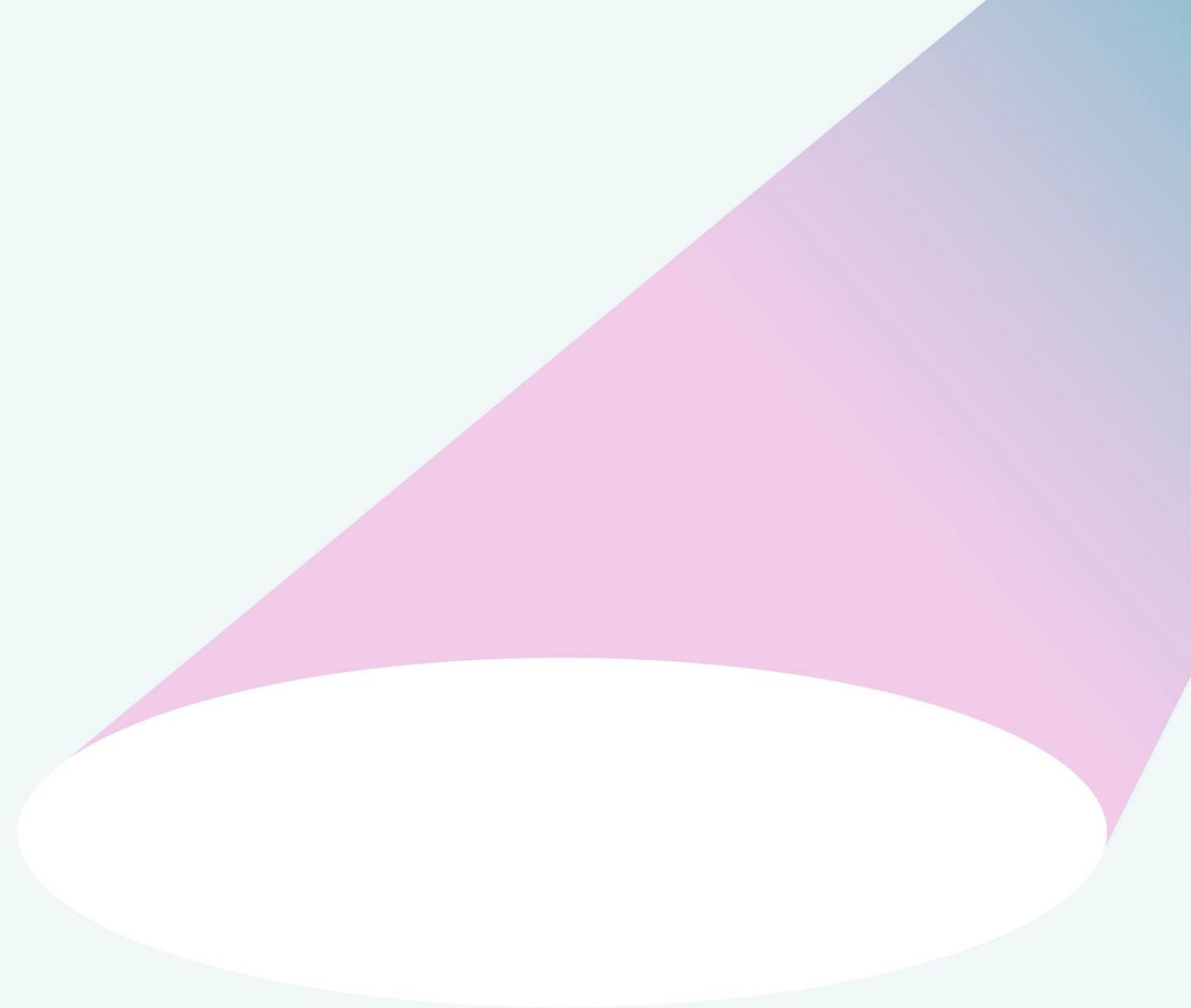


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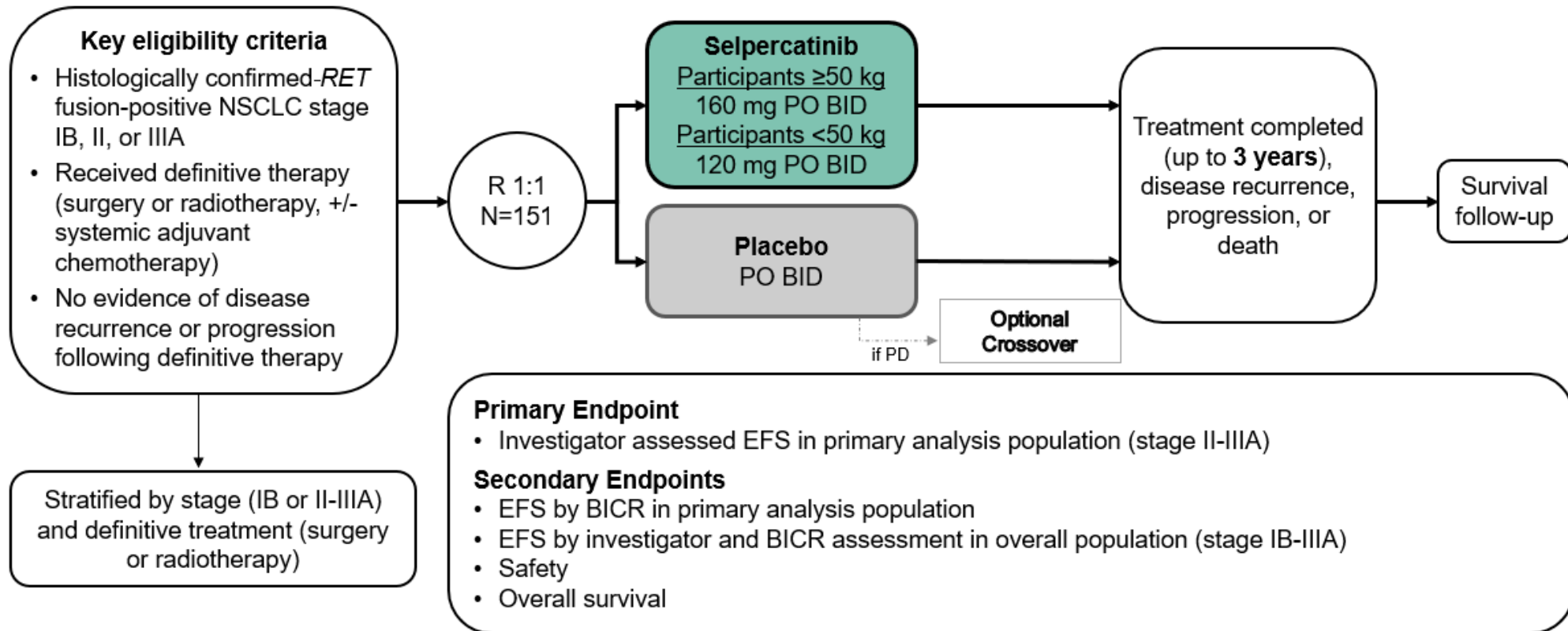
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# Event-free survival with adjuvant selpercatinib in stage IB-IIIA *RET* fusion-positive NSCLC: Primary results of the phase 3 LIBRETTO-432 trial

