ARCHER1050

ARCHER1050 (EGFR-TKI-)

独立中央判定
BICR

Primary Endpoint: PFS (BICR)

Secondary Endpoint: PFS (by investigator), ORR, ORR, TTF, DCR, DoR, safety,

Non-Sq

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
・No Brain meta

n=452

R

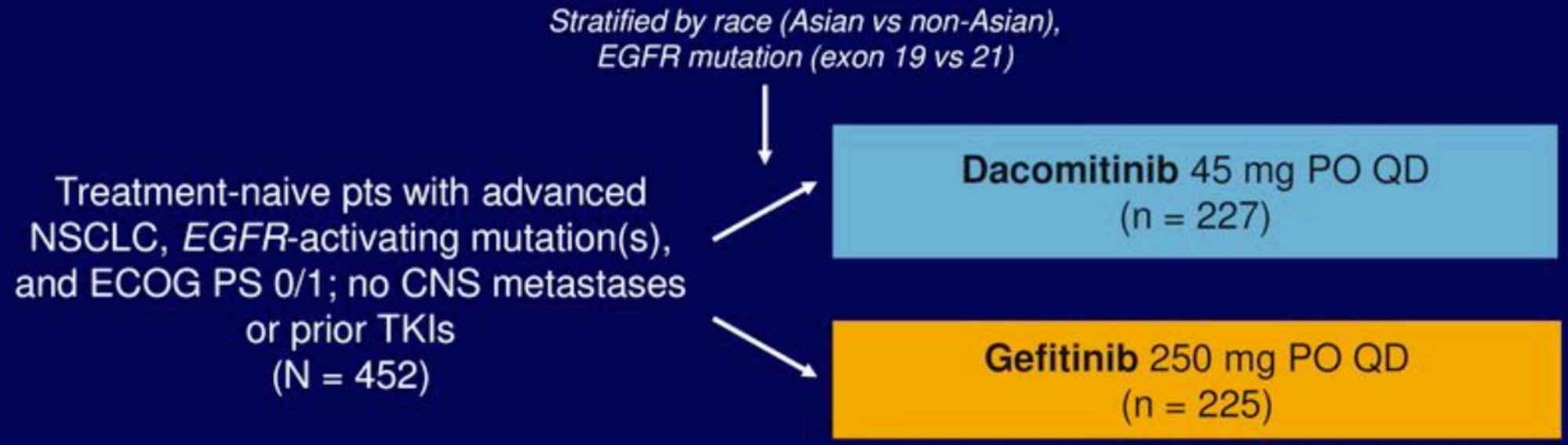
Dacomitinib (45mg/day)
n=227

n=225
Gefitinib (250mg/day)

	BICR mPFS	OR	アジア人 サブ解析OS
Dacomitinib (45mg/day) n=227	14.7ヵ月	34.1ヵ月	34.2ヶ月
	HR=0.59 p<0.0001	HR=0.582 p=0.0428	HR=0.812 p=0.1819
Gefitinib (250mg/day) n=225	9.2ヵ月	26.8ヵ月	29.1ヶ月

