Supplementary material for:

Efficacy and safety of filgotinib in patients with rheumatoid arthritis: Week 156 interim results from a long-term extension study

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Supplemental table 1 Patient disposition

	Methotrexate-IR (FINCH 1)						
	FIL200			FIL100			
	With continued FIL	With de novo FIL*	Total	With continued FIL	With de novo FIL*	Total	Total
Safety analysis set	571	128	699	570	130	700	1399
On FIL	399 (69.9)	84 (65.6)	483 (69.1)	392 (68.8)	78 (60.0)	470 (67.1)	953 (68.1)
Discontinued FIL	172 (30.1)	44 (34.4)	216 (30.9)	178 (31.2)	52 (40.0)	230 (32.9)	446 (31.9)
Reason for discontinuation							
Sponsor's decision†	53 (9.3)	17 (13.3)	70 (10.0)	57 (10.0)	14 (10.8)	71 (10.1)	141 (10.1)
Adverse event	55 (9.6)	14 (10.9)	69 (9.9)	49 (8.6)	14 (10.8)	63 (9.0)	132 (9.4)
Withdrawal by patient	29 (5.1)	9 (7.0)	38 (5.4)	44 (7.7)	10 (7.7)	54 (7.7)	92 (6.6)
Physician's decision	8 (1.4)	2 (1.6)	10 (1.4)	7 (1.2)	6 (4.6)	13 (1.9)	23 (1.6)
Death	10 (1.8)	0	10 (1.4)	8 (1.4)	4 (3.1)	12 (1.7)	22 (1.6)
Lost to follow-up	8 (1.4)	0	8 (1.1)	3 (0.5)	3 (2.3)	6 (0.9)	14 (1.0)
Lack of efficacy	5 (0.9)	1 (0.8)	6 (0.9)	5 (0.9)	1 (0.8)	6 (0.9)	12 (0.9)
Pregnancy	1 (0.2)	1 (0.8)	2 (0.3)	3 (0.5)	0	3 (0.4)	5 (0.4)
Protocol deviation	2 (0.4)	0	2 (0.3)	1 (0.2)	0	1 (0.1)	3 (0.2)
Non-compliance	1 (0.2)	0	1 (0.1)	1 (0.2)	0	1 (0.1)	2 (0.1)
	bDMARD-IR (FINCH 2)						
	FIL200			FIL100			
	With continued FIL	With de novo FIL*	Total	With continued FIL	With de novo FIL*	Total	Total
Safety analysis set	132	59	191	124	55	179	370
On FIL	61 (46.2)	26 (44.1)	87 (45.5)	56 (45.2)	21 (38.2)	77 (43.0)	164 (44.3)
Discontinued FIL	71 (53.8)	33 (55.9)	104 (54.5)	68 (54.8)	34 (61.8)	102 (57.0)	206 (55.7)
Reason for discontinuation							
Sponsor's decision†	7 (5.3)	4 (6.8)	11 (5.8)	7 (5.6)	5 (9.1)	12 (6.7)	23 (6.2)
Adverse event	22 (16.7)	9 (15.3)	31 (16.2)	17 (13.7)	11 (20.0)	28 (15.6)	59 (15.9)
Withdrawal by patient	20 (15.2)	12 (20.3)	32 (16.8)	20 (16.1)	12 (21.8)	32 (17.9)	64 (17.3)

Physician's decision	8 (6.1)	4 (6.8)	12 (6.3)	7 (5.6)	2 (3.6)	9 (5.0)	21 (5.7)
Death	4 (3.0)	2 (3.4)	6 (3.1)	1 (0.8)	0	1 (0.6)	7 (1.9)
Lost to follow-up	2 (1.5)	1 (1.7)	3 (1.6)	7 (5.6)	3 (5.5)	10 (5.6)	13 (3.5)
Lack of efficacy	5 (3.8)	0	5 (2.6)	8 (6.5)	1 (1.8)	9 (5.0)	14 (3.8)
Pregnancy	1 (0.8)	0	1 (0.5)	0	0	0	1 (0.3)
Protocol deviation	1 (0.8)	0	1 (0.5)	1 (0.8)	0	1 (0.6)	2 (0.5)
Non-compliance	1 (0.8)	1 (1.7)	2 (1.0)	0	0	0	2 (0.5)

Methotrexate-naïve (FINCH 3)

	FIL100			**FIL200**			
	With continued FIL	**With de novo FIL***	**Total**	**With continued FIL**	**With de novo FIL***	**Total**	**Total**
Safety analysis set	492	148	640	169	151	320	960
On FIL	311 (63.2)	99 (66.9)	410 (64.1)	97 (57.4)	99 (65.6)	196 (61.3)	606 (63.1)
Discontinued FIL	181 (36.8)	49 (33.1)	230 (35.9)	72 (42.6)	52 (34.4)	124 (38.8)	354 (36.9)
Reason for discontinuation							
Sponsor's decision†	56 (11.4)	15 (10.1)	71 (11.1)	19 (11.2)	13 (8.6)	32 (10.0)	103 (10.7)
Adverse event	38 (7.7)	13 (8.8)	51 (8.0)	26 (15.4)	8 (5.3)	34 (10.6)	85 (8.9)
Withdrawal by patient	43 (8.7)	7 (4.7)	50 (7.8)	17 (10.1)	18 (11.9)	35 (10.9)	85 (8.9)
Physician's decision	10 (2.0)	8 (5.4)	18 (2.8)	4 (2.4)	4 (2.6)	8 (2.5)	26 (2.7)
Death	13 (2.6)	1 (0.7)	14 (2.2)	1 (0.6)	2 (1.3)	3 (0.9)	17 (1.8)
Lost to follow-up	13 (2.6)	2 (1.4)	15 (2.3)	5 (3.0)	5 (3.3)	10 (3.1)	25 (2.6)
Lack of efficacy	2 (0.4)	1 (0.7)	3 (0.5)	0	0	0	3 (0.3)
Pregnancy	4 (0.8)	1 (0.7)	5 (0.8)	0	0	0	5 (0.5)
Protocol deviation	0	0	0	0	1 (0.7)	1 (0.3)	1 (0.1)
Non-compliance	2 (0.4)	1 (0.7)	3 (0.5)	0	1 (0.7)	1 (0.3)	4 (0.4)

Values are n (%). Safety analysis set includes enrolled patients who received at least one dose of study drug.

*Patients re-randomised to FIL in the FINCH 4 LTE from adalimumab (methotrexate-IR; FINCH 1), placebo (bDMARD-IR; FINCH 2) or methotrexate (methotrexate-naïve; FINCH 3) in the parent study.

†Of the 267 discontinuations that were due to the sponsor's decision, 211 were reported from Mexico. At that time, marketing application for filgotinib was not anticipated by the sponsor in Mexico, where alternative effective therapies were available.

bDMARD-IR, biologic disease-modifying anti-rheumatic drug inadequate responder; FIL(100/200), filgotinib (100 mg/200 mg); LTE, long-term extension; methotrexate-IR, methotrexate inadequate responder.

Supplemental table 2 Exposure to FIL in FINCH 4

	FIL200			FIL100			
	With continued FIL	**With de novo FIL**	**Total FIL200**	**With continued FIL**	**With de novo FIL**	**Total FIL100**	**Total**
N	1195	335	1530	863	336	1199	2729
Mean (SD)	200.3 (54.86)	157.4 (54.95)	190.9 (57.66)	197.1 (58.19)	151.9 (58.52)	184.4 (61.69)	188.1 (59.54)
Median	217.6	168.9	209.8	218.6	167.4	199.9	205.6
Q1; Q3	178.9; 233.3	131.9; 193.4	165.3; 229.7	171.6; 235.7	119.9; 190.7	160.0; 229.7	162.0; 229.7
Min; max	26; 293	1; 267	1; 293	25; 292	1; 270	1; 292	1; 293

FIL(100/200), filgotinib (100 mg/200 mg); max, maximum; min, minimum; Q, quartile.

Supplemental table 3 Incidence of TEAEs leading to death in FINCH 4

	FIL200 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)			FIL100 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
COVID-19	9 (0.75) 0.3 (0.1–0.5)	2 (0.60) 0.2 (0.0–0.7)	11 (0.72) 0.2 (0.1–0.4)	3 (0.35) 0.1 (0.0, 0.3)	-	3 (0.25) 0.1 (0.0–0.2)
COVID-19 pneumonia	2 (0.17) 0.1 (0.0–0.2)	-	2 (0.13) 0.0 (0.0–0.2)	3 (0.35) 0.1 (0.0–0.3)	-	3 (0.25) 0.1 (0.0–0.2)
Death of unknown cause	3 (0.25) 0.1 (0.0–0.2)	-	3 (0.20) 0.1 (0.0–0.2)	-	-	-
Myocardial infarction	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	1 (0.12) 0.0 (0.0–0.2)	1 (0.30) 0.1 (0.0–0.6)	2 (0.17) 0.1 (0.0–0.2)
Respiratory failure	2 (0.17) 0.1 (0.0–0.2)	-	2 (0.13) 0.0 (0.0–0.2)	1 (0.12) 0.0 (0.0, 0.2)	-	1 (0.08) 0.0 (0.0, 0.2)
Acute myocardial infarction	2 (0.17) 0.1 (0.0–0.2)	-	2 (0.13) 0.0 (0.0–0.2)	-	-	-
Cardiac arrest	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Cardiopulmonary failure	-	-	-	1 (0.12) 0.0 (0.0–0.2)	1 (0.30) 0.1 (0.0–0.6)	2 (0.17) 0.1 (0.0–0.2)
Cerebrovascular accident	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Pneumonia	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Pulmonary oedema	2 (0.17) 0.1 (0.0–0.2)	-	2 (0.13) 0.0 (0.0–0.2)	-	-	-
Acute kidney injury	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Acute respiratory distress syndrome	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Acute respiratory failure	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-

	FIL200 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)			FIL100 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Aortic dissection	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Brain oedema	1 (0.08) 0.0 (0.0–0.2)		1 (0.07) 0.0 (0.0–0.1)	-	-	-
Candida pneumonia	-	-	-	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Cardiac failure	-	1 (0.30) 0.1 (0.0–0.5)	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Cardiogenic shock	-	-	-	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Diabetic hyperglycaemic coma	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Electrolyte imbalance	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Gastrointestinal haemorrhage	1 (0.08)_ 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Heat illness	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Hydrothorax	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Hyponatraemia	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Ischaemic stroke	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Lung adenocarcinoma	-	1 (0.30) 0.1 (0.0–0.5)	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Lung cancer metastatic	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Malignant peritoneal neoplasm	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Metastatic gastric cancer	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-

	FIL200 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)			FIL100 Number of patients (%) with the TEAE listed EAIR per 100 PYE (95% CI)		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Neoplasm malignant	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Oesophageal squamous cell carcinoma metastatic	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Osmotic demyelination syndrome	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Ovarian cancer	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Pericarditis	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Pulmonary embolism	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Renal cancer metastatic	-	1 (0.30) 0.1 (0.0–0.5)	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Renal failure	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Sepsis	-	-	-	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)
Septic shock	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Staphylococcal sepsis	1 (0.08) 0.0 (0.0–0.2)	-	1 (0.07) 0.0 (0.0–0.1)	-	-	-
Sudden death	-	-	-	1 (0.12) 0.0 (0.0–0.2)	-	1 (0.08) 0.0 (0.0–0.2)
Suspected COVID-19	-	-	-	-	1 (0.30) 0.1 (0.0–0.6)	1 (0.08) 0.0 (0.0–0.2)

TEAEs are defined as any adverse events that began on or after the study drug start date, up to 30 days after permanent discontinuation of study drug. Only adverse events with a start date after LTE treatment start are considered.

