Supplementary material

Updated overall survival in a randomized study comparing dacomitinib with gefitinib as first-line treatment in patients with advanced non-small cell lung cancer and *EGFR*-activating mutations

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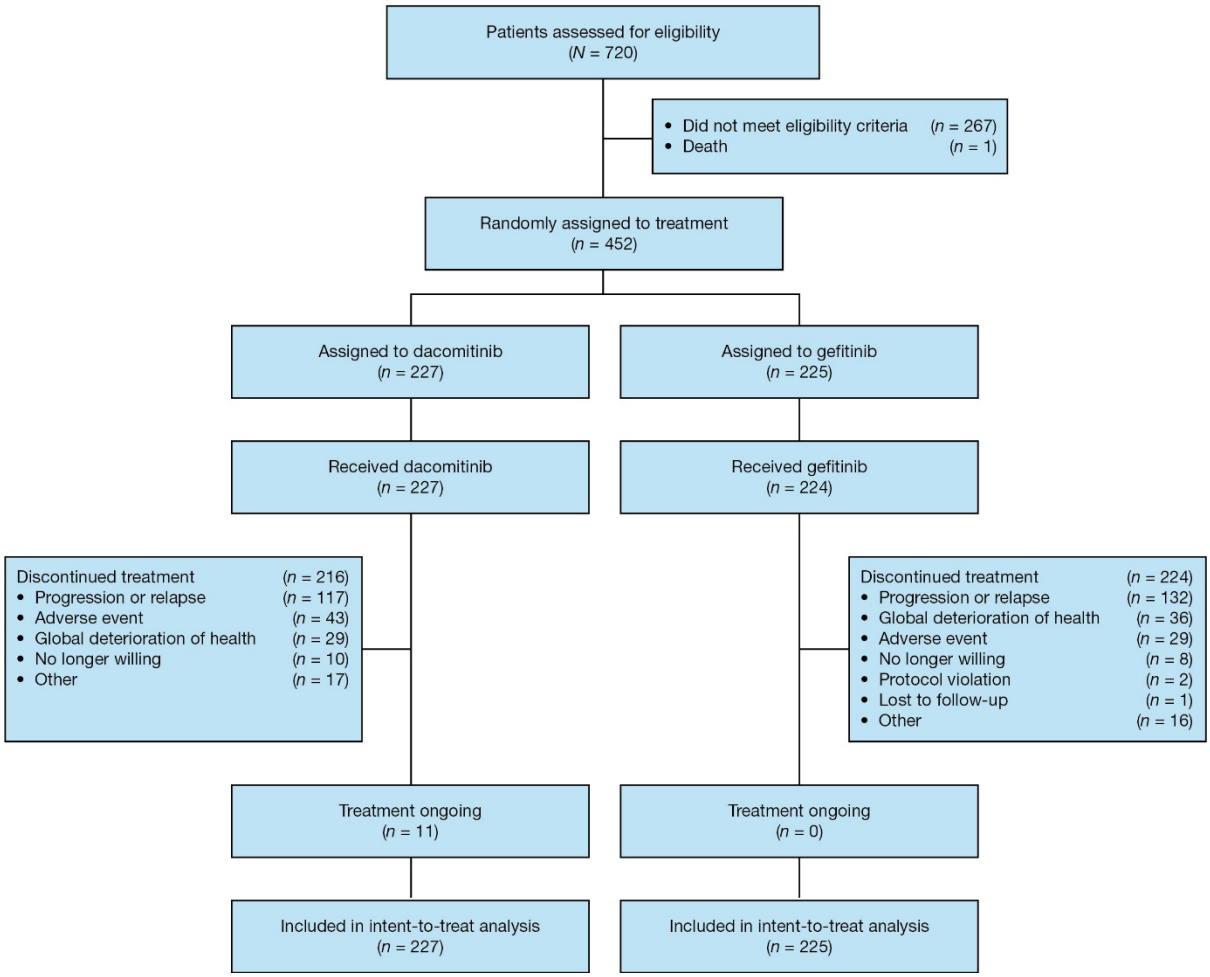
Online Resource 1 CONSORT diagram



