

1839IL/0709

NUMBER OF PATIENTS WITH SERIOUS ADVERSE EVENTS
POPULATION: EVALUABLE-FOR-SAFETY

SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED					
		GEFITINIB			PLACEHO		
		ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL
		N=235	N=891	N=107	N=455		
		N	N	N	N	N	N
		%	%	%	%	%	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BONE PAIN	0	1	0	0	0	0
	CHEST WALL PAIN	0	0	0	0	1	0.2
	INTERVERTEBRAL DISC PROTRUSION	0	0	0	0	0	0.2
	MUSCULAR WEAKNESS	0	1	0	0	0	0
	MUSCULOSKELETAL CHEST PAIN	0	1	0	0	0	0
	PATHOLOGICAL FRACTURE	0	0	0	0	0	0.2
	TOTAL	1	4	0	0	0	0.2
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	CANCER PAIN	0	0	2	0	0	0.2
	MALIGNANT PLEURAL EFFUSION	0	0	1	0	0	0
	METASTASES TO MENINGES	0	0	1	0	0	0
	TUMOUR ASSOCIATED FEVER	1	0	0	0	0	0
	TOTAL	7	3	9	1	0	1.1
NERVOUS SYSTEM DISORDERS	TOTAL	7	3	9	1	0	1.1

(Continued)

MEDDRA VERSION 7.1
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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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SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED							
		GEEFITINIB				PLACEBO			
		ORIENTAL N=235	NON-ORIENTAL N=891	ORIENTAL N=107	NON-ORIENTAL N=455	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL
		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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		GEFITINIB					PLACEBO						
		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL		ORIENTAL		NON-ORIENTAL	
		N=235		N=891		N=107		N=455					
		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	1	0.2	0	0
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
	TOTAL	0	0	2	0.2	0	0	0	0	1	0.2	0	0
RENAL AND URINARY DISORDERS	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	0	0	1	0.2
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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		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	%
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)

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SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED									
		GEFITINIB					PLACEBO				
		ORIENTAL		NON-ORIENTAL			ORIENTAL		NON-ORIENTAL		
		N=891					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

(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														
		%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
VASCULAR DISORDERS	HYPOTENSION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	HYPVOVLAEMIC SHOCK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	PERIPHERAL ISCHAEMIA	0	0	2	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	VENA CAVA THROMBOSIS	0	0	1	0.1	0	0	0	0	0	0	0	0	0	0	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		%
		N=235		N=891				N=107		N=455	
		N	%	N	%		N	%	N	%	
HEPATOBILLIARY DISORDERS											
	TOTAL	2	0.9	0	0	0	0	0	0	0	0.2
	CHOLECYSTITIS ACUTE	1	0.4	0	0	0	0	0	0	0	0
	HEPATIC CIRRHOSIS	1	0.4	0	0	0	0	0	0	0	0
	HEPATOTOXICITY	0	0	0	0	0	0	0	0	0	0.2
INFECTIONS AND INFESTATIONS											
	TOTAL	5	2.1	13	1.5	3	2.8	2	0.4	0	0
	BRONCHITIS ACUTE	0	0	1	0.1	0	0	0	0	0	0
	BRONCHOPNEUMONIA	0	0	0	0	0	0	0	0	2	0.4
	GASTROENTERITIS	0	0	1	0.1	0	0	0	0	0	0
	LUNG ABSCESS	0	0	1	0.1	0	0	0	0	0	0
	PNEUMONIA	4	1.7	5	0.6	3	2.8	0	0	0	0
	PULMONARY SEPSIS	0	0	1	0.1	0	0	0	0	0	0
	RESPIRATORY TRACT INFECTION	0	0	2	0.2	0	0	0	0	0	0

(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	%
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
	TOTAL	0	0	0	0	0	0	1	0.2
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMORAL NECK FRACTURE	0	0	0	0	0	0	1	0.2
	TOTAL	0	0	0	0	0	0	0	0.4
METABOLISM AND NUTRITION DISORDERS	CACHEXIA	0	0	0	0	0	0	0	0.2
	DEHYDRATION	0	0	0	0	0	0	1	0.2
	TOTAL	0	0	1	0.1	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
	TOTAL	1	0.4	1	0.1	0	0	0	0
NERVOUS SYSTEM DISORDERS	CEREBRAL ISCHAEMIA	0	0	1	0.1	0	0	0	0

(Continued)

