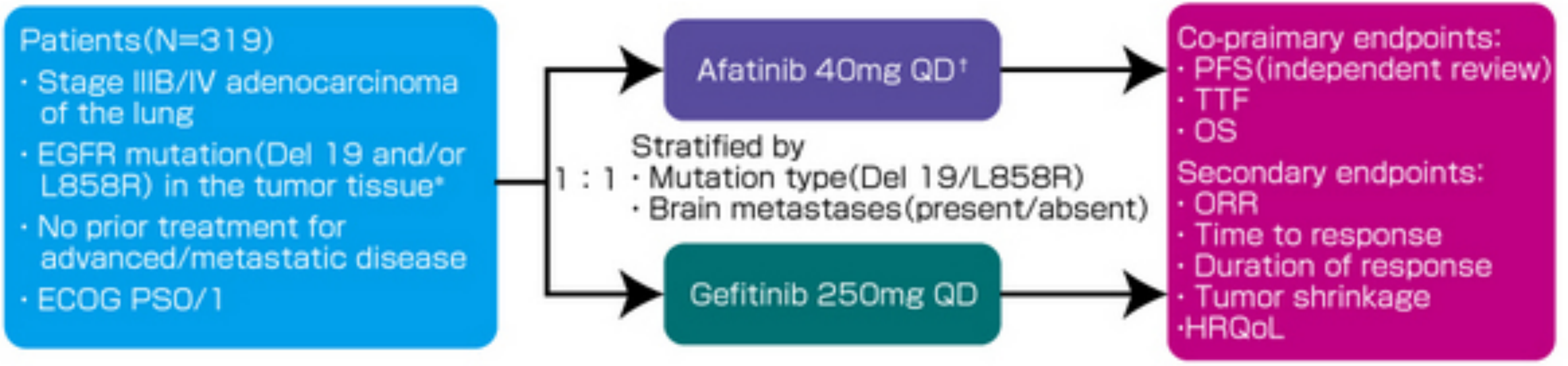
LUX-Lung 7

図1 LUX-LUNG 7 STUDY DESIGN



・Treatment beyond progression allowed if deemed beneficial by investigator
・RECIST assessment performed at Week4, 8 and every 8 weeks thereafter until Week 64, and every 12 weeks thereafter
・Primary PFS analysis conducted after ～250 events ; primary OS analysis conducted after ～213 events and ≥ 32-mo follow-up
・All statistical testing at two-sided 5%alpha level with no adjustment for multiplicity

*Central or local test ; †Dose modification to 50, 30 or 20mg was permitted in line with prescribing information
ECOG PS, Eastern Cooperative Oncology Group performance status ; HRQoL, health-related quality of life ; QD, once daily ; RECIST, Response Evaluation Criteria in Solid Tumors ;

(Luis Paz-Ares, et al. ESMO2016 Abstract No. LBA43)

LUX-Lung 7 (EGFR-TKI-65)

2011年12月から2013年8月までに北米や欧州、アジア（日本は不参加）など13カ国の64施設から患者が登録

Primary Endpoint: PFS, TTF, OS

Secondary Endpoint: ORR, DCR, safety, QOL

Phase IIb

Adeno

化学療法未治療
非小細胞肺癌患者
StageIIIB/IV
（1次治療）
・EGFR遺伝子変異
　Exon19 deletion
　Exon21 L858R
・Asymptomatic
・No Brain meta

