

1839IL/0709

NUMBER OF PATIENTS WITH SERIOUS ADVERSE EVENTS

POPULATION: EVALUABLE-FOR-SAFETY

SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED							
		GEFITINIB				PLACEBO			
		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
		N=891				N=455			
		N	%	N	%	N	%	N	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS	TOTAL	3	1.3	8	0.9	0	0	3	0.7
	ANAEMIA	2	0.9	8	0.9	0	0	2	0.4
	FEBRILE NEUTROPENIA	0	0	0	0	0	0	1	0.2
	NEUTROPENIA	1	0.4	0	0	0	0	0	0
CARDIAC DISORDERS	TOTAL	6	2.6	10	1.1	1	0.9	11	2.4
	ACUTE MYOCARDIAL INFARCTION	1	0.4	1	0.1	0	0	0	0
	ANGINA PECTORIS	0	0	1	0.1	0	0	1	0.2
	ARRHYTHMIA	0	0	1	0.1	0	0	0	0
	ARRHYTHMIA SUPRAVENTRICULAR	0	0	0	0	0	0	1	0.2
	ATRIAL FIBRILLATION	1	0.4	0	0	0	0	1	0.2
	BRADYCARDIA	0	0	0	0	0	0	1	0.2
	CARDIAC FAILURE	1	0.4	1	0.1	0	0	1	0.2

(Continued)

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 ADVERSE EVENTS OCCURRING PRE-TRIAL ARE NOT INCLUDED
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		ORIENTAL			NON-ORIENTAL			ORIENTAL			NON-ORIENTAL		
		N	%	N	%	N	%	N	%	N	%	N	%
CARDIAC DISORDERS	CARDIAC FAILURE CONGESTIVE	0	0	1	0.1	0	0	0	0	0	0	0	0
	CARDIAC TAMPONADE	1	0.4	0	0	0	0	0	0	0	0	0	0
	CARDIOPULMONARY FAILURE	0	0	1	0.1	0	0	0	0	0	0	1	0.2
	COR PULMONALE	0	0	0	0	0	0	0	0	0	0	1	0.2
	CORONARY ARTERY DISEASE	1	0.4	0	0	0	0	0	0	0	0	0	0
	MYOCARDIAL INFARCTION	1	0.4	3	0.3	1	0.3	1	0.9	2	0.4	2	0.4
	MYOCARDIAL ISCHAEMIA	0	0	0	0	0	0	0	0	0	0	1	0.2
	PERICARDIAL EFFUSION	1	0.4	0	0	0	0	0	0	0	0	2	0.4
	SILENT MYOCARDIAL INFARCTION	0	0	1	0.1	0	0	0	0	0	0	0	0
	SUPRAVENTRICULAR TACHYCARDIA	0	0	0	0	0	0	0	0	0	0	1	0.2
TOTAL	0	0	0	0	0	0	0	0	0	0	1	0.2	
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	TRACHEO-OESOPHAGEAL FISTULA	0	0	0	0	0	0	0	0	0	0	1	0.2

(Continued)

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		GEFITINIB				PLACEBO			
		ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
EAR AND LABYRINTH DISORDERS	TOTAL	0	0	1	0.1	0	0	0	0
	VERTIGO	0	0	1	0.1	0	0	0	0
EYE DISORDERS	TOTAL	0	0	1	0.1	0	0	1	0.2
	CATARACT	0	0	0	0	0	0	1	0.2
	RETINITIS	0	0	1	0.1	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	4	1.7	28	3.1	2	1.9	8	1.8
	ABDOMINAL PAIN	0	0	2	0.2	0	0	1	0.2
	ASCITES	0	0	0	0	0	0	1	0.2
	CONSTIPATION	0	0	5	0.6	0	0	0	0
	DIARRHOEA	0	0	9	1.0	0	0	2	0.4
	DYSPHAGIA	0	0	2	0.2	0	0	0	0
	ENTEROVESICAL FISTULA	0	0	0	0	0	0	1	0.2

(Continued)

