


Lung Cancer
UPDATES

ASCO HIGHLIGHTS

29 **MAYO** - 02 **JUNIO** 2026

Chicago, USA





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CNMP metastásico con Driver (no EGFR no ALK)

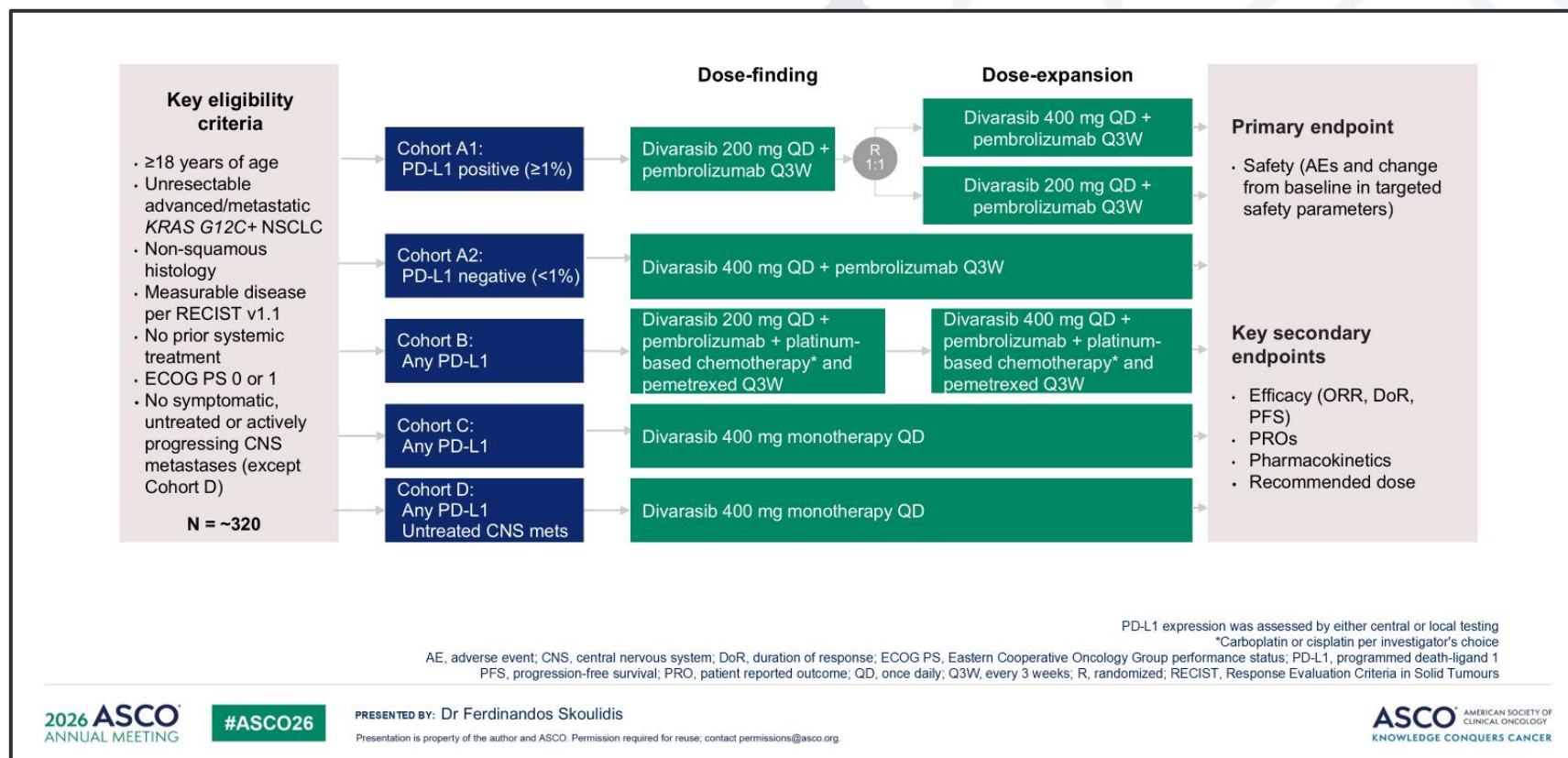
Dra. Eider Azkona Uribelarrea

KRAS

KRAS G12C

First-line divarasisib plus pembrolizumab in advanced or metastatic KRAS G12C+ non-small cell lung cancer: results from the Krascendo 170 study

Ferdinandos Skoulidis



KRAS G12C

First-line divarasil plus pembrolizumab in advanced or metastatic KRAS G12C+ non-small cell lung cancer: results from the Krascendo 170 study

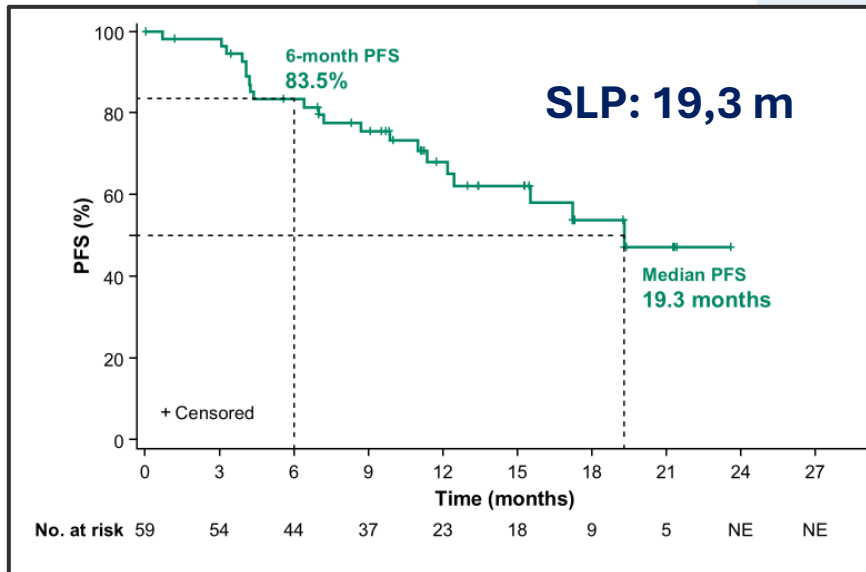
Ferdinandos Skoulidis

COHORTE A1 (PD-L1 +): Divarasil 200 mg +Pembrolizumab

- TR: 72,9%
- DoR: NR
- T a resp 43 días

COHORTE A2 (PD-L1 -): Divarasil 400 mg +Pembrolizumab

- TR: 69,6%
- T a resp: 40,5 m
- EAs \geq G3: 65,4%
 - ALT 20%, AST 18%diarrea 16%; N y V2%
- Disminución de dosis: 52,6%
- Interrupciones: 69,2%
- Stop: 12,8%
- Diarrea, transaminitis, aumento lipasa, N/V.



