of patients with moderate CD; in this subgroup, high baseline CRP was associated with substantially higher remission rates. This analysis suggests that patients with moderate disease can be treated effectively with adalimumab, especially when there is evidence of inflammation. Prospective studies are warranted to confirm these findings.

Abstract PTU-108 Table 1 Per cent of patients in clinical remission at week 4

	Placebo	ADA80/40	ADA160/80
All patients	12% (9/74)	24% (18/75)	36% (27/76)†
CRP ≥10 mg/l, % (n/N)	4% (1/28)	27% (9/33)*	43% (12/28)†
CDAI ≤300, % (n/N)	17% (8/46)	29% (13/45)	46% (19/41)†
CRP ≥10 mg/l, CDAI ≤300, % (n/N)	7% (1/15)	26% (6/23)	57% (8/14)†
CDAI >300, % (n/N)	4% (1/28)	17% (5/30)	23% (8/35)*
CRP ≥10 mg/l, CDAI >300, % (n/N)	0% (0/13)	30% (3/10)	29% (4/14)

*p<0.05 vs placebo.
†p<0.005 vs placebo.

Competing interests W Sandborn: Grant/Research Support from: Centocor Ortho Biotech, Abbott Laboratories, and UCB Pharma., Consultant for: Centocor Ortho Biotech, Abbott Laboratories, UCB Pharma, and Merck (previously Schering Plough), J-F Colombel: Shareholder with: Intestinal Biotech Development, Grant/Research Support from: Astra-Zeneca, Danisco, Danone, Dysphar, Ferring, Giuliani, Lesaffre, Mapi Naxis, Ocerra Therapeutics, Roquette, Schering-Plough and UCB, Consultant for: Abbott Laboratories, ActoGeniX NV, Albireo Pharma, Astra Zeneca, Bayer Schering Pharma, Biogen Idec, Boehringer-Ingelheim, Bristol-Myers Squibb, Cellerix, Centocor, Chemocentryx, Cosmo Technologies, Danone France, Elan, Genentech, Giuliani, Given Imaging, GlaxoSmithKline, Merck, Millennium, NeoVacs, Ocerra, Otsuka American, PDL Biopharma, Pfizer, Ribo Vacs Biotech, Schering-Plough, Shire, Synta, Teva and Petah Tikva, Therakos, UCB, and Wyeth, Speaker bureau with: Abbott Laboratories, Astra Zeneca, Centocor, Elan, Falk, Ferring, Given Imaging, Otsuka American, PDL, Schering-Plough, Shire and UCB, M Castillo Shareholder with: Abbott, Employee of: Abbott, Q Zhou Employee of: Abbott, R Thakkar Shareholder with: Abbott, Employee of: Abbott.

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PTU-109 EFFICACY AND SAFETY OF ADALIMUMAB IN MODERATE COMPARED WITH SEVERE CROHN'S DISEASE: POOLED DATA FROM THE CHARM AND EXTEND TRIALS

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Introduction The efficacy of adalimumab (ADA) in Crohn's disease (CD) by disease duration has been explored,[1] but efficacy and safety of ADA by disease severity have not been investigated. The CHARM[2] and EXTEND[3] trials assessed ADA treatment for the maintenance of remission in patients with moderate to severe CD. Results from CHARM and EXTEND in patients with moderate vs severe CD were pooled to assess efficacy and safety by disease severity.

Methods This analysis of pooled data were performed to assess clinical response and clinical remission at week 56 (CHARM) or 52 (EXTEND) in patients with moderate (CDAI ≤300) or severe (CDAI >300) CD, treated with blinded ADA every other week (eow) or placebo. In both trials, patients received open-label ADA induction (CHARM: 80 mg at week 0, 40 mg at week 2; EXTEND: 160 mg at week 0, 80 mg at week 2), followed by blinded treatment (ADA 40 mg eow or weekly, or placebo in CHARM, 40 mg eow or placebo in EXTEND) from weeks 4 to the end of the trial (week 56 in CHARM, week 52 in EXTEND). Data from the ADA 40 mg eow arm of CHARM was pooled with data from EXTEND; safety and efficacy (proportion of patients in clinical remission, defined as CDAI<150, or clinical response, defined as at least a 70 point decrease in CDAI [CR70]) at week 56/52 were assessed for patients who achieved CR70 at week 4, separated by baseline disease severity (moderate or severe).

Results A total of 438 patients were included in the pooled analysis: 187 with moderate CD (placebo: 92; ADA: 95) and 251 with severe CD (placebo: 126; ADA: 125). For both moderate and severe CD groups, a statistically significantly greater proportion of patients treated with ADA 40 mg eow achieved clinical response and clinical remission at week 56/52 compared with placebo treated patients (Abstract PTU-109 table 1). The safety profiles in the moderate and severe CD subgroups were similar.

Abstract PTU-109 Table 1 Clinical response (CR70) and clinical remission at week 56/52, by baseline CDAI: pooled data from CHARM and EXTEND

	CDAI ≤300			CDAI >300		
	Placebo	ADA 40 mg eow	p Value*	Placebo	ADA 40 mg eow	p Value*
CR70 (%)	16	44	<0.001	14	44	<0.001
Clinical remission (%)	14	40	<0.001	7	34	<0.001

*ADA vs placebo.

Conclusion The analysis of the pooled data from CHARM and EXTEND suggests that ADA 40 mg eow is safe and effective for the treatment of either moderate or severe CD.

Competing interests J-F Colombel Shareholder with: Intestinal Biotech Development, Grant/Research Support from: Astra-Zeneca, Danisco, Danone, Dysphar, Ferring, Giuliani, Lesaffre, Mapi Naxis, Ocerra Therapeutics, Roquette, Schering-Plough, and UCB, Consultant for: Abbott Laboratories, ActoGeniX NV, Albireo Pharma, Astra Zeneca, Bayer Schering Pharma, Biogen Idec, Boehringer-Ingelheim, Bristol-Myers Squibb, Cellerix, Centocor, Chemocentryx, Cosmo Technologies, Danone France, Elan, Genentech, Giuliani, Given Imaging, GlaxoSmithKline, Merck, Millennium, NeoVacs, Ocerra, Otsuka American, PDL Biopharma, Pfizer, Ribo Vacs Biotech, Schering-Plough, Shire, Synta, Teva and Petah Tikva, Therakos, UCB, and Wyeth, Speaker bureau with: Abbott Laboratories, Astra Zeneca, Centocor, Elan, Falk, Ferring, Given Imaging, Otsuka American, PDL, Schering-Plough, Shire and UCB, W Sandborn Grant/Research Support from: Centocor Ortho Biotech, Abbott Laboratories, and UCB Pharma, Consultant for: Centocor Ortho Biotech, Abbott Laboratories, UCB Pharma, and Merck (previously Schering Plough), M Castillo Shareholder with: Abbott, Employee of: Abbott, Q Zhou Employee of: Abbott, R Thakkar Shareholder with: Abbott, Employee of: Abbott.

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PTU-110 ELEVATED C REACTIVE PROTEIN IN ANTI-TNF-NAïVE PATIENTS IS ASSOCIATED WITH HIGHER REMISSION RATES

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Introduction The CHARM trial[1] demonstrated that adalimumab (ADA) was effective for the maintenance of remission in patients with moderate to severe Crohn's disease (CD), and that remission rates are influenced by a patient's baseline C reactive protein (CRP)