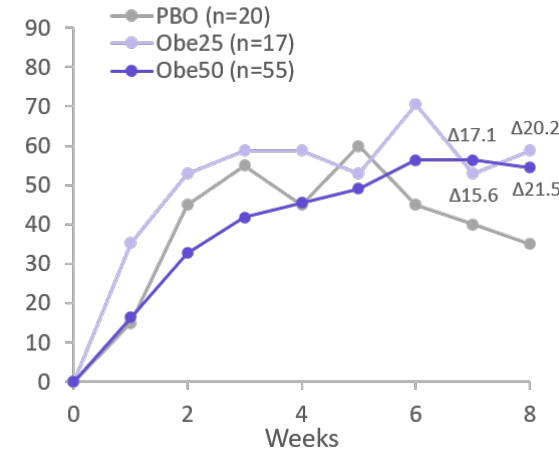
Patients AT-IR (N=602)



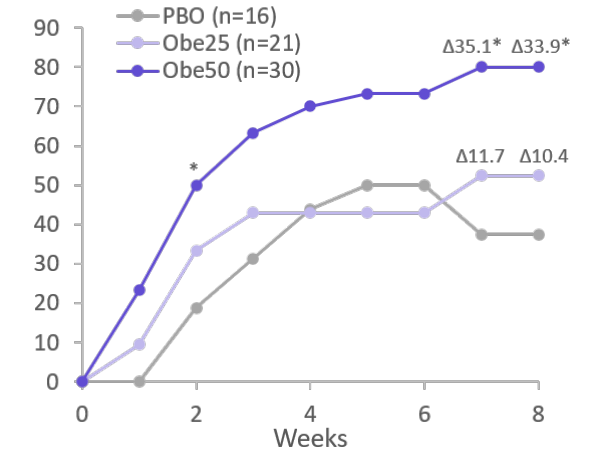
1 TNFi Only (N=114)



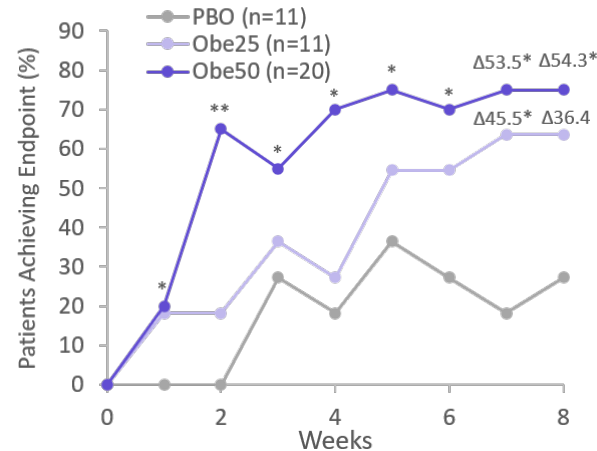
Vedolizumab Only (N=92)



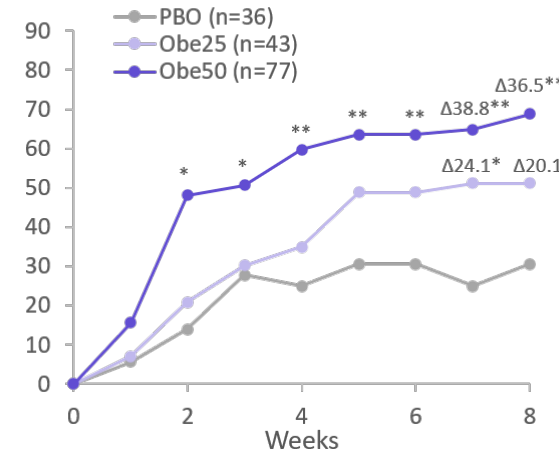
1 TNFi + Vedolizumab Only (N=67)