KRAS G12C

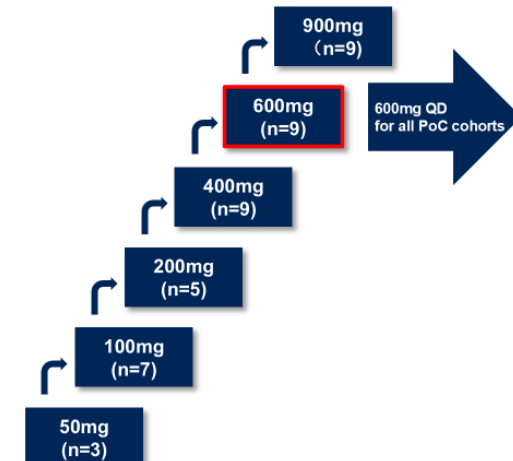
Elisrasib (D3S-001), a next-generation GDP-bound KRAS G12C inhibitor, as first-line therapy for KRAS G12C mutation-positive non-small cell lung cancer (NSCLC)

Shun Lu¹

Ph1 Dose Escalation

Advanced/metastatic solid tumors with KRAS G12Cm
Elisrasib administered orally QD, 21-days per cycle

- Backfill allowed in cohorts > 50mg QD
- KRAS G12Ci pre-treated allowed in cohorts 400-900mg QD



50mg (n=3) → 100mg (n=7) → 200mg (n=5) → 400mg (n=9) → 600mg (n=9) → 900mg (n=9)

600mg QD for all PoC cohorts

• Total 42 pts dosed (25 NSCLC, 13 CRC and 4 PDAC)
• No treatment-related DLT. MTD not reached.

Ph2 Proof-of-Concept

1L NSCLC

Cohort: Monotherapy:

- Elisrasib (N~40)
- PD-L1 <1% (n~20)
- PD-L1 ≥1% (n~20)

Cohort: Combination therapy:

Elisrasib + pembrolizumab* (N~60, including safety run-in 6 pts)

- PD-L1 <1% (n~20)
- PD-L1 1-49% (n~20)
- PD-L1 ≥50% (n~20)

Elisrasib + platinum-doublet chemo(N~20)

- PD-L1 <1% (n~20)

* Pembrolizumab 200mg Q3W
FPI: 2024-08-08; DCO: 2026-01-06

Later-line NSCLC/CRC/PDAC cohorts
Elisrasib monotherapy or combination

Key Eligibility

- Metastatic or locally advanced NSCLC
- Not received prior systemic therapy for advanced/metastatic disease
- Documented KRAS p.G12C mutation from local PCR/NGS testing
- No known EGFR mutations, ALK/ROS1/RET rearrangements, NTRK1/2/3 gene fusions, BRAF V600E mutations, or MET exon 14 skipping mutations
- PD-L1 expression by Dako 22C3
- Untreated asymptomatic brain metastases are allowed

Key Endpoints

- Safety
- Efficacy
- Pharmacokinetics
- Biomarker

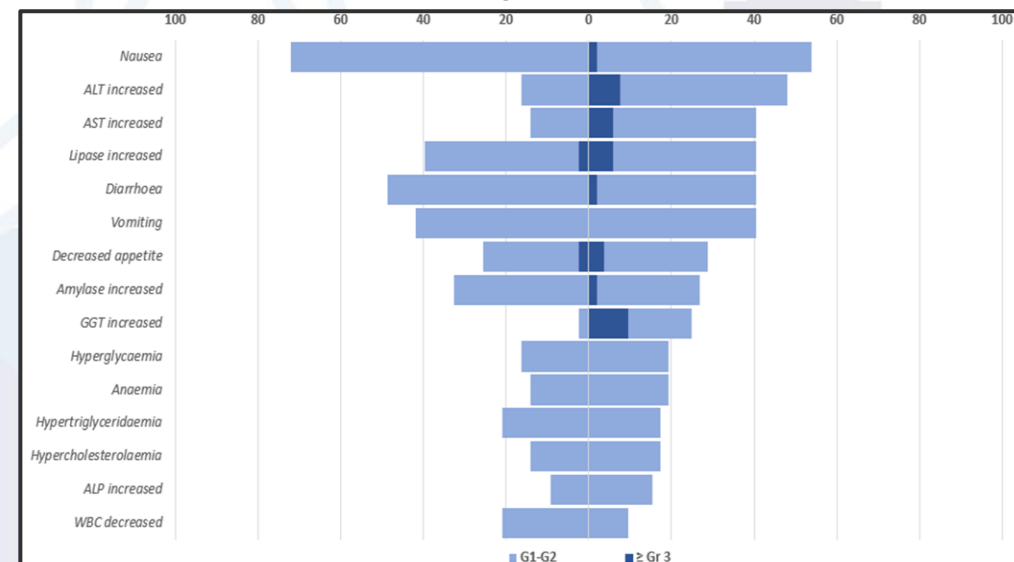
KRAS G12C

Elisrasib (D3S-001), a next-generation GDP-bound KRAS G12C inhibitor, as first-line therapy for KRAS G12C mutation-positive non-small cell lung cancer (NSCLC)