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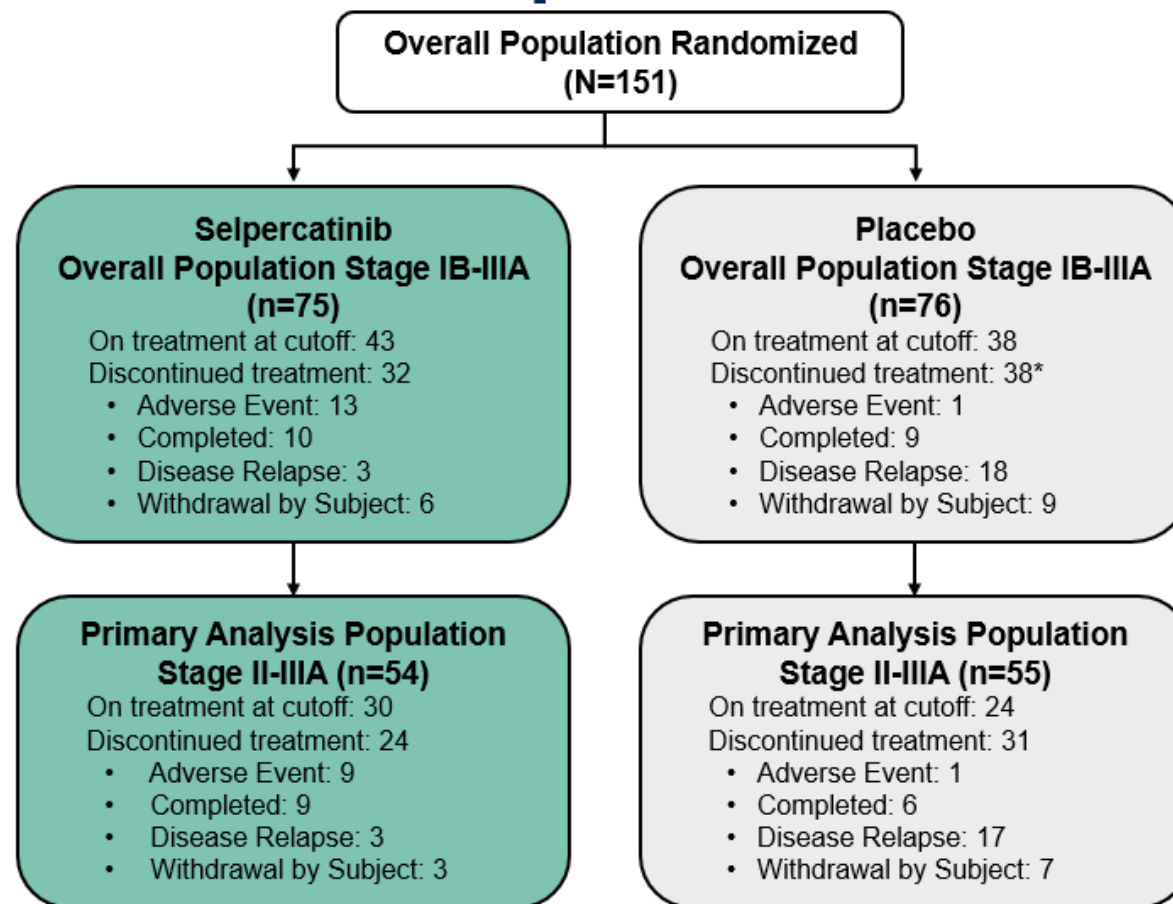
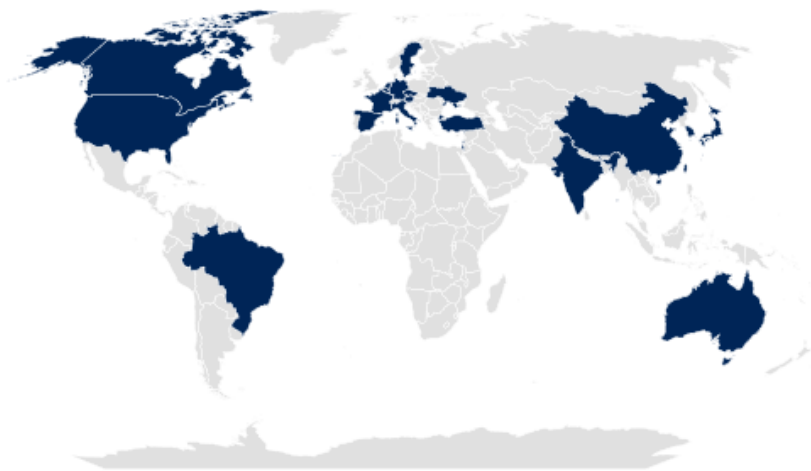
# LIBRETTO-432 Study Design