n=319

R 1:1

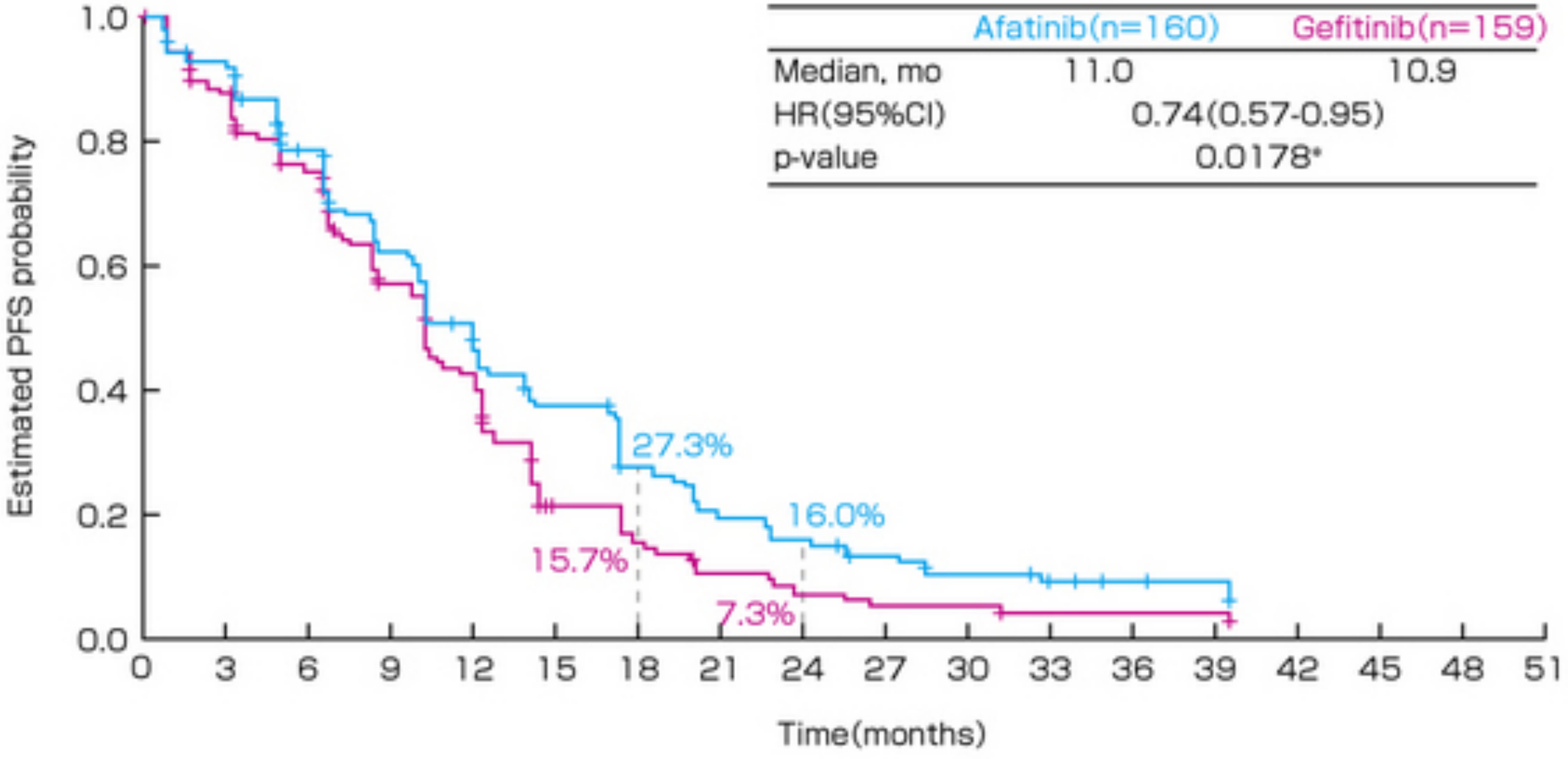
afatinib (40mg/day)
n=160

Exon 19 del :58%
Exon 21 L858R:42%

n=159
Gefitinib (250mg/day)

	mPFS	OS	ORR	TTF
afatinib (40mg/day) n=160	11ヵ月	27.9ヶ月	73%	13.7ヶ月
Exon 19 del :58% / Exon 21 L858R:42%	HR=0.74 p=0.0178	HR=0.86 p=0.258	p=0.002	
Gefitinib (250mg/day) n=159	10.9ヵ月	24.5ヶ月	56%	11.5ヶ月

