



Efficacy and Safety of Adjuvant Selpercatinib in Patients with *RET*+ NSCLC: Results from LIBRETTO-432

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Study was sponsored by Eli Lilly and Company

OBJECTIVE

To evaluate the efficacy and safety of adjuvant selpercatinib versus placebo in Chinese patients with *RET*+ Stage IB–IIIA NSCLC in the LIBRETTO-432 study.

CONCLUSIONS

- ❖ The efficacy of selpercatinib in the Chinese *RET*+ NSCLC subpopulation from the LIBRETTO-432 trial were generally consistent with those in the global Primary Analysis Population (PAP) and Intent-to-Treat (ITT) populations.
- ❖ The safety profile of selpercatinib was consistent with the global study population.

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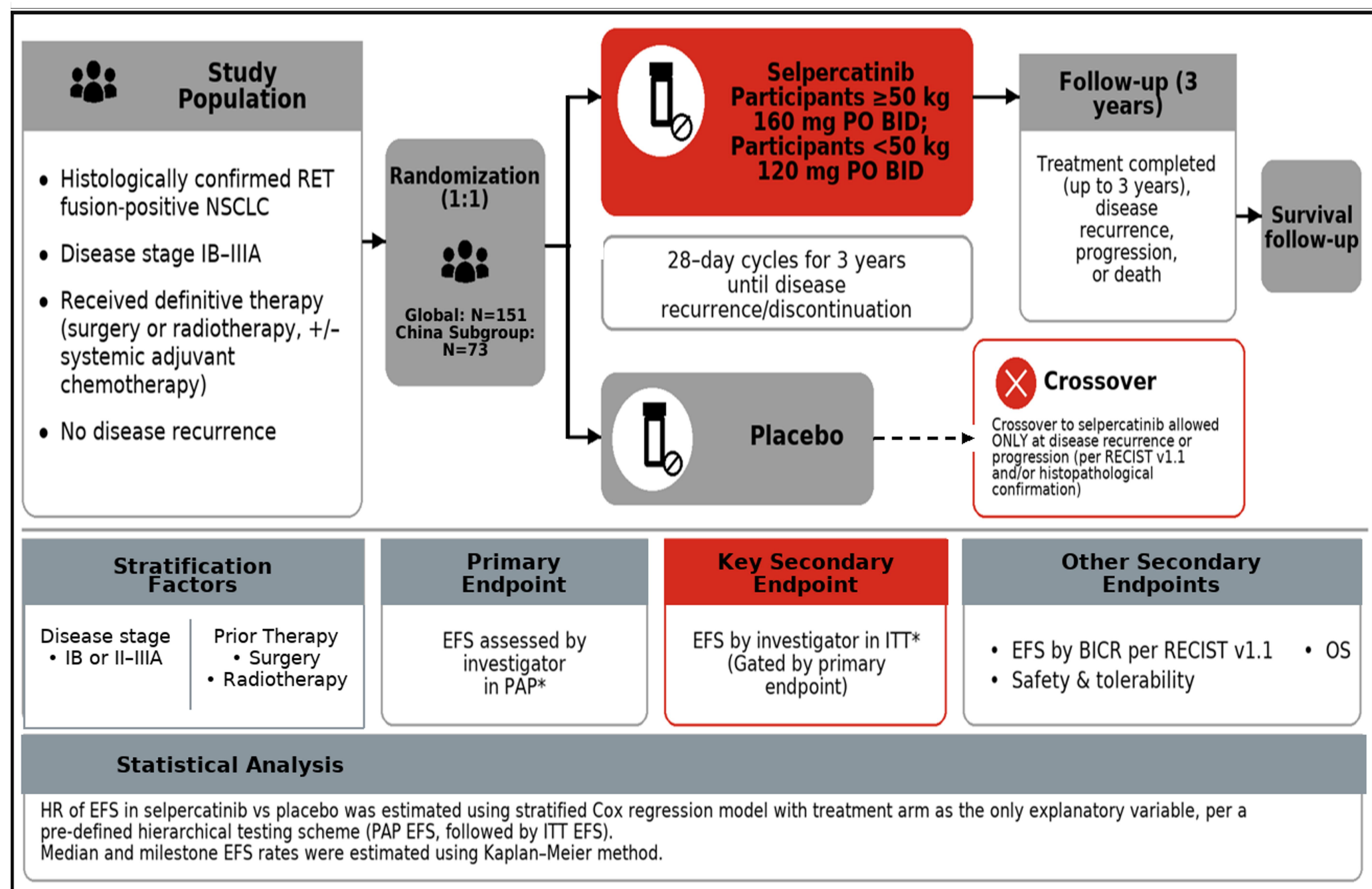
BACKGROUND

