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# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with MET exon 14 (METex14) skipping NSCLC in the VISION study: A ≥3-year follow-up

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## CONCLUSIONS

- Long-term outcomes with tepotinib in clinically relevant subgroups of patients with METex14 skipping NSCLC in the VISION study with ≥3 years of follow-up continued to show robust and durable efficacy, consistent with previously reported findings of the overall population
- Outcomes were consistent irrespective of T+/L+ status, age, smoking history, or the presence of brain metastases at baseline

## PLAIN LANGUAGE SUMMARY

- Tepotinib, an anticancer drug taken by mouth, is approved in many countries in patients with non-small cell lung cancer (NSCLC) that has spread through the body and carries a particular genetic alteration called MET exon 14 (METex14) skipping
- Previous reports have shared results about the effectiveness, safety, and quality of life from the VISION study that studied tepotinib in patients who have NSCLC with METex14 skipping
- On this poster, we show updated results from patients in the VISION study who have been followed for at least 3 years, particularly patients with certain characteristics

- 313 patients with METex14 skipping NSCLC participated in the VISION trial, with an average age of 72 years
- 208 patients had METex14 skipping detected by testing tissue from their lung
- 129 patients were ≥75 years of age
- 57 patients, at the beginning of the study, had cancer that had spread to the brain
- 149 patients had a history of smoking

- Irrespective of the testing methods that are used to detect the METex14 skipping alteration, either by tissue or blood test, more than half of the patients had response to treatment
- Benefits with tepotinib were observed irrespective of the age, smoking habits, or other characteristics of the patients
- Patients with cancer that had spread to the brain also responded to tepotinib treatment
  - Among patients whose brain tumors could be measured, about two out of three (66.7%) showed a significant brain tumor size reduction

- Based on the results presented here, tepotinib provided long-lasting treatment responses and improved survival across patients with different characteristics, including older adults, patients with a history of smoking, and those with brain metastases, showing consistent and meaningful benefits. These results are consistent with what has been reported from the VISION trial in the past

## INTRODUCTION

- Tepotinib, an oral, once-daily, and highly selective MET TKI, has been approved for the treatment of advanced/metastatic METex14 skipping NSCLC in many countries, including the EU<sup>1,2</sup>
- The VISION study demonstrated robust and durable efficacy and safety of tepotinib in patients with METex14 skipping NSCLC with ≥3 years of follow-up (data cut-off: May 20, 2024)<sup>3</sup>
- Here, we report long-term efficacy of tepotinib in clinically relevant subgroups of patients with METex14 skipping NSCLC from the VISION study with ≥3 years of follow-up, including by METex14 skipping detection method, age, smoking status, and the presence of brain metastases (data cut-off: May 20, 2024)

## METHODS

- VISION (NCT02864992) is a single-arm, Phase II trial of tepotinib in patients with advanced NSCLC harboring METex14 skipping
- Patients with advanced/metastatic METex14 skipping NSCLC, detected by tissue (T+) and/or liquid (L+) biopsy, received tepotinib 500 mg (450 mg active moiety) once daily (Supplementary Figure S1)
- Primary endpoint was objective response (RECIST v1.1) by IRC
- Analyses in clinically relevant subgroups (METex14 skipping detection method, age, smoking status, and presence of brain metastases) were preplanned (data cut-off: May 20, 2024)
- A preplanned exploratory analysis of brain lesions was conducted by IRC using RANO-BM criteria

## RESULTS

### Baseline characteristics

- In VISION Cohorts A+C, 313 patients with METex14 skipping NSCLC were included
- 208 patients were T+ (1L: 111; 2L+: 97), 178 were L+ (1L: 95; 2L+: 83), and 74 patients were both T+ and L+ (Supplementary Table S1)
  - Median age of the patients was 72.7 years (range: 41–94) in T+ subgroup and 71.2 years (47–89) in the L+ subgroup
  - Median duration of treatment across all T+ patients (n=208) was 8.3 months (range: 0.03–83.12) and in L+ patients (n=178) was 7.0 months (0.39–83.12) (Supplementary Figure S2)
  - Eleven patients in the T+ subgroup and 13 patients in the L+ subgroup received tepotinib treatment for ≥48 months
- 41.2% patients were ≥75 years of age, 47.6% patients had smoking history, and 18.2% had brain metastases at baseline (Supplementary Table S1)

