重篤な有害事象、有害事象による死亡例、副作用による死亡例

1839IL/0709

CATEGORIES OF ADVERSE EVENTS (BY PATIENTS) BY ETHNIC GROUP
POPULATION: EVALUABLE-FOR-SAFETY

	TREATMENT RECEIVED											
	GEFITINIB				PLACEBO				ALL			
	ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
	N=235		N=891		N=107		N=455		N=342		N=1346	
	N	%	N	%	N	%	N	%	N	%	N	%
Patient had an AE	227	96.6	700	78.6	92	86.0	305	67.0	319	93.3	1005	74.7
Treatment-Related AE	178	75.7	480	53.9	41	38.3	120	26.4	219	64.0	600	44.6
Serious AE	55	23.4	161	18.1	24	22.4	74	16.3	79	23.1	235	17.5
Serious Treatment-Related AE	7	3.0	20	2.2	1	0.9	7	1.5	8	2.3	27	2.0
Non-Fatal Serious AE	52	22.1	128	14.4	19	17.8	64	14.1	71	20.8	192	14.3
Discontinuation Due To AE	17	7.2	44	4.9	2	1.9	11	2.4	19	5.6	55	4.1
Discontinuation Due To Treatment-Related AE	9	3.8	22	2.5	0	0	3	0.7	9	2.6	25	1.9
Discontinuation Due To Serious AE	11	4.7	22	2.5	2	1.9	8	1.8	13	3.8	30	2.2
Discont. Due To Serious Treatment-Related AE	5	2.1	5	0.6	0	0	3	0.7	5	1.5	8	0.6
Death Due To AE	11	4.7	44	4.9	6	5.6	16	3.5	17	5.0	60	4.5
Death Due To Treatment-Related AE	2	0.9	3	0.3	0	0	1	0.2	2	0.6	4	0.3
CTC Grade 3 or 4 AE	101	43.0	240	26.9	38	35.5	113	24.8	139	40.6	353	26.2
CTC Grade 3 or 4 Treatment-Related AE	27	11.5	63	7.1	1	0.9	15	3.3	28	8.2	78	5.8
Interstitial Lung Disorder Type Events	7	3.0	5	0.6	4	3.7	1	0.2	11	3.2	6	0.4

ADVERSE EVENTS OCCURRING DURING FOLLOW-UP (I.E. OCCURRING WITHIN 30 DAYS AFTER DISCONTINUATION OF INVESTIGATIONAL PRODUCT) ARE INCLUDED

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	%
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)

MEDDRA VERSION 7.1
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ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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

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	%
CARDIAC DISORDERS	CARDIAC FAILURE CONGESTIVE	0	0	1	0.1	0	0	0	0
	CARDIAC TAMPONADE	1	0.4	0	0	0	0	0	0
	CARDIOPULMONARY FAILURE	0	0	1	0.1	0	0	1	0.2
	COR PULMONALE	0	0	0	0	0	0	1	0.2
	CORONARY ARTERY DISEASE	1	0.4	0	0	0	0	0	0
	MYOCARDIAL INFARCTION	1	0.4	3	0.3	1	0.9	2	0.4
	MYOCARDIAL ISCHAEMIA	0	0	0	0	0	0	1	0.2
	PERICARDIAL EFFUSION	1	0.4	0	0	0	0	2	0.4
	SILENT MYOCARDIAL INFARCTION	0	0	1	0.1	0	0	0	0
	SUPRAVENTRICULAR TACHYCARDIA	0	0	0	0	0	0	1	0.2
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	TOTAL	0	0	0	0	0	0	1	0.2
	TRACHEO-OESOPHAGEAL FISTULA	0	0	0	0	0	0	1	0.2

(Continued)

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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	%
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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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	%
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

(Continued)

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

(Continued)

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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	%
HEPATOBILIARY DISORDERS	TOTAL	3	1.3	2	0.2	0	0	1	0.2
	CHOLECYSTITIS ACUTE	1	0.4	1	0.1	0	0	0	0
	CHOLELITHIASIS	0	0	1	0.1	0	0	0	0
	HEPATIC CIRRHOSIS	1	0.4	0	0	0	0	0	0
	HEPATITIS	1	0.4	0	0	0	0	0	0
	HEPATOTOXICITY	0	0	0	0	0	0	1	0.2
IMMUNE SYSTEM DISORDERS	TOTAL	1	0.4	0	0	0	0	0	0
	ALLERGY TO ANIMAL	1	0.4	0	0	0	0	0	0
INFECTIONS AND INFESTATIONS	TOTAL	23	9.8	41	4.6	15	14.0	21	4.6
	BRONCHITIS	0	0	1	0.1	0	0	0	0
	BRONCHITIS ACUTE	0	0	1	0.1	0	0	0	0
	BRONCHOPNEUMONIA	1	0.4	3	0.3	0	0	2	0.4