FIL(100/200), filgotinib (100 mg/200 mg); LTE, long-term extension; PYE, patient-years of exposure; TEAE, treatment-emergent adverse event.

Supplemental table 4 Incidence of TEAEs leading to premature discontinuation of filgotinib in FINCH 4

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
COVID-19	20 (1.67)	2 (0.60)	22 (1.44)	5 (0.58)	5 (1.49)	10 (0.83)
COVID-19 pneumonia	8 (0.67)	2 (0.60)	10 (0.65)	4 (0.46)	4 (1.19)	8 (0.67)
Pneumonia	9 (0.75)	4 (1.19)	13 (0.85)	2 (0.23)	1 (0.30)	3 (0.25)
Hepatitis B DNA assay positive	2 (0.17)	3 (0.90)	5 (0.33)	4 (0.46)	2 (0.60)	6 (0.5)
Alanine aminotransferase increased	4 (0.33)	2 (0.60)	6 (0.39)	1 (0.12)	1 (0.30)	2 (0.17)
Pulmonary embolism	4 (0.33)	1 (0.30)	5 (0.33)	2 (0.23)		2 (0.17)
Latent tuberculosis	1 (0.08)	1 (0.30)	2 (0.13)	2 (0.23)	2 (0.60)	4 (0.33)
Rheumatoid arthritis	1 (0.08)	2 (0.60)	3 (0.20)	2 (0.23)	1 (0.30)	3 (0.25)
Aspartate aminotransferase increased	1 (0.08)	2 (0.60)	3 (0.20)	1 (0.12)	1 (0.30)	2 (0.17)
Creatinine renal clearance decreased	5 (0.42)		5 (0.33)			
Cellulitis	3 (0.25)		3 (0.20)	1 (0.12)		1 (0.08)
Pyelonephritis acute	2 (0.17)		2 (0.13)	1 (0.12)	1 (0.30)	2 (0.17)
Urinary tract infection	2 (0.17)		2 (0.13)	2 (0.23)		2 (0.17)
Acute kidney injury	2 (0.17)		2 (0.13)	1 (0.12)		1 (0.08)
Acute myocardial infarction	2 (0.17)		2 (0.13)	1 (0.12)		1 (0.08)
Adenocarcinoma of colon	1 (0.08)		1 (0.07)	2 (0.23)		2 (0.17)
Arthritis bacterial	2 (0.17)	1 (0.30)	3 (0.20)			
Gastric cancer	2 (0.17)		2 (0.13)	1 (0.12)		1 (0.08)
Hepatitis B virus test positive	2 (0.17)		2 (0.13)	1 (0.12)		1 (0.08)
Herpes zoster	2 (0.17)	1 (0.30)	3 (0.20)			

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Malignant melanoma	3 (0.25)		3 (0.20)			
Mycobacterium tuberculosis complex test positive	1 (0.08)		1 (0.07)	1 (0.12)	1 (0.30)	2 (0.17)
Neutropenia				1 (0.12)	2 (0.60)	3 (0.25)
Osteomyelitis	2 (0.17)		2 (0.13)	1 (0.12)		1 (0.08)
Prostate cancer	1 (0.08)	1 (0.30)	2 (0.13)		1 (0.30)	1 (0.08)
Renal failure	1 (0.08)	1 (0.30)	2 (0.13)	1 (0.12)		1 (0.08)
Uterine cancer				1 (0.12)	2 (0.60)	3 (0.25)
Abdominal pain				2 (0.23)		2 (0.17)
Acute respiratory failure	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Anaemia	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Chronic kidney disease	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Deep vein thrombosis	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Diabetic ketoacidosis	1 (0.08)		1 (0.07)		1 (0.30)	1 (0.08)
Diffuse large B-cell lymphoma	2 (0.17)		2 (0.13)			
Diverticulitis	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Endometrial cancer				2 (0.23)		2 (0.17)
Gamma-glutamyltransferase increased	2 (0.17)		2 (0.13)			
Hepatic cirrhosis		1 (0.30)	1 (0.07)	1 (0.12)		1 (0.08)
Hepatitis B		1 (0.30)	1 (0.70)	1 (0.12)		1 (0.08)
Hypertension	2 (0.17)		2 (0.13)			
Hypertransaminasaemia	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Hypokalaemia	2 (0.17)		2 (0.13)			

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
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Infectious pleural effusion	1 (0.08)	1 (0.30)	2 (0.13)			
Interstitial lung disease		1 (0.30)	1 (0.07)	1 (0.12)		1 (0.08)
Leukopenia				1 (0.12)	1 (0.30)	2 (0.17)
Lymphocyte count decreased		1 (0.30)	1 (0.07)	1 (0.12)		1 (0.08)
Pleural effusion	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Postoperative wound infection	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Pyelonephritis				1 (0.12)	1 (0.30)	2 (0.17)
Pyonephrosis		1 (0.30)	1 (0.07)	1 (0.12)		1 (0.08)
Respiratory failure	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Sepsis	1 (0.08)		1 (0.07)		1 (0.30)	1 (0.08)
Staphylococcal sepsis	1 (0.08)		1 (0.07)	1 (0.12)		1 (0.08)
Thrombocytopenia	2 (0.17)		2 (0.13)			
Urosepsis				2 (0.23)		2 (0.17)
Abscess limb	1 (0.08)		1 (0.07)			
Acute respiratory distress syndrome	1 (0.08)		1 (0.07)			
Acute sinusitis	1 (0.08)		1 (0.07)			
Adenocarcinoma	1 (0.08)		1 (0.07)			
Adenocarcinoma gastric		1 (0.03)	1 (0.07)			
Adenocarcinoma of appendix					1 (0.30)	1 (0.08)
Adenocarcinoma of the cervix				1 (0.12)		1 (0.08)
Adenocarcinoma pancreas				1 (0.12)		1 (0.08)

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Adenomyosis	1 (0.08)		1 (0.07)			
Anxiety		1 (0.30)	1 (0.07)			
Aortic aneurysm	1 (0.08)		1 (0.07)			
Arthralgia		1 (0.30)	1 (0.07)			
Ascites				1 (0.12)		1 (0.08)
Atrial fibrillation	1 (0.08)		1 (0.07)			
Atypical pneumonia				1 (0.12)		1 (0.08)
B-cell lymphoma		1 (0.30)	1 (0.07)			
Bacteraemia	1 (0.08)		1 (0.07)			
Basal cell carcinoma				1 (0.12)		1 (0.08)
Bile duct cancer		1 (0.30)	1 (0.07)			
Bladder cancer		1 (0.30)	1 (0.07)			
Bladder transitional cell carcinoma				1 (0.12)		1 (0.08)
Blood creatine phosphokinase increased					1 (0.30)	1 (0.08)
Brain oedema	1 (0.08)		1 (0.07)			
Breast cancer	1 (0.08)		1 (0.07)			
Brucellosis	1 (0.08)		1 (0.07)			
Candida pneumonia					1 (0.30)	1 (0.08)
Carcinoid tumour					1 (0.30)	1 (0.08)
Cardiac arrest	1 (0.08)		1 (0.07)			
Central nervous system lymphoma				1 (0.12)		1 (0.08)
Cerebral small vessel ischaemic disease				1 (0.12)		1 (0.08)

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Cerebrovascular accident					1 (0.30)	1 (0.08)
Cervix carcinoma	1 (0.08)		1 (0.07)			
Chikungunya virus infection	1 (0.08)		1 (0.07)			
Cholecystitis acute	1 (0.08)		1 (0.07)			
Chronic obstructive pulmonary disease	1 (0.08)		1 (0.07)			
Community acquired infection	1 (0.08)		1 (0.07)			
Conjunctival melanoma	1 (0.08)		1 (0.07)			
Deafness neurosensory	1 (0.08)		1 (0.07)			
Dehydration	1 (0.08)		1 (0.07)			
Dementia				1 (0.12)		1 (0.08)
Device dislocation				1 (0.12)		1 (0.08)
Diverticulum intestinal				1 (0.12)		1 (0.08)
Diverticulum intestinal haemorrhagic				1 (0.12)		1 (0.08)
Dizziness		1 (0.30)	1 (0.07)			
Drug-induced liver injury	1 (0.08)		1 (0.07)			
Dyspnoea		1 (0.30)	1 (0.07)			
Encephalopathy	1 (0.08)		1 (0.07)			
Endometrial adenocarcinoma					1 (0.30)	1 (0.08)
Endometrial hyperplasia	1 (0.08)		1 (0.07)			
Epstein-Barr viraemia	1 (0.08)		1 (0.07)			
Erysipelas	1 (0.08)		1 (0.07)			
Extradural abscess	1 (0.08)		1 (0.07)			

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	With de novo FIL PYE=1018.5 (n=335)	Total PYE=4591.2 (n=1530)	With continued FIL PYE=2568.5 (n=863)	With de novo FIL PYE=985.2 (n=336)	Total PYE=3553.8 (n=1199)
Femur fracture				1 (0.12)		1 (0.08)
Flank pain		1 (0.30)	1 (0.07)			
Gastric perforation	1 (0.08)		1 (0.07)			
Gastric ulcer perforation				1 (0.12)		1 (0.08)
Gastroenteritis				1 (0.12)		1 (0.08)
Gastroenteritis salmonella				1 (0.12)		1 (0.08)
Gastrointestinal perforation				1 (0.12)		1 (0.08)
Gastrointestinal stromal tumour	1 (0.08)		1 (0.07)			
H1N1 influenza				1 (0.12)		1 (0.08)
Haemoptysis				1 (0.12)		1 (0.08)
Hepatic steatosis				1 (0.12)		1 (0.08)
Herpes zoster cutaneous disseminated	1 (0.08)		1 (0.07)			
Herpes zoster disseminated	1 (0.08)		1 (0.07)			
Hilar lymphadenopathy	1 (0.08)		1 (0.07)			
Human ehrlichiosis	1 (0.08)		1 (0.07)			
Hydrometra				1 (0.12)		1 (0.08)
Hypertensive crisis	1 (0.08)		1 (0.07)			
Hypertonic bladder				1 (0.12)		1 (0.08)
Hypomagnesaemia	1 (0.08)		1 (0.07)			
Hyponatraemia	1 (0.08)		1 (0.07)			
Infected skin ulcer	1 (0.08)		1 (0.07)			
Infection	1 (0.08)		1 (0.07)			
Infective keratitis	1 (0.08)		1 (0.07)			

