Electronic Supplementary Material

Article title: **Efficacy and Safety of CT-P13 in Inflammatory Bowel Disease after Switching from Originator Infliximab: Exploratory Analyses from the NOR-SWITCH Main and Extension Trials**

Journal: **BioDrugs**

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Funding: This work was supported by the Norwegian Ministry of Health and Care Services

Conflict of interest statements: KKJ reports personal fees from Intercept, Norgine and Celltrion. GLG reports personal fees from AbbVie, Biogen, Eli Lilly, MSD, Novartis, Pfizer, Roche, Sandoz, Orion Pharma, Celltrion and Boehringer Ingelheim. NB reports personal fees received from Orion Pharma, Roche, Napp Pharmaceuticals, Pfizer, and Takeda. ICO reports grants from Norwegian Ministry of Health and Care Services during the conduct of the study, and personal fees from Pfizer. EAH reports grants from AbbVie, Pfizer, UCB, Roche, and MSD. IPB reports personal fees from AbbVie, MSD, Takeda, Hospira, and Ferring. KEAL reports grants from MSD, personal fees from Takeda, Orion, Abbvie, Pfizer, and MSD. JJ reports personal fees from MSD, AbbVie, Celltrion, Orion Pharma, Takeda, Napp Pharm, AstroPharma, Hikma and Pfizer. TKK reports reports grants from Norwegian Ministry of Health and Care Services during the conduct of the study and personal fees from AbbVie, Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly, Epirus, Janssen, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz, and UCB Pharma. SOF reports personal fees from Takeda, Pharmacosmos, Tillotts, Janssen, Intercept and Pfizer. The remaining authors have no conflicts of interest to declare.

Table S1 Demographics and baseline characteristics in extension study (week 52) in Crohn's disease and ulcerative colitis, full analysis set

	CD, N=127		UC, N=80	
	CT-P13 maintenance n=65	IFX/CT-P13 switch n=62	CT-P13 maintenance n=42	IFX/CT-P13 switch n=38
Demographics				
Age (years)	40.1 (13.9)	40.2 (13.1)	46.5 (14.7)	45.9 (13.4)
Female	22 (34%)	27 (44%)	12 (29%)	14 (37%)
Disease duration (years)	15.8 (8.8)	15.2 (9.1)	13.3 (7.5)	13.7 (9.5)
Duration of ongoing IFX treatment (years)	6.1 (3.3)	6.7 (3.5)	5.4 (2.5)	5.4 (2.2)
CD distribution				
Ileum (L1)	11 (17%)	11 (18%)	-	-
Colonic (L2)	18 (28%)	18 (29%)	-	-
Ileocolonic (L3)	33 (51%)	32 (52%)	-	-
Upper GI tract (L4)	5 (8%)	6 (10%)	-	-
CD type				
Non-stricturing, non-penetrating (B1)	36 (55%)	31 (50%)	-	-
Stricturing (B2)	12 (19%)	16 (26%)	-	-
Penetrating (B3)	17 (26%)	15 (24%)	-	-
Perianal disease	25 (39%)	14 (23%)	-	-
UC distribution				
Ulcerative proctitis (E1)	-	-	0	1 (3%)
Proctosigmoiditis	-	-	6 (14%)	5 (13%)
Left sided (E2)	-	-	6 (14%)	7 (18%)
Pancolitis (E3)	-	-	30 (71%)	25 (66%)
Surgery[†]	28 (43%)	26 (42%)	0	0
Ileocoecal resection	10 (36%)	14 (54%)	-	-
Perianal disease	8 (29%)	7 (27%)		
Internal fistula/abscess	6 (21%)	4 (15%)	-	-
Small bowel resection/stricturoplastic	3 (11%)	3 (12%)	-	-
Colonic resection	3 (11%)	4 (15%)	-	-
Concomitant therapies				
Immunosuppressive therapy[‡]	31 (48%)	22 (36%)	16 (38%)	16 (42%)
Prednisolone	0	2 (3%)	1 (2%)	2 (5%)
Pre-infusion steroids iv	3 (4.6%)	3 (4.8%)	0 (0.0%)	0 (0.0%)
Previous therapies				
Biologic treatment naive	53 (82%)	49 (79%)	40 (95%)	37 (97%)
One previous	12 (19%)	13 (21%)	2 (5%)	1 (3%)
Two previous	0	0	0	0
Current smokers	14 (21.5%)	11 (17.7%)	4 (9.5%)	3 (7.9%)
Disease characteristics				
C-reactive protein (mg/L)	1.6 (1.0 -5.0)	2.1 (1.0 - 4.5)	2 (1.0 - 5.0)	1.9 (1.0 - 3.8)
Faecal calprotectin (mg/kg)	183 (48 - 390)	68 (25 - 271)	29 (19 - 102)	46 (15 - 116)
Harvey-Bradshaw Index*	1 (0 - 4)	1 (0.2 -4)	-	-
Partial Mayo Score*	-	-	0 (0 - 0)	0 (0 - 1)
Patient's global assessment of disease activity (0-10)	2.3 (2.1)	1.8 (1.8)	1.5 (2.2)	1.2 (1.5)
Physician's global assessment of disease activity (0-10)	1.7 (1.7)	1.6 (2.0)	1.0 (1.7)	0.7 (1.1)
EQ-5D index score	0.8 (0.2)	0.8 (0.3)	0.9 (0.2)	0.9 (0.1)

