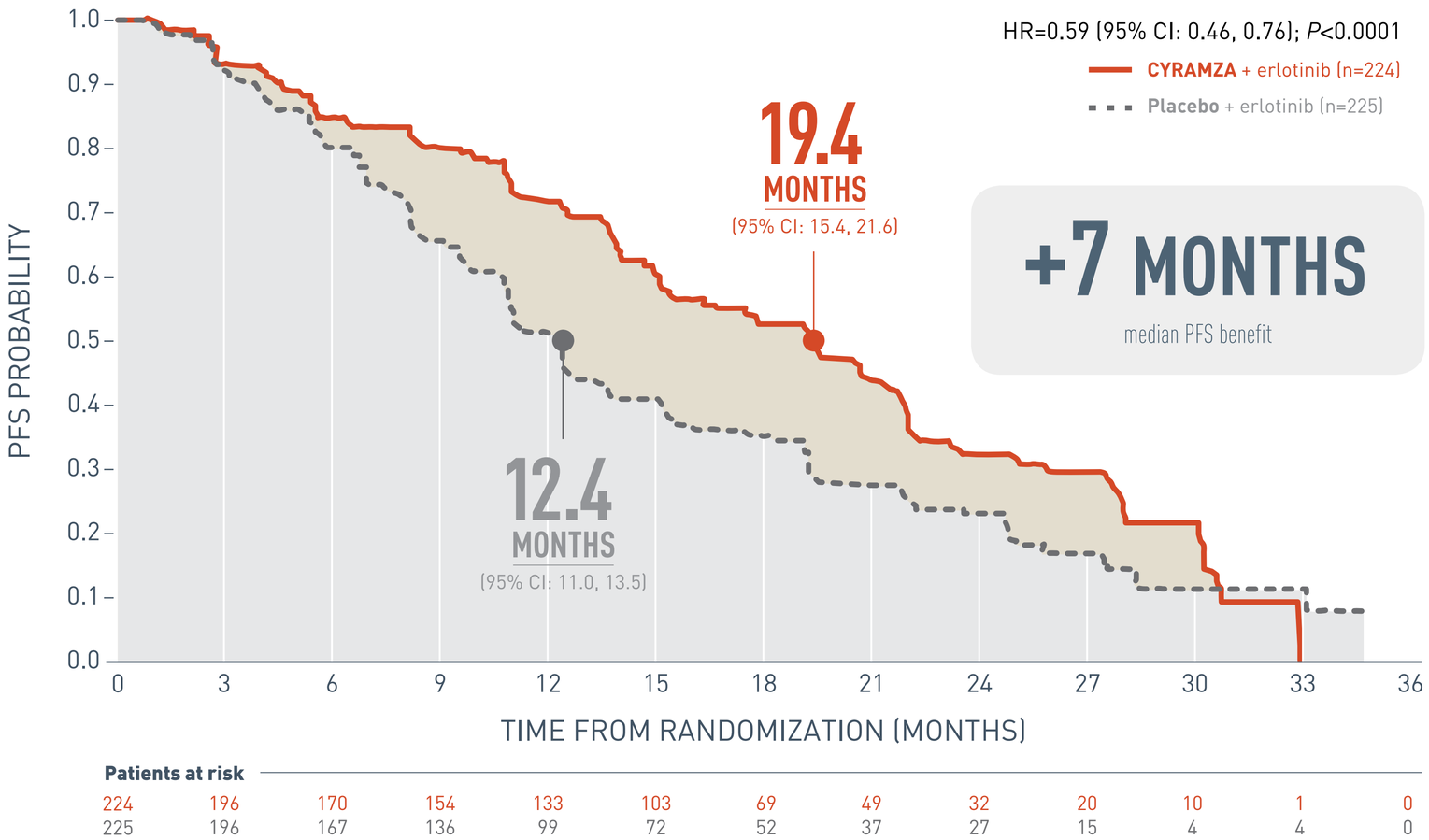
A clinically meaningful combination[6]

CYRAMZA + erlotinib demonstrated 19.4 months of median PFS vs 12.4 months with erlotinib alone in the ITT population[6]



HR=0.59 (95% CI: 0.46, 0.76); *P*<0.0001

CYRAMZA + erlotinib (n=224)