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Inflammation				1 (0.12)		1 (0.08)
Intraductal proliferative breast lesion	1 (0.08)		1 (0.07)			
Invasive breast carcinoma	1 (0.08)		1 (0.07)			
Ischaemic stroke	1 (0.08)		1 (0.07)			
Liver disorder				1 (0.12)		1 (0.08)
Localised infection	1 (0.08)		1 (0.07)			
Lung adenocarcinoma	1 (0.08)		1 (0.07)			
Lung cancer metastatic	1 (0.08)		1 (0.07)			
Lung disorder				1 (0.12)		1 (0.08)
Lung neoplasm				1 (0.12)		1 (0.08)
Lymph node tuberculosis				1 (0.12)		1 (0.08)
Malignant neoplasm of unknown primary site		1 (0.30)	1 (0.07)			
Malignant peritoneal neoplasm				1 (0.12)		1 (0.08)
Mental impairment				1 (0.12)		1 (0.08)
Metastases to bone		1 (0.30)	1 (0.07)			
Metastases to liver		1 (0.30)	1 (0.07)			
Metastases to salivary gland		1 (0.30)	1 (0.07)			
Metastatic neoplasm				1 (0.12)		1 (0.08)
Microscopic polyangiitis	1 (0.08)		1 (0.07)			
Mouth ulceration	1 (0.08)		1 (0.07)			
Myocardial infarction				1 (0.12)		1 (0.08)
Nasal sinus cancer				1 (0.12)		1 (0.08)

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Necrotising fasciitis	1 (0.08)		1 (0.07)			
Nephrolithiasis		1 (0.30)	1 (0.07)			
Neuroendocrine carcinoma of the skin	1 (0.08)		1 (0.07)			
Non-Hodgkin’s lymphoma				1 (0.12)		1 (0.08)
Non-small cell lung cancer		1 (0.30)	1 (0.07)			
Not coded				1 (0.12)		1 (0.08)
Oesophageal candidiasis	1 (0.08)		1 (0.07)			
Oesophageal carcinoma				1 (0.12)		1 (0.08)
Oesophageal squamous cell carcinoma metastatic	1 (0.08)		1 (0.07)			
Osmotic demyelination syndrome	1 (0.08)		1 (0.07)			
Otitis media acute	1 (0.08)		1 (0.07)			
Ovarian cancer				1 (0.12)		1 (0.08)
Ovarian granulosa cell tumour	1 (0.08)		1 (0.07)			
Ovarian neoplasm					1 (0.30)	1 (0.08)
Pancreatitis acute				1 (0.12)		1 (0.08)
Pancreatitis chronic				1 (0.12)		1 (0.08)
Pancytopenia				1 (0.12)		1 (0.08)
Papillary thyroid cancer	1 (0.08)		1 (0.07)			
Paraplegia					1 (0.30)	1 (0.08)
Paraspinal abscess	1 (0.08)		1 (0.07)			
Peripheral artery aneurysm	1 (0.08)		1 (0.07)			

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	With de novo FIL PYE=1018.5 (n=335)	Total PYE=4591.2 (n=1530)	With continued FIL PYE=2568.5 (n=863)	With de novo FIL PYE=985.2 (n=336)	Total PYE=3553.8 (n=1199)
Pharyngeal cancer metastatic	1 (0.08)		1 (0.07)			
Plasma cell myeloma				1 (0.12)		1 (0.08)
Pleuritic pain	1 (0.08)		1 (0.07)			
Pneumonia aspiration	1 (0.08)		1 (0.07)			
Pneumonia cryptococcal	1 (0.08)		1 (0.07)			
Pneumonia pneumococcal	1 (0.08)		1 (0.07)			
Pneumonia viral		1 (0.30)	1 (0.07)			
Pneumonitis		1 (0.30)	1 (0.07)			
Post procedural infection				1 (0.12)		1 (0.08)
Prostate cancer metastatic		1 (0.30)	1 (0.07)			
Pulmonary mass				1 (0.12)		1 (0.08)
Pulmonary oedema	1 (0.08)		1 (0.07)			
Pulmonary tuberculosis	1 (0.08)		1 (0.07)			
Pyelonephritis chronic	1 (0.08)		1 (0.07)			
Rectal neoplasm				1 (0.12)		1 (0.08)
Rectosigmoid cancer	1 (0.08)		1 (0.07)			
Renal cancer	1 (0.08)		1 (0.07)			
Renal cancer metastatic		1 (0.30)	1 (0.07)			
Renal cell carcinoma				1 (0.12)		1 (0.08)
Renal function test abnormal				1 (0.12)		1 (0.08)
Renal impairment				1 (0.12)		1 (0.08)
Restlessness				1 (0.12)		1 (0.08)
SARS-CoV-2 test positive					1 (0.30)	1 (0.08)

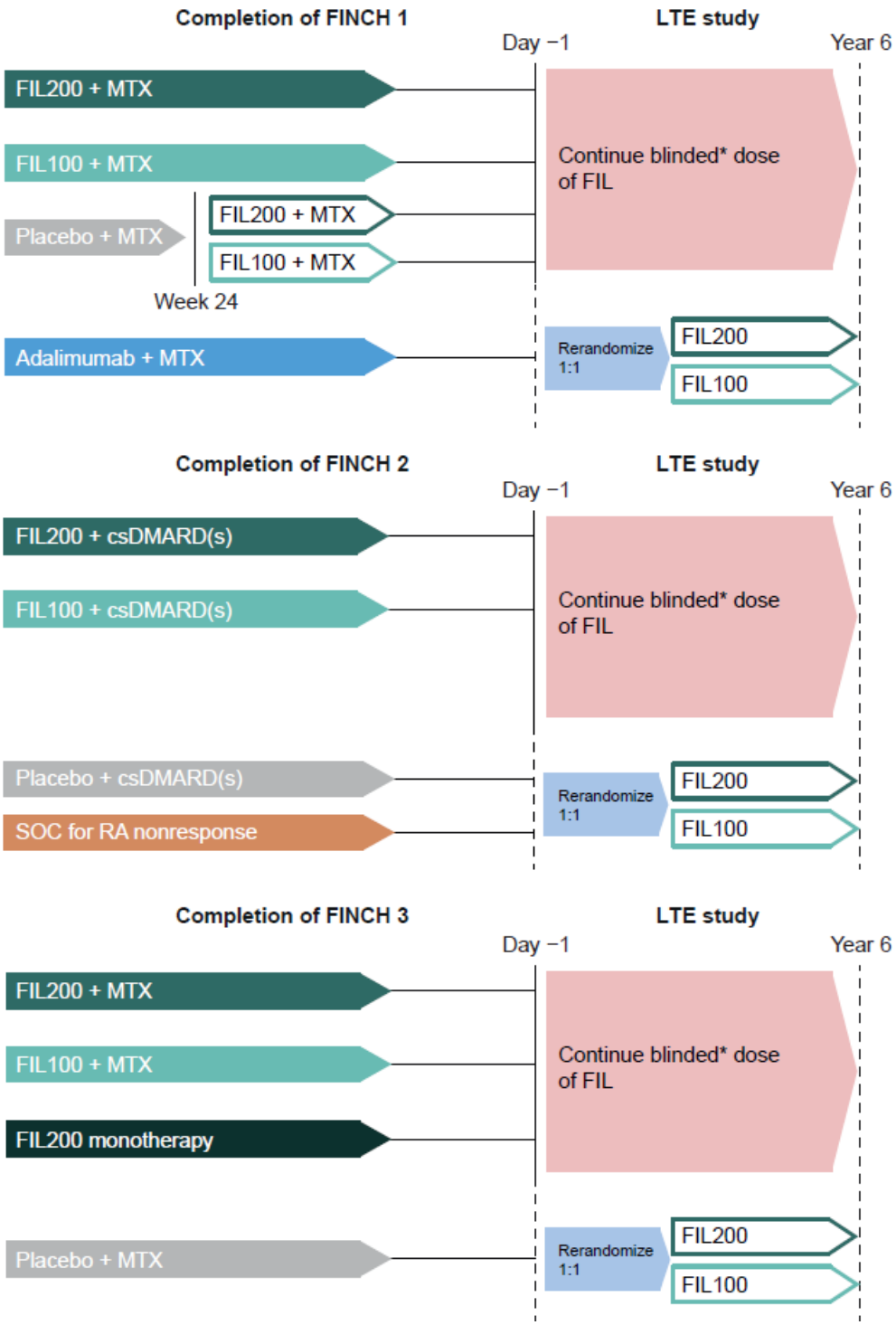
	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Seborrhoeic dermatitis	1 (0.08)		1 (0.07)			
Sinus arrhythmia					1 (0.30)	1 (0.08)
Sinus bradycardia					1 (0.30)	1 (0.08)
Sinus tachycardia	1 (0.08)		1 (0.07)			
Skin ulcer	1 (0.08)		1 (0.07)			
Spinal osteoarthritis				1 (0.12)		1 (0.08)
Squamous cell carcinoma of the skin	1 (0.08)		1 (0.07)			
Staphylococcal bacteraemia				1 (0.12)		1 (0.08)
Stroma site infection				1 (0.12)		1 (0.08)
Stress cardiomyopathy	1 (0.08)		1 (0.07)			
Subarachnoid haemorrhage					1 (0.30)	1 (0.08)
Subcutaneous emphysema	1 (0.08)		1 (0.07)			
Superficial vein thrombosis	1 (0.08)		1 (0.07)			
Supraventricular tachycardia				1 (0.12)		1 (0.08)
Syphilis				1 (0.12)		1 (0.08)
T-cell lymphoma					1 (0.30)	1 (0.08)
Thrombotic cerebral infarction	1 (0.08)		1 (0.07)			
Thyroid mass	1 (0.08)		1 (0.07)			
Tibia fracture				1 (0.12)		1 (0.08)
Transitional cell carcinoma					1 (0.30)	1 (0.08)
Tremor	1 (0.08)		1 (0.07)			
Tuberculosis				1 (0.12)		1 (0.08)

	FIL200 Number of patients (%) with the TEAE listed			FIL100 Number of patients (%) with the TEAE listed		
	With continued FIL PYE=3572.7 (n=1195)	**With de novo FIL PYE=1018.5 (n=335)**	**Total PYE=4591.2 (n=1530)**	**With continued FIL PYE=2568.5 (n=863)**	**With de novo FIL PYE=985.2 (n=336)**	**Total PYE=3553.8 (n=1199)**
Urinary tract infection bacterial				1 (0.12)		1 (0.08)
Urticarial vasculitis				1 (0.12)		1 (0.08)
Vaginal haemorrhage				1 (0.12)		1 (0.08)
Varicella	1 (0.08)		1 (0.07)			
Vomiting	1 (0.08)		1 (0.07)			
Wound infection					1 (0.30)	1 (0.08)

TEAEs are defined as any adverse events that began on or after the study drug start date, up to 30 days after permanent discontinuation of study drug. Only adverse events with a start date after LTE treatment start are considered.