A global, multicenter, phase 3, double-blind, randomized, placebo-controlled study



## Enrollment and Patient Disposition

151 patients | 65 sites | 22 countries  
Enrollment: Jan 2022 – Mar 2025  
Database cut-off date: Jan 2026



3446 patients were assessed for eligibility (No RET fusions were most common exclusion, n=3149). Abbreviations: n, number of patients; RET = Rearranged during transfection. \*1 patient was non-compliant

## Baseline Characteristics – Primary Analysis Population

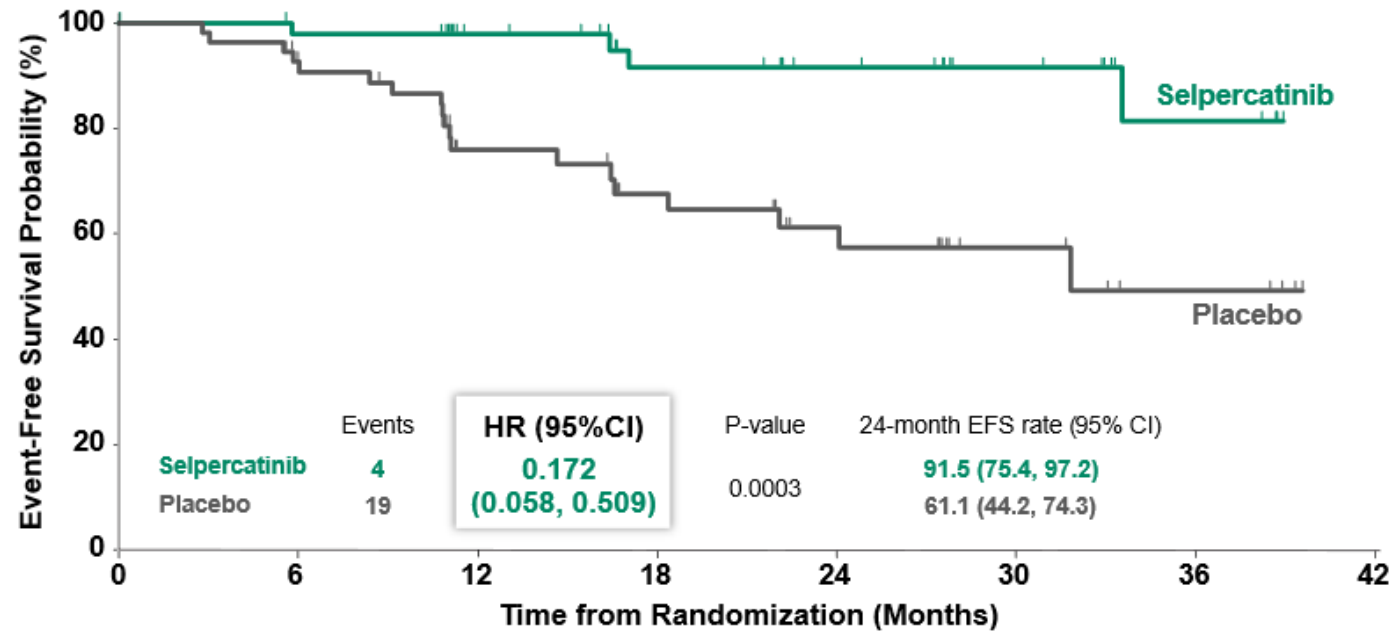
		Selpercatinib N=54	Placebo N=55
<b>Age, years</b>	Median (range)	59.5 (41.0-84.0)	61.0 (26.0-78.0)
<b>Sex, n (%)</b>	Female	34 (63.0)	30 (54.5)
	Male	20 (37.0)	25 (45.5)
<b>Race, n (%)<sup>a</sup></b>	Asian	33 (61.1)	32 (58.2)
	White	21 (38.9)	21 (38.2)
<b>Geographic Region, n (%)</b>	East Asia	31 (57.4)	31 (56.4)
	Europe/North America	18 (33.3)	21 (38.2)
	Other	5 (9.3)	3 (5.5)
<b>Smoking Status, n (%)</b>	Never	37 (68.5)	38 (69.1)
	Former / Current	17 (31.5)	17 (30.9)
<b>ECOG PS, n (%)<sup>b</sup></b>	0	30 (55.6)	36 (65.5)
	1	24 (44.4)	18 (32.7)
<b>RET fusion, n (%)</b>	KIF5B:: RET	33 (61.1)	34 (61.8)
	CCDC6:: RET	14 (25.9)	11 (20.0)
	Other	7 (13.0)	10 (18.2)
<b>PD-L1, n (%)<sup>c</sup></b>	Negative	11 (20.4)	16 (29.1)
	Positive	25 (46.3)	28 (50.9)
	Unknown	17 (31.5)	11 (20.0)
<b>Prior anti-cancer therapy, n (%)</b>	Surgery	54 (100.0)	54 (98.2)
	Radiotherapy	2 (3.7)	6 (10.9)
	Systemic therapy	50 (92.6)	50 (90.9)

