直近の化学療法に忍容でなかった患者における死亡例に関する資料

別添資料 16-1

1839IL/0709

CAUSE OF DEATH
POPULATION: EFS PATIENTS WHO WERE INTOLERANT TO LAST CHEMO REGIMEN & WHO DIED WITHIN 4 MONTHS OF RANDOMISATION

RANDOMISED TREATMENT = GEFITINIB

PATIENT	TIME TO DEATH	PRIMARY CAUSE OF DEATH	PRIMARY CAUSE PREFERRED TERM	SECONDARY CAUSE OF DEATH	SECONDARY CAUSE PREFERRED TERM	AUTOPSY DONE	DEATH RELATED TO CANCER
E0113004	1.87	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E0147002	1.28	Non-small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E0150005	2.53	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E0341002	1.25	Pulmonary embolism	PULMONARY EMBOLISM	Non-small call lung cancer	NON-SMALL CELL LUNG CANCER	No	Yes
E0505018	0.92	Respiratory insufficiency	RESPIRATORY FAILURE	Progression of nsclc	NON-SMALL CELL LUNG CANCER	No	Yes
E0505056	3.25	Kardio - resp insuff	CARDIOPULMONARY FAILURE	Caused by progressive lung cancer	LUNG NEOPLASM MALIGNANT	No	Yes
E0505058	3.29	Respiratory failure	RESPIRATORY FAILURE	Progression of nsclc	NON-SMALL CELL LUNG CANCER	No	Yes
E0568004	0.79	Multiple organ failure	MULTI-ORGAN FAILURE	Pneumonia	PNEUMONIA	No	Yes
E0587004	2.63	Respiratory insuficiency due to sepsis	SEPSIS			No	No
E0622011	0.66	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E1108005	1.15	Non-small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E1125008	1.08	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E1126005	1.45	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E1165001	3.32	NSCLC	NON-SMALL CELL LUNG CANCER			No	Yes
E1356004	1.12	Non small cell lung cancer - progressive disease	NON-SMALL CELL LUNG CANCER			No	Yes
E1460006	0.69	Lung cancer progression	LUNG NEOPLASM MALIGNANT			No	Yes
E1461027	1.08	Respiratory insufficiency	RESPIRATORY FAILURE	Pulmonary metastases of non small cell lung cancer	NON-SMALL CELL LUNG CANCER METASTATIC	No	Yes
E1461032	1.41	Respiratory insufficiency	RESPIRATORY FAILURE	Hemoptysis	HAEMOPTYSIS	No	Yes
E1461056	1.94	Acute respiratory insufficiency	ACUTE RESPIRATORY FAILURE			No	No

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CAUSE OF DEATH
POPULATION: EFS PATIENTS WHO WERE INTOLERANT TO LAST CHEMO REGIMEN & WHO DIED WITHIN 4 MONTHS OF RANDOMISATION