FIL(100/200), filgotinib (100 mg/200 mg); LTE, long-term extension; PYE, patient-years of exposure; TEAE, treatment-emergent adverse event.

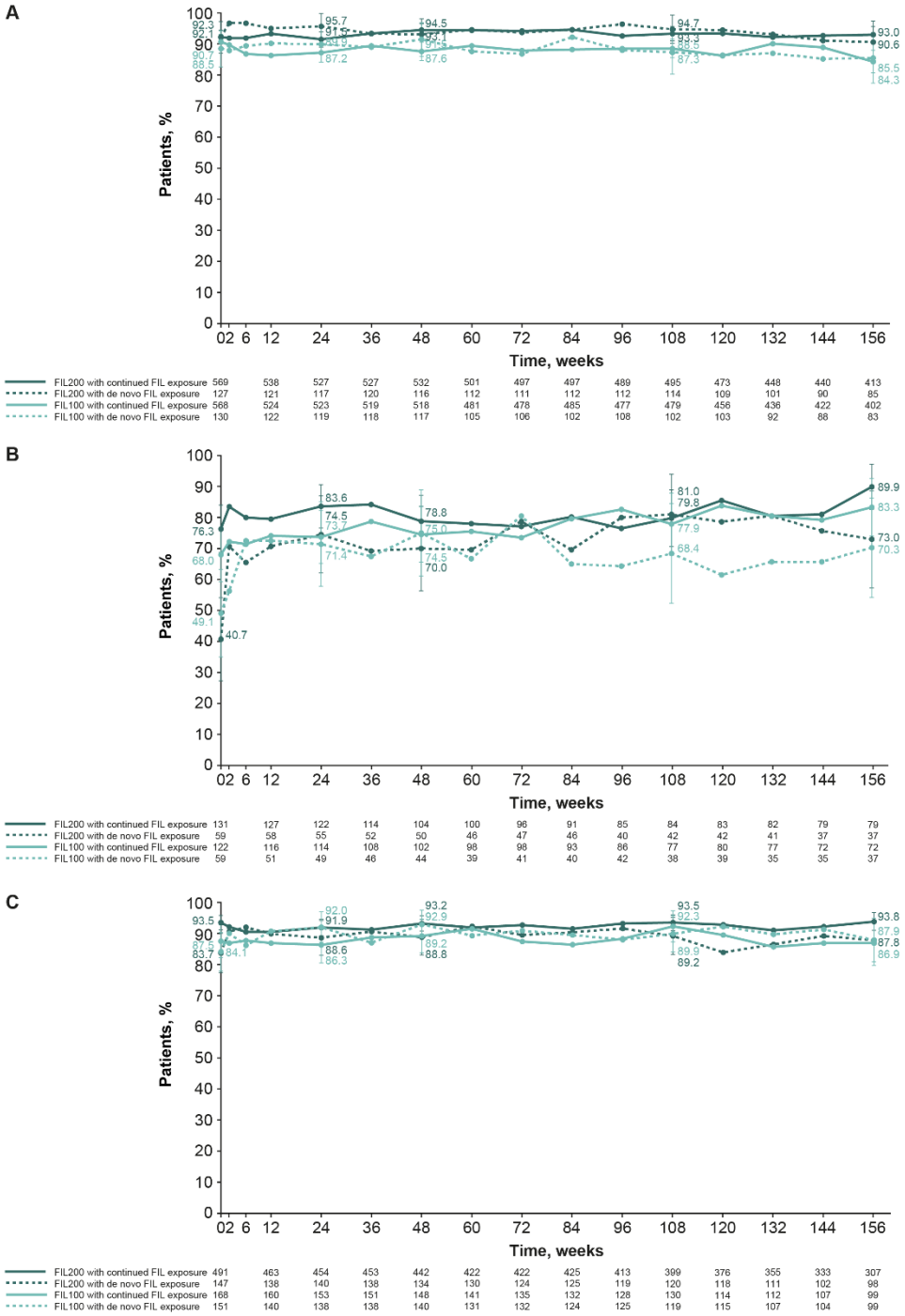
Supplemental figure 1 Study design



*Until study becomes open label.

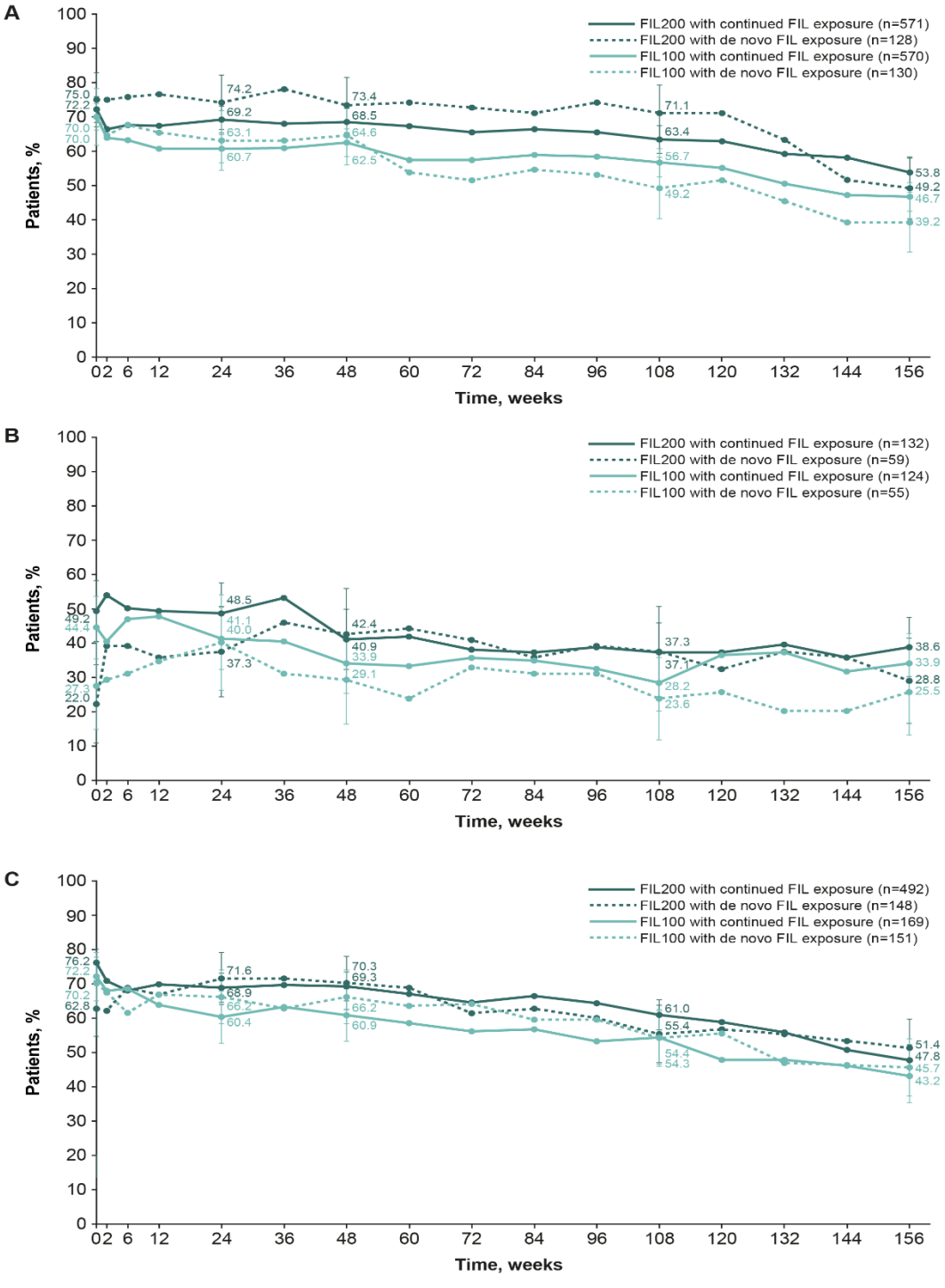
csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; FIL(100/200), filgotinib (100 mg/200 mg); LTE, long-term extension; MTX, methotrexate; RA, rheumatoid arthritis; SOC, standard of care.

Supplemental figure 2 The proportion of patients who achieved ACR20 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



ACR20 was calculated based on parent study baseline. Error bars show 95% CIs. ACR20, American College of Rheumatology 20% response; FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