Placebo + erlotinib (n=225)

+7 MONTHS

median PFS benefit

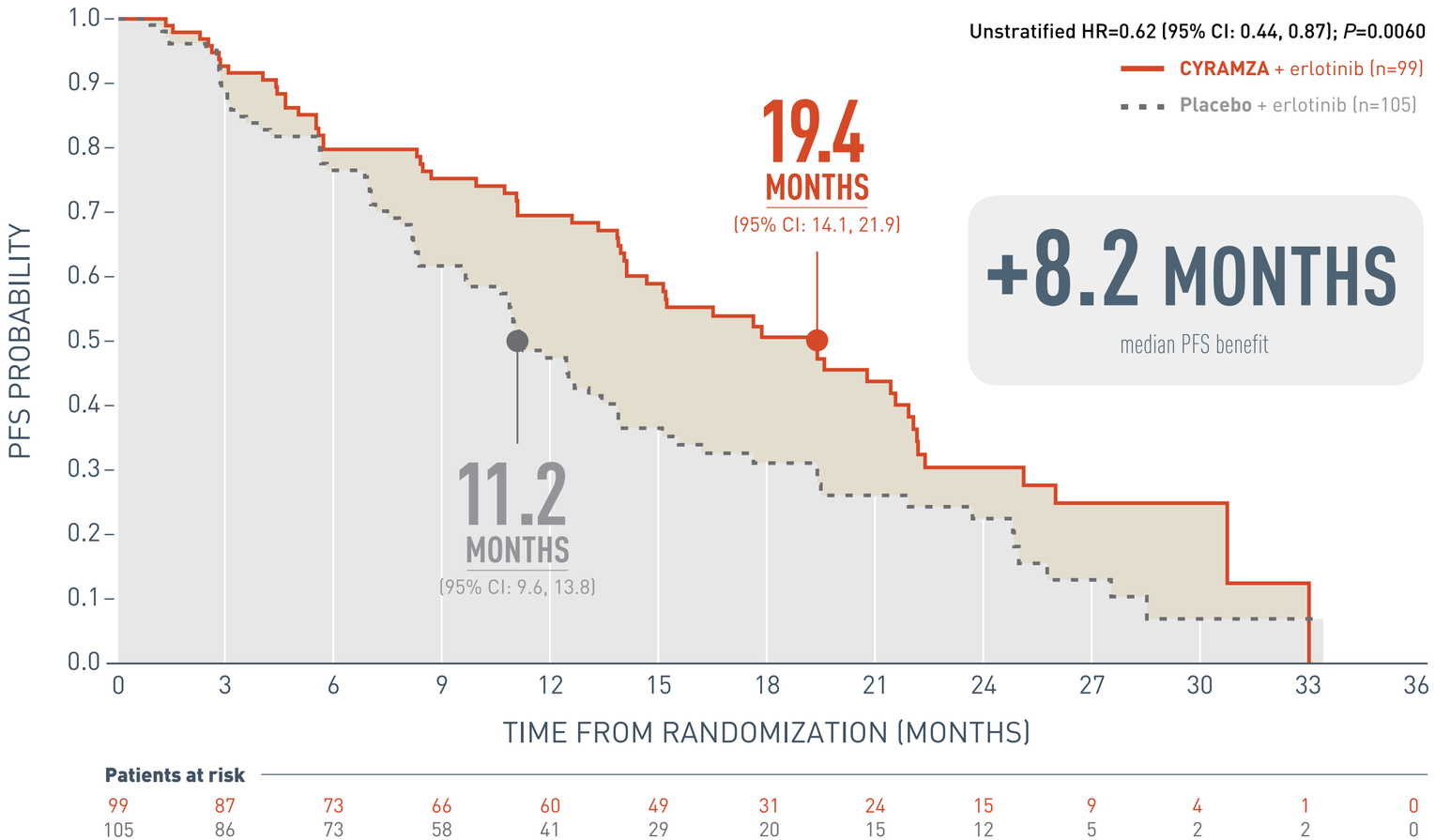
- ~1 in 3 patients survived 2 years or longer without progression when treated with CYRAMZA + erlotinib (32.4% vs 22.9% with placebo + erlotinib)[14]

CI=confidence interval; HR=hazard ratio.