- Adjuvant targeted therapy in oncogene-driven early-stage metastatic non-small-cell lung cancer (NSCLC) has yielded substantial improvements in disease-free survival.^{1,2}
- REarranged during Transfection (*RET*) is a key oncogenic driver in NSCLC and a promising target for adjuvant targeted therapy.²
- Selpercatinib, a highly selective and potent *RET* inhibitor, recently demonstrated longer progression-free survival than platinum-based chemotherapy in patients with advanced *RET* fusion positive NSCLC.³

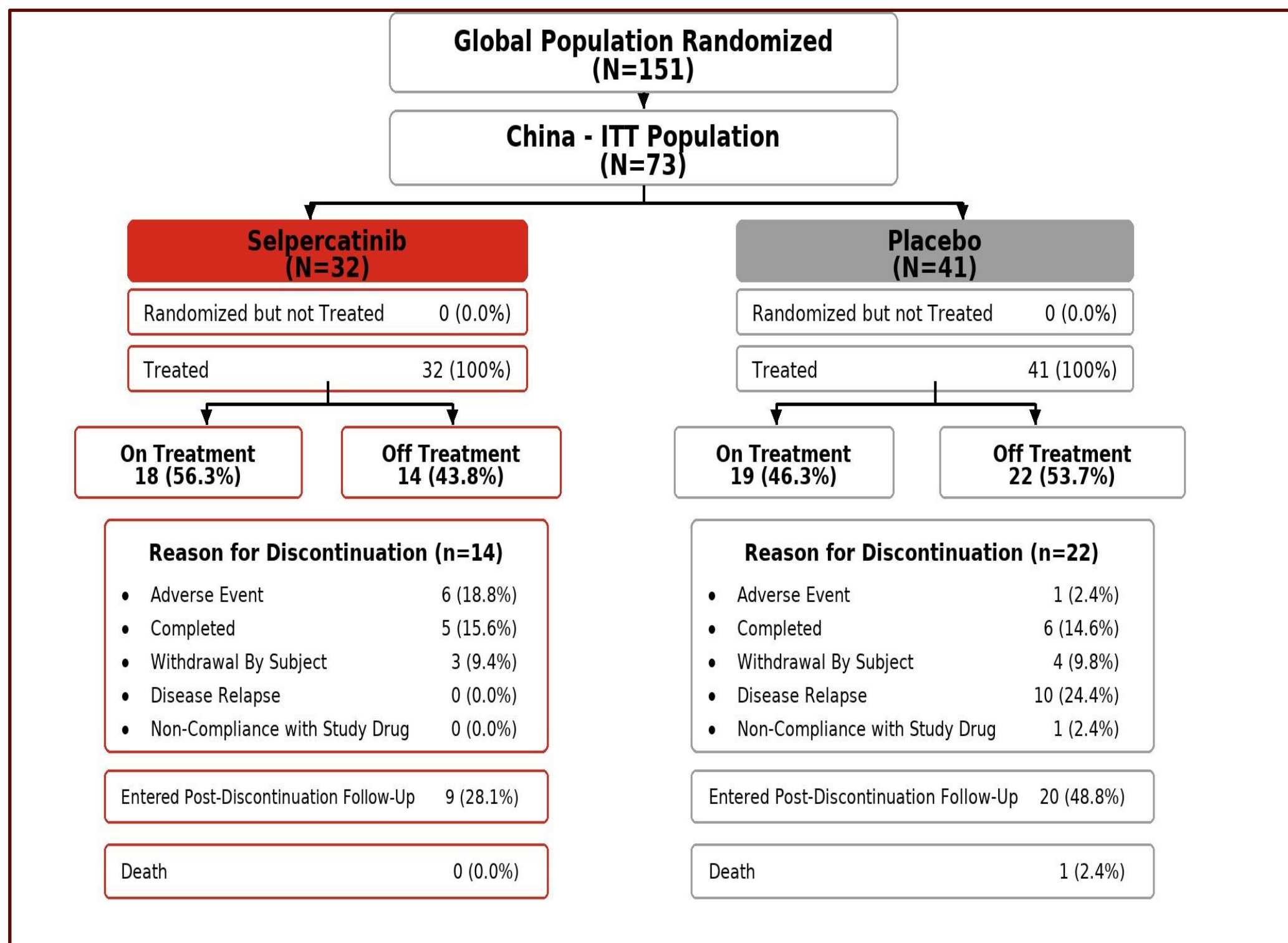
LIBRETTO-432 trial reports that adjuvant selpercatinib significantly improved event-free survival (EFS) versus placebo in patients with Stage IB–IIIA *RET*+ NSCLC.

STUDY DESIGN OR METHODS

LIBRETTO-432 Study Design



Patient Disposition - China Subgroup



*PAP; Stage IB–IIIA *RET*+ NSCLC; #ITT; Stage IB–IIIA *RET*+ NSCLC

REFERENCES

- Wu YL, et al. *N Engl J Med.* 2020;383(18):1711–23.
- Wu YL, et al. *N Engl J Med.* 2024;390(14):1265–76.
- Goldman JW, et al. *J Clin Oncol.* 2024;42(16_suppl):TPS8115.
- Zhou C, et al. *N Engl J Med.* 2023;389(20):1839–50.