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		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS	GASTRIC ULCER	0	0	0	0	1	0.9	0	0
	GASTRITIS	1	0.4	1	0.1	0	0	0	0
	GASTROINTESTINAL HAEMORRHAGE	0	0	0	0	0	0	2	0.4
	GASTROINTESTINAL OBSTRUCTION	0	0	0	0	1	0.9	0	0
	INTESTINAL INFARCTION	0	0	0	0	0	0	1	0.2
	NAUSEA	0	0	6	0.7	0	0	2	0.4
	PANCREATITIS	0	0	1	0.1	0	0	0	0
	PANCREATITIS ACUTE	1	0.4	0	0	0	0	0	0
	SMALL INTESTINAL OBSTRUCTION	0	0	1	0.1	0	0	0	0
	SWOLLEN TONGUE	0	0	1	0.1	0	0	0	0
	UPPER GASTROINTESTINAL HAEMORRHAGE	1	0.4	0	0	0	0	0	0

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		ORIENTAL		NON-ORIENTAL		%	ORIENTAL		NON-ORIENTAL		%
		N=235		N=891		N=107		N=455			
		N	%	N	%	N	%	N	%	N	%
GASTROINTESTINAL DISORDERS	VOMITING	1	0.4	5	0.6	0	0	1	0.2	1	0.2
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	5	2.1	16	1.8	0	0	8	1.8	8	1.8
	ASTHENIA	1	0.4	4	0.4	0	0	0	0	0	0
	DEATH	0	0	2	0.2	0	0	3	0.7	3	0.7
	FATIGUE	0	0	3	0.3	0	0	2	0.4	2	0.4
	GENERAL PHYSICAL HEALTH DETERIORATION	0	0	1	0.1	0	0	0	0	0	0
	GENERALISED OEDEMA	1	0.4	1	0.1	0	0	0	0	0	0
	MALaise	0	0	1	0.1	0	0	0	0	0	0
	NON-CARDIAC CHEST PAIN	0	0	0	0	0	0	1	0.2	1	0.2
	OEDEMA PERIPHERAL	0	0	0	0	0	0	0	0	1	0.2
	PYREXIA	3	1.3	4	0.4	0	0	1	0.2	1	0.2

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		GEFITINIB					PLACEBO				
		ORIENTAL		NON-ORIENTAL		%	ORIENTAL		NON-ORIENTAL		%
		N=235	N=891	N=107	N=455						
		N	%	N	%	N	%	N	%	N	%
HEPATOBIILIARY DISORDERS	TOTAL	3	1.3	2	0.2	0	0	1	0.2	0	0
	CHOLECYSTITIS ACUTE	1	0.4	1	0.1	0	0	0	0	0	0
	CHOLELITHIASIS	0	0	1	0.1	0	0	0	0	0	0
	HEPATIC CIRRHOSIS	1	0.4	0	0	0	0	0	0	0	0
	HEPATITIS	1	0.4	0	0	0	0	0	0	0	0
	HEPATOTOXICITY	0	0	0	0	0	0	0	0	1	0.2
IMMUNE SYSTEM DISORDERS	TOTAL	1	0.4	0	0	0	0	0	0	0	0
	ALLERGY TO ANIMAL	1	0.4	0	0	0	0	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	23	9.8	41	4.6	15	14.0	21	4.6	0	0
	BRONCHITIS	0	0	1	0.1	0	0	0	0	0	0
	BRONCHITIS ACUTE	0	0	1	0.1	0	0	0	0	0	0
	BRONCHOPNEUMONIA	1	0.4	3	0.3	0	0	0	0	2	0.4

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		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS	CELLULITIS	0	0	0	0	0	0	1	0.2
	DIABETIC FOOT INFECTION	1	0.4	0	0	0	0	0	0
	DIARRHOEA INFECTION	0	0	1	0.1	0	0	0	0
	DIVERTICULITIS	0	0	1	0.1	0	0	0	0
	EMPHYEMA	2	0.9	1	0.1	0	0	0	0
	GASTROENTERITIS	1	0.4	1	0.1	0	0	0	0
	HERPES ZOSTER	1	0.4	1	0.1	0	0	0	0
	INFECTION	0	0	1	0.1	1	0.9	0	0
	INFLUENZA	0	0	0	0	0	0	1	0.2
	LARYNGOTRACHEITIS	0	0	0	0	0	0	1	0.2
	LOBAR PNEUMONIA	1	0.4	0	0	1	0.9	1	0.2