Shun Lu¹

	MONOTERAPIA	+ PEMBROLIZUMAB
TR	78%	81,3%
TCE	95,1%	97,9%
SLP	12,4m (12m: 50,8%)	NR (a 12m: 53,7%)
SV a 12 m	90,0%	88,8%
DoR	NR • a 12m: 52,6%	NR • a 12m: 73,2%
Respuesta a las 6 s	65,6%	82,1%

Elisrasib Monotherapy **E + Pembrolizumab**

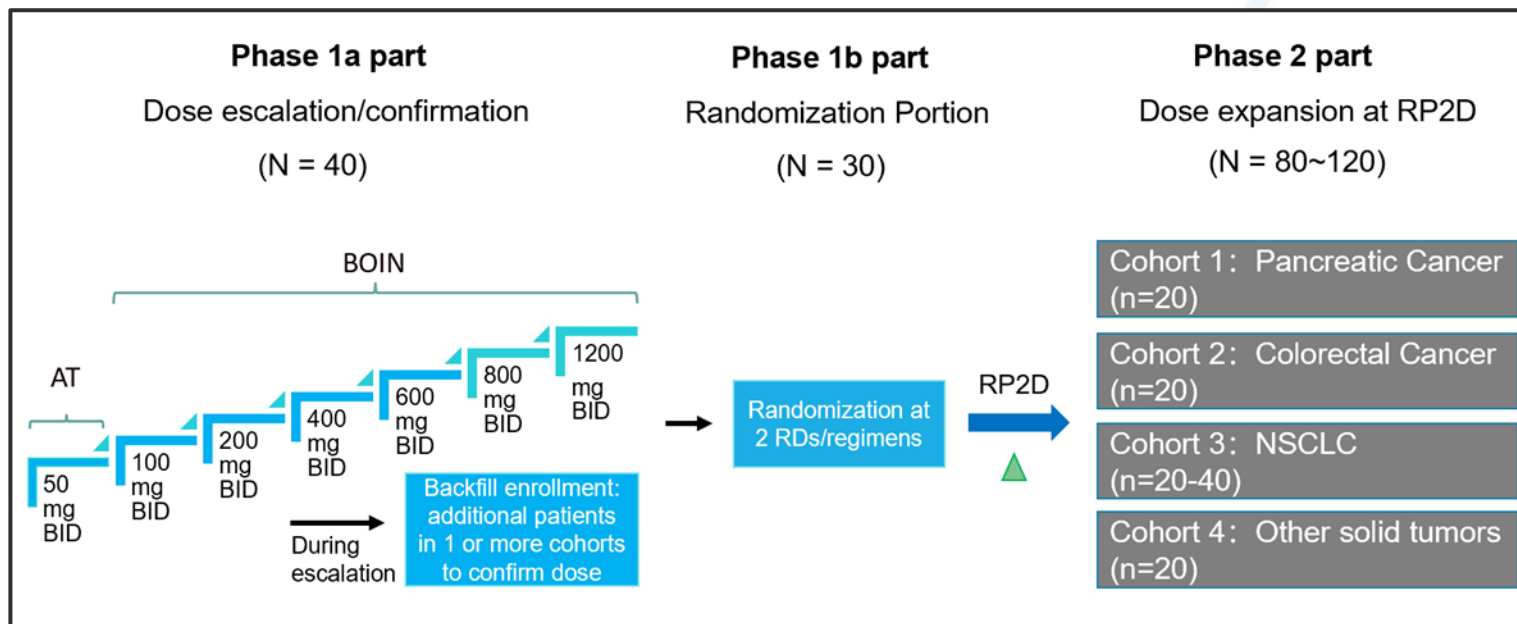


	MONOTERAPIA	+ PEMBROLIZUMAB
EAa _≥ G3	7%	32,7%
Disminución dosis	0	23,1%
Interrupciones	9,3%	50%

→ Actividad robusta y duradera
 → Fase 3

KRAS G12D

A phase 1/2 study of TSN1611, a highly selective oral KRAS G12D inhibitor, in solid tumors: encouraging efficacy and manageable safety in KRAS G12D mutated NSCLC patients



- EAs G3: 21,4%
- Interrupciones de dosis: 14,3%
- Disminución dosis: 23,8%
- Stop: 0%
- Lo mas frec: diarrea: aumento lipasa, N/V, anemia y linfopenia

	1 ^a L (n=5)	Previamente tratados (n=22)	Total (n=27)
TR	80%	36,4%	44,4%
TCE	100%	86,4%	88,9%

DoR: 8,4m

KRAS G12D

Phase I/IIa study of DN022150, a novel selective noncovalent small molecule KRAS^{G12D} inhibitor in patients with advanced KRAS^{G12D}-mutant solid tumors

Yuejuan Cheng, MD

Criterios de inclusión:

- Tumores solidos avanzados KRAS G12D
- Previamente tratados con tto estándar
- ECOG 01-1

Obj 1º: seguridad, MTD, dosis, TR

Eas ≥G3: 50,7%

7,5% AST, 13,4% neutropenia, 7,5% anemia

Disminución dosis: 4,5%

Stop: 4,5%

	Dose Escalation	Dose Expansion	Indication Exploration	Total
	N=28	N=29	N=10	N=67
Median age, year	59.5	63	67	63
Male, N(%)	11(39.3)	21(72.4)	4(40.0)	36(53.7)
ECOG PS 1, N(%)	26(92.9)	24(82.8)	7(70.0)	57(85.1)
Tumor type, N(%)				
NSCLC	3(10.7)	0(0.0)	0(0.0)	3(4.5)
CRC	8(28.6)	0(0.0)	0(0.0)	8(11.9)
PDAC	15(53.6)	29(100.0)	10(100.0)	54(80.6)
Others	2(7.1)	0(0.0)	0(0.0)	2(3.0)