ARCHER 1050: Study Design

- Multicenter, randomized, open-label phase III study

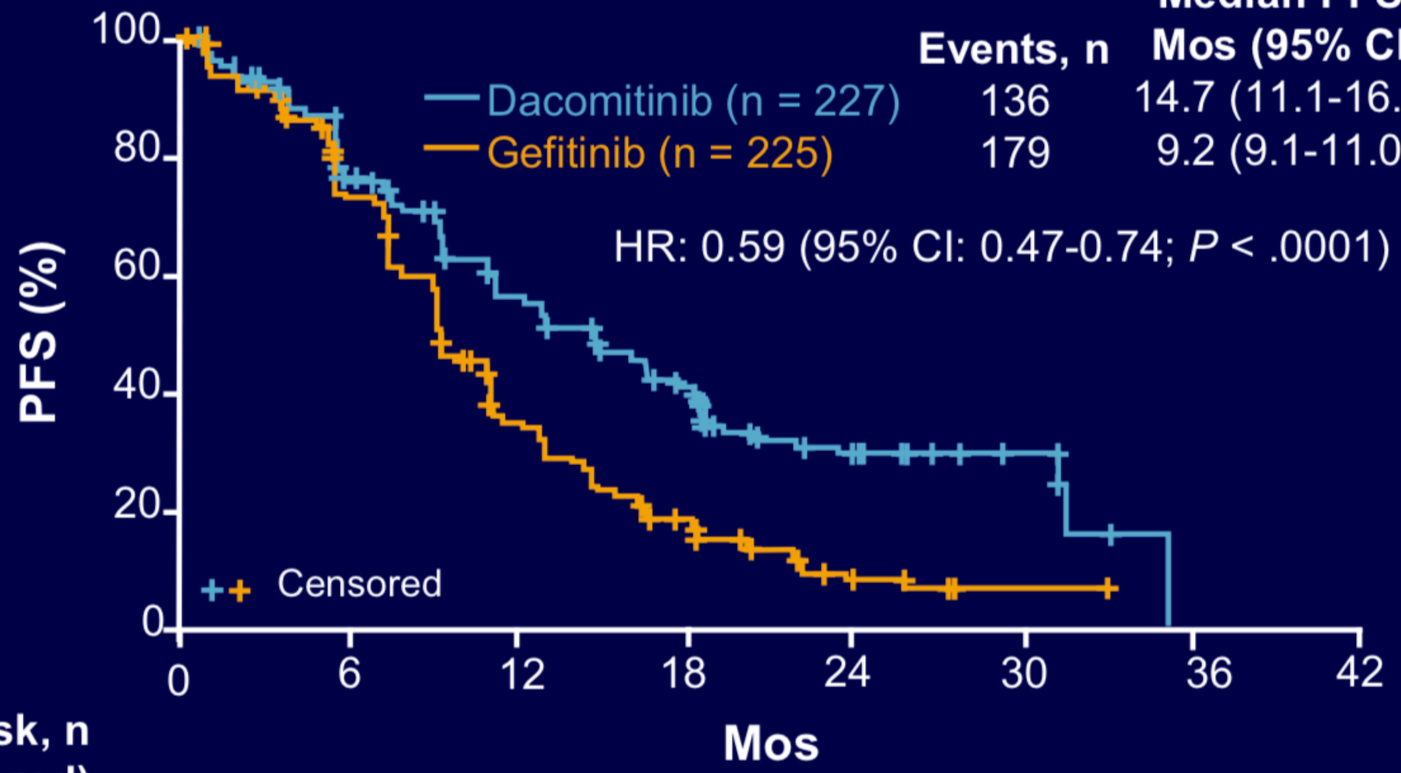


- Primary endpoint: PFS by blinded independent review
- Secondary endpoints: PFS by investigator assessment, ORR, DoR, TTF, OS, safety, pt-reported outcomes

Mok T, et al. ASCO 2017. Abstract LBA9007.

Slide credit: clinicaloptions.com

ARCHER 1050: PFS by Independent Review Committee



Patients at Risk, n (no. censored)								
Dacomitinib	227 (0)	154 (23)	106 (31)	73 (36)	20 (74)	6 (88)	0 (91)	0 (91)
Gefitinib	225 (0)	155 (15)	69 (23)	34 (27)	7 (40)	1 (45)	0 (46)	0 (46)

Wu YL, et al. Lancet Oncol. 2017;18:1454-1466.