ACKNOWLEDGMENTS

We would like to thank the clinical trial participants and their caregivers, without whom this work would not be possible. We would like to thank the trial investigators and study staff. Medical writing support was provided by Dr. Swati George from Syneos Health and funded by Eli Lilly and Company.

RESULTS

Table 1: Baseline Characteristics of Chinese ITT population

		Selpercatinib N=32	Placebo N=41
Age, years, Mean (SD)		56.4 (10.8)	55.9 (12.7)
Age categories, n (%)	<65 years	24 (75.0)	28 (68.3)
	≥65 years	8 (25.0)	13 (31.7)
Sex, n (%)	Female	17 (53.1)	22 (53.7)
	Male	15 (46.9)	19 (46.3)
Duration of disease (months) ^a , Mean (SD)		3.9 (1.5)	4.1 (1.6)
Disease stage, n (%)	IB	13 (40.6)	15 (36.6)
	II	8 (25.0)	11 (26.8)
	IIIA	11 (34.4)	15 (36.6)
Baseline ECOG, n (%)	0	16 (50.0)	27 (65.9)
	1	16 (50.0)	14 (34.1)
<i>RET</i> fusion partner, n (%)	CCDC6	7 (21.9)	7 (17.1)
	KIF5B	23 (71.9)	28 (68.3)
	Other	2 (6.3)	6 (14.6)
PD-L1, n (%)	Positive	4 (12.5)	14 (34.1)
Smoking Status n (%)	Former/current	6 (18.8)	13 (31.7)
	Never	26 (81.3)	28 (68.3)
Prior anti-cancer therapy, n (%)	Surgery	32 (100.0)	41 (100.0)
	Radiotherapy	0 (0.0)	1 (2.4)
	Systemic/Locoregional therapy	22 (68.8)	29 (70.7)

Baseline characteristics were generally balanced between the 2 treatment arms.

Table 2: EFS by Investigator in Global and Chinese PAP Populations

	Global		Chinese	
	Selpercatinib N=54	Placebo N=55	Selpercatinib N=19	Placebo N=26
Events, n (%)	4 (7.4)	19 (34.5)	0	9 (34.6)
Median EFS, months (95% CI)	- (33.54, -)	31.84 (18.37, -)	- (-, -)	31.84 (14.65, -)
HR [*] (95% CI)	0.17 (0.06, 0.51)		Not Calculable	
1-year EFS rate%, (95% CI)	97.8, (85.6, 99.7)	75.9, (61.3, 85.6)	100.0, (100.0, 100.0)	78.6, (55.6, 90.6)
2-year EFS rate%, (95% CI)	91.5, (75.4, 97.2)	61.1, (44.2, 74.3)	100.0, (100.0, 100.0)	59.5, (33.5, 78.1)

Table 3: EFS by Investigator in Global and Chinese ITT Populations

	Global		Chinese	
	Selpercatinib N=75	Placebo N=76	Selpercatinib N=32	Placebo N=41
Events, n (%)	4 (5.3)	20 (26.3)	0	10 (24.4)
Median EFS, months (95% CI)	- (-, -)	- (31.84, -)	- (-, -)	- (31.84, -)
HR [*] (95% CI)	0.16 (0.06, 0.48)		Not Calculable	
1-year EFS rate%, (95% CI)	98.4, (89.4, 99.8)	80.8, (69.2, 88.4)	100.0, (100.0, 100.0)	83.3, (66.3, 92.2)
2-year EFS rate%, (95% CI)	93.8, (81.5, 98.0)	69.6, (55.5, 80.1)	100.0, (100.0, 100.0)	70.8, (50.3, 84.1)

^aDuration of disease is the time from date of initial diagnosis to the date of randomization.*HR cannot be reliably estimated due to zero events in selpercatinib arm. Median follow-up for EFS in the ITT population: **Global:** Selpercatinib arm 23.9 months, Placebo arm 27.1 months; **China:** Selpercatinib arm 23.5 months, Placebo arm 27.2 months.

Abbreviations: ALT, Alanine transaminase; AST, Aspartate Transaminase; BICR, Blinded Independent Central Review; BID, Bis In Die; CCDC6, coiled-coil domain-containing protein 6; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; EFS, event-free survival; ITT, intent-to-treat; HR, hazard ratio; KIF5B, Kinesin family member 5B; N, total number of population; n, number of subjects in the specified category; NSCLC, non-small-cell lung cancer; OS, overall survival; PAP, primary analysis population; PD-L1, programmed death-ligand 1; PO, per oral; RECIST, *RET*, REarranged during Transfection; SD, standard deviation; TEAE, treatment-emergent adverse event.