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		GEFITINIB			PLACEBO				
		ORIENTAL N=235	NON-ORIENTAL N=891	ORIENTAL N=107	NON-ORIENTAL N=455	ORIENTAL	NON-ORIENTAL		
		N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	0	0	1	0.1	1	0.9	5	1.1
	LUNG ABSCESS	0	0	2	0.2	0	0	0	0
	LUNG INFECTION	0	0	0	0	0	0	1	0.2
	ORCHITIS	0	0	0	0	0	0	1	0.2
	PNEUMONIA	14	6.0	19	2.1	9	8.4	6	1.3
	PNEUMONIA BACTERIAL	0	0	1	0.1	0	0	0	0
	PNEUMONIA KLEBSIELLA	1	0.4	0	0	0	0	0	0
	PNEUMONIA MORAXELLA	0	0	0	0	0	0	1	0.2
	PNEUMONIA STREPTOCOCCAL	1	0.4	0	0	0	0	0	0
	PULMONARY SEPSIS	0	0	1	0.1	0	0	0	0
	PYOTHORAX	0	0	1	0.1	0	0	0	0

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SYSTEM ORGAN CLASS	PREFERRED TERM	GREGITINIB						PLACEBO					
		ORIENTAL			NON-ORIENTAL			ORIENTAL			NON-ORIENTAL		
		N	%	N	%	N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	0	0	4	0.4	2	1.9	1	0.2				
	SEPSIS	2	0.9	2	0.2	1	0.9	0	0				
	SEPTIC SHOCK	3	1.3	1	0.1	1	0.9	0	0				
	SPLENIC INFECTION	0	0	0	0	0	0	1	0.2				
	STAPHYLOCOCCAL INFECTION	0	0	1	0.1	0	0	0	0				
	SUBCUTANEOUS ABSCESS	1	0.4	0	0	0	0	0	0				
	URINARY TRACT INFECTION	0	0	1	0.1	0	0	0	0				
	VIRAL INFECTION	1	0.4	0	0	0	0	0	0				
	WOUND INFECTION	1	0.4	0	0	1	0.9	0	0				
	TOTAL	0	0	6	0.7	0	0	2	0.4				
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMORAL NECK FRACTURE	0	0	1	0.1	0	0	1	0.2				
	FEMUR FRACTURE	0	0	2	0.2	0	0	0	0				

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		N=235		N=891				N=107		N=455	
		N	%	N	%		N	%	N	%	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HIP FRACTURE	0	0	2	0.2	0	0	0	0	0	0
	HUMERUS FRACTURE	0	0	1	0.1	0	0	0	0	0	0
	RADIATION FIBROSIS - LUNG	0	0	0	0	0	0	0	0	0	0.2
	UPPER LIMB FRACTURE	0	0	1	0.1	0	0	0	0	0	0
	TOTAL	0	0	2	0.2	0	0	0	0	0	0.2
INVESTIGATIONS	BLOOD CREATININE INCREASED	0	0	1	0.1	0	0	0	0	0	0
	HEPATIC ENZYME INCREASED	0	0	1	0.1	0	0	0	0	0	0
	PLATELET COUNT DECREASED	0	0	0	0	0	0	0	0	0	0.2
	TOTAL	6	2.6	19	2.1	2	1.9	8	1.8		
METABOLISM AND NUTRITION DISORDERS	ANOREXIA	0	0	1	0.1	0	0	0	0	0	0
	CACHEXIA	0	0	0	0	0	0	0	0	0	0.2
	DECREASED APPETITE	1	0.4	0	0	0	0	0	0	0	0
	TOTAL	1	0.4	1	0.1	0	0	0	0	0	0.2

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		ORIENTAL		NON-ORIENTAL		%	ORIENTAL		NON-ORIENTAL		%
		N=235		N=891				N=107		N=455	
		N	%	N	%		N	%	N	%	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	0	0	13	1.5	1	0.9	5	1.1		
	DIABETIC FOOT	1	0.4	0	0	0	0	0	0		
	HYPERCALCAEMIA	1	0.4	0	0	0	0	0	0		
	HYPERGLYCAEMIA	0	0	2	0.2	0	0	1	0.2		
	HYPERKALAEMIA	0	0	0	0	0	0	1	0.2		
	HYPOCALCAEMIA	0	0	1	0.1	0	0	0	0		
	HYPOGLYCAEMIA	1	0.4	1	0.1	1	0.9	0	0		
	HYPONATRAEMIA	1	0.4	1	0.1	0	0	0	0		
	MALNUTRITION	0	0	1	0.1	0	0	0	0		
	METABOLIC ACIDOSIS	1	0.4	0	0	0	0	0	0		
	TOTAL	2	0.9	3	0.3	0	0	3	0.7		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	2	0.9	0	0	0	0	0	0		

(Continued)

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