The primary (N=109) and overall (N=151) treatment populations had similar and balanced baseline characteristics

<sup>a</sup> 2 patients in placebo arm reported Black or African American for race; <sup>b</sup> 1 patient in placebo arm had missing ECOG score; <sup>c</sup> 1 patient in selpercatinib arm had 'other' PDL1

# Event-Free Survival by Investigator Assessment

## Primary Analysis Population, Stage II-IIIa *RET* fusion-positive NSCLC

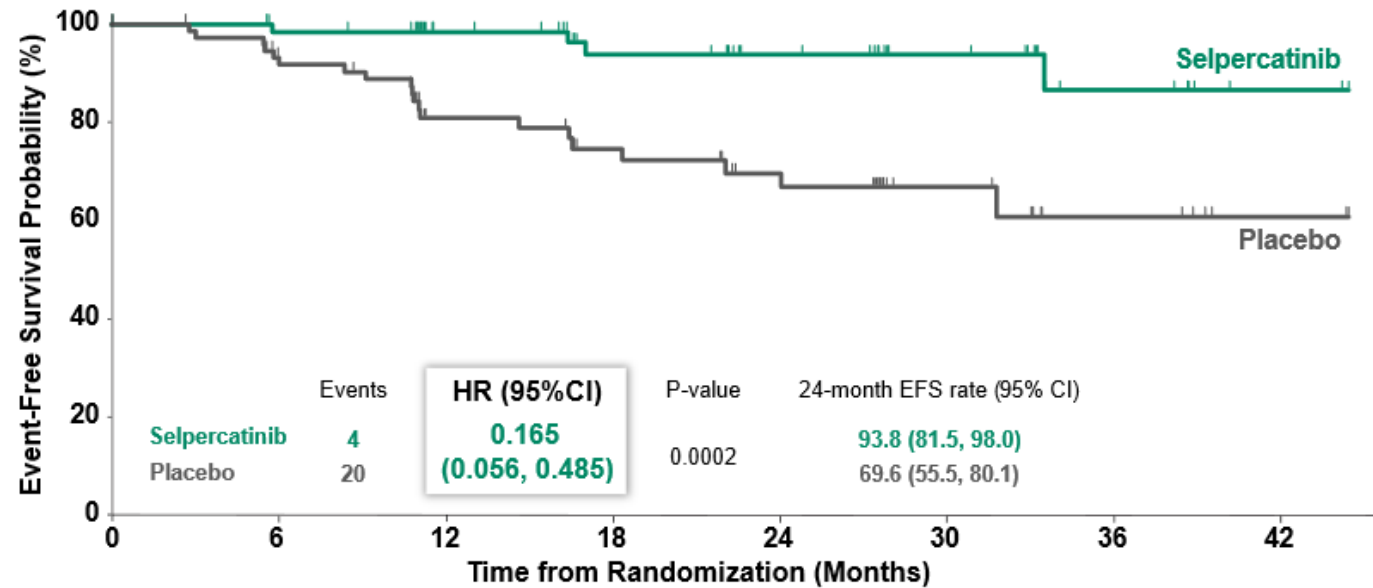


Number at risk									
	0	6	12	18	24	30	36	42	
Selpercatinib	54	45	37	27	22	15	7	0	
Placebo	55	47	28	22	16	8	4	0	