Figure 1: EFS by Investigator Assessment in Global and Chinese PAP Populations

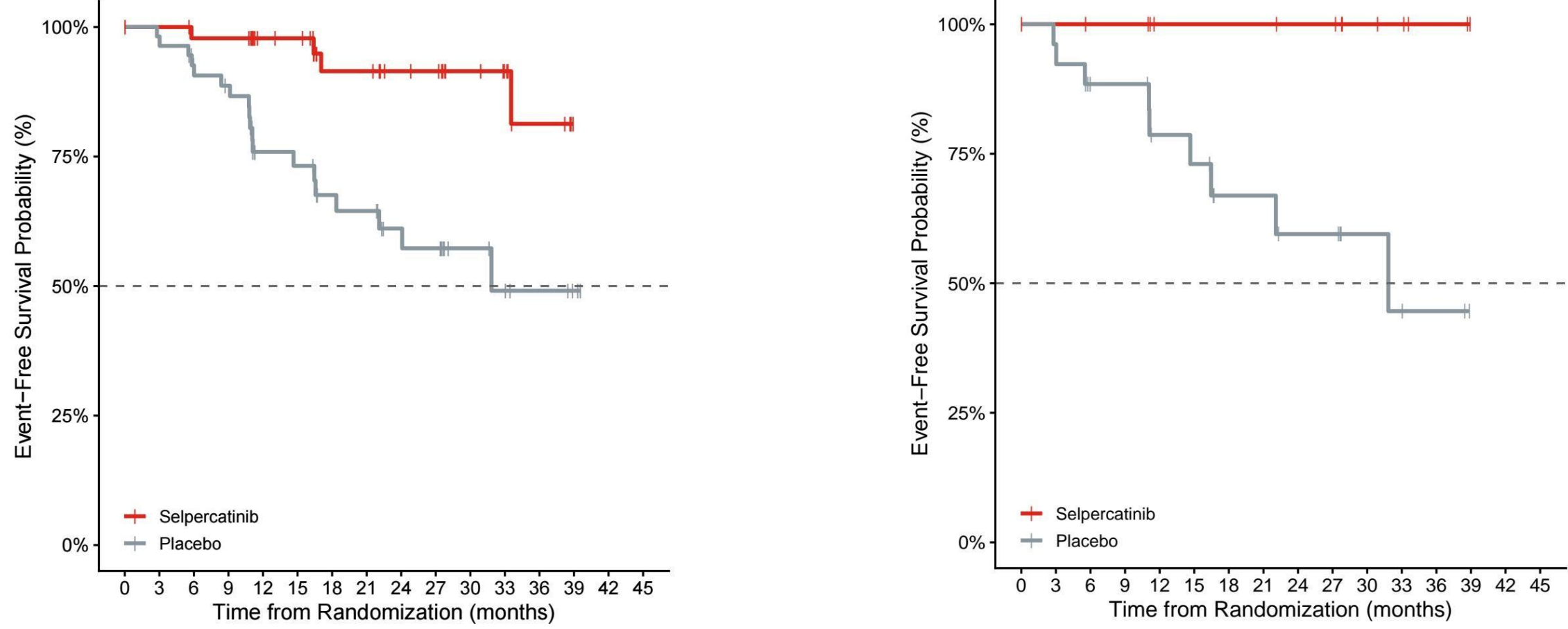
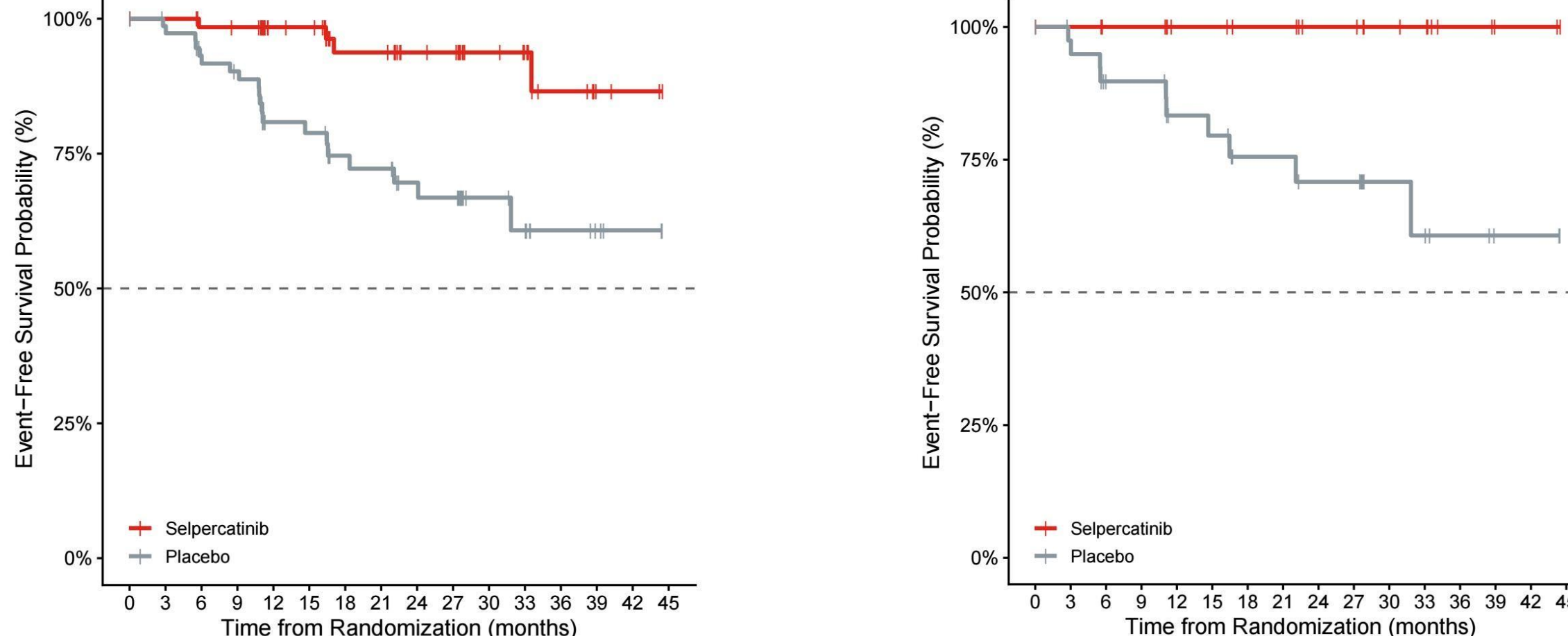


