

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=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BONE PAIN	0	0	1	0.1	0	0	0	0
	CHEST WALL PAIN	0	0	0	0	0	0	1	0.2
	INTERVERTEBRAL DISC PROTRUSION	0	0	0	0	0	0	1	0.2
	MUSCULAR WEAKNESS	0	0	1	0.1	0	0	0	0
	MUSCULOSKELETAL CHEST PAIN	0	0	1	0.1	0	0	0	0
	PATHOLOGICAL FRACTURE	0	0	0	0	0	0	1	0.2
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	1	0.4	4	0.4	0	0	1	0.2
	CANCER PAIN	0	0	2	0.2	0	0	1	0.2
	MALIGNANT PLEURAL EFFUSION	0	0	1	0.1	0	0	0	0
	METASTASES TO MENINGES	0	0	1	0.1	0	0	0	0
	TUMOUR ASSOCIATED FEVER	1	0.4	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	7	3.0	9	1.0	1	0.9	5	1.1

(Continued)

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 WITHIN SYSTEM ORGAN CLASS

ADVERSE EVENTS OCCURRING PRE-TRIAL ARE NOT INCLUDED
 ADVERSE EVENTS OCCURRING DURING FOLLOW-UP (I.E. OCCURRING WITHIN 30 DAYS AFTER DISCONTINUATION OF INVESTIGATIONAL PRODUCT) ARE INCLUDED

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		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS									
	CEREBRAL ISCHAEMIA	0	0	2	0.2	0	0	0	0
	CEREBROVASCULAR ACCIDENT	1	0.4	0	0	0	0	0	0
	CONSCIOUSNESS FLUCTUATING	1	0.4	0	0	0	0	0	0
	CONVULSION	3	1.3	0	0	1	0.9	2	0.4
	DEPRESSED LEVEL OF CONSCIOUSNESS	1	0.4	0	0	0	0	0	0
	DIZZINESS	0	0	1	0.1	0	0	0	0
	EPILEPSY	0	0	0	0	0	0	1	0.2
	HAEMORRHAGE INTRACRANIAL	1	0.4	0	0	0	0	0	0
	HEMIPARESIS	0	0	1	0.1	0	0	1	0.2
	INTRACRANIAL PRESSURE INCREASED	0	0	1	0.1	0	0	0	0
	ISCHAEMIC STROKE	0	0	0	0	0	0	1	0.2

(Continued)

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		N	%	N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS	NEUROPATHIC PAIN	0	0	1	0.1	0	0	0	0	0	0	0	0
	TRANSIENT ISCHAEMIC ATTACK	0	0	2	0.2	0	0	0	0	0	0	0	0
	TREMOR	0	0	1	0.1	0	0	0	0	0	0	0	0
	TOTAL	0	0	3	0.3	0	0	0	0	0	0	1	0.2
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	0	0	3	0.3	0	0	0	0	0	0	0	0
	HALLUCINATION	0	0	0	0	0	0	0	0	0	0	1	0.2
RENAL AND URINARY DISORDERS	TOTAL	0	0	2	0.2	0	0	0	0	0	0	1	0.2
	RENAL ARTERY THROMBOSIS	0	0	1	0.1	0	0	0	0	0	0	0	0
	RENAL FAILURE ACUTE	0	0	1	0.1	0	0	0	0	0	0	0	0
	URINARY RETENTION	0	0	0	0	0	0	0	0	0	0	1	0.2
TOTAL	21	8.9	49	5.5	8	7.5	22	4.8					
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ACUTE RESPIRATORY FAILURE	0	0	1	0.1	0	0	0	0	0	0	1	0.2

(Continued)

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		ORIENTAL		NON-ORIENTAL		%	ORIENTAL		NON-ORIENTAL		%	
		N=235	N=891	N=107	N=455							
		N	N	N	N	%	N	N	N	%	N	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASTHMA	0	0	0	0	0.0	0	0	0	0.0	1	0.2
	CHRONIC OBSTRUCTIVE AIRWAYS DISEASE EXACERBATED	2	0.9	0	0	0.0	0	1	0.9	0.2	1	0.2
	DYSPNOEA	2	0.9	12	1.3	1.3	1	0.9	4	0.9	4	0.9
	DYSPNOEA EXACERBATED	0	0	4	0.4	0.4	0	0	1	0.2	1	0.2
	FOREIGN BODY ASPIRATION	0	0	0	0	0.0	0	1	0.9	0	0	0
	HAEMOPTYSIS	1	0.4	6	0.7	0.7	0	0	2	0.4	2	0.4
	INTERSTITIAL LUNG DISEASE	2	0.9	0	0	0.0	0	0	0	0.0	0	0
	LUNG INFILTRATION	0	0	1	0.1	0.1	0	0	0	0.0	0	0
	PLEURAL EFFUSION	8	3.4	3	0.3	0.3	1	0.9	5	1.1	5	1.1
	PLEURITIC PAIN	0	0	0	0	0.0	0	0	3	0.7	3	0.7
	PNEUMONIA ASPIRATION	1	0.4	0	0	0.0	0	0	0	0.0	0	0