The primary endpoint was met, as selpercatinib demonstrated a statistically significant improvement in EFS

# Event-Free Survival by Investigator Assessment

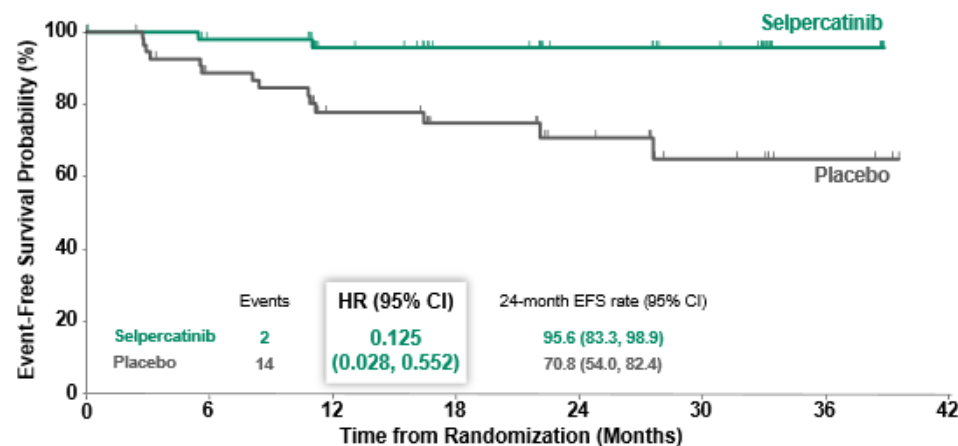
## Overall Population, Stage IB-IIIa *RET* fusion-positive NSCLC



Number at risk		0	6	12	18	24	30	36	42
Selpercatinib	75	63	51	37	30	20	10	2	
Placebo	76	64	40	31	25	12	6	2	

## Event-Free Survival by Blinded Independent Central Review

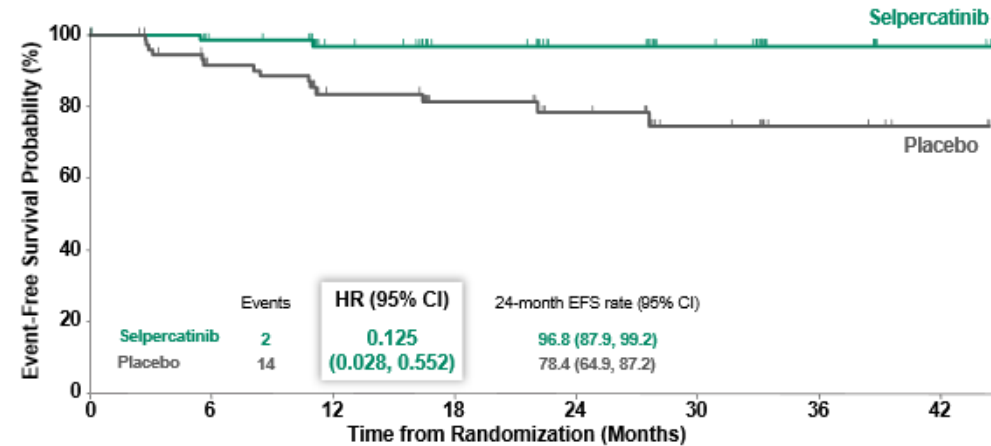
Primary analysis population



Number at risk

	0	6	12	18	24	30	36	42
Selpercatinib	54	44	35	27	21	16	5	0
Placebo	55	42	27	21	16	7	3	0