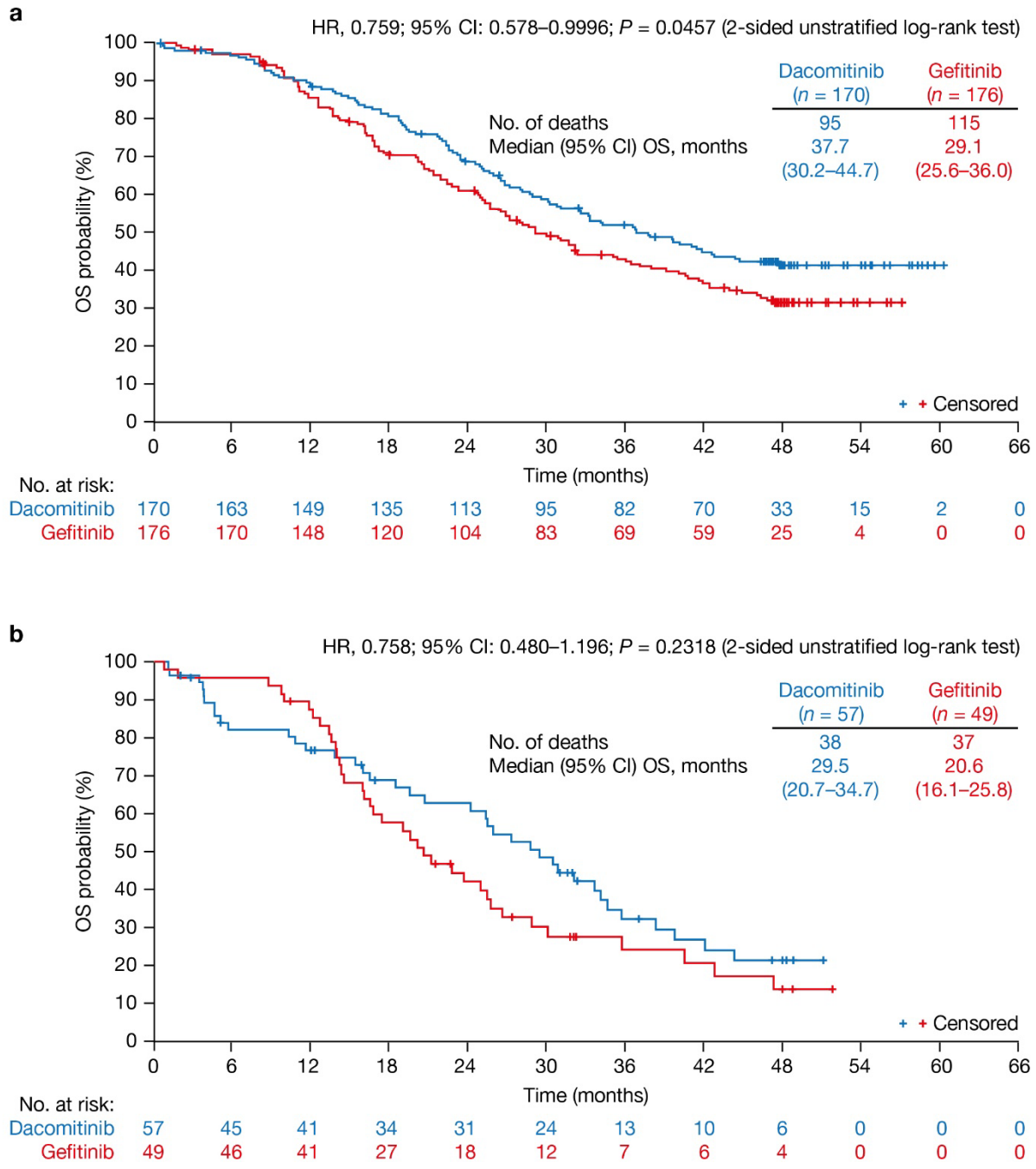
Online Resource 2 Baseline demographics and disease characteristics (ITT)

Characteristic	Dacomitinib (*n* = 227)	Gefitinib (*n* = 225)
Age, years		
Median (range)	62.0 (28–87)	61.0 (33–86)
<65, *n* (%)	133 (58.6)	140 (62.2)
≥65, *n* (%)	94 (41.4)	85 (37.8)
Sex, *n* (%)		
Male	81 (35.7)	100 (44.4)
Female	146 (64.3)	125 (55.6)
Race, *n* (%)		
White	56 (24.7)	49 (21.8)
Black	1 (0.4)	0
Asian	170 (74.9)	176 (78.2)
Chinese	114 (50.2)	117 (52.0)
Japanese	40 (17.6)	41 (18.2)
Other	16 (7.0)	18 (8.0)
ECOG PS, *n* (%)		
0	75 (33.0)	62 (27.6)
1	152 (67.0)	163 (72.4)
Smoking status, *n* (%)		
Never	147 (64.8)	144 (64.0)
Former	65 (28.6)	62 (27.6)
Current	15 (6.6)	19 (8.4)
Current disease stage, *n* (%)		