図2■UPDATED PFS（INDEPENDENT REVIEW）



	Afatinib(n=160)	Gefitinib(n=159)
Median, mo	11.0	10.9
HR(95%CI)	0.74(0.57-0.95)	
p-value	0.0178*	

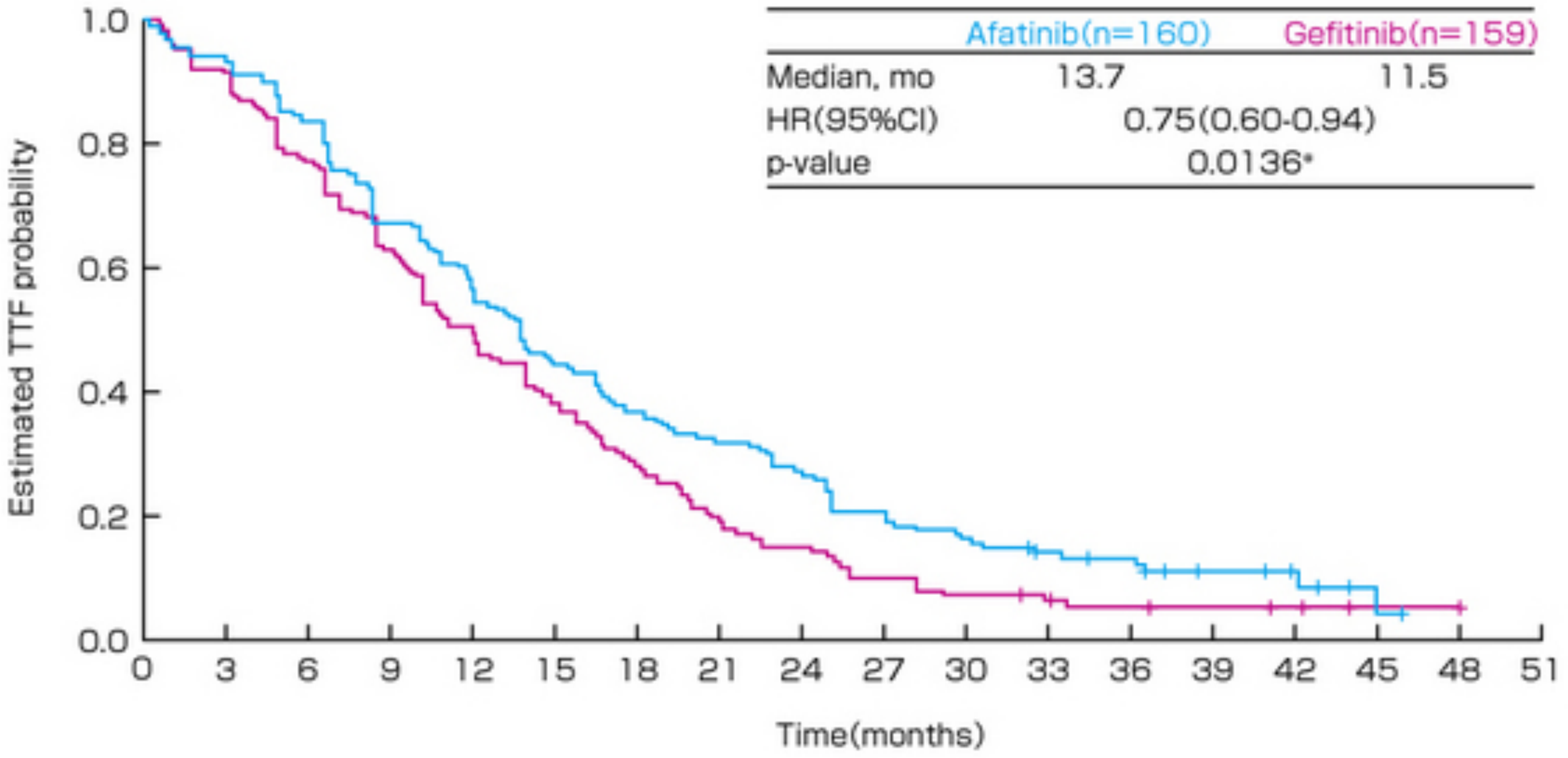
No. at risk

Afatinib	160	142	113	94	67	47	34	26	20	13	10	8	4	3	0	0	0	0
Gefitinib	159	132	105	82	51	21	15	10	7	5	5	3	3	3	0	0	0	0

*unadjusted

(Luis Paz-Ares, et al. ESMO2016 Abstract No. LBA43)