TR; 33,9%

TCE 78%

KRAS G12D

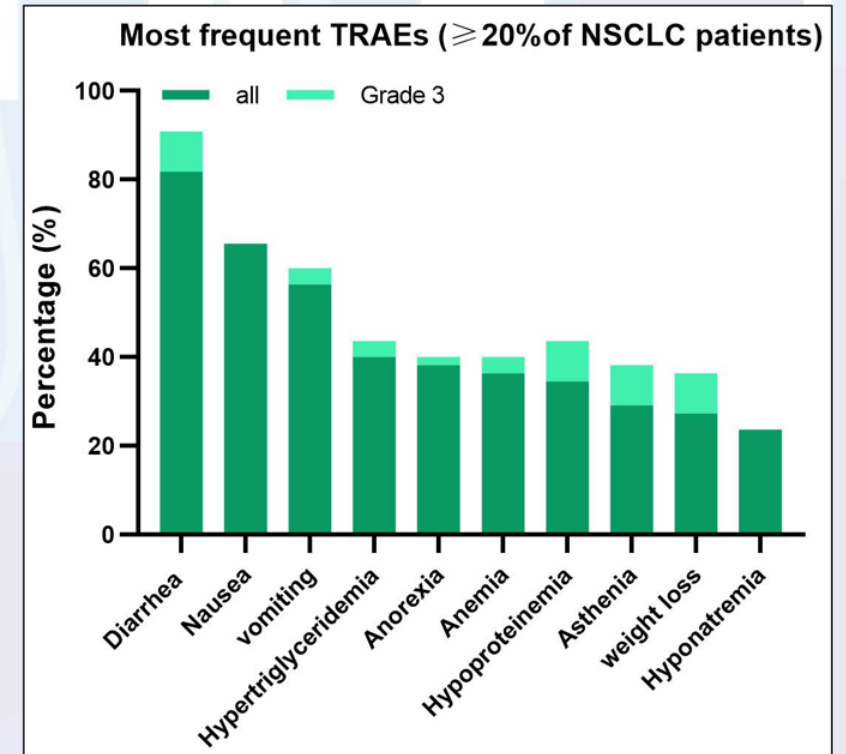
*Clinical Activity and Safety of RNK08954 in Advanced Non-Small Cell Lung Cancer (NSCLC)
 Patients with KRAS G12D Mutation (NCT06667544)*

Zhengbo Song

- 1º: Fase de escalada de dosis:
- 2º parte: 3 cohortes:
 - Cohorte A: PDAC
 - Cohorte B: CNMP
 - N= 55 (39: 1200mg)
 - Cohorte C: otros tumores olidos

- EAs ≥G3: 25,5%
- Disminución dosis: 10,9%
- Interrupciones: 25,5%
- Stop: 0%

	TR	TCE
400-1200 mg (n=47)	42,6%	95,7%
1200 mg pretratados (n= 20)	23,1%	95%
1200 mg, no taxano previo (n=18)	50%	94,4%



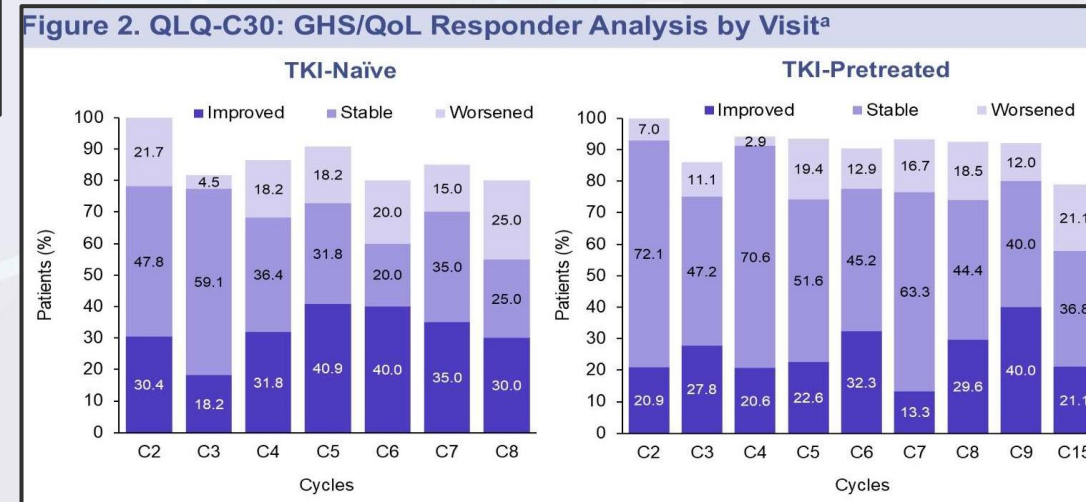
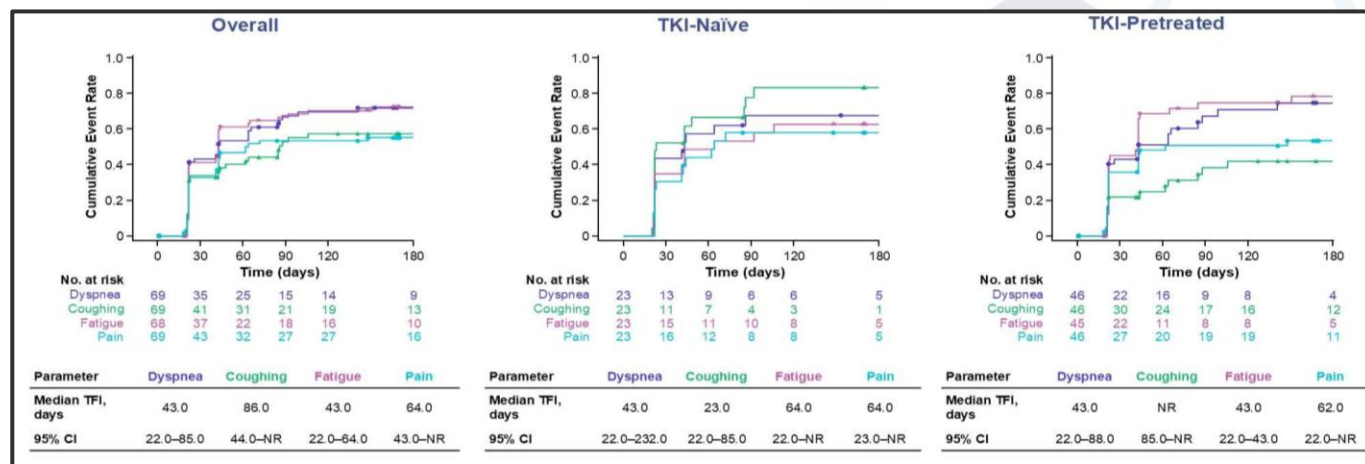
ROS
RET
HER 2

ROS1

Patient-reported outcomes (PROs) and health-related quality of life (HRQoL) with taletrectinib in advanced ROS1+ non small cell lung cancer (NSCLC) from the TRUST-II study.

