Supplemental Table 1. Exposure-adjusted incidence of serious adverse events

	Double-blind treatment phase				Long-term extension phase		
	Placebo	Erenumab			Erenumab		
		70 mg	140 mg	All	70 mg	140 mg	All
	N = 1043 (pt-yr = 321.7)	N = 893 (pt-yr = 285.7)	N = 507 (pt-yr = 193.5)	N = 1400 (pt-yr = 479.3)	N = 1891 (pt-yr = 1782.5)	N = 933 (pt-yr = 822.9)	N = 2375 (pt-yr = 2605.3)
	n [r]	n [r]	n [r]	n [r]	n [r]	n [r]	n [r]
Serious adverse events	20 [6.3]	18 [6.4]	10 [5.2]	28 [5.9]	72 [4.1]	38 [4.7]	106 [4.2]
SAEs by preferred term							
Migraine	2 [0.6]	3 [1.1]	0 [0.0]	3 [0.6]	2 [0.1]	2 [0.2]	4 [0.2]
Noncardiac chest pain	1 [0.3]	2 [0.7]	1 [0.5]	3 [0.6]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Intervertebral disc protrusion	1 [0.3]	2 [0.7]	0 [0.0]	2 [0.4]	3 [0.2]	0 [0.0]	3 [0.1]
Cholelithiasis	0 [0.0]	2 [0.7]	0 [0.0]	2 [0.4]	0 [0.0]	0 [0.0]	0 [0.0]
Uterine leiomyoma	1 [0.3]	0 [0.0]	1 [0.5]	1 [0.2]	2 [0.1]	2 [0.2]	4 [0.2]
Syncope	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	4 [0.2]	0 [0.0]	4 [0.2]
Appendicitis	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	1 [< 0.1]	2 [0.2]	3 [0.1]
Ovarian cyst	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Gastroenteritis viral	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Abdominal adhesions	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	1 [< 0.1]	0 [0.0]	1 [< 0.1]

Abdominal pain	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Vertigo	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	1 [0.1]	1 [< 0.1]
Radius fracture	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	1 [0.1]	1 [< 0.1]
Costochondritis	0 [0.0]	1 [0.3]	0 [0.0]	1 [0.2]	0 [0.0]	1 [0.1]	1 [< 0.1]
Vestibular neuronitis	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Back pain	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Kidney infection	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Clostridium difficile colitis	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Pyelonephritis	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Sepsis	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Fibroma	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Post-traumatic neck syndrome	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Pyelonephritis acute	0 [0.0]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Ankle fracture	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Cartilage injury	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Cerebral venous thrombosis	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Urinary tract infection	2 [0.6]	1 [0.4]	0 [0.0]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Spinal pain	0 [0.0]	0 [0.0]	1 [0.5]	1 [0.2]	0 [0.0]	0 [0.0]	0 [0.0]
Depression	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	4 [0.2]	0 [0.0]	4 [0.2]
Diverticulitis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	3 [0.4]	3 [0.1]

Breast cancer	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	2 [0.1]	1 [0.1]	3 [0.1]
Adjustment disorder	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	1 [0.1]	2 [< 0.1]
Deep vein thrombosis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	2 [0.1]	0 [0.0]	2 [< 0.1]
Ligament rupture	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	2 [0.1]	0 [0.0]	2 [< 0.1]
Pneumonia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	1 [0.1]	2 [< 0.1]
Papillary thyroid cancer	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	2 [0.1]	0 [0.0]	2 [< 0.1]
Myocardial ischemia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	2 [0.1]	0 [0.0]	2 [< 0.1]
Osteoarthritis	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Cholecystitis	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Hypersensitivity	2 [0.6]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Endometriosis	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Fall	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Intentional overdose	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Vomiting	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Arthralgia	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Parotitis	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Pancreatitis	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Hyponatremia	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Flank pain	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]
Cholecystitis acute	1 [0.3]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]

Visual impairment	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Faecaloma	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Cellulitis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Abdominal hernia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Metatarsalgia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Menorrhagia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Musculoskeletal chest pain	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Pulmonary embolism	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Thrombosis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Lumbar radiculopathy	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Fallopian tube cyst	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Colitis ischaemic	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Diverticulum	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Optic neuritis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Postprocedural edema	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Pelvi-ureteric obstruction	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Hepatic cyst	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Rectal prolapse	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Rotator cuff syndrome	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Gastroenteritis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]