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SYSTEM ORGAN CLASS	PREFERRED TERM	TREATMENT RECEIVED									
		GEFITINIB					PLACEBO				
		ORIENTAL		NON-ORIENTAL			ORIENTAL		NON-ORIENTAL		
		N=891					N=455				
		N	%	N	%	N	%	N	%	N	%
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	1	0.4	0	0	0	0	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASITINAL 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)

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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	%
VASCULAR DISORDERS	TOTAL	0	0	0	0	0	0	0	0
	HYPVOLEAEMIC SHOCK	0	0	0	0	0	0	1	0.2

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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	ORIENTAL	NON-ORIENTAL	ORIENTAL	NON-ORIENTAL
		N=235	N=891	N=107	N=455				
		N	%	N	%	N	%	N	%
HEPATOBIILIARY 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

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ILD 症例に関する資料

ILD有害事象発現症例の内訳

国名	割付薬	年齢	性別	人種	PS	胸部手術	胸部放射線	有害事象		CTC	発現日	ステロイド治療	因果関係	有害事象の転帰	重篤度
								MedDRA(日本語)	MedDRA(日本語)						
マレーシア	イレッサ	55	女性	東洋人	1	無し	無し	肺臓炎	肺臓炎	4	31	無し	有り	回復	重篤 ¹⁾
フィリピン	イレッサ	61	女性	東洋人	0	無し	無し	間質性肺疾患	間質性肺疾患	3	20	有り	有り	不変	重篤 ²⁾
タイ	イレッサ	65	男性	東洋人	1	無し	無し	肺臓炎	肺臓炎	2	47	無し	無し	不変	重篤でない
タイ	イレッサ	52	男性	東洋人	2	無し	有り	肺臓炎	肺臓炎	2	32	無し	無し	不変	重篤でない
タイ	イレッサ	67	男性	東洋人	0	無し	有り	肺臓炎	肺臓炎	3	92	無し	無し	回復	重篤でない
タイ	プラセボ	61	女性	東洋人	2	無し	無し	肺臓炎	肺臓炎	4	48	無し	無し	死亡	重篤 ³⁾
台湾	イレッサ	74	男性	東洋人	1	無し	無し	間質性肺疾患	間質性肺疾患	4	20	有り	有り	回復	重篤 ⁴⁾
台湾	イレッサ	48	男性	東洋人	2	無し	無し	肺臓炎	肺臓炎	3	13	無し	無し	不変	重篤でない
シンガポール	プラセボ	59	女性	東洋人	2	有り	無し	肺臓炎	肺臓炎	3	36	無し	有り	不変	重篤 ⁵⁾
台湾	プラセボ	66	女性	東洋人	1	無し	無し	肺臓炎	肺臓炎	1	29	無し	無し	不変	重篤でない
台湾	プラセボ	67	男性	東洋人	1	無し	無し	肺臓炎	肺臓炎	3	47	無し	無し	回復	重篤でない
オーストラリア	イレッサ	64	女性	白人	1	無し	無し	肺臓炎	肺臓炎	2	28	有り	有り	不変	重篤でない
オランダ	イレッサ	50	女性	白人	1	無し	有り	肺臓炎	肺臓炎	2	63	無し	無し	回復	重篤でない
オランダ	イレッサ	65	男性	白人	1	無し	無し	肺浸潤	肺浸潤	3	96	無し	無し	回復	重篤 ⁶⁾
ノルウェー	イレッサ	53	男性	白人	2	無し	有り	肺浸潤	肺浸潤	1	59	無し	有り	回復	重篤でない
スロバキア	プラセボ	45	男性	白人	1	無し	有り	放射線肺線維症	放射線肺線維症	3	91	有り	無し	不変	重篤 ⁷⁾
ブラジル	イレッサ	59	女性	その他	1	無し	有り	放射線性肺臓炎	放射線性肺臓炎	2	31	有り	無し	不変	重篤でない

Additional Deaths since Jan 20th

N Cox HR(95% CI) Medians: Gefitinib vs Placebo	Never smoked	Smokers	All
Oriental	N=141 +1 (+1 vs 0)	N=201 +1 (0 vs +1)	N=342 +2 (+1 vs +1)
Non-oriental	N=234 +0	N=1116 +5 (+1 vs +4)	N=1350 +5 (+1 vs +4)
All	N=375 +1 (+1 vs 0)	N=1317 +6 (+1 vs +5)	N=1692 +7 (+2 vs +5)

最終バリデーション後の結果では死亡例数が増加（各群ごとに増加例数を表示（イレッサ群 vs プラセボ群））