Figure 2: EFS by Investigator Assessment in Global and Chinese ITT Populations



- Improved investigator-assessed EFS with selpercatinib (100%, 2-year EFS rate) versus placebo (60% in the PAP and 71% in the ITT population) were observed in the Chinese subpopulation consistent with the Blinded Independent Central Review (BICR) findings and the global efficacy results.

Table 4: TEAEs (Any Grade) Reported in ≥20% of Chinese Patients in Either Arm

	Selpercatinib N=32	Placebo N=41
Subjects with ≥1 TEAE, n(%)	32 (100)	39 (95.1)
ALT increased	25 (78.1)	9 (22.0)
AST increased	24 (75.0)	8 (19.5)
Hyperuricemia	14 (43.8)	6 (14.6)
Blood bilirubin increased	12 (37.5)	10 (24.4)
Dry mouth	12 (37.5)	7 (17.1)
Gamma-glutamyltransferase increased	11 (34.4)	3 (7.3)
Diarrhoea	10 (31.3)	7 (17.1)
Upper respiratory tract infection	8 (25.0)	12 (29.3)
Hypertension	8 (25.0)	6 (14.6)
Hypoproteinaemia	8 (25.0)	5 (12.2)
Blood creatinine increased	8 (25.0)	3 (7.3)
Weight decreased	8 (25.0)	1 (2.4)
Cough	7 (21.9)	12 (29.3)
Hypoalbuminaemia	7 (21.9)	4 (9.8)
Weight increased	4 (12.5)	9 (22.0)

- Increase in ALT and AST were the most common TEAEs.
- The safety profiles observed in this subpopulation were comparable to those reported in metastatic *RET*+ NSCLC.
- One death occurred in the placebo arm, attributed to study disease and no deaths occurred in the selpercatinib arm.

Efficacy and Safety of Adjuvant Selpercatinib in Patients with *RET*+ NSCLC: China Subpopulation Results from LIBRETTO-432