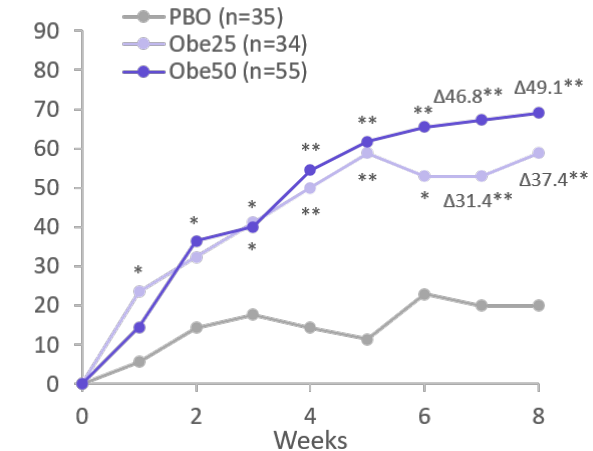
1 TNFi + Vedolizumab + Ustekinumab Only (N=42)



Ustekinumab in Any Line of Therapy (N=156)



JAKi in Any Line of Therapy (N=124)



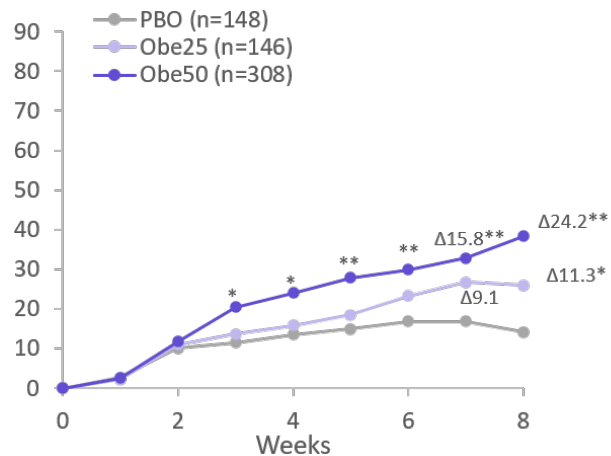
Pooled ABTECT trials: Proportion of patients at AT-IR achieving symptomatic remission over time (week 1 to week 8), categorized by AT class

ABTECT-1

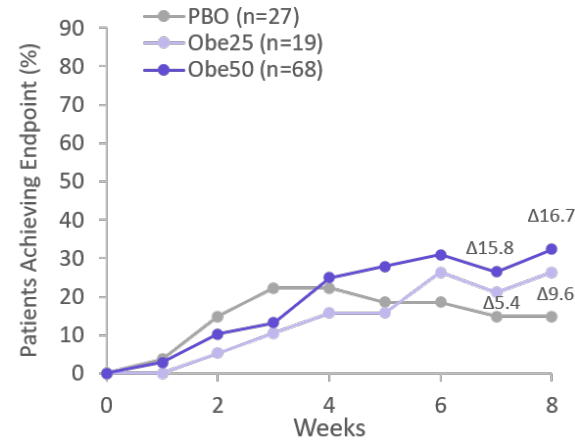
ABTECT-2

All p-values are nominal

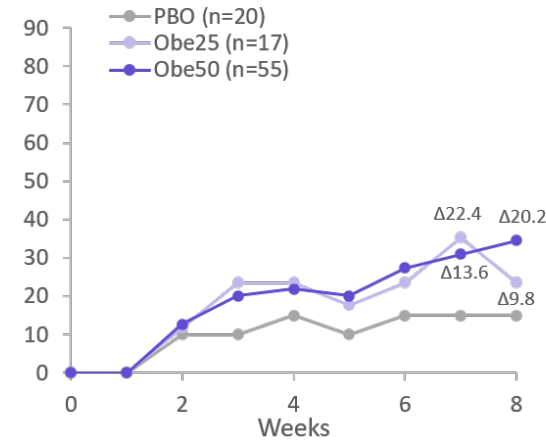
Patients AT-IR (N=602)