図3 UPDATED TTF



	Afatinib(n=160)	Gefitinib(n=159)
Median, mo	13.7	11.5
HR(95%CI)	0.75(0.60-0.94)	
p-value	0.0136*	

No. at risk

Afatinib	160	148	133	113	91	68	56	48	40	29	25	19	16	7	6	1	0	0
Gefitinib	159	144	120	103	74	59	43	30	21	14	10	9	6	5	4	2	0	0

*unadjusted

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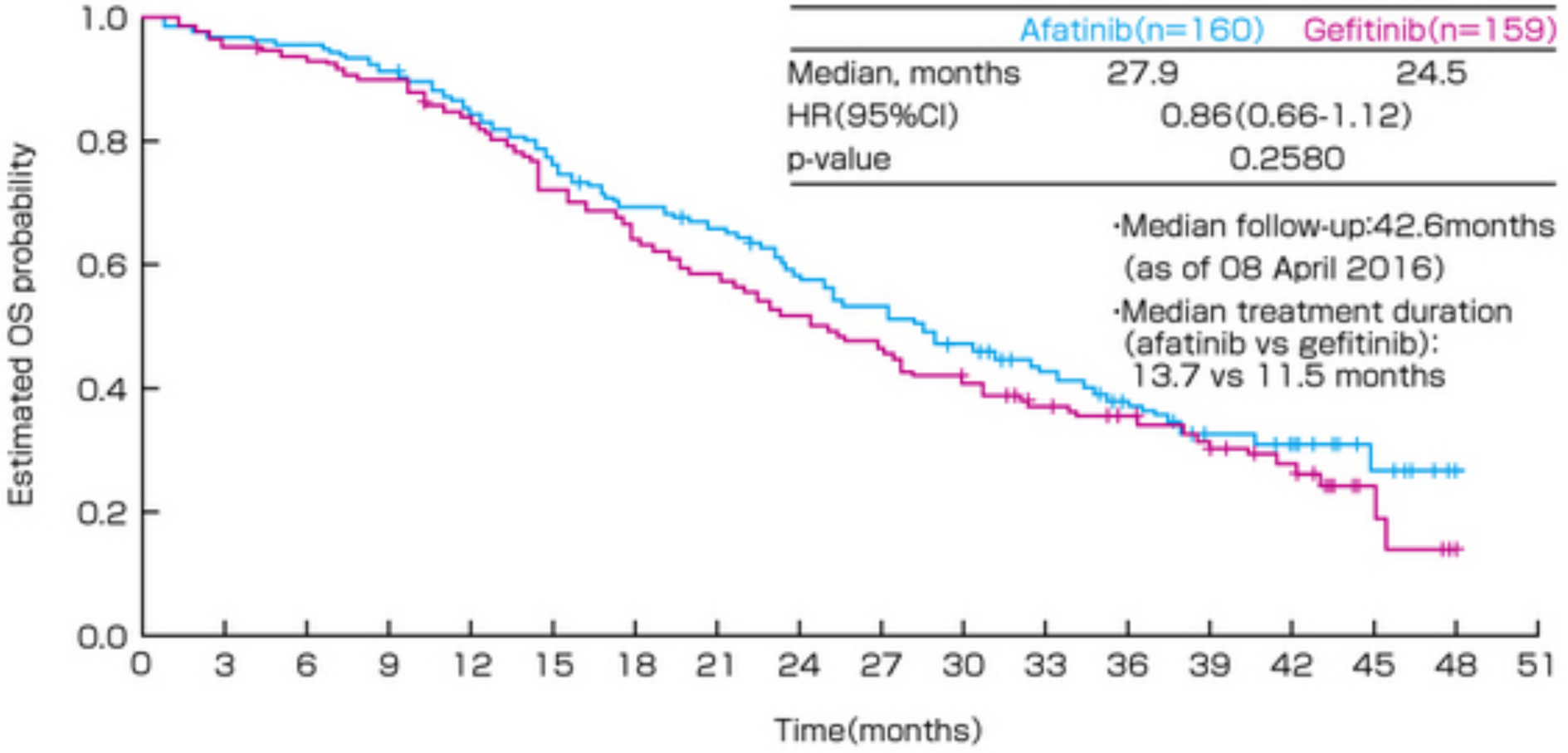
図4■OS(OVERALL POPULATION)