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OBJECTIVES

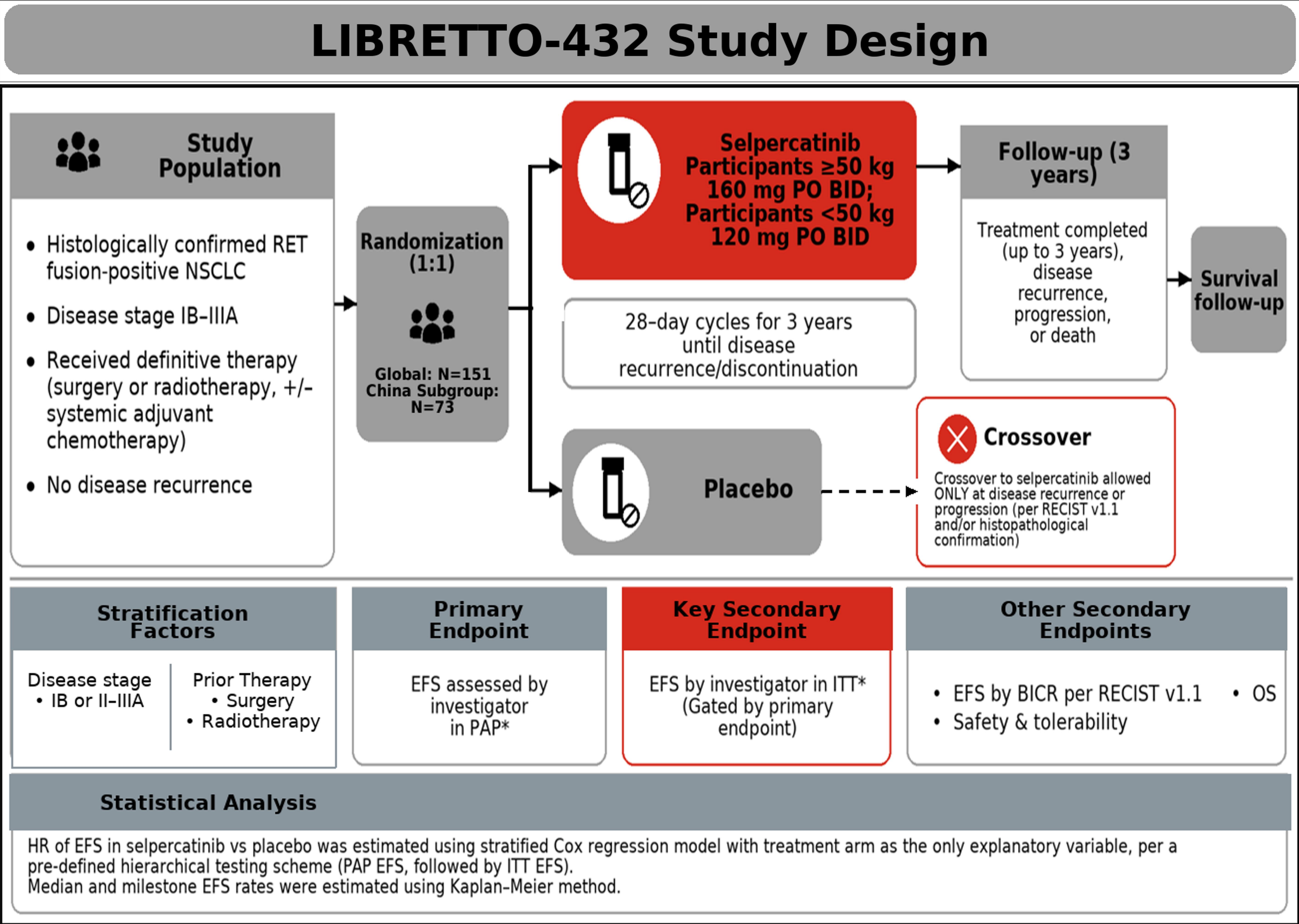
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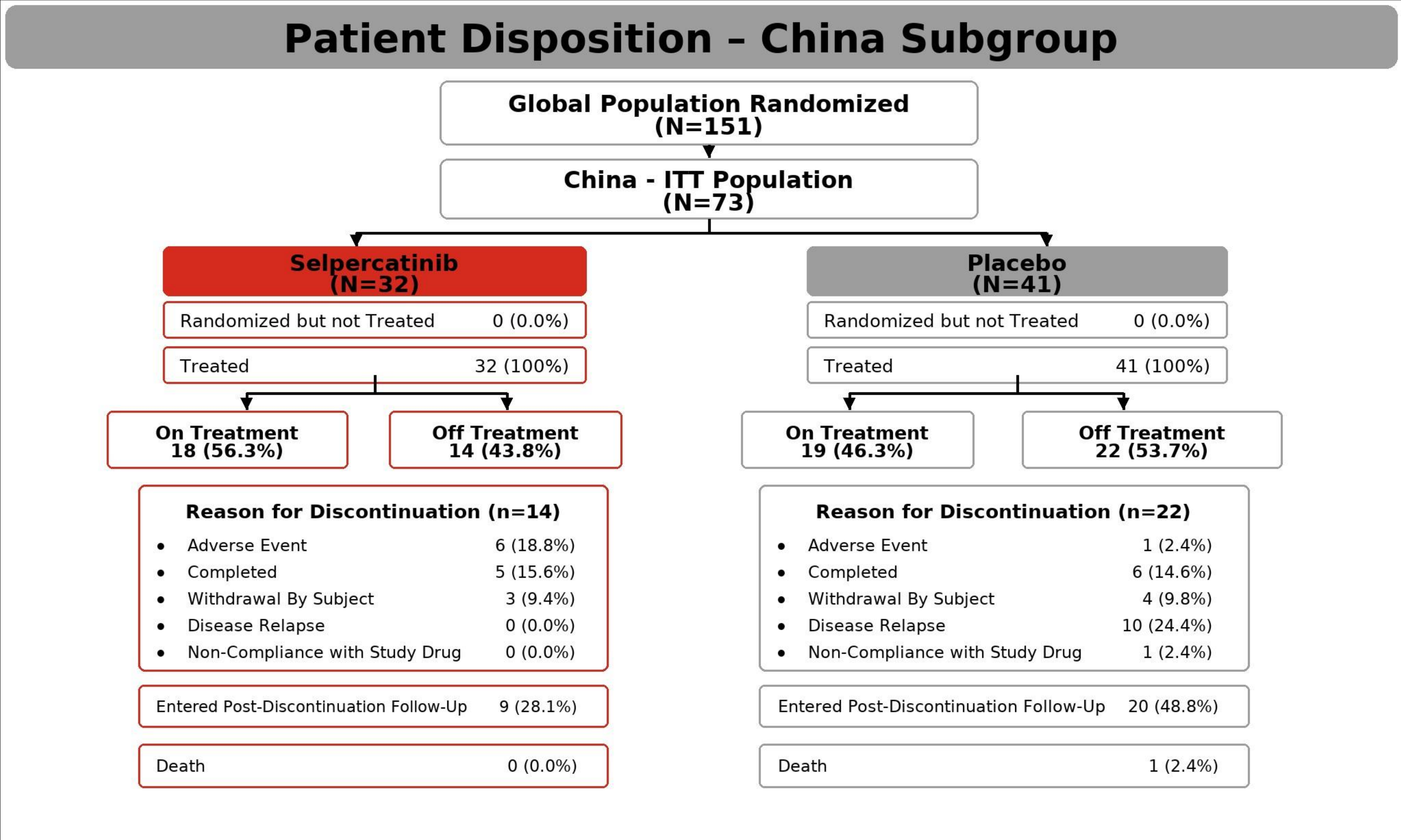
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RESULTS