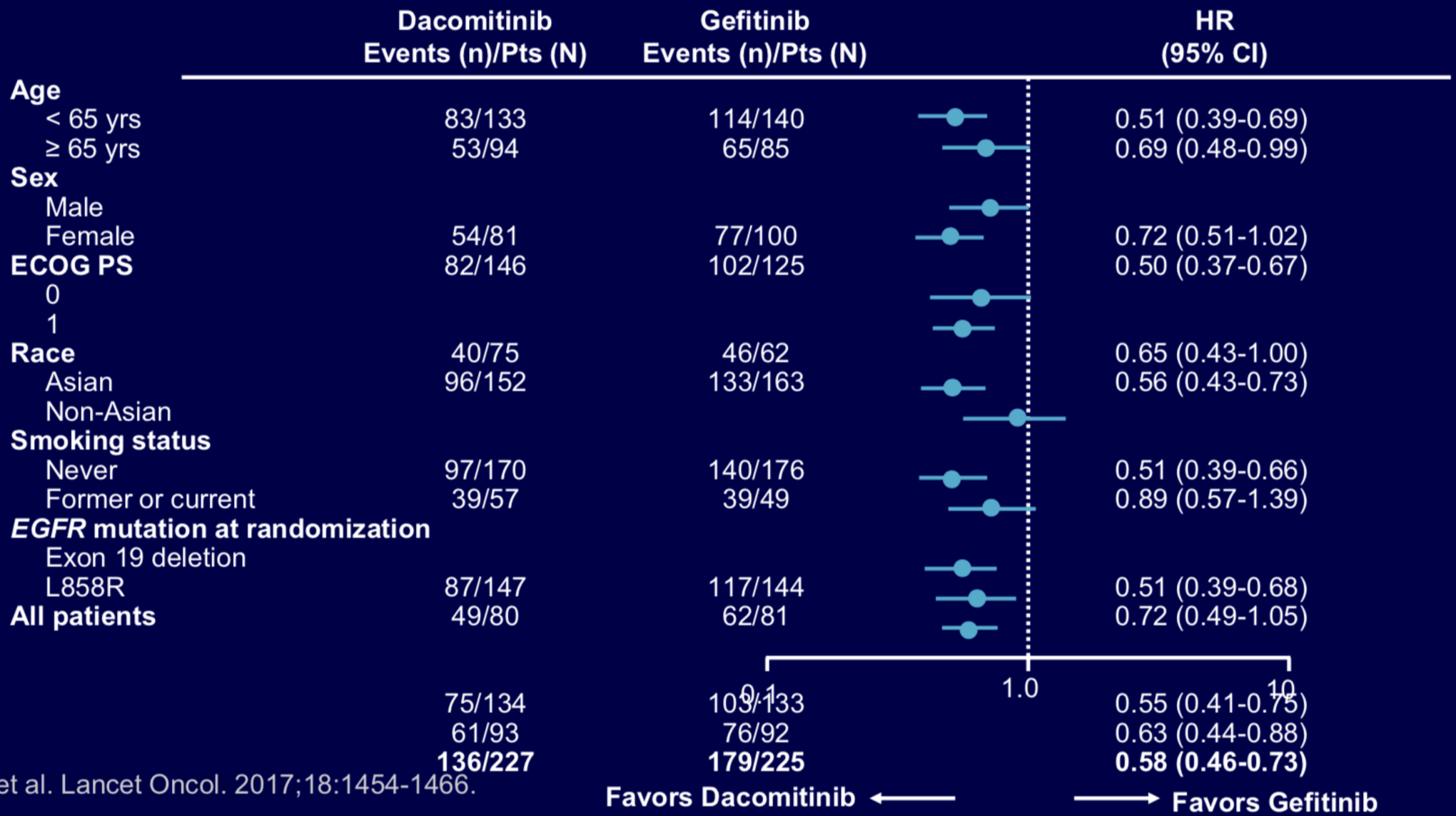
ARCHER 1050: Best Overall Response

Outcome	Dacomitinib (n = 227)	Gefitinib (n = 225)	HR (95% CI)	*P* Value
ORR, % (95% CI)	74.9 (68.7-80.4)	71.6 (65.2-77.4)	--	.3883
Median DoR, mos (95% CI)	14.8 (12.0-17.4)	8.3 (7.4-9.2)	--	< .0001
Median TTF, mos (95% CI)	11.1 (9.2-14.6)	9.2 (7.6-9.4)	0.67 (0.54-0.83)	< .001

- OS data not yet mature (36.9% of events at data cutoff)

Mok T, et al. ASCO 2017. Abstract LBA9007.

ARCHER 1050: PFS by IRC Subgroup Analysis



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