### Long-term efficacy according to method of METex14 skipping detection

- T+ patients had an ORR of 54.8% (95% CI: 47.8, 61.7) with an mDOR of 17.4 months (12.4, 31.7), mPFS of 13.7 months (11.0, 17.1), and mOS of 22.3 months (18.8, 25.9) (Table 1, Supplementary Figure S3)
  - Patients in the 1L T+ subgroup had an ORR of 59.5% (49.7, 68.7) with an mDOR of 31.7 months (15.2, 53.7), while patients in the 2L+ T+ subgroup had an ORR of 49.5% (39.2, 59.8) with an mDOR of 12.4 months (8.3, 18.0)
- L+ patients had an ORR of 51.7% (44.1, 59.2) with an mDOR of 15.2 months (9.7, 33.6), mPFS of 8.9 months (7.8, 11.0), and mOS of 17.6 months (12.6, 21.3)
  - Patients in the 1L L+ subgroup had an ORR of 58.9% (48.4, 68.9) with an mDOR of 17.4 months (8.3, 46.4), while patients in the 2L+ L+ subgroup had an ORR of 43.4% (32.5, 54.7) with an mDOR of 12.4 months (8.4, 33.6)
  - L+ patients had shorter time-dependent endpoints, potentially due to a higher baseline disease burden<sup>4</sup> (Table 1, Supplementary Figure S3)

Table 1. Long-term efficacy outcomes in T+ and L+ subgroups after ≥3 years of follow-up

| Tepotinib efficacy   | ORR, % (95% CI)   | mDOR, months (95% CI) | mPFS, months (95% CI) | mOS, months (95% CI) |
|----------------------|-------------------|-----------------------|-----------------------|----------------------|
| <b>T+ (n=208)</b>    | 54.8 (47.8, 61.7) | 17.4 (12.4, 31.7)     | 13.7 (11.0, 17.1)     | 22.3 (18.8, 25.9)    |
| <b>1L T+ (n=111)</b> | 59.5 (49.7, 68.7) | 31.7 (15.2, 53.7)     | 15.9 (11.0, 33.1)     | 24.6 (18.8, 31.6)    |
| <b>2L+ T+ (n=97)</b> | 49.5 (39.2, 59.8) | 12.4 (8.3, 18.0)      | 11.5 (8.2, 14.7)      | 19.7 (17.0, 24.5)    |
| <b>L+ (n=178)</b>    | 51.7 (44.1, 59.2) | 15.2 (9.7, 33.6)      | 8.9 (7.8, 11.0)       | 17.6 (12.6, 21.3)    |
| <b>1L L+ (n=95)</b>  | 58.9 (48.4, 68.9) | 17.4 (8.3, 46.4)      | 10.3 (8.0, 16.5)      | 17.6 (10.4, 23.7)    |
| <b>2L+ L+ (n=83)</b> | 43.4 (32.5, 54.7) | 12.4 (8.4, 33.6)      | 8.2 (5.7, 11.0)       | 16.2 (12.0, 21.0)    |

### Long-term efficacy by age and smoking history

- In patients aged <75 years, ORR was 55.4% (47.9, 62.7) with an mDOR of 19.4 months (12.4, 53.7), versus 46.5% (37.7, 55.5) and 15.7 months (9.3, 31.8) in patients ≥75 years (Table 2, Figures 1 and 2, and Supplementary Figures S4 and S5)
- Patients with a history of smoking had an ORR of 56.4% (48.0, 64.5) with an mDOR of 18.0 months (10.4, 39.5), versus 47.4% (39.3, 55.6) and 20.8 months (9.5, ne) in patients without (Table 2, Figures 1 and 2, and Supplementary Figures S4 and S5)