YasirY. Elamin. Abstract #: 8629

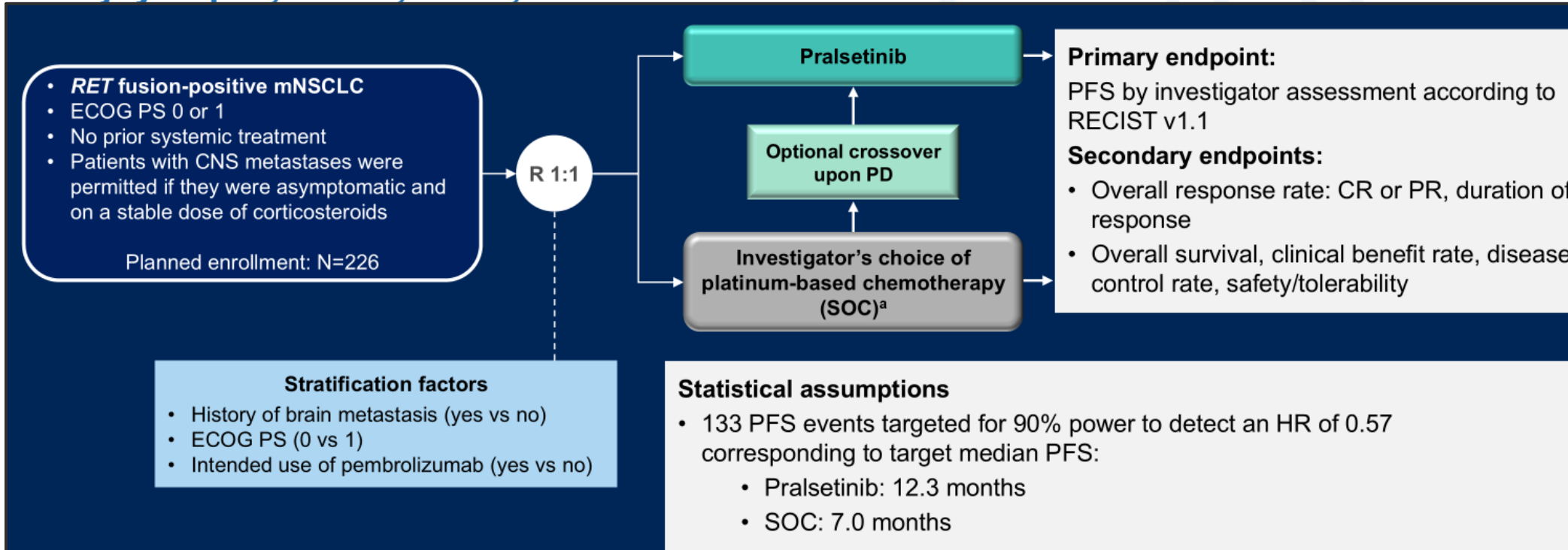
n=69 (23-TKI naïve y 46 TKI pre-tto)



RET

Efficacy and Safety of Pralsetinib as First-Line Treatment of RET Fusion-Positive Advanced or Metastatic Non-Small Cell Lung Cancer: The Phase 3 AcceleRET-Lung Study