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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	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	1	0.4	0	0	2	1.9	0	0	0	0
	PNEUMOTHORAX	0	0	1	0.1	1	0.9	0	0	0	0
	PRODUCTIVE COUGH	0	0	1	0.1	0	0	0	0	0	0
	PULMONARY EMBOLISM	1	0.4	8	0.9	1	0.9	4	0.9	0	0
	PULMONARY HAEMORRHAGE	1	0.4	0	0	0	0	0	0	0	0
	PULMONARY OEDEMA	1	0.4	2	0.2	0	0	0	0	0	0
	RESPIRATORY ARREST	0	0	1	0.1	0	0	0	0	0	0
	RESPIRATORY DISTRESS	0	0	1	0.1	0	0	0	0	0	0
	RESPIRATORY FAILURE	2	0.9	10	1.1	0	0	1	0.2	0	0
	TOTAL	0	0	7	0.8	0	0	3	0.7	0	0
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	0	0	3	0.3	0	0	1	0.2	0	0
	FEMORAL ARTERIAL STENOSIS	0	0	1	0.1	0	0	0	0	0	0
		0	0	1	0.1	0	0	0	0	0	0

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		GEFITINIB				PLACEBO			
		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
VASCULAR DISORDERS	HYPOTENSION	0	0	0	0	0	0	0	0.2
	HYPVOLEAEMIC SHOCK	0	0	0	0	0	0	1	0.2
	PERIPHERAL ISCHAEMIA	0	0	2	0.2	0	0	0	0
	VENA CAVA THROMBOSIS	0	0	1	0.1	0	0	0	0

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NUMBER OF PATIENTS WITH ADVERSE EVENTS LEADING TO DEATH

POPULATION: EVALUABLE-FOR-SAFETY

SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED					
		GEFITINIB			PLACEBO		
		ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL
		N=235			N=455		
		N=891			N=107		
		N	%	N	%	N	%
		3	1.3	6	0.7	1	0.9
		1	0.4	0	0	0	0
		0	0	1	0.1	0	0
		1	0.4	1	0.1	0	0
		0	0	1	0.1	0	0
		1	0.4	2	0.2	1	0.9
		0	0	0	0	0	0
		0	0	1	0.1	0	0
		0	0	0	0	0	0
		0	0	2	0.2	0	0
		0	0	2	0.2	0	0

(Continued)

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		GEFITINIB				PLACEBO			
		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
HEPATOBILLIARY DISORDERS									
	TOTAL	2	0.9	0	0	0	0	1	0.2
	CHOLECYSTITIS ACUTE	1	0.4	0	0	0	0	0	0
	HEPATIC CIRRHOSIS	1	0.4	0	0	0	0	0	0
	HEPATOTOXICITY	0	0	0	0	0	0	1	0.2
	TOTAL	5	2.1	13	1.5	3	2.8	2	0.4
INFECTIONS AND INFESTATIONS									
	BRONCHITIS ACUTE	0	0	1	0.1	0	0	0	0
	BRONCHOPNEUMONIA	0	0	0	0	0	0	2	0.4
	GASTROENTERITIS	0	0	1	0.1	0	0	0	0
	LUNG ABSCESS	0	0	1	0.1	0	0	0	0
	PNEUMONIA	4	1.7	5	0.6	3	2.8	0	0
	PULMONARY SEPSIS	0	0	1	0.1	0	0	0	0
	RESPIRATORY TRACT INFECTION	0	0	2	0.2	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	%
INFECTIONS AND INFESTATIONS	SEPSIS	1	0.4	1	0.1	1	0.9	0	0	0	0
	SEPTIC SHOCK	1	0.4	0	0	1	0.9	0	0	0	0
	STAPHYLOCOCCAL INFECTION	0	0	1	0.1	0	0	0	0	0	0
	TOTAL	0	0	0	0	0	0	1	0.2	1	0.2
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMORAL NECK FRACTURE	0	0	0	0	0	0	0	0	1	0.2
	TOTAL	0	0	0	0	0	0	0	0	2	0.4
METABOLISM AND NUTRITION DISORDERS	CACHEXIA	0	0	0	0	0	0	0	0	1	0.2
	DEHYDRATION	0	0	0	0	0	0	0	0	1	0.2
	TOTAL	0	0	1	0.1	0	0	0	0	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	METASTASES TO MENINGES	0	0	1	0.1	0	0	0	0	0	0
	TOTAL	1	0.4	1	0.1	0	0	0	0	0	0
NERVOUS SYSTEM DISORDERS	CEREBRAL ISCHAEMIA	0	0	1	0.1	0	0	0	0	0	0

(Continued)

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		ORIENTAL	NON-ORIENTAL	%	ORIENTAL	NON-ORIENTAL	%
		N=235	N=891	N=107	N=455		
		N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMORRHAGE INTRACRANIAL	1	0.4	0	0	0	0
	TOTAL	2	0.9	22	2.5	2	1.9
	ACUTE RESPIRATORY FAILURE	0	0	1	0.1	0	0
	DYSPNOEA	0	0	2	0.2	0	0
	FOREIGN BODY ASPIRATION	0	0	0	0	1	0.9
	HAEMOPTYSIS	0	0	3	0.3	0	0
	PNEUMONITIS	0	0	0	0	1	0.9
	PULMONARY EMBOLISM	1	0.4	5	0.6	0	0
	PULMONARY OEDEMA	0	0	1	0.1	0	0
	RESPIRATORY ARREST	0	0	1	0.1	0	0
	RESPIRATORY DISTRESS	0	0	1	0.1	0	0
	RESPIRATORY FAILURE	1	0.4	9	1.0	0	0

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		GEFTINIB				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	%
VASCULAR DISORDERS	TOTAL	0	0	0	0	0	0	0	0
	HYPOLAEMIC SHOCK	0	0	0	0	0	0	0	0

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