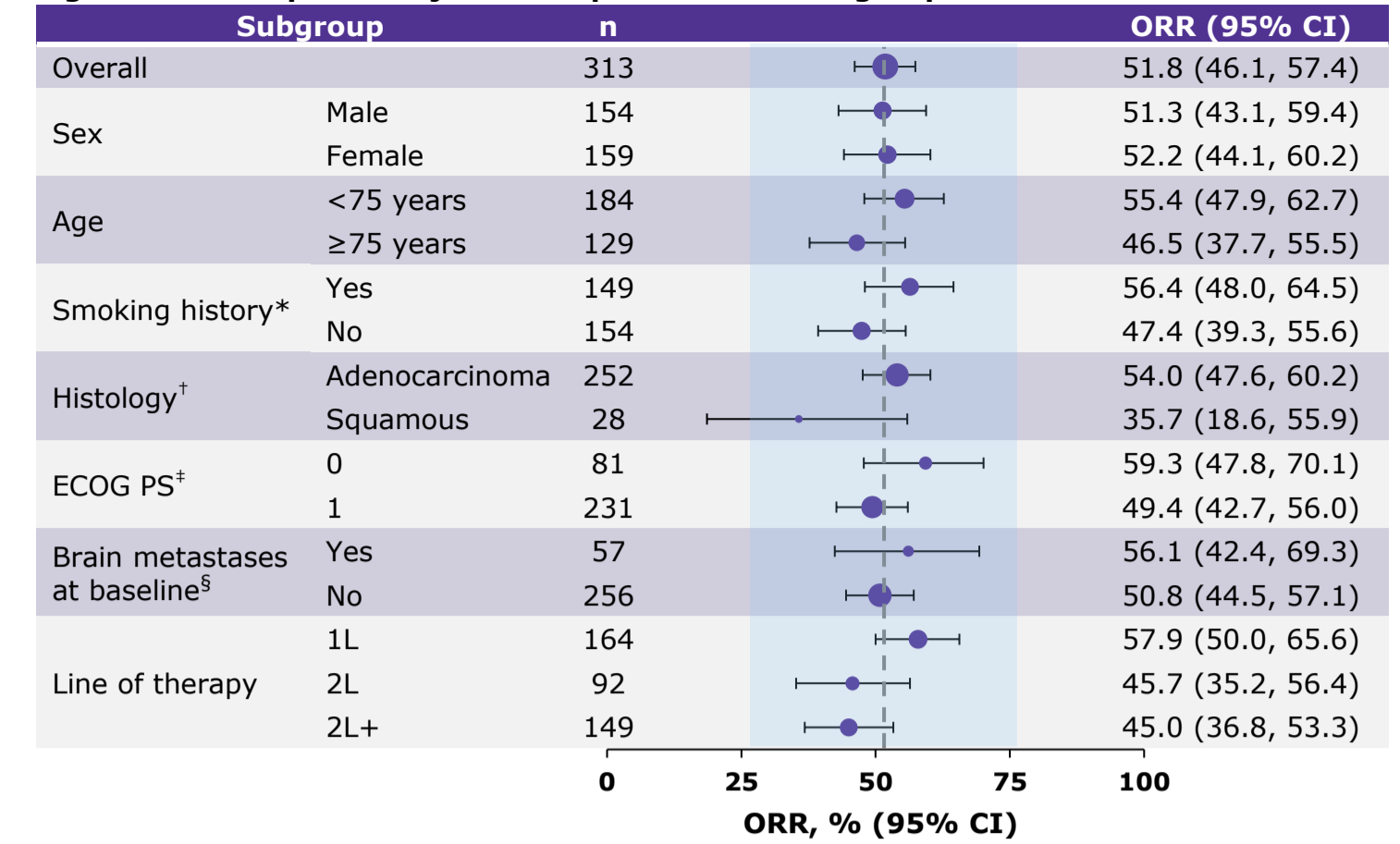
Table 2. Long-term efficacy outcomes in patients by age and smoking history after ≥3 years of follow-up