Consistent PFS improvements across common EGFR mutation types[12]

CYRAMZA + erlotinib offered more than 19 months of median PFS to patients in RELAY with exon 21 (L858R) mutation

RELAY trial—PFS by EGFR mutation type: exon 21 (prespecified subgroup analysis)



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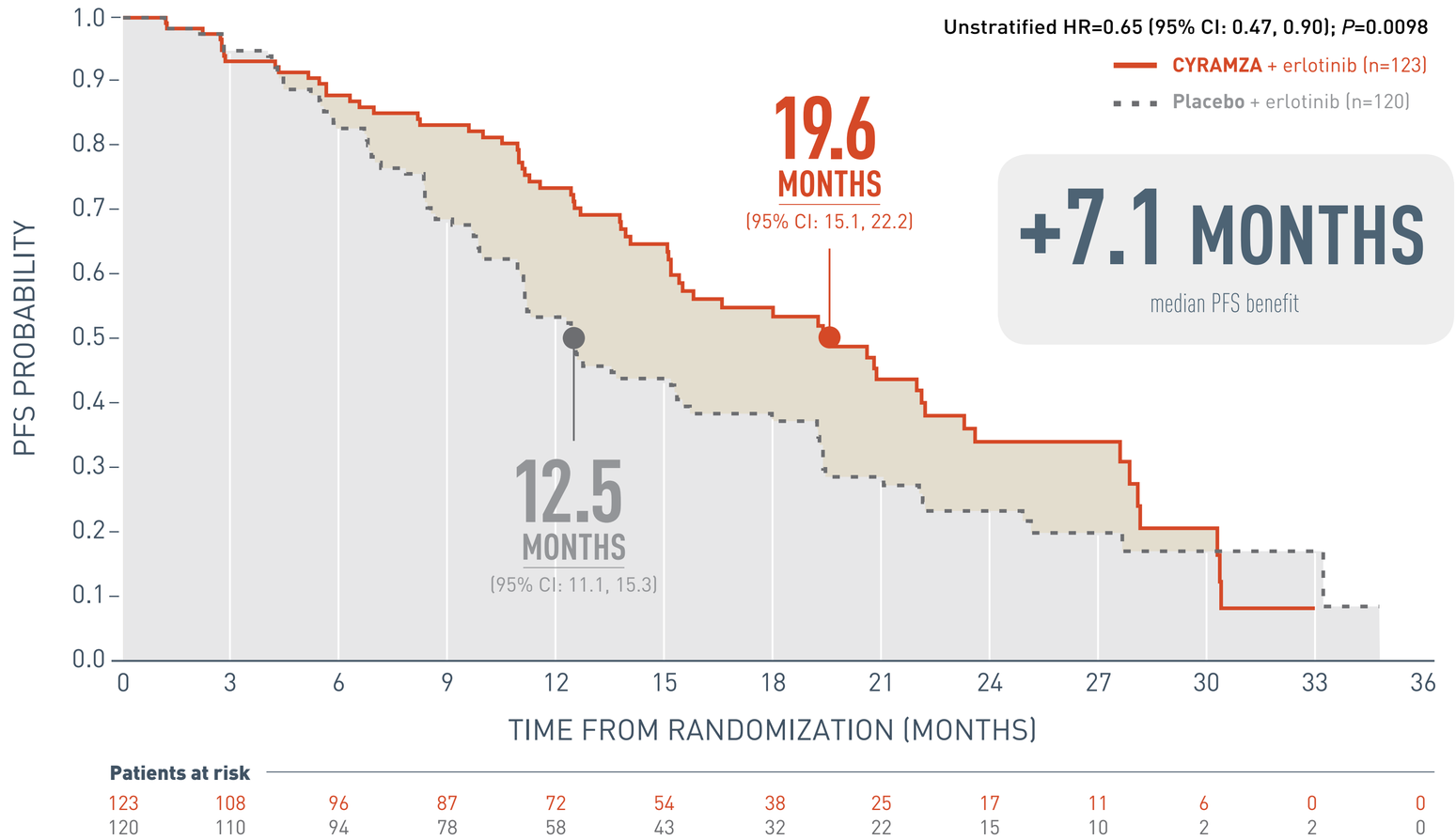
RELAY was not powered for subgroup analyses. Results of the subgroup analyses should be interpreted with caution.