(Continued)

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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	%
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 INFECTIOUS	0	0	1	0.1	0	0	0	0
	DIVERTICULITIS	0	0	1	0.1	0	0	0	0
	EMPYEMA	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

(Continued)

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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	%
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

(Continued)

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ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% *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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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	%
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
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	6	0.7	0	0	2	0.4
	FEMORAL NECK FRACTURE	0	0	1	0.1	0	0	1	0.2
	FEMUR FRACTURE	0	0	2	0.2	0	0	0	0

(Continued)

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

(Continued)

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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	%
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
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	TOTAL	2	0.9	3	0.3	0	0	3	0.7
	BACK PAIN	2	0.9	0	0	0	0	0	0

(Continued)

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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)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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

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	%
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)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100%
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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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	%
NERVOUS SYSTEM DISORDERS	*NEUROPATHIC PAIN*	0	0	1	0.1	0	0	0	0
	TRANSIENT ISCHAEMIC ATTACK	0	0	2	0.2	0	0	0	0
	TREMOR	0	0	1	0.1	0	0	0	0
PSYCHIATRIC DISORDERS	TOTAL	0	0	3	0.3	0	0	1	0.2
	CONFUSIONAL STATE	0	0	3	0.3	0	0	0	0
	HALLUCINATION	0	0	0	0	0	0	1	0.2
RENAL AND URINARY DISORDERS	TOTAL	0	0	2	0.2	0	0	1	0.2
	RENAL ARTERY THROMBOSIS	0	0	1	0.1	0	0	0	0
	RENAL FAILURE ACUTE	0	0	1	0.1	0	0	0	0
	URINARY RETENTION	0	0	0	0	0	0	1	0.2
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	21	8.9	49	5.5	8	7.5	22	4.8
	ACUTE RESPIRATORY FAILURE	0	0	1	0.1	0	0	1	0.2

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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

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

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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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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	%
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	1	0.4	0	0	2	1.9	0	0
	PNEUMOTHORAX	0	0	1	0.1	1	0.9	0	0
	PRODUCTIVE COUGH	0	0	1	0.1	0	0	0	0
	PULMONARY EMBOLISM	1	0.4	8	0.9	1	0.9	4	0.9
	PULMONARY HAEMORRHAGE	1	0.4	0	0	0	0	0	0
	PULMONARY OEDEMA	1	0.4	2	0.2	0	0	0	0
	RESPIRATORY ARREST	0	0	1	0.1	0	0	0	0
	RESPIRATORY DISTRESS	0	0	1	0.1	0	0	0	0
	RESPIRATORY FAILURE	2	0.9	10	1.1	0	0	1	0.2
VASCULAR DISORDERS	TOTAL	0	0	7	0.8	0	0	3	0.7
	DEEP VEIN THROMBOSIS	0	0	3	0.3	0	0	1	0.2
	FEMORAL ARTERIAL STENOSIS	0	0	1	0.1	0	0	0	0

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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

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	%
VASCULAR DISORDERS	HYPOTENSION	0	0	0	0	0	0	1	0.2
	HYPOVOLAEMIC 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

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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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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	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
CARDIAC DISORDERS	TOTAL	3	1.3	6	0.7	1	0.9	3	0.7
	ACUTE MYOCARDIAL INFARCTION	1	0.4	0	0	0	0	0	0
	ARRHYTHMIA	0	0	1	0.1	0	0	0	0
	CARDIAC FAILURE	1	0.4	1	0.1	0	0	1	0.2
	CARDIOPULMONARY FAILURE	0	0	1	0.1	0	0	1	0.2
	MYOCARDIAL INFARCTION	1	0.4	2	0.2	1	0.9	0	0
	MYOCARDIAL ISCHAEMIA	0	0	0	0	0	0	1	0.2
	SILENT MYOCARDIAL INFARCTION	0	0	1	0.1	0	0	0	0
GASTROINTESTINAL DISORDERS	TOTAL	0	0	0	0	0	0	1	0.2
	GASTROINTESTINAL HAEMORRHAGE	0	0	0	0	0	0	1	0.2
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	TOTAL	0	0	2	0.2	0	0	3	0.7
	DEATH	0	0	2	0.2	0	0	3	0.7