IIIB	17 (7.5)	16 (7.1)
IV	203 (89.4)	206 (91.6)
Unknown	7 (3.1)	3 (1.3)
EGFR mutation, *n* (%)		
Exon 19 deletion	134 (59.0)	133 (59.1)
Exon 21 L858R	93 (41.0)	92 (40.9)

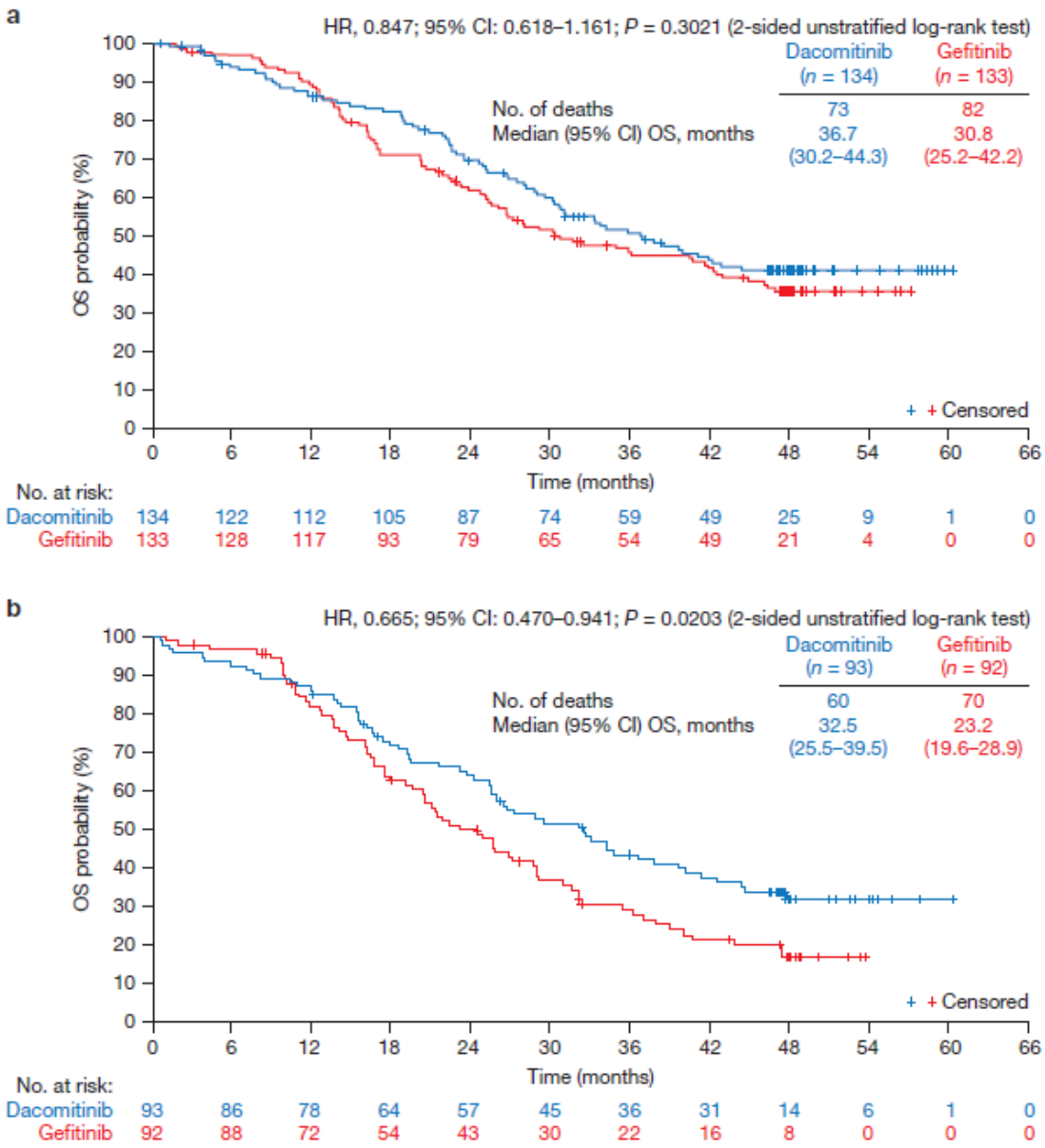
ECOG, Eastern Cooperative Oncology Group; *EGFR*, epidermal growth factor receptor; ITT, intent-to-treat; PS, performance status