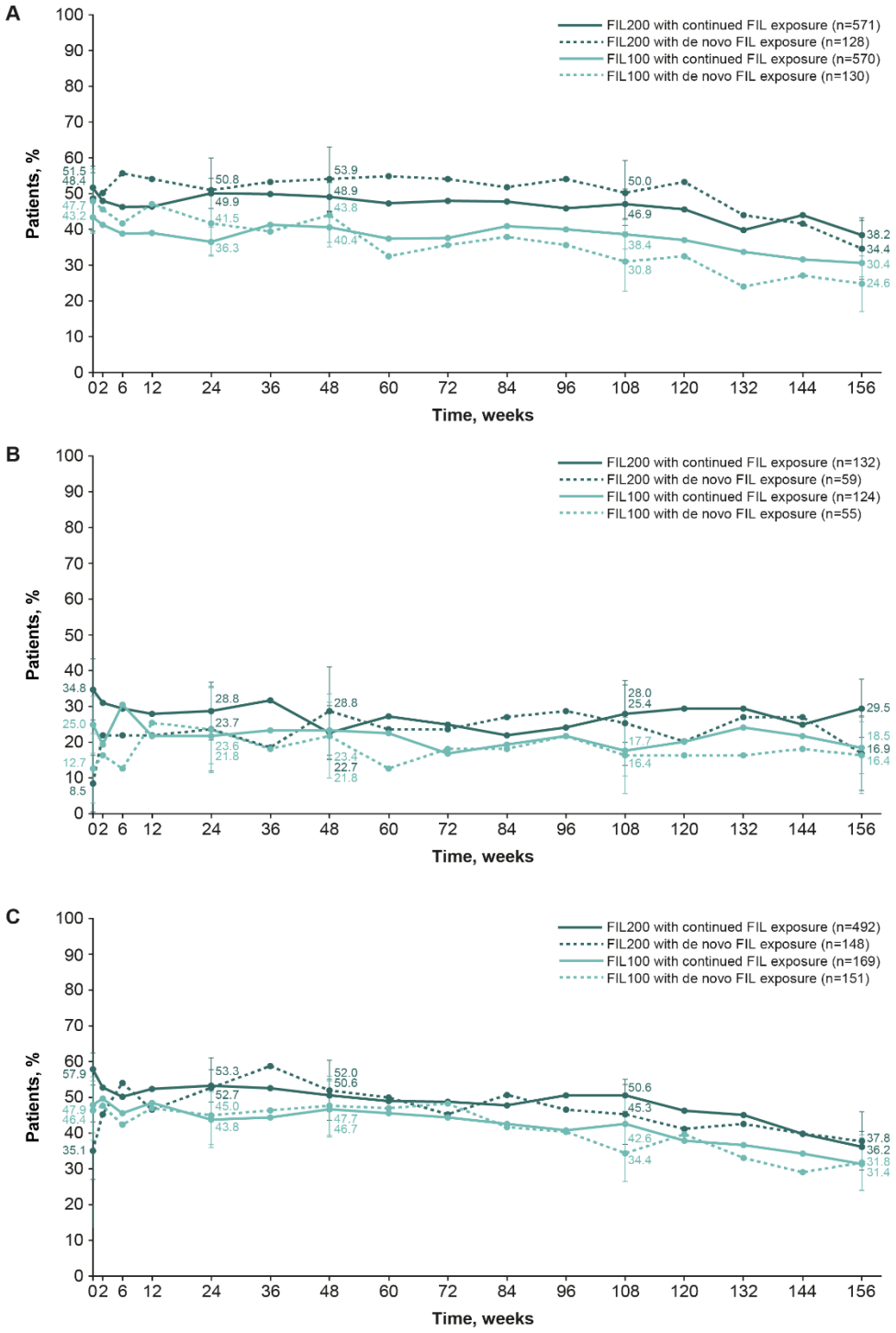
Supplemental figure 3 The proportion of patients who achieved ACR50 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, NRI)



Patients with missing outcomes were set as non-responders. ACR50 was calculated based on the parent study baseline. Error bars show 95% CIs.

ACR50, American College of Rheumatology 50% response; FIL(100/200), filgotinib (100 mg/200 mg); NRI, non-responder imputation.

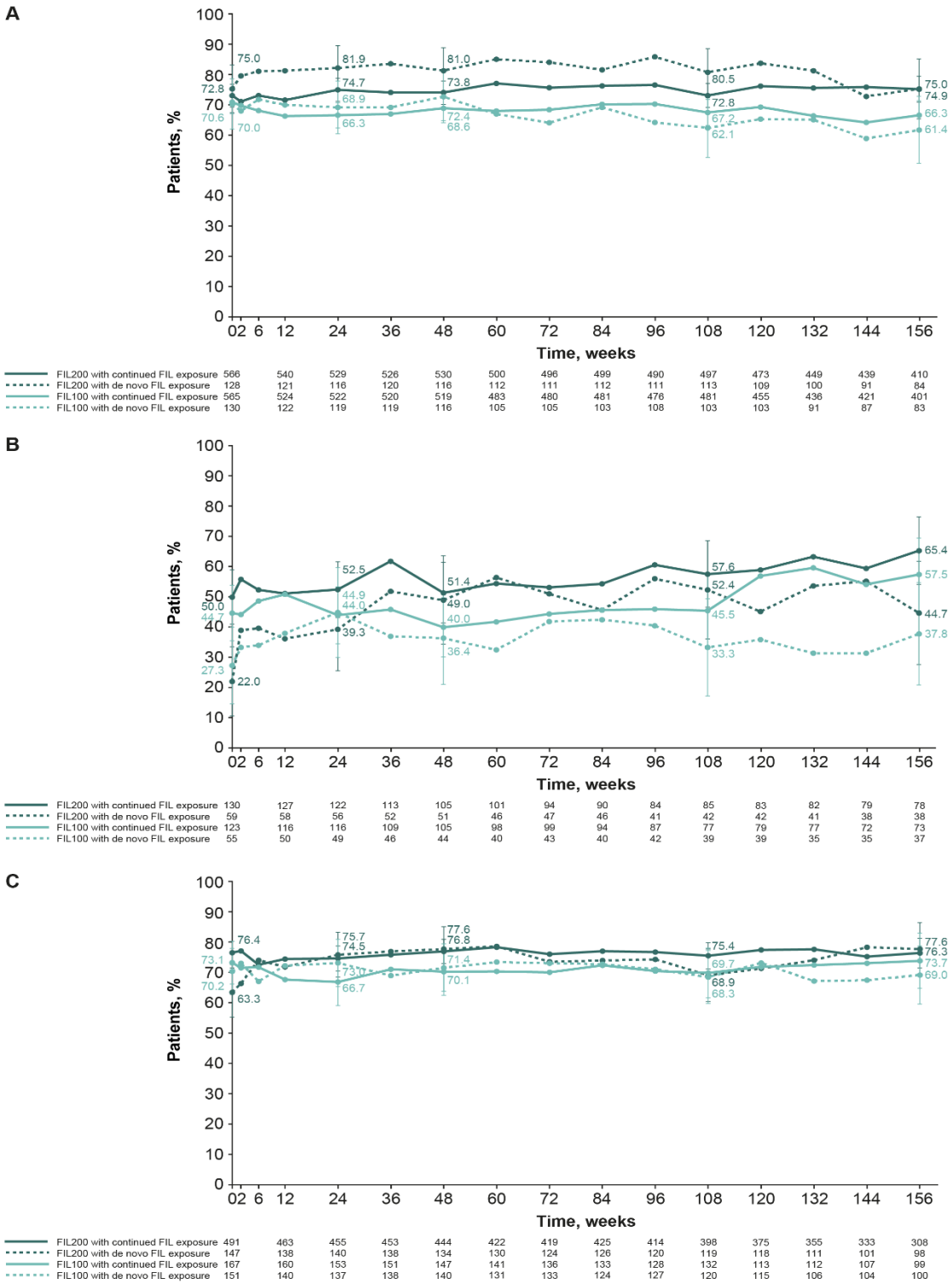
Supplemental figure 4 The proportion of patients who achieved ACR70 responses in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, NRI)



Patients with missing outcomes were set as non-responders. ACR70 was calculated based on the parent study baseline. Error bars show 95% CIs.

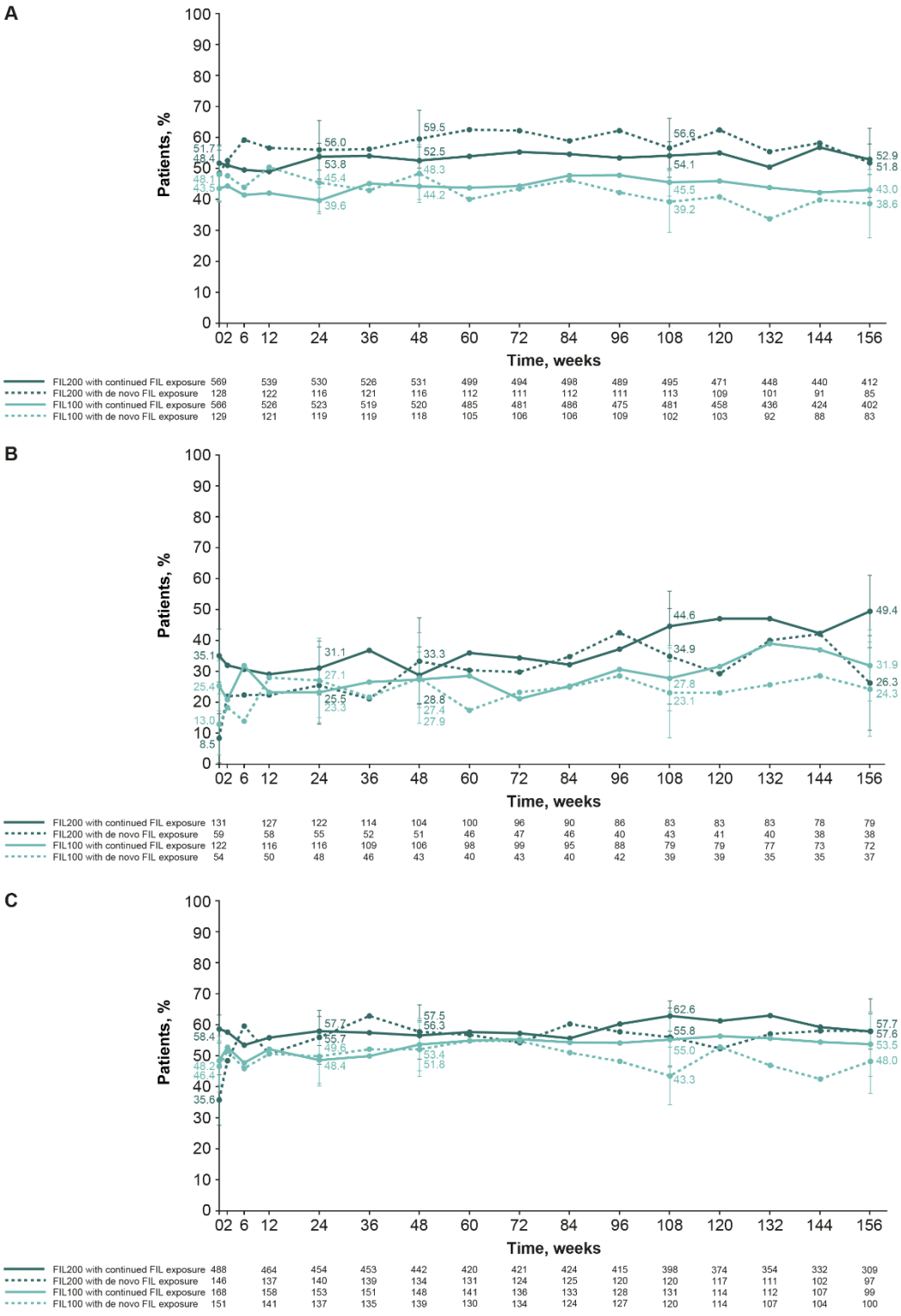
ACR70, American College of Rheumatology 70% response; FIL(100/200), filgotinib (100 mg/200 mg); NRI, non-responder imputation.