Sanjay Popat, MBBS, FRCP, PhD¹



+/-70% europeos
 +/- 30% M1 SNC

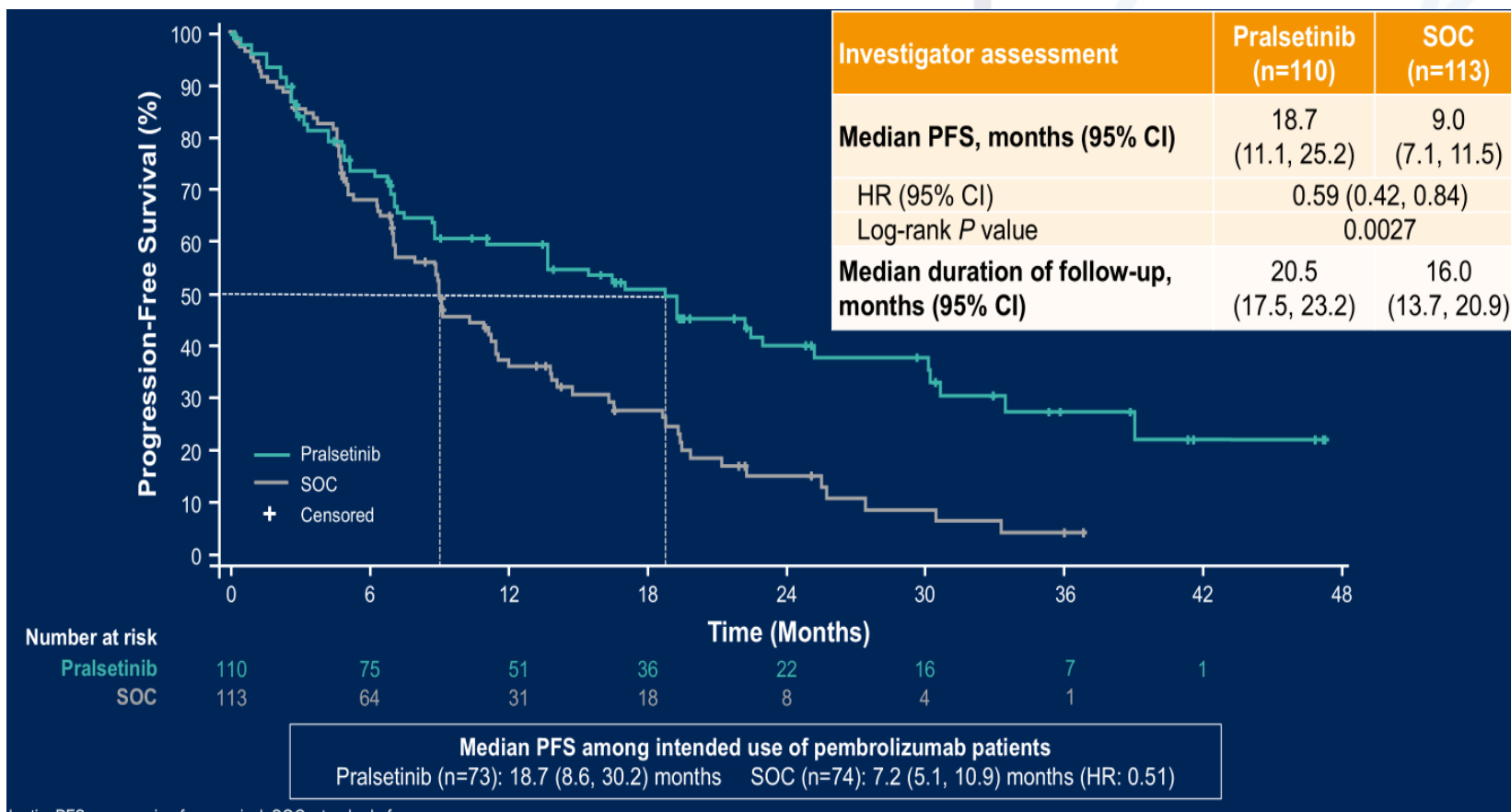
^aIn patients with non-squamous histology, SOC regimens could include carboplatin/cisplatin + pemetrexed ± pembrolizumab. In patients with squamous histology, SOC regimens could include carboplatin/cisplatin + gemcitabine, or pembrolizumab + carboplatin + paclitaxel/nab-paclitaxel.

1L, first-line; CNS, central nervous system; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HR, hazard ratio; mNSCLC, metastatic non-small cell lung cancer; PD, progressive disease; PFS, progression-free survival; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SOC, standard of care.

RET

Efficacy and Safety of Pralsetinib as First-Line Treatment of RET Fusion-Positive Advanced or Metastatic Non-Small Cell Lung Cancer: The Phase 3 AcceleRET-Lung Study

Sanjay Popat, MBBS, FRCP, PhD1



- TR: 65,5 vs. 41,6%
- DoR: 20,6 vs. 9,7 m
- EAs G3-5: 77,8 vs. 57,7%
- Muertes por EAs: 14,8 vs. 4,8%
 - Infecciones : 7,4 vs. 0%
- Modificaciones: 74,1 vs. 54,8%
- Stop por EAs: 16,7 vs. 24%
- Infecciones ≥G3: 28,7 vs. 9,6%
- Infecciones oportunistas ≥G3: 6,5 vs. 0%

RET

Efficacy and safety of lunbotinib (A400/EP0031), a next-generation selective RET inhibitor (SRI), from a pivotal phase II study in patients with advanced RET-fusion positive non-small cell lung cancer

Qing Zhou¹

Pivotal phase 2 study of lunbotinib in RET fusion-positive NSCLC (NCT05265091)

Cohort 1: Prior Treatment

Prior platinum-based chemotherapy and immunotherapy^a (N = 71)

32,9% M1 SNC

Cohort 2: Treatment-Naïve

No prior systemic therapy (N=92)

17,6% M1 SNC

Key eligibility criteria

- LA/M RET fusion-positive NSCLC
- ECOG PS 0–1
- At least one measurable lesion per RECIST v1.1

Lunbotinib dosing
90 mg QD

- Tumor assessment: every 8 weeks for the first 48 weeks and every 12 weeks afterward.

Endpoints

Primary endpoint

- ORR by IRC

Secondary endpoints

- ORR by investigator, PFS, DOR, TTR, DCR
- OS
- CNS ORR/DOR^b
- Safety

- cTR:
 - 1^aL: 81,3%
 - Otras L: 87,1%
- icTR: 79,5%
- icTCE: 89,7%
- DoR:
 - 1^aL: NR; a 21m: 67,1%
 - Otras: 25,7 m; a 24m: 55,4%
- ctDNA basal+ → <SLP
 - 80,9% aclara en la semana 8

^a Combination or sequential therapy; if neither is eligible, a rational justification must be provided and clearly documented.

^b CNS ORR/DOR was assessed by IRC and investigator per response assessment in neuro-oncology brain metastases (RANO-BM).