Data are n (%), mean (SD), or median (25-75 percentiles). 95% CI= 95% confidence interval of the adjusted treatment difference. *EQ-5D* EuroQol questionnaire time trade-off (UK weighted), *GI* gastrointestinal, *IFX* infliximab. [†]some patients had undergone more than one procedure. [‡]Immunosuppressive therapy includes azathioprine, 6-mercaptopurine and methotrexate. *Ref. [24]

Table S2a Secondary efficacy endpoints in the extension study (week 52-78) in Crohn's disease, per-protocol set

	52 weeks		78 weeks		
	CT-P13 maintenance (n=63)	IFX/CT-P13 switch (n=61)	CT-P13 maintenance (n=63)	IFX/CT-P13 switch (n=61)	Difference at 78 weeks (95% CI)
Change variables					
Harvey-Bradshaw Index*	2.49 (2.9)	2.77 (3.18)	2.93 (3.24)	2.44 (3.28)	0.57 (-0.2 to 1.33)
Physician's global assessment of disease activity	1.68 (1.65)	1.56 (2.02)	1.43 (1.55)	1.16 (1.82)	0.13 (-0.37 to 0.63)
Patient's global assessment of disease activity	2.21 (2.12)	1.77 (1.84)	1.94 (2.06)	1.53 (1.92)	0.19 (-0.35 to 0.73)
C-reactive protein (mg/L), log10	0.56 (0.38)	0.53 (0.33)	0.52 (0.30)	0.54 (0.25)	-0.02 (-0.10 to 0.06)
Faecal calprotectin (mg/kg), log10	2.18 (0.63)	1.92 (0.53)	2.24 (0.62)	1.98 (0.53)	0.12 (-0.09 to 0.33)
Patient-reported outcome measures					
SF-36 physical functioning	93.19 (14.08)	90.22 (15.45)	93.97 (13.9)	89.97 (16.10)	1.55 (-1.82 to 4.92)
SF-36 role limitation physical	69.67 (41.61)	68.10 (41.83)	72.05 (38.47)	73.88 (34.97)	-2.35 (-13.63 to 8.93)
SF-36 pain	78.48 (20.87)	76.90 (26.23)	80.61 (17.41)	79.13 (23.57)	0.22 (-5.97 to 6.41)
SF-36 general health	59.84 (23.84)	62.50 (26.13)	62.33 (24.62)	60.19 (25.29)	4.63 (0.29 to 8.97)
SF-36 emotional well-being	79.41 (16.34)	71.45 (21.89)	78.44 (17.23)	74.32 (20.51)	-0.39 (-4.68 to 3.91)
SF-36 role limitation emotional	73.77 (39.49)	75.29 (35.63)	74.44 (35.65)	71.73 (39.43)	5.45 (-5.01 to 15.92)
SF-36 social functioning	83.81 (23.75)	81.47 (27.93)	84.11 (20.64)	87.50 (17.06)	-3.22 (-9.38 to 2.94)
SF-36 energy fatigue	53.52 (26.74)	50.95 (27.57)	52.80 (25.44)	53.84 (26.72)	-2.44 (-8.43 to 3.54)
SF-36 physical component summary score	49.76 (7.41)	49.86 (9.28)	50.79 (7.38)	50.26 (7.83)	0.3 (-1.78 to 2.38)
SF-36 mental component summary score	47.12 (12.04)	44.95 (13.76)	46.59 (11.44)	46.22 (12.13)	-0.19 (-3.11 to 2.73)
EQ-5D index	0.83 (0.18)	0.80 (0.25)	0.89 (0.14)	0.83 (0.23)	0.04 (-0.01 to 0.1)
WPAI percent work missed due to specified problem (absenteeism)	0.10 (0.22)	0.03 (0.12)	0.08 (0.2)	0.11 (0.29)	-0.02 (-0.11 to 0.08)
WPAI percent impairment while working due to specified problem (presenteeism)	0.18 (0.24)	0.15 (0.23)	0.14 (0.17)	0.18 (0.27)	0 (-0.08 to 0.08)
WPAI percent overall work impairment due to specified problem	0.25 (0.29)	0.13 (0.21)	0.17 (0.21)	0.19 (0.28)	0.01 (-0.09 to 0.11)
WPAI percent activity impairment due to specified problem	0.25 (0.28)	0.22 (0.27)	0.18 (0.24)	0.2 (0.23)	-0.02 (-0.10 to 0.05)
IBDQ total score	186.61 (30.11)	183.49 (31.24)	185.35 (30.10)	187 (30.58)	-4.28 (-10.26 to 1.7)