- Improved investigator-assessed EFS was observed with selpercatinib (100%, 2-year EFS rate) vs versus placebo (60% in the primary analysis population [PAP] and 71% in the intent-to-treat [ITT] population) in the Chinese subpopulation, consistent with the Blinded Independent Central Review (BICR) findings and the global efficacy results.

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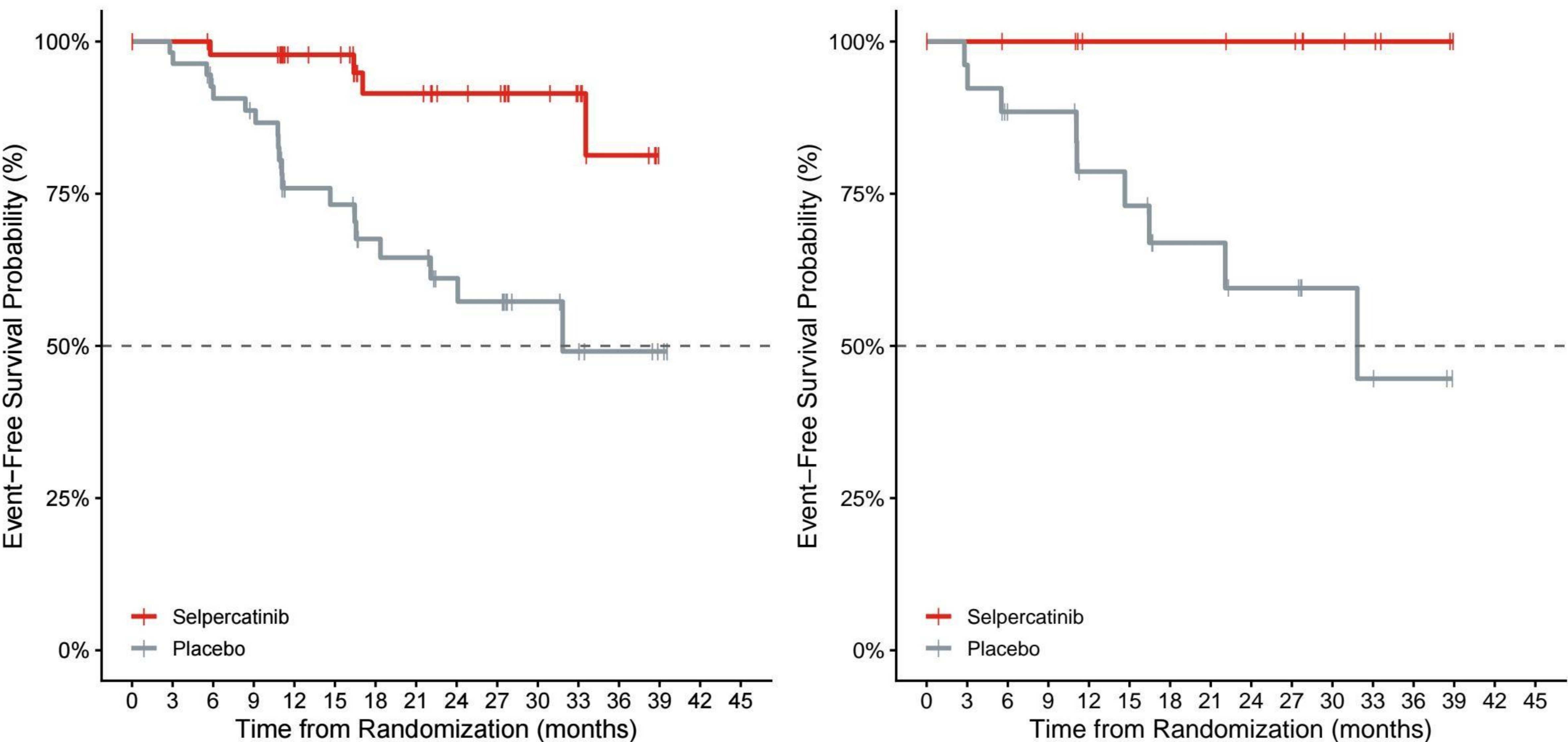