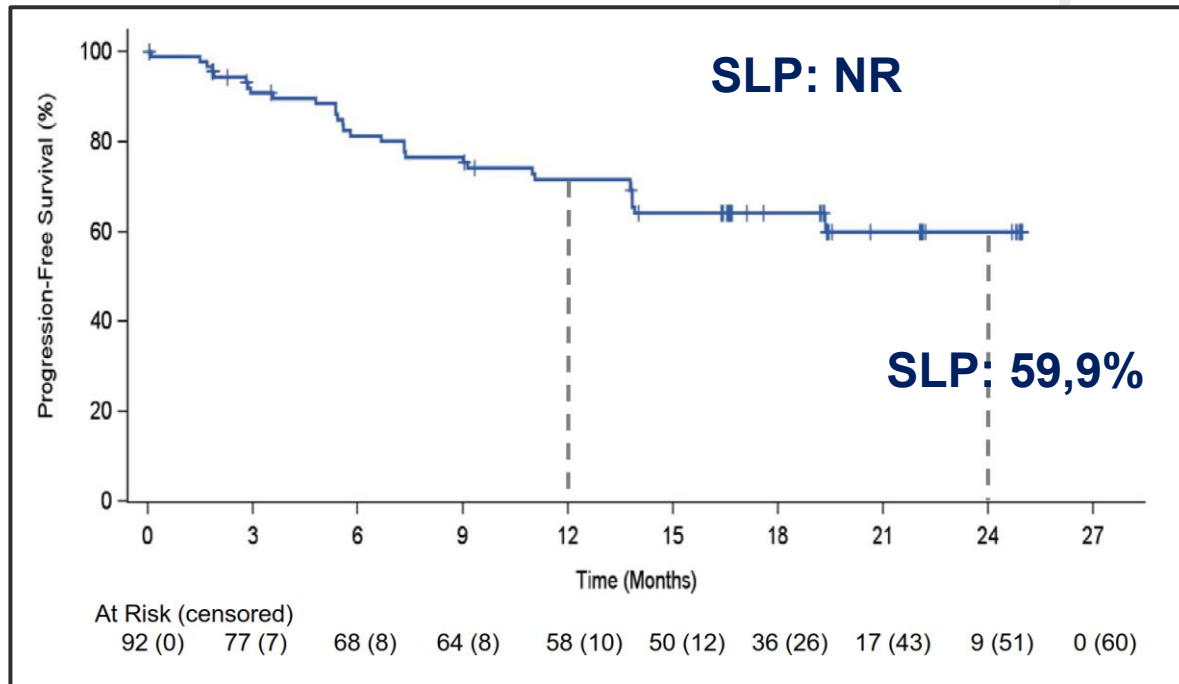
DCR, disease control rate; DOR, duration of response; ECOG PS, eastern cooperative oncology group performance score; IRC, independent review committee; LA/M, locally advanced/metastatic; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; QD, quaque die; RECIST, response evaluation criteria in solid tumors; TTR, time to response.

RET

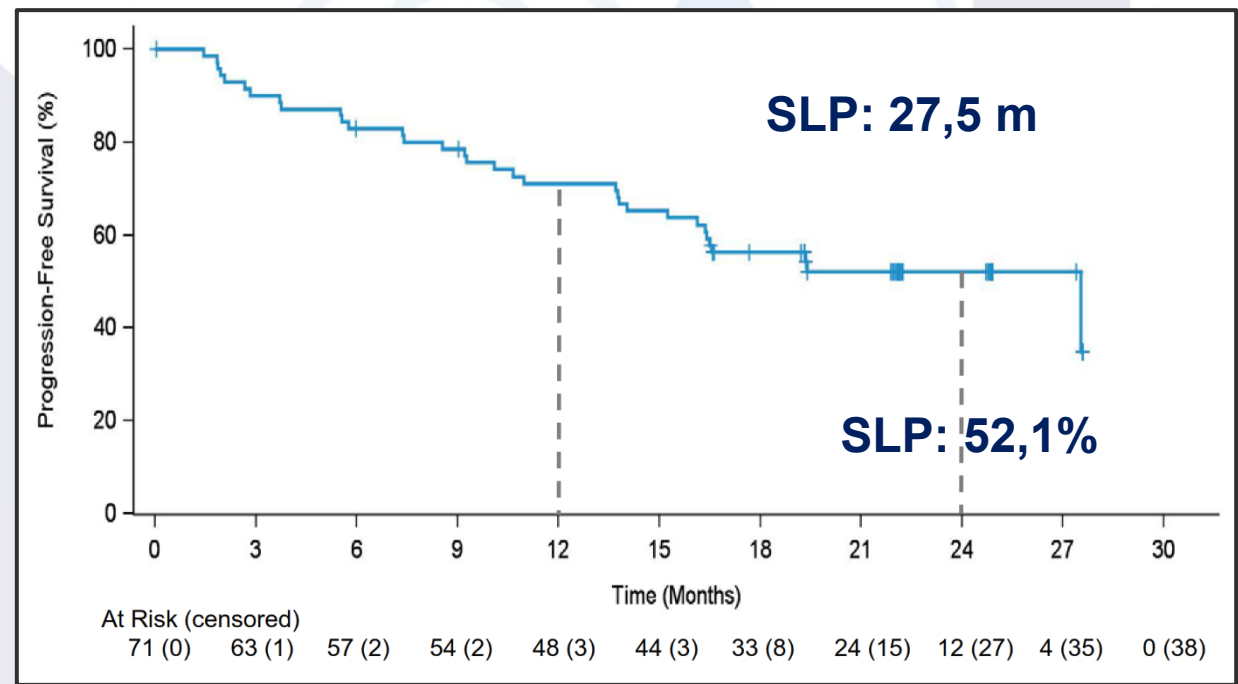
Efficacy and safety of lunbotinib (A400/EP0031), a next-generation selective RET inhibitor (SRI), from a pivotal phase II study in patients with advanced RET-fusion positive non-small cell lung cancer

