

SAFETY AND EFFICACY OF ABT-494 (UPADACITINIB), AN ORAL JAK1 INHIBITOR, AS INDUCTION THERAPY IN PATIENTS WITH CROHN'S DISEASE: RESULTS FROM CELEST

Endpoints, n (%)	PBO N = 37	3 mg BID N = 39	6 mg BID N = 37	12 mg BID N = 36	24 mg BID N = 36	24 mg QD N = 35
Clinical Remission	4 (11)	5 (13)	10 (27)*	4 (11)	8 (22)	5 (14)
Endoscopic Remission	0 (0)	4 (10)*	3 (8)	3 (8)*	8 (22)***	5 (14)**
Clinical Response [†]	12 (32)	17 (44)	21 (57)**	17 (47)	22 (61)**	17 (49)
Modified Clinical Remission [‡]	4 (12)	6 (16)	10 (30)*	9 (27)	11 (37)**	6 (19)
Endoscopic Response [¥]	5 (14)	9 (23)	16 (43)***	14 (39)***	18 (50)***	17 (49)***
Endoscopic Improvement [Ⓐ]	1 (3)	5 (13)	7 (21)**	10 (29)***	10 (33)***	8 (25)**
CDAI<150	6 (16)	8 (21)	11 (30)	14 (39)**	11 (31)	7 (20)
CR100	10 (27)	13 (33)	15 (41)	16 (44)	20 (56)**	11 (31)
CR70	13 (35)	18 (46)	20 (54)	16 (44)	23 (64)**	17 (49)
Change in hsCRP, Mean (SD)	-0.1 (12.0)	-3.0 (19.6)	-3.9 (19.5)	-6.6 (27.1)	-14.8 (26.4)***	-2.7 (13.7)
Adverse Events, n (%)	PBO N = 37	3 mg BID N = 39	6 mg BID N = 37	12 mg BID N = 36	24 mg BID N = 36	24 mg QD N = 35
Any AE	27 (73)	33 (85)	28 (76)	29 (81)	30 (83)	30 (86)
Any Serious AE	2 (5)	5 (13)	2 (5)	10 (28)	3 (8)	7 (20)
Any AE Leading to Discontinuation	5 (14)	5 (13)	1 (3)	9 (25)	3 (8)	5 (14)
AEs of Special Interest						
Infections	12 (32)	16 (41)	18 (49)	14 (39)	18 (50)	12 (34)
Serious Infections [#]	0	3 (8)	0	3 (8)	1 (3)	2 (6)
Herpes Zoster	0	0	0	0	1 (3)	0
Tuberculosis	0	0	0	0	0	0
Malignancies*	0	0	0	0	1 (3)	0
Cardiovascular events adjudicated by CAC**	0	0	0	2 (6)	0	0
GI perforations excluding fistulas [†]	0	0	0	0	1 (3)	1 (3)