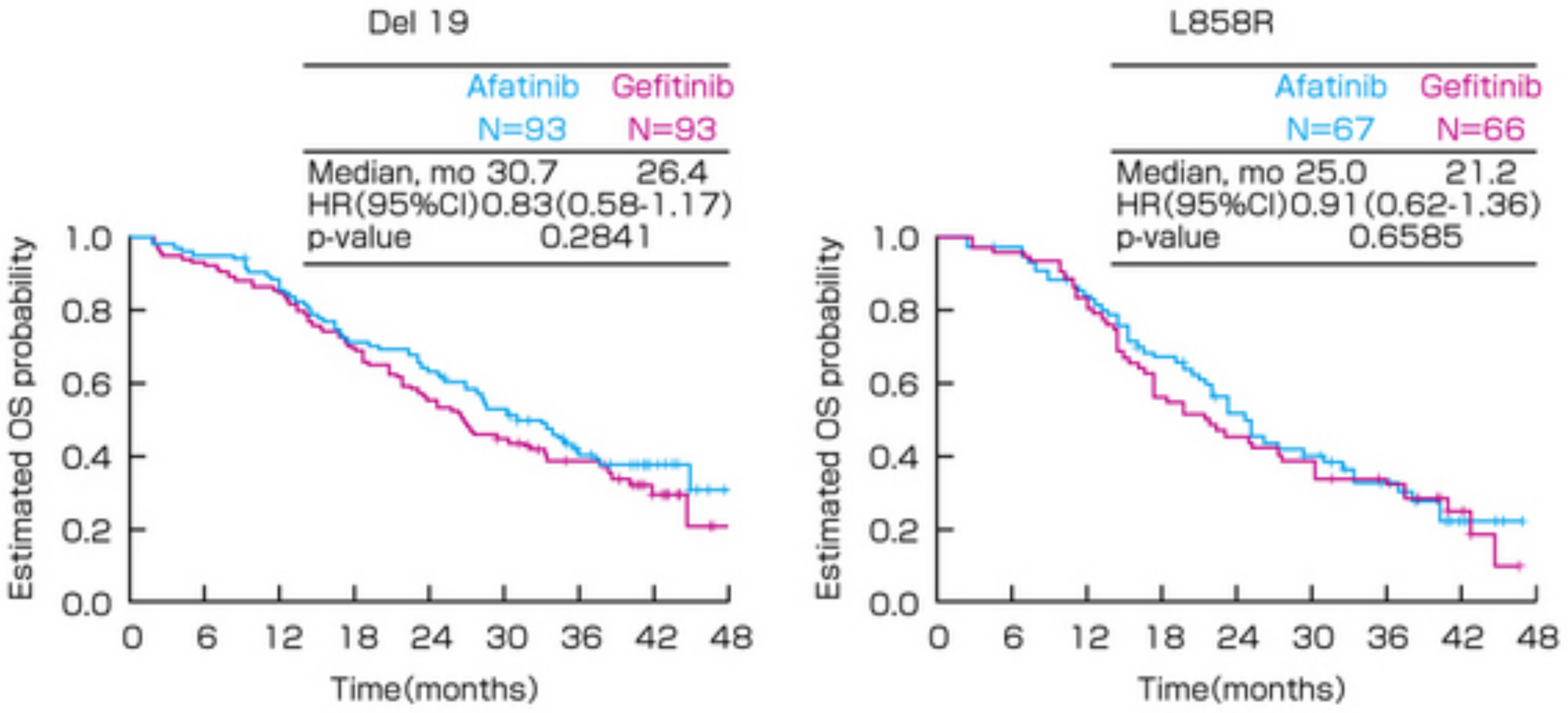


No. at risk

Afatinib	160	156	153	148	139	125	111	104	94	81	74	61	50	36	30	12	2	0
Gefitinib	159	153	148	142	133	119	105	90	80	71	62	56	48	44	27	7	0	0

(Luis Paz-Ares, et al. ESMO2016 Abstract No. LBA43)