Migraine with aura	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Dyspepsia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Gastritis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Femur fracture	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Cauda equina syndrome	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Lumbar spinal stenosis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Spinal compression fracture	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Wound	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Anemia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Laryngeal hematoma	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Presyncope	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Radicular syndrome	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Volvulus	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Toxic encephalopathy	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Pneumococcal bacteraemia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Acute respiratory distress syndrome	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Tubo-ovarian abscess	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Hypoglycaemia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Atrial fibrillation	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Blood potassium decreased	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]

Urticaria	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Oesophagitis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Nasal septal operation	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Postprocedural infection	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Gastro-oesophageal reflux disease	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Pancreatic cysts	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Postoperative abscess	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Alcoholism	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Prolactin-producing pituitary tumor	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Erysipelas	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Breast fibroma	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Idiopathic orbital inflammation	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Nasal septum deviation	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Breast cyst	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Myocardial bridging	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Iridocyclitis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Abdominal pain lower	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Alcoholic liver disease	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Medication overuse headache	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Tooth abscess	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]

Postprocedural pulmonary embolism	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Adenocarcinoma of the cervix	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Invasive lobular breast carcinoma	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Visual acuity reduced	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Appendicitis noninfective	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Vestibular migraine	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Cervicobrachial syndrome	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Subdural hematoma	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Transient ischemic attack	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Suicide attempt	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Dehydration	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Idiopathic intracranial hypertension	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Lung adenocarcinoma stage III	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Gastrointestinal hemorrhage	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Peritoneal hemorrhage	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Pericarditis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Arrhythmogenic right ventricular dysplasia	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [< 0.1]
Arteriosclerosis	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]
Hypertensive heart disease	0 [0.0]	0 [0.0]	0 [0.0]	0 [0.0]	1 [< 0.1]	0 [0.0]	1 [< 0.1]

MedDRA, Medical Dictionary for Regulatory Activities; pt-yr, patient-years;

N = number of patients who receied at least one dose of erenumab or placebo; n = number of patients reporting at least one occurrence of an adverse event; e = sum across all patients, the total time at risk in years; r = exposure-adjusted patient incidence rate per 100 pt-yr (n/e * 100). Multiple occurrences of the same event for a patient are counted once within a dose level. Coded using MedDRA version 20.0

Supplemental Table 2. Onset and duration of constipation adverse events

	Erenumab 70/140 mg during DBTP N = 1400 (pt-yr = 479.3)	**Erenumab 70/140 mg during entire study[a] N = 2499 (pt-yr = 3084.6)**
Constipation, n [r]	33 [7.0]	73 [2.4]
Time to onset of constipation, days, median (Q1, Q3)	7.0 (2.0, 41.0)	48 (4.0, 190.0)
Time to onset, n		
< 1 week	16	21
1–2 weeks	3	3
2–3 weeks	2	4
3–4 weeks	2	2
1–2 months	5	7
≥ 2 months	5	36
Duration, days, median (Q1, Q3)	42.0 (18.0, 87.0)	37.5 (14.0, 115.0)

DBTP, double-blind placebo-controlled treatment phase; pt-yr, patient-years; Q, quartile

Multiple occurrences of constipation adverse event for a patient were counted once. N = number of patients in the analysis set exposed to erenumab 70 or 140 mg; n = number of patients reporting at least one occurrence of constipation; e = sum across all patients, the total time at risk in years; r = exposure-adjusted patient incidence rate per 100 pt-yr (n/e * 100). Time to onset was calculated as the time to the start date of the first occurrence of constipation since the first dose of erenumab 70 mg or 140 mg

[a]Includes patients from 7/21 mg groups in the DBTP who received 70 mg or 140 mg during extension phases and patients who received 70/140 mg during the DBTP who did not enroll in the extension phase

Supplemental Table 3. Anti-erenumab antibodies during double-blind treatment phase

	Erenumab 70 mg N = 893	Erenumab 140 mg N = 507	Total N = 1400
Patients with an on-study result	893	507	1400
Binding antibody–positive, n (%)	57 (6.4)	14 (2.8)	71 (5.1)
Neutralizing antibody–positive, n (%)	3 (0.3)	0 (0.0)	3 (0.2)
Patients with a result at baseline	886	505	1381
Pre-existing binding antibody, n (%)	1 (0.1)	1 (0.2)	2 (0.1)
Patients with postbaseline result	885	504	1391
Developing binding antibody–positive,[a] n (%)	56 (6.3)	13 (2.6)	69 (5.0)
Developing neutralizing antibody–positive,[a] n (%)	3 (0.3)	0 (0.0)	3 (0.2)