Qing Zhou1

1ª Línea



Otras líneas

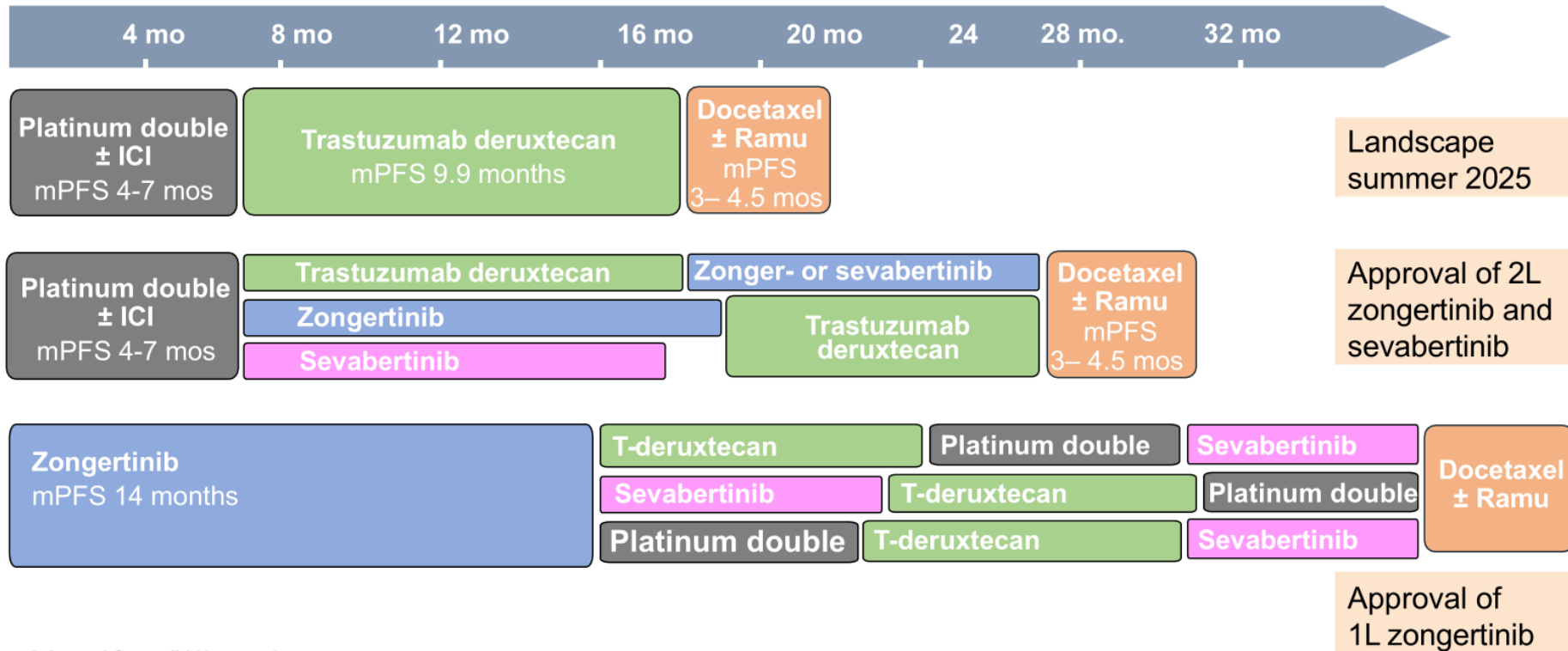


- EAs≥G3: 40,5%
- Disminución de dosis: 48,5%; Stop: 1,2%
- Aumento de transaminasas, anemia, retención de orina, ojo seco.

HER2

Xiuning Le, M.D., Ph.D.

Evolution of HER2 mutant NSCLC landscape with new approvals



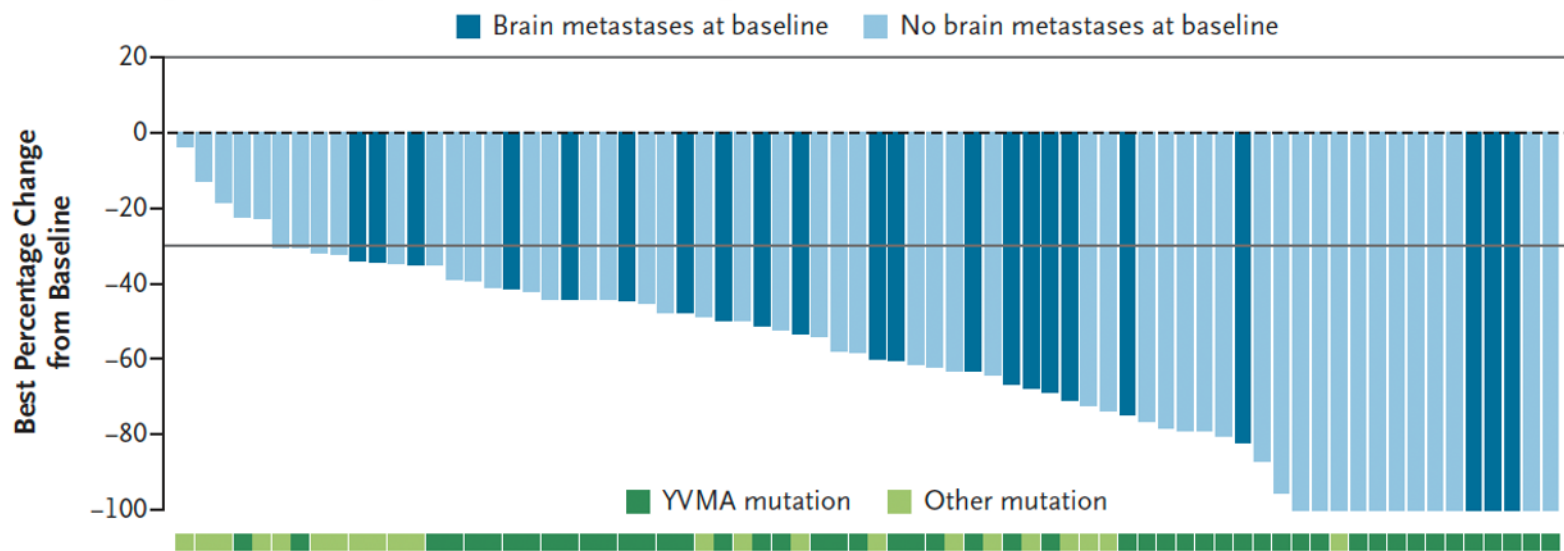
Adapted from JV Heymach

HER2

Zongertinib in treatment-naïve patients with TKD HER2 mutations. BEAMION-Lung-01 trial

Xiuning Le, M.D., Ph.D.

A Best Change in Sum of Target-Lesion Diameters among Patients in Cohort 2



Zongertinib, n=74

TR	77%
TCE	96%
SLP	14,4 m
DoR	15,2 m

PRO results from the Beamion LUNG-1 trial in treatment-naïve patients with HER2-mutant advanced NSCLC.

Poster session. Abstract #: 8616

Mejoría funcional en C1. 70% mejoría síntomas C5.
 8% preocupados por EAs.



Gracias