図5■OS BY EGFR MUTATION SUBTYPE



No. at risk									
Afatinib	93	88	82	68	61	50	35	20	1
Gefitinib	93	86	79	66	52	39	29	17	0

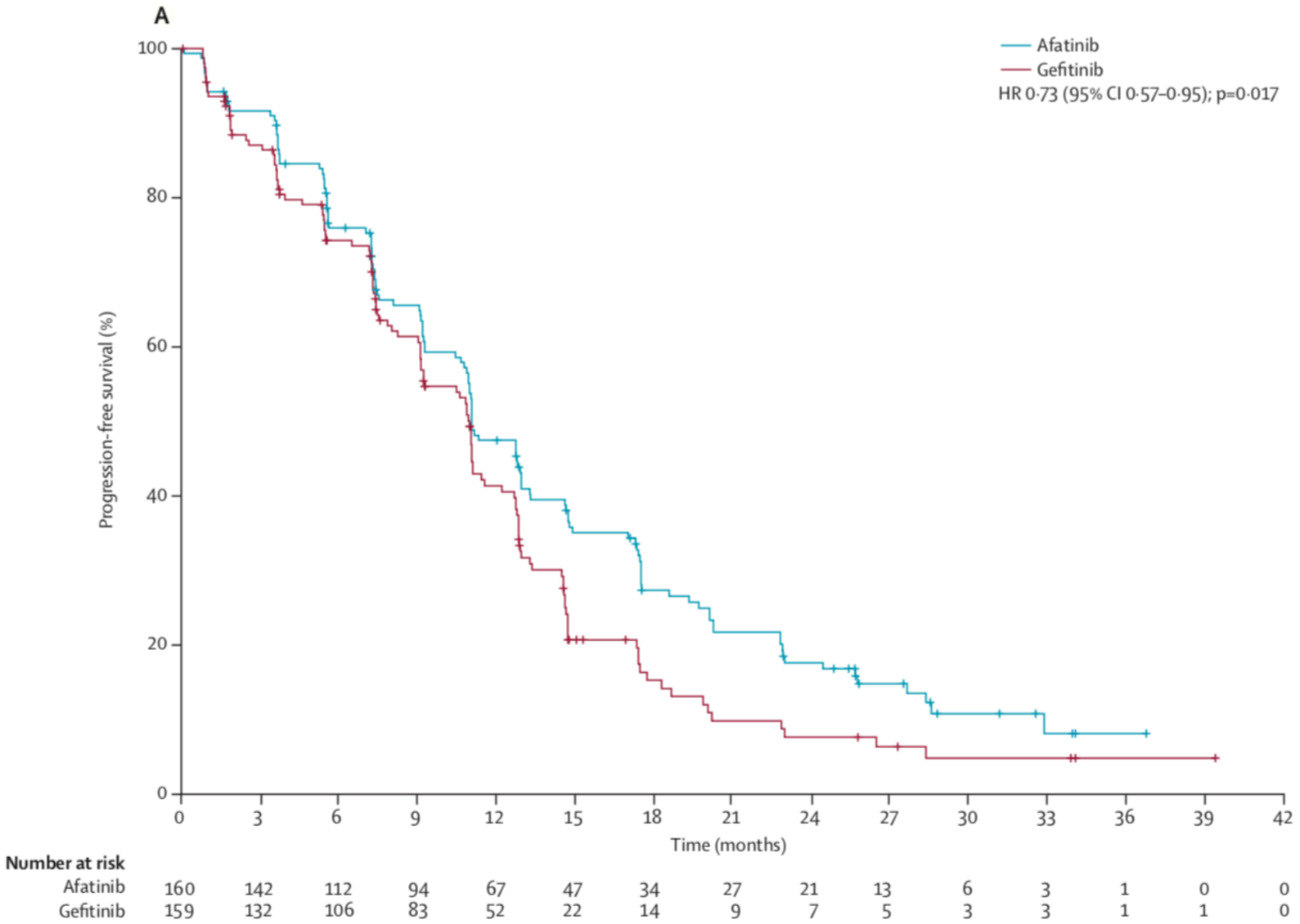
No. at risk									
Afatinib	67	65	57	43	33	24	15	10	1
Gefitinib	66	62	54	39	28	23	19	10	0