Supplemental figure 5 The proportion of patients who achieved ACR50 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



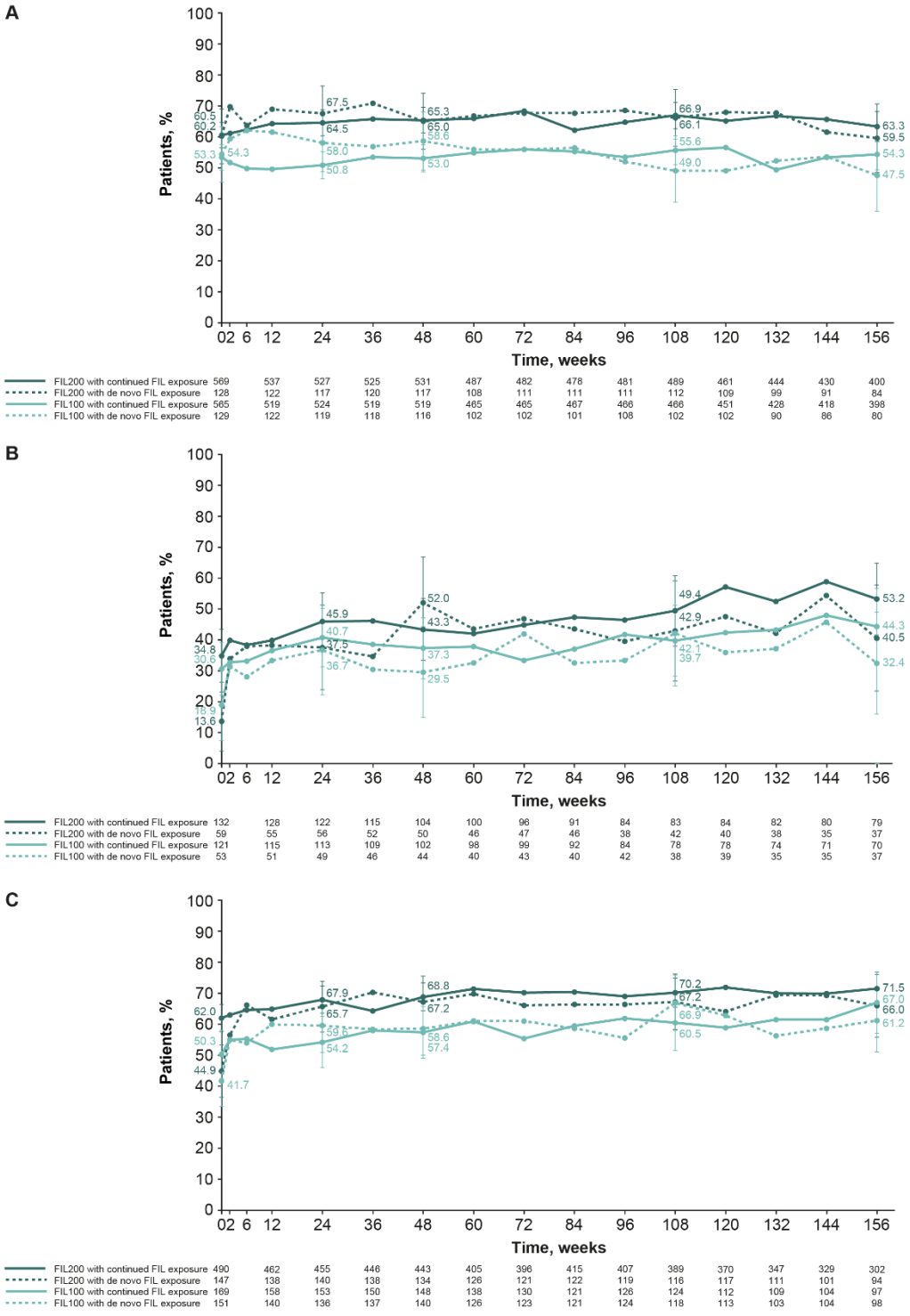
ACR50 was calculated based on the parent study baseline. Error bars show 95% CIs. ACR50, American College of Rheumatology 50% response; FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

Supplemental figure 6 The proportion of patients who achieved ACR70 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



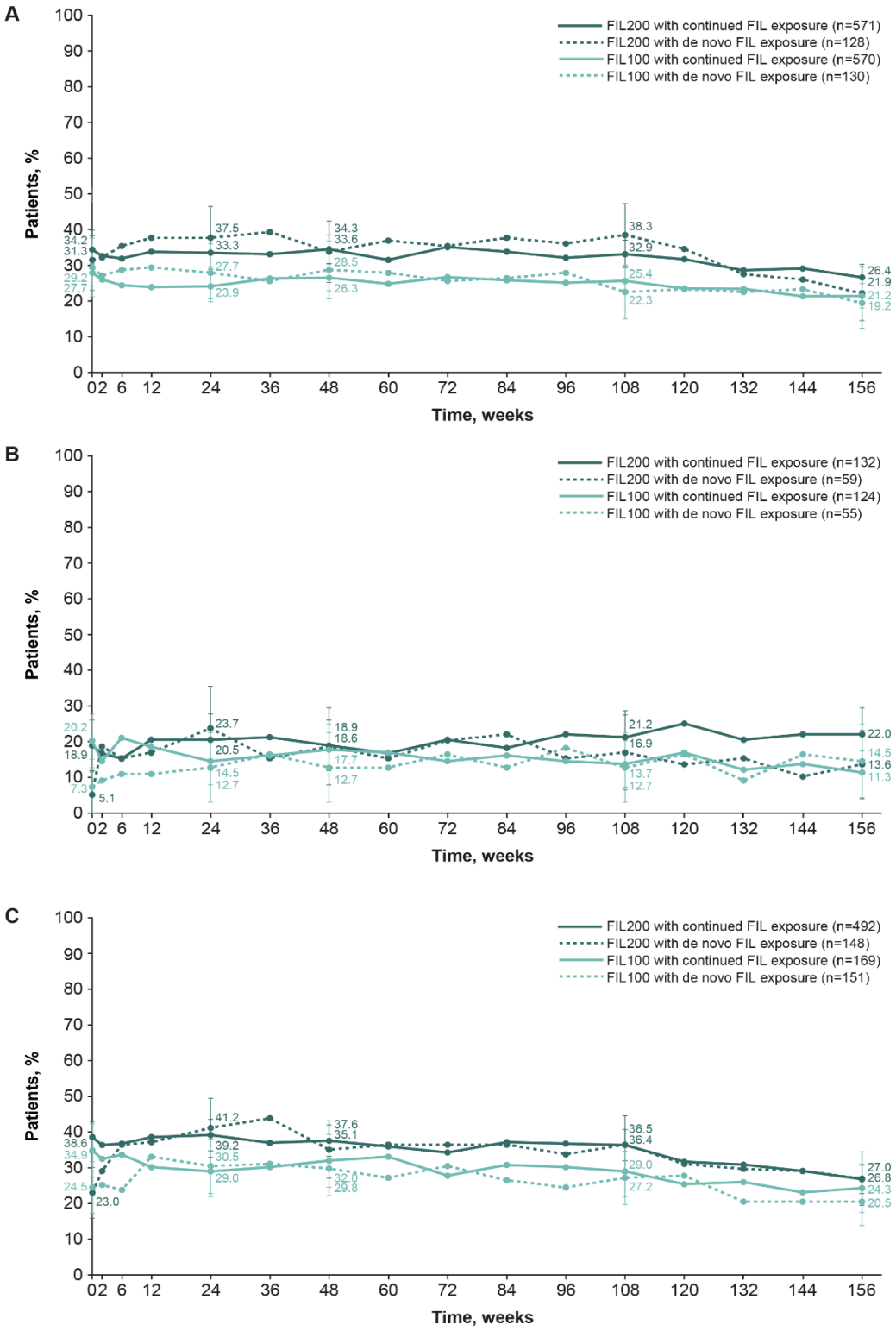
ACR70 was calculated based on the parent study baseline. Error bars show 95% CIs. ACR70, American College of Rheumatology 70% response; FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

Supplemental figure 7 The proportion of patients who achieved DAS28-CRP <2.6 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



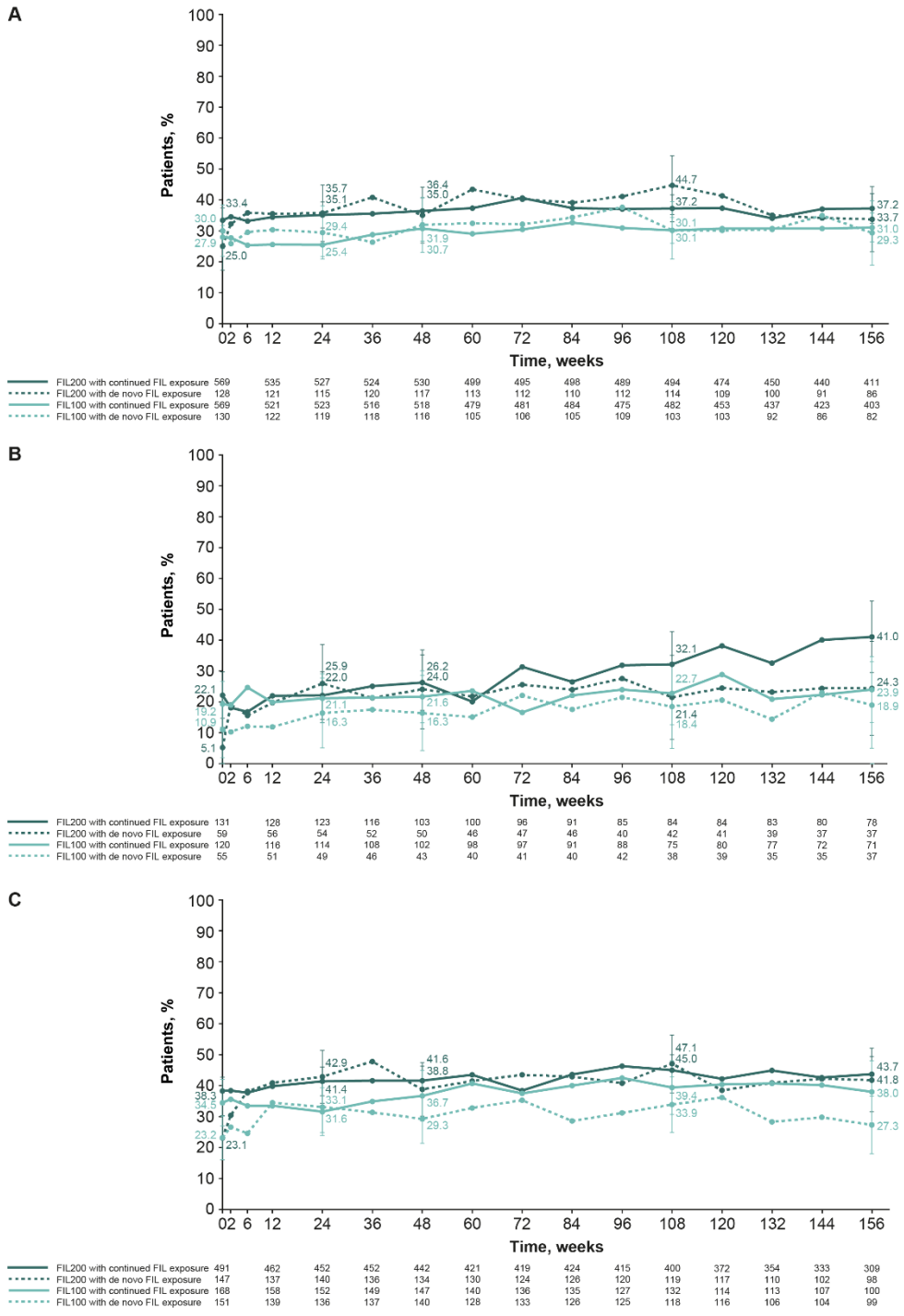
DAS28-CRP was calculated based on the parent study baseline. Error bars show 95% CIs. DAS28-CRP, Disease Activity Score 28 using C-reactive protein; FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

Supplemental figure 8 The proportion of patients who achieved SDAI ≤3.3 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, NRI)



Patients with missing outcomes were set as non-responders. Error bars show 95% CIs. FIL(100/200), filgotinib (100 mg/200 mg); NRI, non-responder imputation; SDAI, Simplified Disease Activity Index.