Consistent PFS improvements across common EGFR mutation types[12]

CYRAMZA + erlotinib offered more than 19 months of median PFS to patients in RELAY with exon 19 deletion

RELAY trial—PFS by EGFR mutation type: exon 19 (prespecified subgroup analysis)



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RELAY was not powered for subgroup analyses. Results of the subgroup analyses should be interpreted with caution.

CYRAMZA + erlotinib demonstrated a consistent PFS benefit across all clinically relevant subpopulations[12,14]

Median PFS improvement in the CYRAMZA + erlotinib arm was consistent with the overall study population across race—19.4 months in Asian patients and 21.4 months in Caucasian patients[14]

PFS analysis by subgroup, ITT population[12,14]

		CYRAMZA + erlotinib	Placebo + erlotinib	
				Favors CYRAMZA + erlotinib / Favors placebo + erlotinib (0.2, 1.0, 1.6)
Category	**Subgroup**	**Patients**	**Patients**	**HR (95% CI)**
Overall		224	225	0.64 (0.51, 0.81)
Gender	Male	83	83	0.51 (0.34, 0.75)
	Female	141	142	0.73 (0.54, 0.99)
Age	<65	102	114	0.53 (0.38, 0.75)
	≥65	122	111	0.77 (0.55, 1.09)
Geographical region*	East Asia	166	170	0.64 (0.49, 0.83)
	Other	58	55	0.61 (0.36, 1.01)
Race	Asian	172	174	0.64 (0.49, 0.83)
	Caucasian	52	48	0.62 (0.36, 1.01)
ECOG PS at baseline	0	116	119	0.58 (0.41, 0.83)
	1	108	106	0.67 (0.49, 0.93)
Smoking history	Ever	64	73	0.58 (0.37, 0.90)
	Never	134	139	0.69 (0.51, 0.95)
	Unknown	26	13	0.24 (0.10, 0.57)
Disease stage at diagnosis	Stage IV	195	189	0.62 (0.48, 0.80)
	Other	29	34	0.74 (0.35, 1.54)
Liver metastases at baseline	Yes	21	24	0.48 (0.23, 1.02)
	No	203	201	0.65 (0.51, 0.84)
EGFR mutation type	**Exon 21 mutation**	99	105	0.62 (0.44, 0.87)
	Exon 19 deletion	123	120	0.65 (0.47, 0.90)
EGFR testing method	*therascreen®/cobas®*	96	101	0.40 (0.27, 0.58)
	Other	128	124	0.87 (0.64, 1.19)

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*East Asia includes Hong Kong, Japan, South Korea, and Taiwan, and Other includes Canada, France, Germany, Italy, Romania, Spain, Turkey, United Kingdom, and United States.[12]

Supportive outcome measures[12]

DoR: Median—Months

HR=0.62 (95% CI: 0.48, 0.81); *P*=0.0003

18.0 MONTHS (13.9, 19.8)

CYRAMZA + erlotinib (n=171)

VS

11.1 MONTHS (9.7, 12.3)

Placebo + erlotinib (n=168)

- DoR was defined as time from first documented response to the date of objective progression or the date of death, whichever is earlier
- The percentage of events at the time of analysis was 59% (101 patients) and 76% (128 patients) in the CYRAMZA + erlotinib and placebo + erlotinib treatment arms, respectively

ORR: Percentage of Patients (95% CI)

76% (71, 82)

CYRAMZA + erlotinib (n=224)

VS

75% (69, 80)

Placebo + erlotinib (n=225)

- ORR was defined as CR + PR. ORR does not include SD
- Disease progression and tumor response were assessed by investigators in accordance with RECIST 1.1
- ORR was not statistically significantly different between treatment arms

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The DCR was 95% and 96% in the CYRAMZA + erlotinib and placebo + erlotinib arms, respectively

- DCR was defined as CR + PR + SD

CR=complete response; PR=partial response; RECIST=Response Evaluation Criteria in Solid Tumors; SD=stable disease.