Overall population



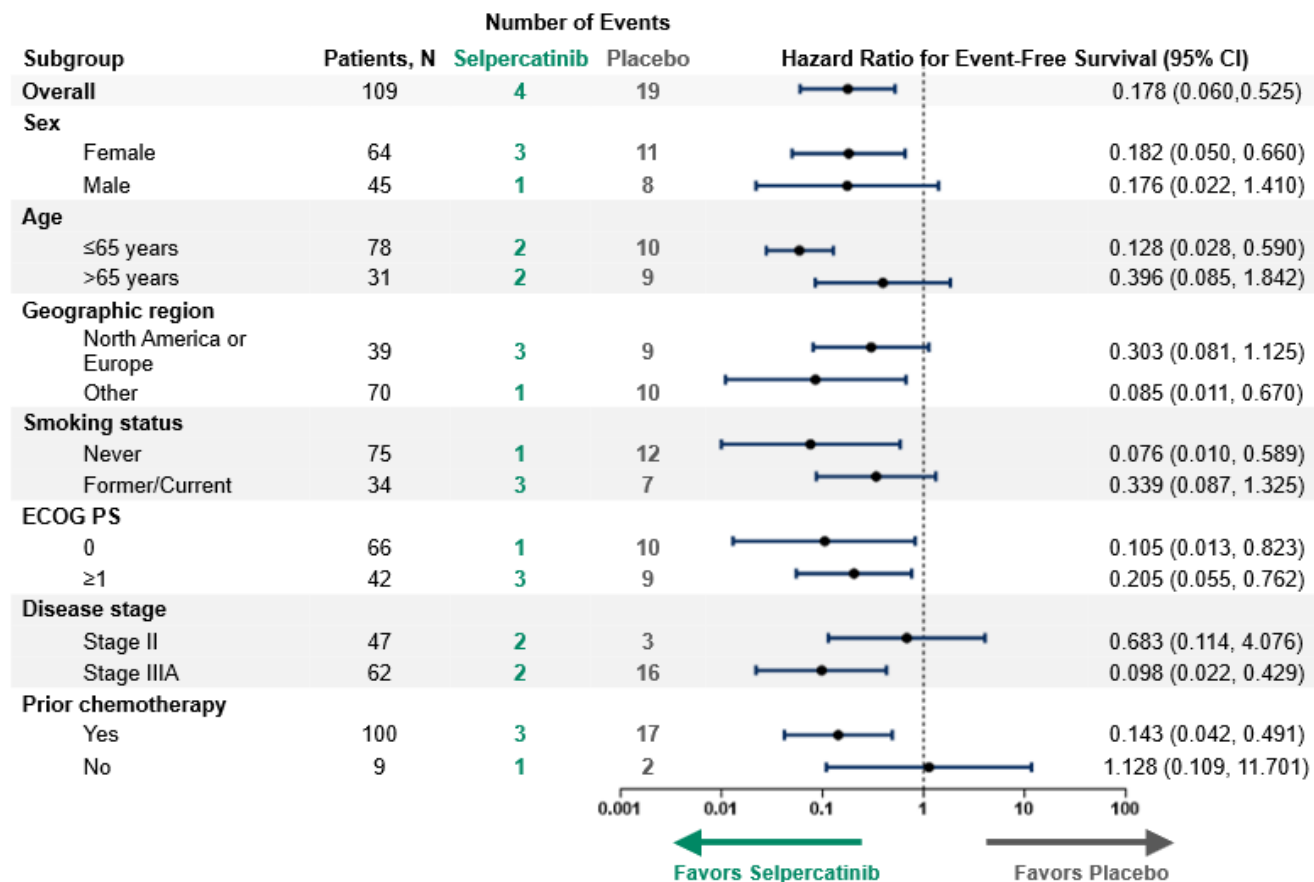
Number at risk

	0	6	12	18	24	30	36	42
Selpercatinib	75	62	48	36	28	19	7	2
Placebo	76	59	39	30	25	11	5	2