Online Resource 3 Overall survival in (a) the Asian subgroup and (b) the non-Asian subgroup (ITT)



CI, confidence interval. HR, hazard ratio; ITT, intent-to-treat; OS, overall survival

Online Resource 4 Overall survival by *EGFR* mutation status at randomization: (a) exon 19 deletion; (b) exon 21 L858R substitution mutation (ITT)



CI, confidence interval; *EGFR*, epidermal growth factor receptor; HR, hazard ratio; ITT, intent-to-treat; OS, overall survival

Online Resource 5 Subsequent systemic therapy (ITT)

	Dacomitinib (*n* = 227)	Gefitinib (*n* = 225)
Received subsequent systemic therapy, n (%)		
None	97 (42.7)	79 (35.1)
Any	130 (57.3)	146 (64.9)
1	55 (24.2)	69 (30.7)
2	25 (11.0)	32 (14.2)
3	23 (10.1)	21 (9.3)
>3	27 (11.9)	24 (10.7)
Number of subsequent systemic therapies		
n	130	146
Median (range)	2 (1-7)	2 (1–9)
Subsequent systemic therapy, *n* (%)[a]		
Pemetrexed	71 (31.3)	73 (32.4)
Osimertinib	48 (21.1)	53 (23.6)
Cisplatin	43 (18.9)	45 (20.0)
Carboplatin	35 (15.4)	43 (19.1)
Docetaxel	30 (13.2)	18 (8.0)
Gefitinib	20 (8.8)	26 (11.6)
Erlotinib	19 (8.4)	23 (10.2)
First subsequent systemic therapy (most common categories)		
Chemotherapy[b]	69 (30.4)	77 (34.2)
Third-generation EGFR TKI[c]	32 (14.1)	27 (12.0)
First-/second-generation EGFR TKI[d]	21 (9.3)	30 (13.3)

Any subsequent systemic therapy (most common categories)		
Chemotherapy[b]	94 (41.4)	103 (45.8)
Third-generation EGFR TKI[c]	56 (24.7)	57 (25.3)
First-/second-generation EGFR TKI[d]	44 (19.4)	59 (26.2)

[a]The most common subsequent systemic therapies (received by ≥10% of patients in either treatment arm) are shown

[b]Includes pemetrexed, cisplatin alone or combination, carboplatin alone or combination, paclitaxel alone or combination, etoposide, cis-DDP, tegafur, vinorelbine, capecitabine, nedaplatin, gimeracil with oteracil/tegafur, amrubicin, nedaplatin, temozolomide, lobaplatin, docetaxel, gemcitabine, TAS-102, irinotecan hydrochloride hydrate, and other unspecified chemotherapeutics

[c]Includes osimertinib (AZD9291), olmutinib (HM61713), rociletinib (CO-1686), avitinib (AC0010), TAS-121, PF-06747775, and EGF816

[d]Other than dacomitinib; includes gefitinib, erlotinib, icotinib, afatinib, and other unspecified EGFR TKI

EGFR, epidermal growth factor receptor; ITT, intent-to-treat; TKI, tyrosine kinase inhibitor

Online Resource 6 Summary of adverse events (safety population)

	All causality		Treatment-related	
	Dacomitinib *n* = 227	Gefitinib *n* = 224	Dacomitinib *n* = 227	Gefitinib *n* = 224
Any AE, *n* (%)	226 (99.6)	220 (98.2)	220 (96.9)	213 (95.1)
Serious AE, *n* (%)	69 (30.4)	53 (23.7)	22 (9.7)	10 (4.5)
Grade 3 AE, *n* (%)	145 (63.9)	96 (42.9)	115 (50.7)	49 (21.9)
Grade 4 AE, *n* (%)	13 (5.7)	14 (6.3)	3 (1.3)	3 (1.3)
Grade 3 or 4 AEs	146 (64.3)	101 (45.1)	116 (51.1)	49 (21.9)
Grade 5 AE, *n* (%)	24 (10.6)	22 (9.8)	2 (0.9)	2 (0.9)
Discontinued treatment due to AEs, *n* (%)	42 (18.5)	29 (12.9)	23 (10.1)	15 (6.7)
Dose reduced due to AEs, *n* (%)	153 (67.4)	18 (8.0)	150 (66.1)	18 (8.0)
Dose interruption due to AEs, *n* (%)	134 (59.0)	61 (27.2)	122 (53.7)	47 (21.0)

AE, adverse event