| Tepotinib efficacy     | ORR, % (95% CI)   | mDOR, months (95% CI) | mPFS, months (95% CI) | mOS, months (95% CI) |
|------------------------|-------------------|-----------------------|-----------------------|----------------------|
| <b>Age</b>             |                   |                       |                       |                      |
| <75 years (n=184)      | 55.4 (47.9, 62.7) | 19.4 (12.4, 53.7)     | 11.5 (8.9, 15.9)      | 21.1 (17.6, 24.9)    |
| ≥75 years (n=129)      | 46.5 (37.7, 55.5) | 15.7 (9.3, 31.8)      | 10.8 (8.3, 15.1)      | 16.2 (12.7, 20.7)    |
| <b>Smoking history</b> |                   |                       |                       |                      |
| Yes (n=149)            | 56.4 (48.0, 64.5) | 18.0 (10.4, 39.5)     | 12.1 (8.9, 16.5)      | 21.7 (18.0, 25.8)    |
| No (n=154)             | 47.4 (39.3, 55.6) | 20.8 (9.5, ne)        | 11.0 (8.2, 13.8)      | 16.2 (13.7, 20.5)    |

### Long-term efficacy in patients with brain metastases

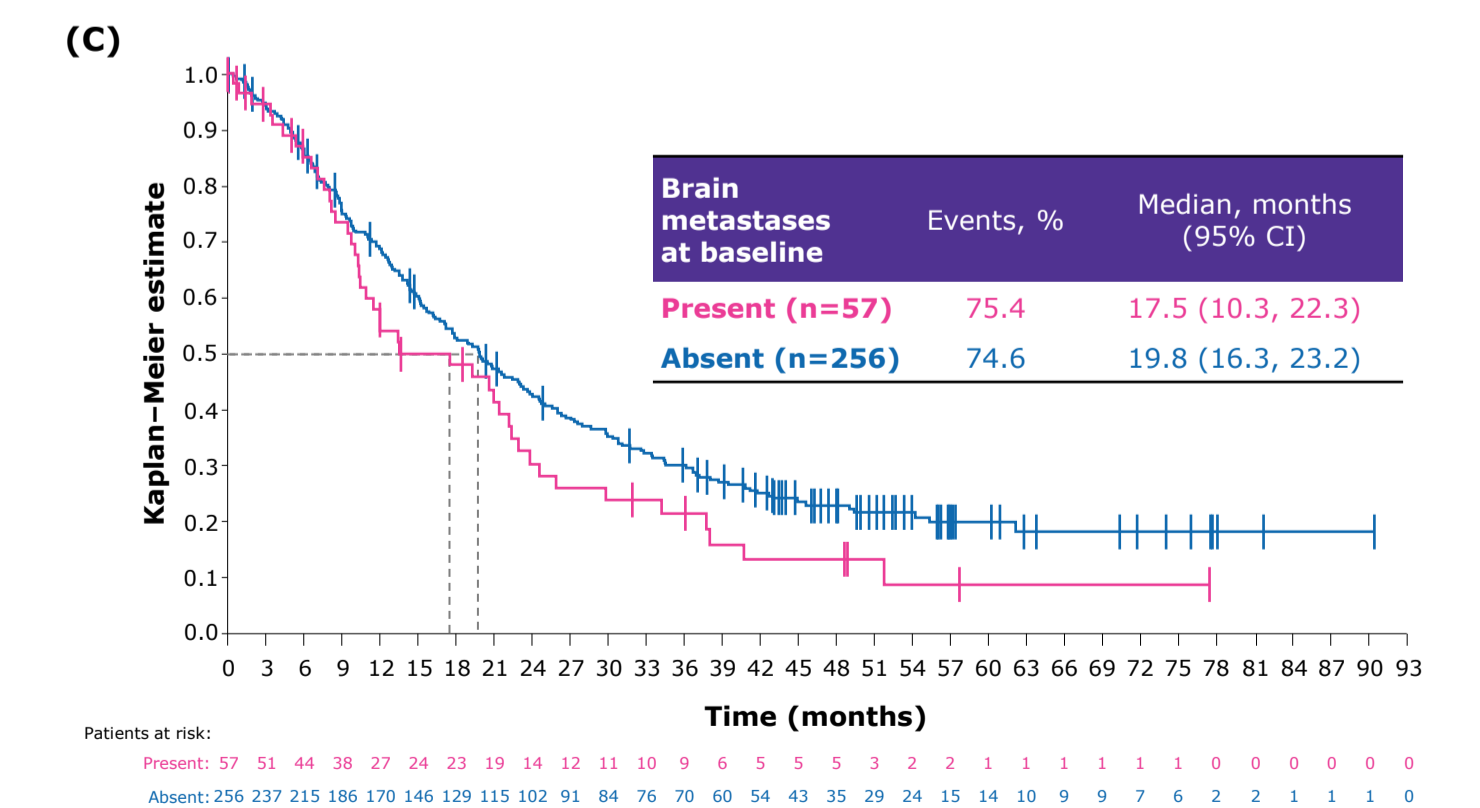
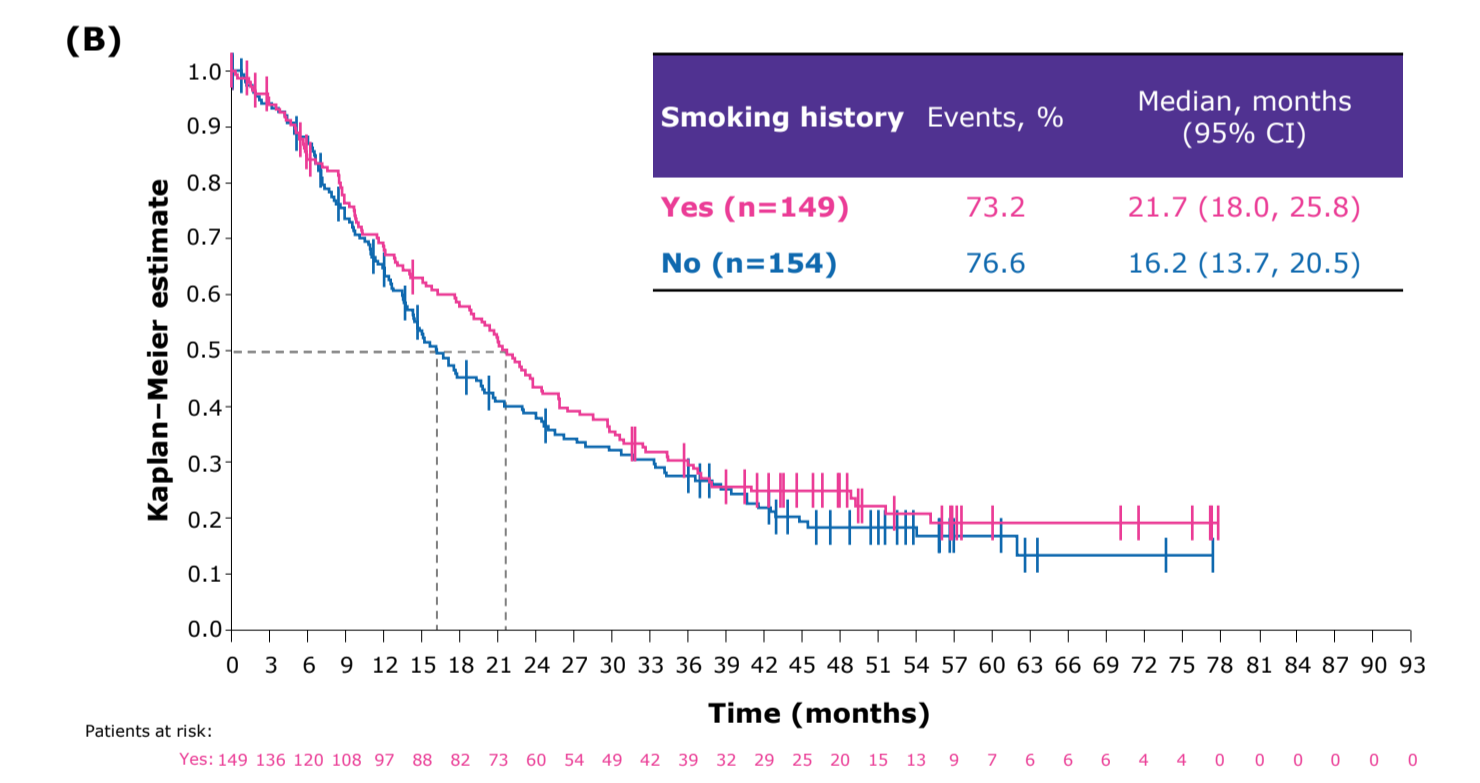
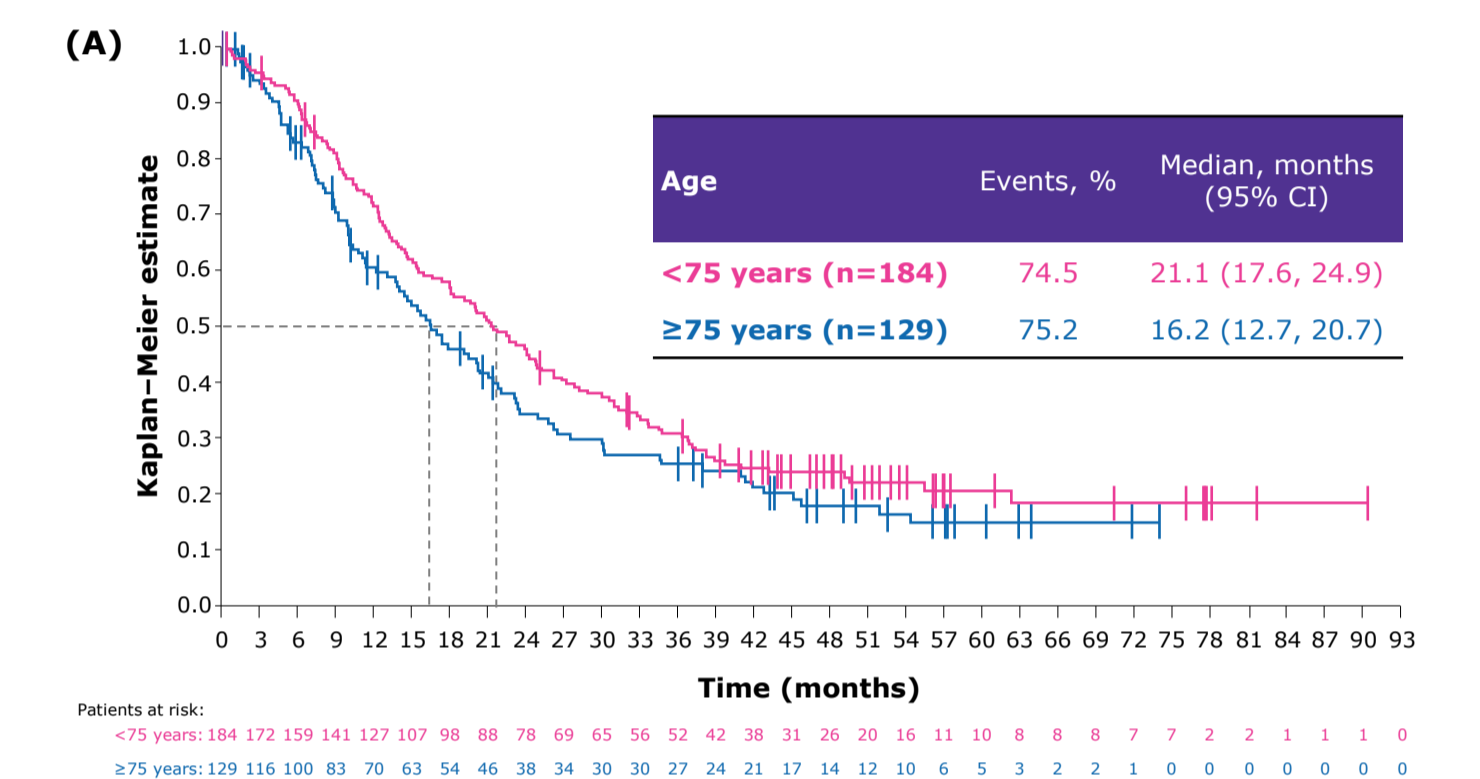
- Among 57 patients with baseline brain metastases, systemic ORR was 56.1% (42.4, 69.3) with an mDOR of 9.0 months (5.6, 31.7), versus 50.8% (44.5, 57.1) and 19.4 months (13.4, 39.5) in patients without (n=256) (Supplementary Table S2, Figure 2, and Supplementary Figures S4 and S5)
- In patients with brain tumors as target lesions evaluable by RANO-BM (n=15), intracranial ORR was 66.7% (38.4, 88.2) with a DCR of 86.7% (59.5, 98.3); 12 of these patients had previous radiotherapy for brain metastases (Supplementary Table S3, Supplementary Figure S6)
  - Overall, three patients had a CR (one patient received prior radiotherapy) and seven patients had a PR (all patients received prior radiotherapy); among patients in 1L (n=10), three patients had a CR and three had a PR, while in patients in 2L+ (n=5), four patients had a PR