(Luis Paz-Ares, et al. ESMO2016 Abstract No. LBA43)

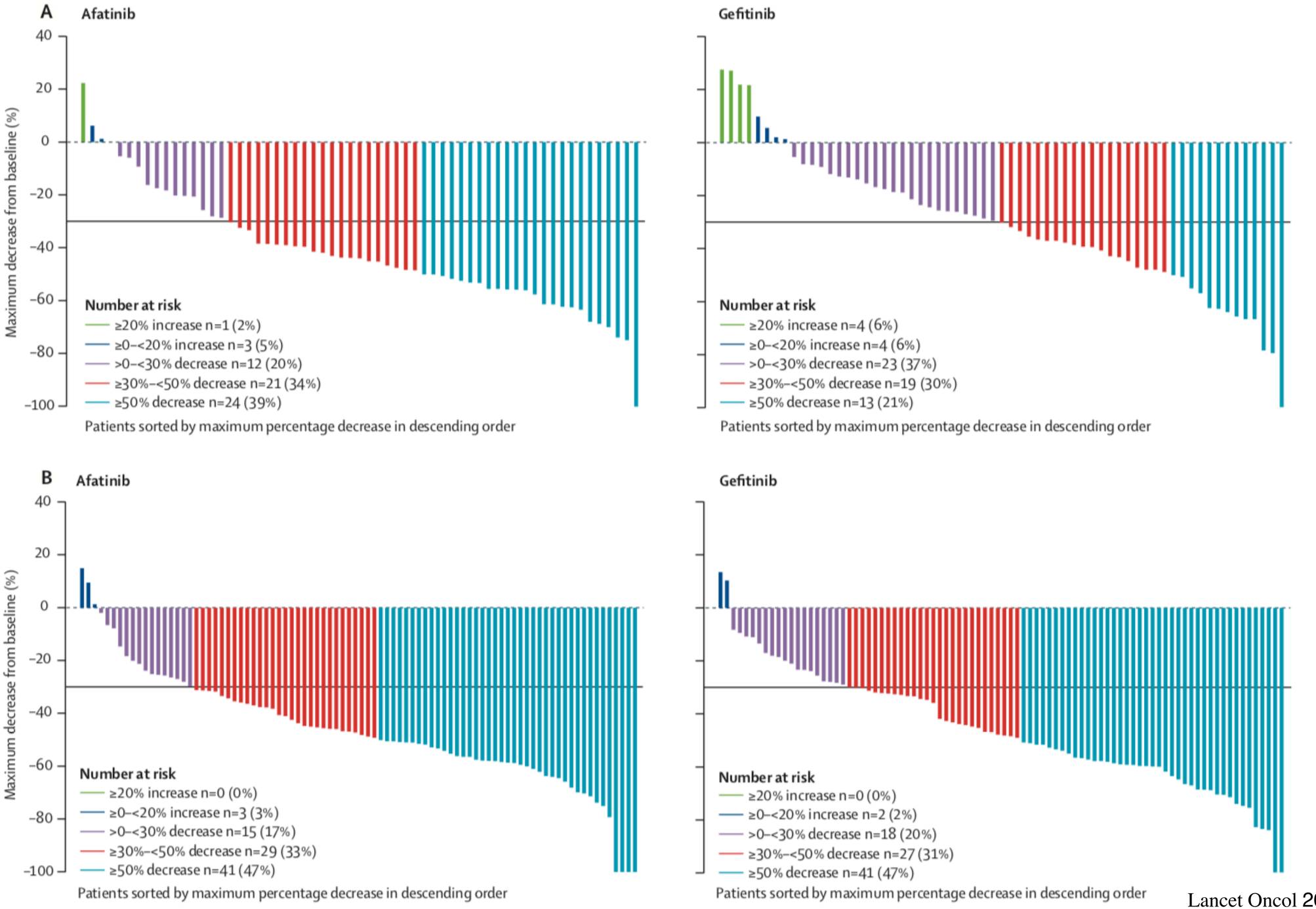
	Afatinib (n=160)	Gefitinib (n=159)
Sex		
Men	69 (43%)	53 (33%)
Women	91 (57%)	106 (67%)
Age	63 (30–86)	63 (32–89)
Ethnic origin		
Asian	94 (59%)	88 (55%)
Black/African American	1 (1%)	0
White	48 (30%)	54 (34%)
Missing*	17 (11%)	17 (11%)
Smoking status		
Never smoked	106 (66%)	106 (67%)
Light ex-smoker†	21 (13%)	19 (12%)
Other current or ex-smokers	33 (21%)	34 (21%)
Baseline ECOG PS		
0	51 (32%)	47 (30%)
1	109 (68%)	112 (70%)
Histological classification		
Adenocarcinoma	159 (99%)	158 (99%)
Mixed	1 (1%)	1 (1%)
Clinical stage at screening		
IIIb	8 (5%)	3 (2%)
IV	152 (95%)	156 (98%)
EGFR mutation category		
Leu858Arg	67 (42%)	66 (42%)
Leu858Arg alone	67 (42%)	65 (41%)
Leu858Arg+exon 19 deletion	0	1 (1%)
Exon 19 deletion‡	93 (58%)	93 (58%)
Metastases at screening		
Adrenal glands	12 (8%)	16 (10%)
Bone	80 (50%)	73 (46%)
Brain	26 (16%)	24 (15%)
Liver	16 (10%)	24 (15%)
Lung ipsilateral	86 (54%)	88 (55%)
Lung contralateral	65 (41%)	73 (46%)
Other	100 (63%)	104 (65%)

Data are n (%) or median (range). ECOG PS=Eastern Cooperative Oncology Group performance status. *Patients recruited in French sites did not have their ethnic origin recorded. †Less than 15 pack-years and stopped more than 1 year before diagnosis. ‡One patient in the afatinib group with wild-type *EGFR* was erroneously included in the trial and was reported as exon 19 deletion at the time of randomisation by the investigator.

Table 1: **Baseline demographics and disease characteristics**



Lancet Oncol 2016; 17: 577–89



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