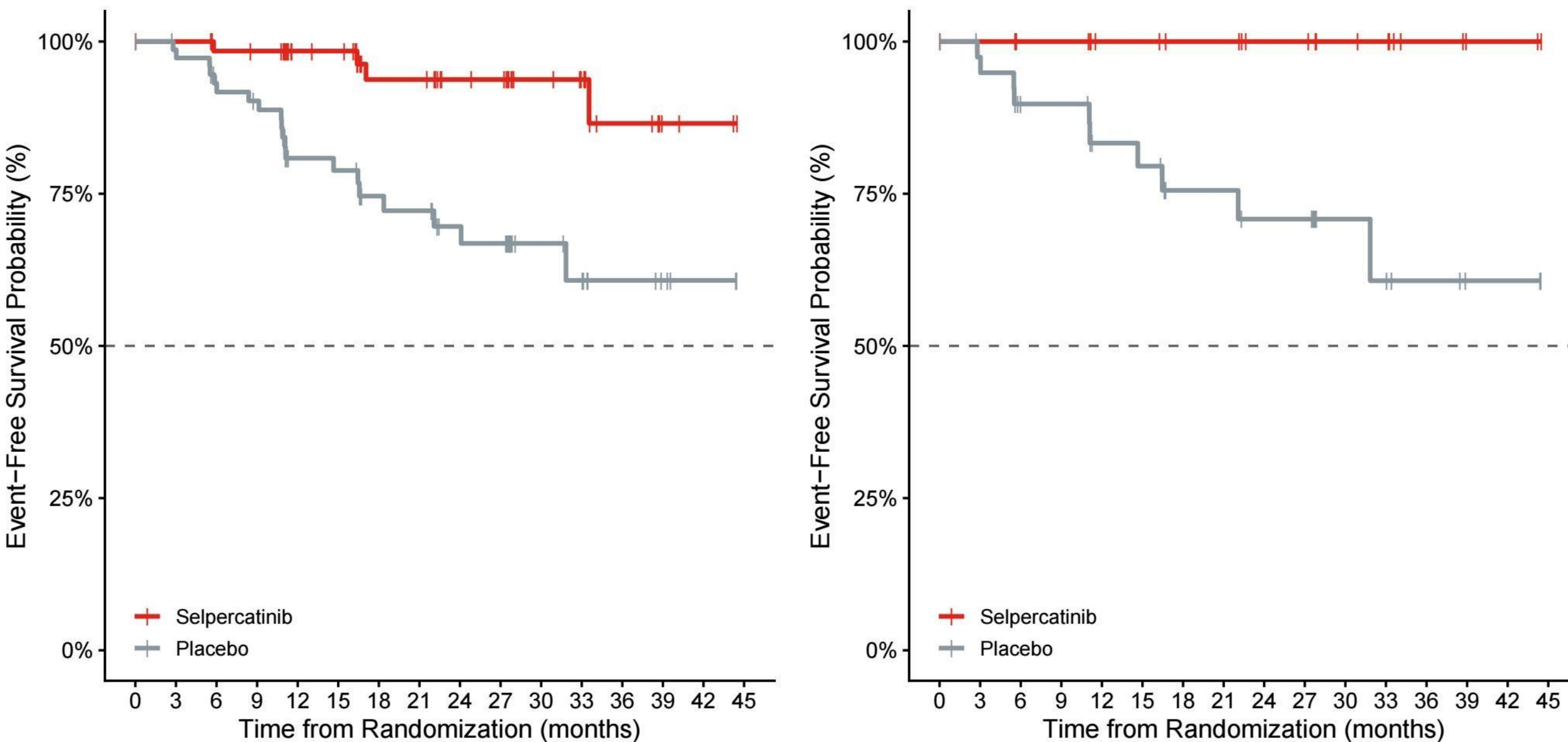


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CONCLUSIONS

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REFERENCES

1. Wu YL, et al. *N Engl J Med*. 2020;383(18):1711–23.
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PRESENTING AUTHOR DISCLOSURE

Xue-Ning Yang served as a Clinical Trial Investigator and received research grants from Eli Lilly and Company.