Data are mean (SD) at baseline and mean (SD) change from baseline (follow-up minus baseline). Difference is adjusted treatment difference of change from baseline with 95% CI
CI confidence interval, *EQ-5D* EuroQol questionnaire time trade-of UK weighted, *IBDQ* Inflammatory Bowel Disease Questionnaire, *WPAI* Work Productivity and Impairment Questionnaire
*Ref. [24]

Table S2b Secondary efficacy endpoints in the extension study (week 52-78) in ulcerative colitis, per-protocol set

	52 weeks		78 weeks		
	CT-P13 maintenance (n=39)	IFX/CT-P13 switch (n=35)	CT-P13 maintenance (n=39)	IFX/CT-P13 switch (n=35)	Difference at 78 weeks (95% CI)
Change variables					
Partial Mayo score*	0.44 (1.07)	0.71 (1.10)	0.88 (1.55)	0.47 (0.82)	0.44 (-0.13 to 1.01)
Physician's global assessment of disease activity	1.08 (1.71)	0.79 (1.09)	1.33 (1.67)	0.62 (1.02)	0.48 (-0.11 to 1.06)
Patient's global assessment of disease activity	1.59 (2.29)	1.26 (1.52)	1.96 (2.12)	0.98 (1.20)	0.90 (0.19 to 1.62)
C-reactive protein (mg/L), log10	0.55 (0.28)	0.47 (0.27)	0.54 (0.30)	0.53 (0.32)	-0.03 (-0.13 to 0.07)
Faecal calprotectin (mg/kg), log10	1.77 (0.64)	1.82 (0.75)	1.99 (0.80)	1.91 (0.71)	0.33 (0.04 to 0.62)
Patient-reported outcome measures					
SF-36 physical functioning	92.56 (14.77)	93.25 (12.86)	88.75 (21.28)	93.57 (12.02)	-3.77 (-6.85 to -0.69)
SF-36 role limitation physical	78.95 (35.13)	85.61 (26.54)	74.77 (34.36)	82.42 (33.73)	-0.88 (-13.88 to 12.12)
SF-36 pain	80.77 (22.85)	84.62 (16.4)	82.05 (18.64)	82.34 (20.41)	1.79 (-5.68 to 9.26)
SF-36 general health	67.88 (25.11)	72.88 (23.05)	65.56 (24.48)	71.25 (22.42)	-2.12 (-8.15 to 3.90)
SF-36 emotional well-being	78.86 (15.63)	81.33 (13.55)	77.12 (13.90)	81.55 (12.09)	-2.78 (-7.44 to 1.87)
SF-36 role limitation emotional	76.32 (35.44)	85.86 (30.08)	78.09 (35.58)	89.06 (22.24)	-3.71 (-14.56 to 7.14)
SF-36 social functioning	87.18 (19.34)	95.45 (11.19)	82.64 (21.24)	95.90 (8.93)	-9.26 (-16.11 to-2.41)
SF-36 energy fatigue	58.85 (25.94)	59.85 (21.88)	54.42 (23.14)	58.68 (22.96)	-3.30 (-9.9 to 3.30)
SF-36 physical component summary score	52.17 (8.33)	52.60 (7.60)	50.25 (8.57)	51.45 (8.14)	-0.58 (-3.15 to 1.99)
SF-36 mental component summary score	47.87 (10.72)	50.65 (7.68)	47.22 (10.53)	51.30 (6.43)	-1.82 (-4.73 to 1.10)
EQ-5D index	0.84 (0.20)	0.89 (0.12)	0.85 (0.16)	0.87 (0.20)	0.01 (-0.05 to 0.06)
WPAI percent work missed due to specified problem (absenteeism)	0.11 (0.25)	0.04 (0.13)	0.01 (0.24)	0.03 (0.13)	0.02 (-0.09 to 0.14)
WPAI percent impairment while working due to specified problem (presenteeism)	0.18 (0.24)	0.10 (0.13)	0.18 (0.24)	0.08 (0.13)	0.08 (-0.02 to 0.19)
WPAI percent overall work impairment due to specified problem	0.24 (0.33)	0.13 (0.19)	0.23 (0.31)	0.10 (0.19)	0.07 (-0.06 to 0.20)
WPAI percent activity impairment due to specified problem	0.22 (0.30)	0.09 (0.16)	0.22 (0.23)	0.11 (0.16)	0.04 (-0.05 to 0.13)
IBDQ total score	190.86 (24.38)	199.16 (17.09)	185.84 (25.56)	199.34 (17.07)	-6.29 (-12.97 to 0.38)