N = Number of patients who received at least one dose of study drug during double-blind treatment phase

[a]Negative or no result at baseline

Supplemental Table 4. Anti-erenumab antibodies during long-term analysis (DBTP + OLTP)

	DBTP, placebo OLTP, erenumab 70/140 mg N = 924	DBTP, erenumab OLTP, erenumab 70/140 mg N = 1400	Total N = 2324
Developing binding antibody–positive[a]	74 (8.1)	110 (7.9)	184 (8.0)
Transient[b]	34 (45.9)	60 (54.5)	94 (51.1)
Developing neutralizing antibody–positive[a]	3 (0.3)	5 (0.4)	8 (0.3)
Transient[b]	1 (33.3)	5 (100.0)	6 (75.0)
Onset of developing binding antibody–positive[c]	N1 = 74	N1 = 110	N1 = 184
Month 1	3 (4.1)	13 (11.8)	16 (8.7)
Months 2–3	17 (23.0)	37 (33.6)	54 (29.3)
Months 4–6	25 (33.8)	26 (23.6)	51 (27.7)
Months 6–12	24 (32.4)	26 (23.6)	50 (27.2)
Months 12–18	4 (5.4)	7 (6.4)	11 (6.0)
Months 18–24	1 (1.4)	1 (0.9)	2 (1.1)
Months > 24	0 (0.0)	0 (0.0)	0 (0.0)

Data reported are n (%) unless otherwise indicated; % = n/N or n/N1 as appropriate. DBTP, double-blind placebo-controlled treatment phase; OLTP, open-label treatment phase. N = Number of patients whose first dose of erenumab during the DBTP or OLTP was 70 mg or 140 mg.

[a]Negative or no result at baseline

[b]Negative result at last on-study time point; percentage was calculated using the number of patients who developed binding or neutralizing antibodies, respectively, as denominator

[c]Time from erenumab exposure to the first occurrence of developing binding antibody–positive; percentage was calculated using the number of patients who developed binding antibodies as a denominator

Supplemental Table 5. Exposure-adjusted adverse event rates by anti-erenumab antibody status

	Placebo	**Erenumab 70/140 mg**	
		Binding antibody negative	**Binding antibody positive**
	N = 1043	**N1 = 2116**	**N1 = 184**
	(pt-yr = 321.7)	**(pt-yr = 2421.3)**	**(pt-yr = 216.0)**
	n [r]	**n [r]**	**n [r]**
Any adverse event	72 [23.6]	331 [15.8]	28 [14.5]
Hypersensitivity[a]	45 [14.5]	204 [9.1]	17 [8.4]
Immune system disorders[b]	6 [1.9]	48 [2.0]	1 [0.5]
Injection site reactions[c]	34 [10.8]	151 [6.7]	14 [6.8]
		Neutralizing antibody negative	**Neutralizing antibody positi**
		N2 = 176	**N2 = 8**
	N = 1043	**(pt-yr = 207.7)**	**(pt-yr = 8.2)**
	(pt-yr = 321.7)		
Any adverse event	72 [23.6]	26 [14.0]	2 [28.0]
Hypersensitivity[a]	45 [14.5]	16 [8.2]	1 [12.9]
Immune system disorders[b]	6 [1.9]	1 [0.5]	0 [0.0]
Injection site reactions[c]	34 [10.8]	13 [6.6]	1 [13.1]

N = Number of patients who received at least one dose of placebo in the DBTP; Anti-erenumab antibodies were not tested in patients randomized to placebo

N1 = Number of patients who received first erenumab dose at 70 mg or 140 mg and had a binding antibody result

N2 = Number of patients who received first erenumab dose at 70 mg or 140 mg and had a neutralizing antibody result; Neutralizing antibodies were not tested in patients without bi

antibody–positive

MedDRA, Medical Dictionary for Regulatory Activities; pt-yr, patient-years

Multiple occurrences of the same event for a patient are counted as single events within a treatment group. Coded using MedDRA version 20.0

[a]Potential hypersensitivity reactions were identified using the hypersensitivity standardized MedDRA query

[b]Potential immune system disorders were identified using the immune system disorder MedDRA system order class

[c]Potential ISRs were identified using preferred terms consistent with ISRs from the administration-site reactions and ISRs high-level terms