EFS by BICR consistent with the investigator assessment in both populations

# Event-Free Survival in Key Subgroups

## Primary Analysis Population



**Selpercatinib demonstrated consistent benefit across subgroups**

HR is unstratified

## Overall Survival and Patient Disposition

	Selpercatinib N=54	Placebo N=55
Median follow-up, months (IQR)	25 (13.9, 33.2)	27 (15.8, 34.1)
On treatment, n (%)	30 (55.6)	24 (43.6)
Off treatment, n (%)	24 (44.4)	31 (56.4)
Death, n	0	3

16 stage II-IIIa patients crossed over to selpercatinib following disease recurrence

- 12 of these patients remain on selpercatinib at data cutoff
- 3 deaths occurred in patients who crossed over\*

**No deaths occurred in the selpercatinib arm**

## Safety Overview – Overall Population

Events, n (%)	Selpercatinib N=75	Placebo N=76
Any TEAE	75 (100)	74 (97.4)
Grade ≥3 TEAEs	50 (66.7)	18 (23.7)
Serious TEAEs ≥1	17 (22.7)	10 (13.2)
Discontinued study treatment due to TEAEs*	13 (17.3)	1 (1.3)
Discontinued due to SAE	2 (2.7)	1 (1.3)
Dose modifications	66 (88.0)	35 (46.1)
Dose interruptions due to TEAEs	58 (77.3)	20 (26.3)
Dose reductions due to TEAEs	41 (54.7)	6 (7.9)
TEAEs leading to death, on study treatment	0	0

**Grade ≥3 TEAEs were manageable with dose modifications**

**Discontinuations were mostly due to low grade events in the selpercatinib arm**

\*Most common reasons for selpercatinib discontinuation were ALT increase n=4; AST increase n=2; interstitial lung disease n=2

## Safety – Overall Population

	Selpercatinib N=75		Placebo N=76	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
<b>Patients with ≥1 TEAE (≥ 20%), no. (%)</b>	<b>75 (100.0)</b>	<b>50 (66.7)</b>	<b>74 (97.4)</b>	<b>18 (23.7)</b>
ALT increase	47 (62.7)	13 (17.3)	14 (18.4)	1 (1.3)
AST increase	45 (60.0)	14 (18.7)	12 (15.8)	2 (2.6)
Diarrhea	29 (38.7)	3 (4.0)	13 (17.1)	0
Dry mouth	30 (40.0)	0	12 (15.8)	0
Cough	20 (26.7)	0	18 (23.7)	0
Bilirubin increase	20 (26.7)	1 (1.3)	11 (14.5)	0
Hypertension	23 (30.7)	8 (10.7)	8 (10.5)	2 (2.6)
Constipation	17 (22.7)	0	10 (13.2)	0
Hyperuricemia	15 (20.0)	0	8 (10.5)	0
<b>Other AEs of special Interest</b>				
Hypersensitivity	5 (6.7)	0	0	0
ECG QT prolongation	7 (9.3)	1 (1.3)	1 (1.3)	1 (1.3)

**AEs were generally consistent with the known safety profile of selpercatinib**

## Conclusions

- Selpercatinib demonstrated a statistically significant and clinically meaningful event-free survival improvement in patients with *RET* fusion-positive NSCLC versus placebo
  - **HR 0.17** ( $p < 0.001$ ) in the stage II-IIIa population
  - Consistent clinical benefit was observed across predefined subgroups and by blinded independent central review
- Selpercatinib AEs were generally consistent with known safety profile
  - Grade  $\geq 3$  TEAEs were managed with dose modifications
  - TEAEs leading to discontinuations were mostly due to low grade events
- Results reinforce the value of comprehensive biomarker testing for actionable oncogenic drivers at the time of diagnosis to inform optimal therapeutic decision-making

**Adjuvant selpercatinib should be considered as a new standard of care  
in early-stage *RET* fusion-positive NSCLC**