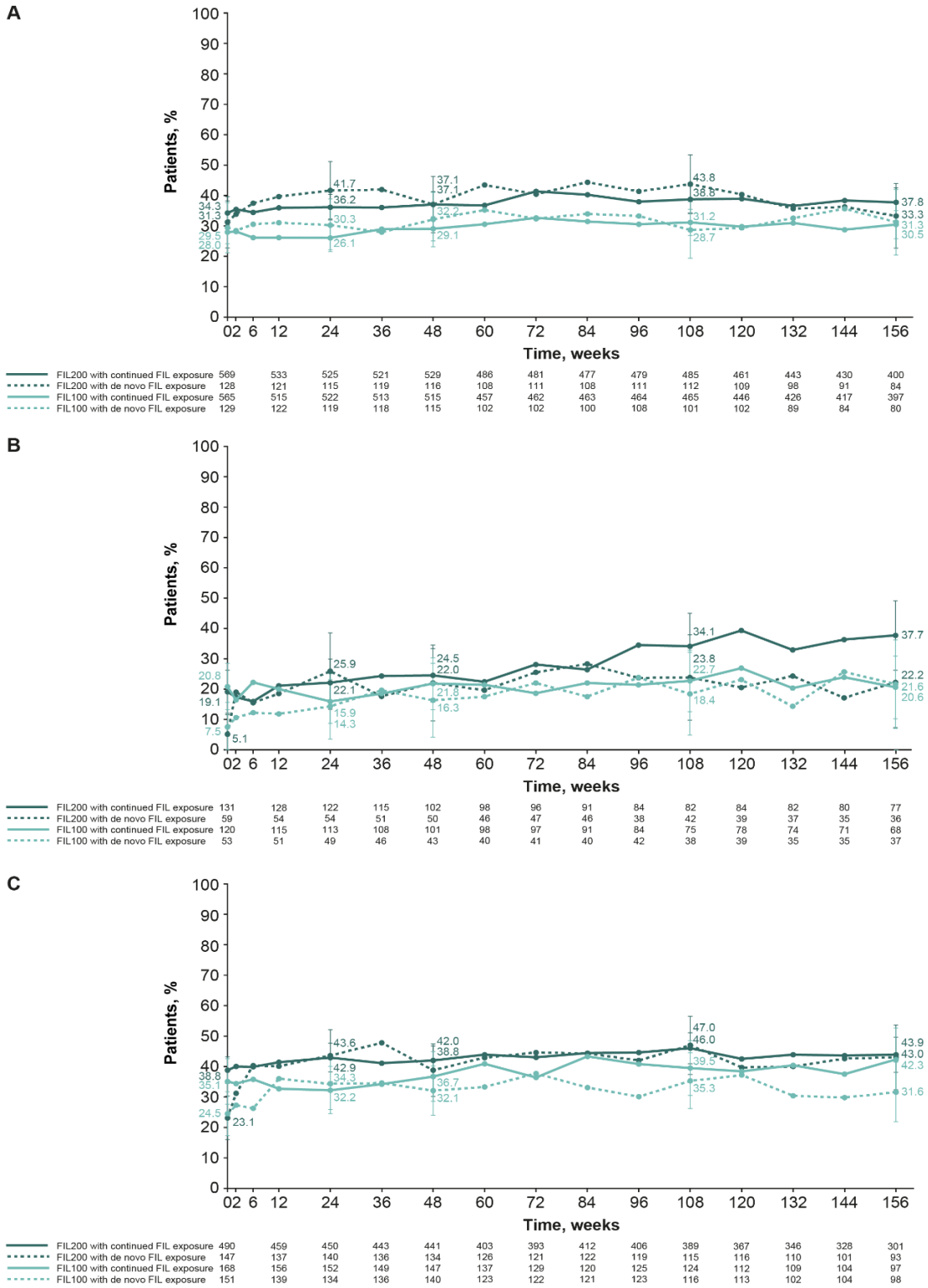
Supplemental figure 9 The proportion of patients who achieved CDAI ≤2.8 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



Error bars show 95% CIs.

CDAI, Clinical Disease Activity Index; FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

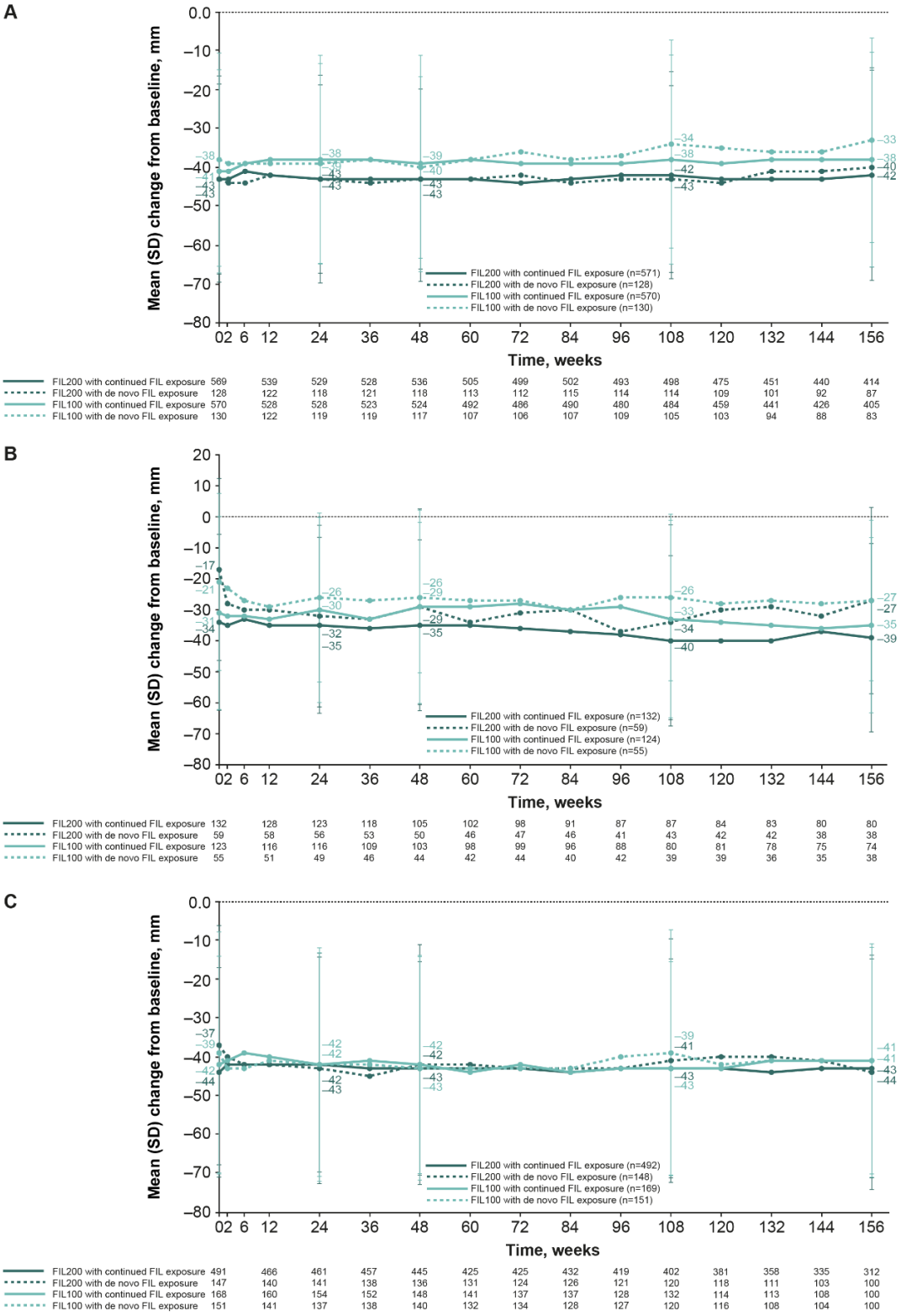
Supplemental figure 10 The proportion of patients who achieved SDAI ≤3.3 in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



Error bars show 95% CIs.

FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case; SDAI, Simplified Disease Activity Index.