RANDOMISED TREATMENT = GEFITINIB

PATIENT	TIME TO DEATH	PRIMARY CAUSE OF DEATH	PRIMARY CAUSE PREFERRED TERM	SECONDARY CAUSE OF DEATH	SECONDARY CAUSE PREFERRED TERM	AUTOPSY DONE	DEATH RELATED TO CANCER
E1461057	0.43	Respiratory insufficiency	RESPIRATORY FAILURE	Lung cancer	LUNG NEOPLASM MALIGNANT	No	Yes
E1461075	0.72	Multiple organs collapse	MULTI-ORGAN FAILURE	Lung cancer	LUNG NEOPLASM MALIGNANT	No	Yes
E1461080	1.38	Respiratory insufficiency	RESPIRATORY FAILURE			No	No
E1461087	3.19	Carcinomatosis	METASTATIC NEOPLASM	Lung carcinoma	LUNG NEOPLASM MALIGNANT	Yes	Yes
E1509011	3.29	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER	Cardiorespiratoric failure	CARDIOPULMONARY FAILURE	No	Yes
E1729003	1.74	Progression of subject's nsclc	NON-SMALL CELL LUNG CANCER			No	Yes
E1730012	3.42	NSCLC progression	NON-SMALL CELL LUNG CANCER			No	Yes
E1733004	3.02	Metastaic lung cancer	LUNG CANCER METASTATIC			No	Yes
E1910001	3.58	NSCLC	NON-SMALL CELL LUNG CANCER			No	Yes
E5300003	1.58	Cardiopulmonary arrest probably secondary to disseminated malignancy.	CARDIO-RESPIRATORY ARREST	Bronchogenic/non small cell lung cancer stage iv brain metastases and pleural effusion (right) s/p closed tube thoracostomy and removal (right)	NON-SMALL CELL LUNG CANCER STAGE IV	No	Yes
E5706006	2.43	Not known as patient expired in a remote place	DEATH			No	No
E5804020	2.92	Progression of non small cell lung cancer	NON-SMALL CELL LUNG CANCER	Respiratory failure	RESPIRATORY FAILURE	No	Yes
E6003008	3.29	Metastatic, progressive non-small cell lung cancer.	NON-SMALL CELL LUNG CANCER METASTATIC			No	Yes
E6003039	1.22	Progressive metastatic non small cell lung cancer	NON-SMALL CELL LUNG CANCER METASTATIC			No	Yes
E6108006	0.85	Respiratory faile	RESPIRATORY FAILURE	Non-small cell lung cancer	NON-SMALL CELL LUNG CANCER	No	Yes
E6600001	1.18	Non small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes

1839IL/0709

CAUSE OF DEATH
POPULATION: EFS PATIENTS WHO WERE INTOLERANT TO LAST CHEMO REGIMEN & WHO DIED WITHIN 4 MONTHS OF RANDOMISATION

RANDOMISED TREATMENT = PLACEBO

PATIENT	TIME TO DEATH	PRIMARY CAUSE OF DEATH	PRIMARY CAUSE PREFERRED TERM	SECONDARY CAUSE OF DEATH	SECONDARY CAUSE PREFERRED TERM	AUTOPSY DONE	DEATH RELATED TO CANCER
E0505005	0.46	Respiratory failure	RESPIRATORY FAILURE	Progression of nsclc	NON-SMALL CELL LUNG CANCER	No	Yes
E1009015	2.46	NSCLC	NON-SMALL CELL LUNG CANCER			No	Yes
E1151001	0.53	Progression of non-small cell lung cancer	NON-SMALL CELL LUNG CANCER			No	Yes
E1173001	2.30	Lung cancer	LUNG NEOPLASM MALIGNANT			No	Yes
E1201001	2.99	Lung cancer	LUNG NEOPLASM MALIGNANT			No	Yes
E1210001	1.61	Superior vena cava syndrom	SUPERIOR VENA CAVAL OCCLUSION	Progression of non-small cell lung cancer	NON-SMALL CELL LUNG CANCER	No	Yes
E1461093	3.45	Pulmonary insufficiency	RESPIRATORY FAILURE	Lung cancer	LUNG NEOPLASM MALIGNANT	No	Yes
E1462003	0.36	Bronchopneumonia	BRONCHOPNEUMONIA			No	Yes
E1701028	3.35	Chronic obstructive pulmonary disease	CHRONIC OBSTRUCTIVE AIRWAYS DISEASE	Lung cancer	LUNG NEOPLASM MALIGNANT	No	Yes

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

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)

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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	%
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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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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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)

MEDDRA VERSION 7.1
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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)

MEDDRA VERSION 7.1
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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	%
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)

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	%
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)

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

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	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)

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
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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	%
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)

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
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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)

MEDDRA VERSION 7.1
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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	%
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
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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
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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	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
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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	%
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
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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	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
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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	%
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
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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	%
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
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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 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
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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	%
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)

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1839IL/0709

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)

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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 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

1839IL/0709

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

1839IL/0709

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
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