Data are mean (SD) at baseline and mean (SD) change from baseline (follow-up minus baseline). Difference is adjusted treatment difference of change from baseline with 95% CI
CI confidence interval, *EQ-5D* EuroQol questionnaire time trade-of UK weighted, *IBDQ* Inflammatory Bowel Disease Questionnaire, *WPAI* Work Productivity and Impairment Questionnaire
*Ref. [24]

Table S3a Predictors of disease worsening in Crohn's disease. Univariate associations from logistic regression

	Main study		Extension study	
	Odds Ratio log (SE)	P-value	Odds Ratio log (SE)	P-value
Age <40 years	-0.08 (0.37)	0.824	0.28 (0.4)	0.4782
Male sex	-0.22 (0.38)	0.5548	-0.35 (0.4)	0.3831
Disease duration <5 years	0.11 (0.56)	0.8457	-0.69 (0.64)	0.283
Duration of ongoing IFX treatment <2 years	0.17 (0.52)	0.7458	-0.57 (0.64)	0.3765
Concomitant immuno-suppressive therapy	-0.6 (0.41)	0.1504	-0.12 (0.42)	0.7654
Previous biologic therapy	0.32 (0.43)	0.4538	-0.39 (0.65)	0.5436
Smoking	-0.32 (0.5)	0.5232	-0.2 (0.58)	0.728
Surgery	-0.1 (0.38)	0.8007	-0.4 (0.49)	0.4139
Disease distribution				
Ileum (L1)	-0.09 (0.51)	0.8517	-0.4 (0.67)	0.5511
Colonic (L2)	0.04 (0.4)	0.9253	-0.14 (0.52)	0.7906
Ileocolonic (L3)	0.02 (0.37)	0.9635	0.05 (0.46)	0.9162
Disease type				
Non-stricturating, non-penetrating	0.57 (0.39)	0.1438	-0.03 (0.46)	0.9507
Penetrating	-0.61 (0.49)	0.2162	0.06 (0.53)	0.9135
Stricturating	-0.24 (0.47)	0.6195	-0.02 (0.56)	0.9686
Calprotectin	0.12 (0.15)	0.4339	0.2 (0.15)	0.1669

IFX infliximab, *SE* standard error

Table S3b Predictors of disease worsening in ulcerative colitis. Univariate associations from logistic regression

	Main study		Extension study	
	Odds Ratio log (SE)	P-value	Odds Ratio log (SE)	P-value
Age <40 years	-0.25 (0.24)	0.3038	0.28 (0.4)	0.4782
Male sex	-0.38 (0.22)	0.0812	-0.35 (0.4)	0.3831
Disease duration <5 years	-0.32 (0.39)	0.4131	-0.69 (0.64)	0.283
Duration of ongoing IFX treatment <2 years	-0.5 (0.43)	0.2417	-0.57 (0.64)	0.3765
Concomitant immuno-suppressive therapy	-0.2 (0.22)	0.3443	-0.12 (0.42)	0.7654
Previous biologic therapy	0.54 (0.24)	0.0252	-0.39 (0.65)	0.5436
Smoking	-0.2 (0.29)	0.4855	-0.2 (0.58)	0.728
Disease distribution				
Proctosigmoiditis	-0.04 (1.12)	0.9716	-16.38 (1966.65)	0.9934
Left sided colitis	-16.43 (1581.97)	0.9917	-16.42 (1809.05)	0.9928
Pancolitis	1.29 (1.09)	0.2388	17.64 (2150.8)	0.9935
Calprotectin	0.22 (0.13)	0.0875	0.2 (0.15)	0.1669

IFX infliximab, *SE* standard error