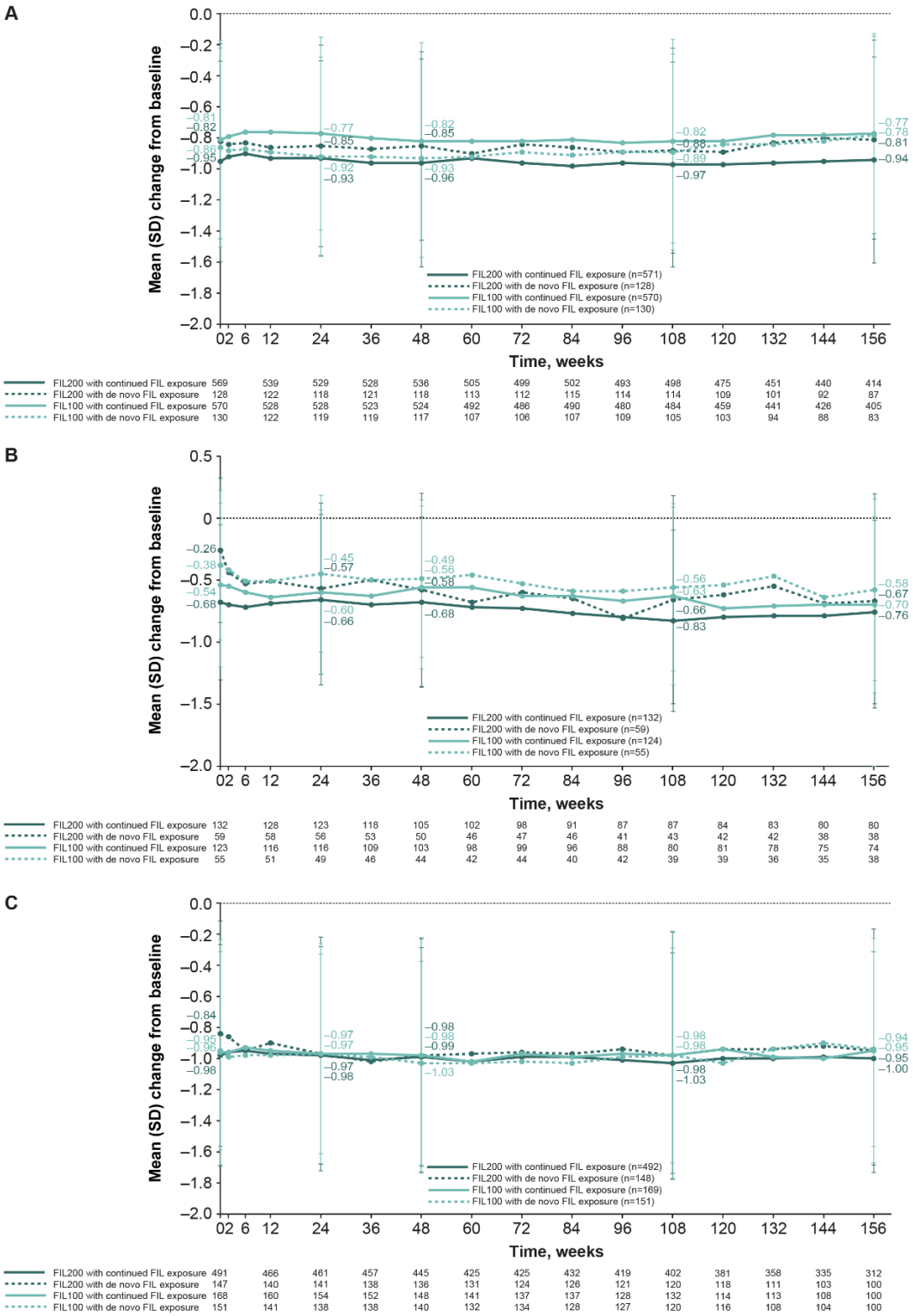
Supplemental figure 11 Change from baseline in pain in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set)



Baseline value was the last available value collected on or prior to the first dose of study drug. Error bars show SD.

FIL(100/200), filgotinib (100 mg/200 mg).

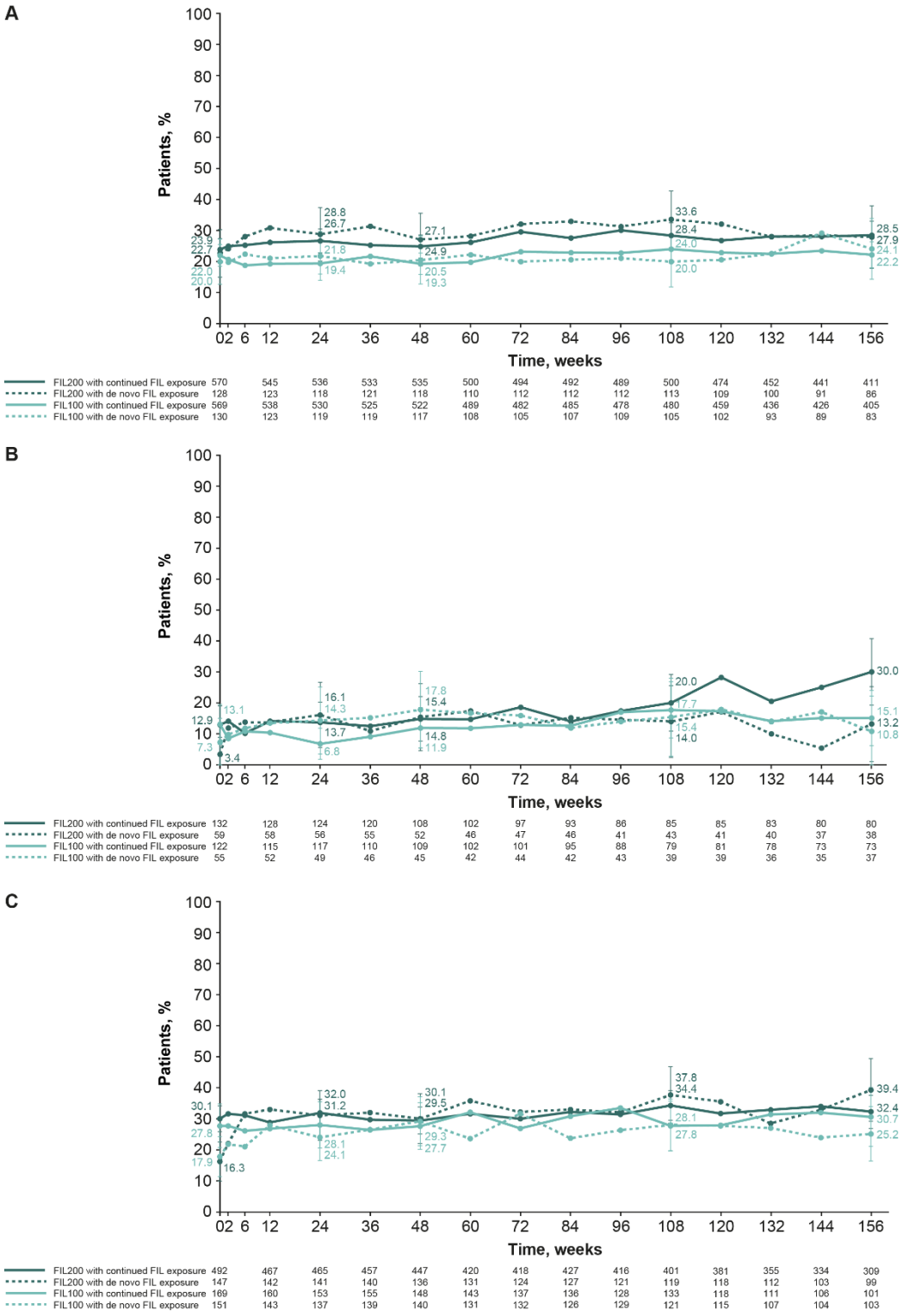
Supplemental figure 12 Change from baseline in HAQ-DI in FINCH 4 according to parent study: FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set)



Baseline value was the last available value collected on or prior to the first dose of study drug. Error bars show SD.

FIL(100/200), filgotinib (100 mg/200 mg); HAQ-DI, Health Assessment Questionnaire–Disability Index.

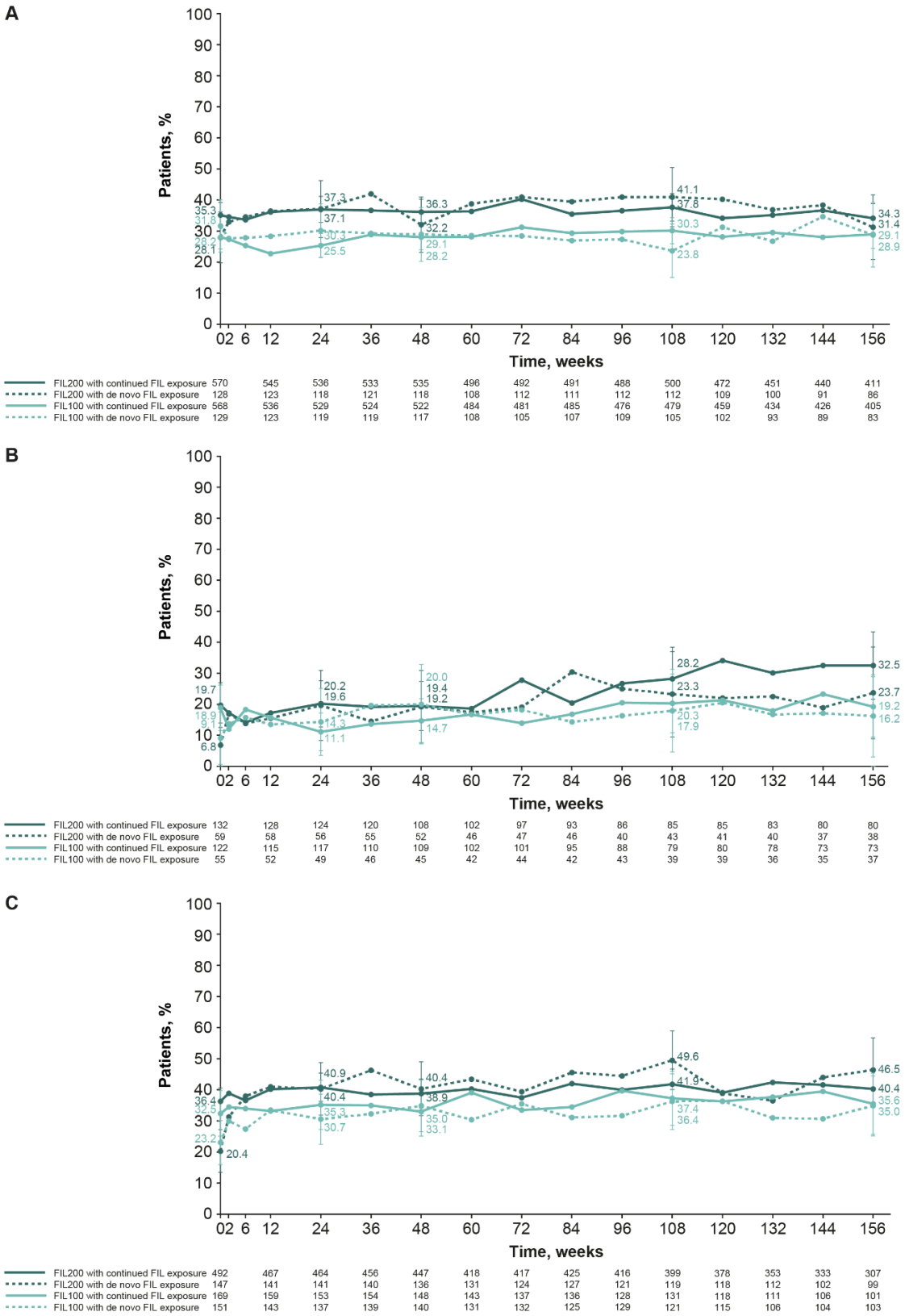
Supplemental figure 13 The proportion of patients who achieved Boolean remission 1.0 in FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



Error bars show 95% CIs.

FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.

Supplemental figure 14 The proportion of patients who achieved Boolean remission 2.0 in FINCH 1 (A), FINCH 2 (B) and FINCH 3 (C) (safety analysis set, OC)



Error bars show 95% CIs.

FIL(100/200), filgotinib (100 mg/200 mg); OC, observed case.