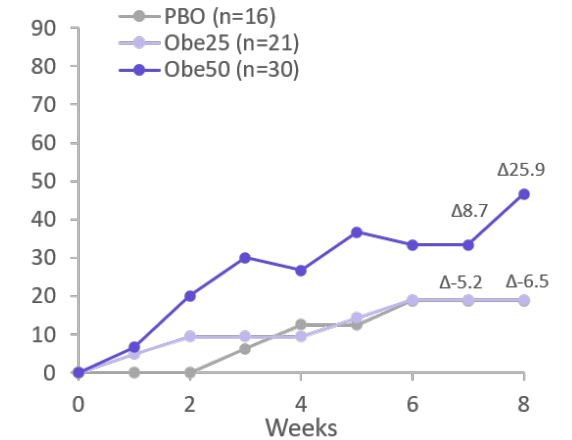
1 TNFi Only (N=114)



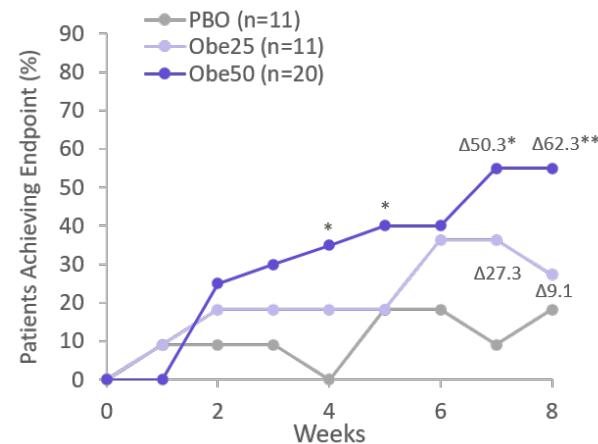
Vedolizumab Only (N=92)



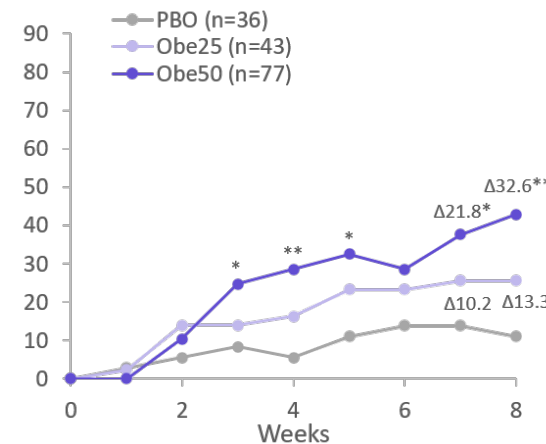
1 TNFi + Vedolizumab Only (N=67)



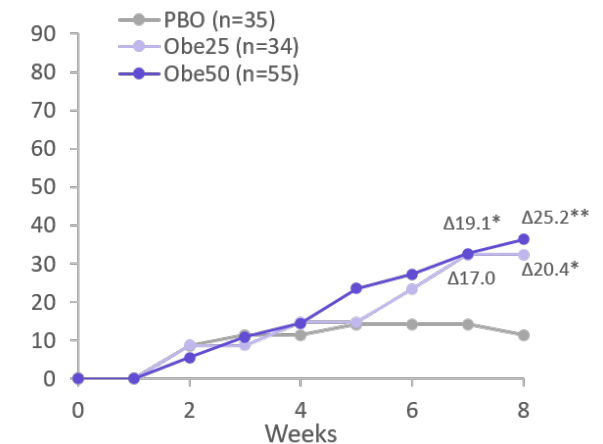
1 TNFi + Vedolizumab + Ustekinumab Only (N=42)



Ustekinumab in Any Line of Therapy (N=156)



JAKi in Any Line of Therapy (N=124)



Conclusions

- Obefazimod demonstrated clinically meaningful symptomatic improvements as early as week 1.
- Proportions of patients with symptomatic improvements continued to increase through Week 8.
- Symptom improvement consistently increased over time, regardless of prior inadequate response to AT or by the class of AT received