

Supplementary Table S1: Serious Adverse Events, PF-00547659 vs. Placebo

Patient ID (Gender/Age, y)	Suspect Drug / Dose*	Preferred Term	Event Onset / Stop (Day)	Outcome
10341011 (female/19)	Placebo	Rectal stenosis	69/71	Recovered/resolved
10441007 (female/50)	Placebo	Crohn's disease	34/59	Recovered/resolved
10441009 (female/26)	Placebo	Crohn's disease	2/12	Recovered/resolved
10951012 (male/40)	Placebo	Crohn's disease	47/56	Recovered/resolved
11201002 (male/30)	Placebo	Pyrexia	1/4	Recovered/resolved
		Anal abscess	13/14	Recovered/resolved
10031004 (female/54)	22.5 mg	Appendicitis	36/43	Recovered/resolved with sequel
10621001 (male/32)	22.5 mg	Gastrointestinal inflammation	60/74	Recovered/resolved with sequel
		Subileus	81/83	Recovered/resolved
10751008 (female/58)	22.5 mg	Liver abscess	30/NA	Recovering/resolving
10801005 (male/50)	22.5 mg	Crohn's disease	71/90	Recovered/resolved
10941008 (female/36)	22.5 mg	Crohn's disease	30/58	Recovered/resolved
11071026 (female/23)	22.5 mg	Appendicitis	25/41	Recovered/resolved
11141001 (female/29)	22.5 mg	Rectal abscess	14/219	Recovered/resolved
11261002 (female/29)	22.5 mg	Condition aggravated (worsening Crohn's disease)	8/32	Recovered/resolved
11381004 (female/20)	22.5 mg	Crohn's disease	4/114	Recovered/resolved
11731004 (female/42)	22.5 mg	Crohn's disease	27/55	Recovered/resolved
12021001 (female/24)	22.5 mg	Arthritis	17/43	Recovered/resolved
12141004 (female/43)	22.5 mg	Chest pain	49/63	Recovered/resolved
10431002 (male/27)	75 mg	Pyrexia	1/7	Recovered/resolved
		Crohn's disease	14/29	Recovered/resolved with sequel
		Gastrointestinal stoma complication	37/72	Recovered/resolved
10451004 (female/60)	75 mg	Myalgia	29/NA	Recovering/resolving
		Crohn's disease	29/238	Recovered/resolved
10621002 (male/49)	75 mg	Anal abscess	57/64	Recovered/resolved
10781001 (female/47)	75 mg	Small intestinal obstruction	30/32	Recovered/resolved
11641005 (female/24)	75 mg	Crohn's disease	35/113	Recovered/resolved
10831001 (female/25)	75 mg	Staphylococcal sepsis	17/53	Recovered/resolved
		Implant site infection	17/53	Recovered/resolved

Patient ID (Gender/Age, y)	Suspect Drug / Dose*	Preferred Term	Event Onset / Stop (Day)	Outcome
		Crohn's disease	32/36	Recovered/resolved
		Dehydration	95/96	Recovered/resolved
10901001 (female/27)	75 mg	Intestinal obstruction	25/77	Recovered/resolved with sequel
		Sepsis	53/67	Recovered/resolved
		Staphylococcal infection	93/99	Recovered/resolved
11581001 (male/47)	75 mg	Cerebellar infarction	72/NA	Not recovered/not resolved
11621002 (female/19)	75 mg	Crohn's disease	32/NA	Not recovered/not resolved
10131001 (male/26)	225 mg	Anal abscess	89/459	Recovered/resolved
10251003 (male/36)	225 mg	Colitis ulcerative	20/21	Recovered/resolved with sequel
10801004 (female/22)	225 mg	Pulmonary cavitation	39/NA	Not recovered/not resolved
10931016 (male/20)	225 mg	Crohn's disease	31/45	Recovered/resolved
		Pyrexia	46/48	Recovered/resolved
10941001 (female/26)	225 mg	Crohn's disease	3/9	Recovered/resolved
10941007 (female/31)	225 mg	Headache	6/31	Recovered/resolved
11191005 (male/39)	225 mg	Small intestinal obstruction	20/22	Recovered/resolved
11531004 (female/44)	225 mg	Small intestinal obstruction	34/39	Recovered/resolved
		Crohn's disease	41/42	Recovered/resolved
11621005 (female/56)	225 mg	Abdominal adhesions	46/50	Recovered/resolved
		Urinary tract infection	46/52	Recovered/resolved
11641004 (female/25)	225 mg	Crohn's disease	76/102	Recovered/resolved
11731006 (male/31)	225 mg	Calculus urinary	7/8	Recovered/resolved

*PF-00547659 dosage.

NA, not available.

Data on file, Pfizer Inc, New York, NY USA