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT *GROUP AND DO NOT NECESSARILY* ADD UP TO 100% 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

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	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
HEPATOBILIARY 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
INFECTIONS AND INFESTATIONS	TOTAL	5	2.1	13	1.5	3	2.8	2	0.4
	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

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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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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	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
INFECTIONS AND INFESTATIONS	SEPSIS	1	0.4	1	0.1	1	0.9	0	0
	SEPTIC SHOCK	1	0.4	0	0	1	0.9	0	0
	STAPHYLOCOCCAL INFECTION	0	0	1	0.1	0	0	0	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOTAL	0	0	0	0	0	0	1	0.2
	FEMORAL NECK FRACTURE	0	0	0	0	0	0	1	0.2
METABOLISM AND NUTRITION DISORDERS	TOTAL	0	0	0	0	0	0	2	0.4
	CACHEXIA	0	0	0	0	0	0	1	0.2
	DEHYDRATION	0	0	0	0	0	0	1	0.2
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	TOTAL	0	0	1	0.1	0	0	0	0
	METASTASES TO MENINGES	0	0	1	0.1	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	1	0.4	1	0.1	0	0	0	0
	CEREBRAL ISCHAEMIA	0	0	1	0.1	0	0	0	0

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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

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	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	1	0.4	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	2	0.9	22	2.5	2	1.9	4	0.9
	ACUTE RESPIRATORY FAILURE	0	0	1	0.1	0	0	1	0.2
	DYSPNOEA	0	0	2	0.2	0	0	1	0.2
	FOREIGN BODY ASPIRATION	0	0	0	0	1	0.9	0	0
	HAEMOPTYSIS	0	0	3	0.3	0	0	1	0.2
	PNEUMONITIS	0	0	0	0	1	0.9	0	0
	PULMONARY EMBOLISM	1	0.4	5	0.6	0	0	1	0.2
	PULMONARY OEDEMA	0	0	1	0.1	0	0	0	0
	RESPIRATORY ARREST	0	0	1	0.1	0	0	0	0
	RESPIRATORY DISTRESS	0	0	1	0.1	0	0	0	0
	RESPIRATORY FAILURE	1	0.4	9	1.0	0	0	0	0

(Continued)

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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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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	
		N=235		N=891		N=107		N=455	
		N	%	N	%	N	%	N	%
VASCULAR DISORDERS	TOTAL	0	0	0	0	0	0	1	0.2
	HYPOVOLAEMIC SHOCK	0	0	0	0	0	0	1	0.2

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100%
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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NUMBER OF PATIENTS WITH GEFITINIB/PLACEBO TREATMENT-RELATED ADVERSE EVENTS LEADING TO DEATH

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	%
HEPATOBILIARY DISORDERS	TOTAL	1	0.4	0	0	0	0	1	0.2
	HEPATIC CIRRHOSIS	1	0.4	0	0	0	0	0	0
	HEPATOTOXICITY	0	0	0	0	0	0	1	0.2
INFECTIONS AND INFESTATIONS	TOTAL	0	0	1	0.1	0	0	0	0
	PULMONARY SEPSIS	0	0	1	0.1	0	0	0	0
NERVOUS SYSTEM DISORDERS	TOTAL	1	0.4	1	0.1	0	0	0	0
	CEREBRAL ISCHAEMIA	0	0	1	0.1	0	0	0	0
	HAEMORRHAGE INTRACRANIAL	1	0.4	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TOTAL	0	0	1	0.1	0	0	0	0
	DYSPNOEA	0	0	1	0.1	0	0	0	0

MEDDRA VERSION 7.1
A PATIENT CAN ONLY BE COUNTED ONCE WITHIN ANY SPECIFIC PREFERRED TERM
ALL PERCENTAGES SHOWN ARE OF TOTAL PATIENTS IN TREATMENT GROUP AND DO NOT NECESSARILY ADD UP TO 100% 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