Figure 1. Forest plot of objective response rate in subgroups of interest



\*Smoking history was missing for 10 patients. †33 patients had histology other than squamous and adenocarcinoma. ‡One patient had ECOG PS 2. §Identified at baseline (investigator or independent review).

Figure 2. Overall survival KM curves according to (A) patient age, (B) smoking history, and (C) presence of brain metastases at baseline



Abbreviations: 1L, first line; 2L, second line; 2L+, second-or-later line; CI, confidence interval; CR, complete response; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, Independent Review Committee; L+, METex14 skipping detected by liquid biopsy; MET, mesenchymal-epithelial transition factor; m, median; METex14, MET exon 14; ne, not estimable; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; RANO-BM, Response Assessment in Neuro-Oncology-Brain Metastases; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; T+, METex14 skipping detected by tissue biopsy; TKI, tyrosine kinase inhibitor.  
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# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

### Supplementary Table S1. Baseline characteristics of the overall patient population and in T+ and L+ subgroups

| Parameter                            |                        | Overall (N=313) | T+ (n=208)   | L+(n=178)    |
|--------------------------------------|------------------------|-----------------|--------------|--------------|
| Sex, n (%)                           | Male                   | 154 (49.2)      | 108 (51.9)   | 83 (46.6)    |
|                                      | Female                 | 159 (50.8)      | 100 (48.1)   | 95 (53.4)    |
| Race*, n (%)                         | White                  | 195 (62.3)      | 120 (57.7)   | 123 (69.1)   |
|                                      | Asian                  | 106 (33.9)      | 83 (39.9)    | 48 (27.0)    |
|                                      | Black/African American | 3 (1.0)         | 2 (1.0)      | 1 (0.6)      |
| Age, years                           | Median (range)         | 72.0 (41-94)    | 72.7 (41-94) | 71.2 (47-89) |
|                                      | Adenocarcinoma         | 252 (80.5)      | 170 (81.7)   | 143 (80.3)   |
| Histology <sup>†</sup> , n (%)       | Squamous               | 28 (8.9)        | 14 (6.7)     | 20 (11.2)    |
|                                      | Sarcomatoid            | 10 (3.2)        | 5 (2.4)      | 6 (3.4)      |
| Smoking history <sup>‡</sup> , n (%) | No                     | 154 (49.2)      | 100 (48.1)   | 90 (50.6)    |
|                                      | Yes                    | 149 (47.6)      | 98 (47.1)    | 84 (47.2)    |
| ECOG PS <sup>§</sup> , n (%)         | 0                      | 81 (25.9)       | 57 (27.4)    | 42 (23.6)    |
|                                      | 1                      | 231 (73.8)      | 150 (72.1)   | 136 (76.4)   |
| Line of treatment, n (%)             | 1L                     | 164 (52.4)      | 111 (53.4)   | 95 (53.4)    |
|                                      | 2L+                    | 149 (47.6)      | 97 (46.6)    | 83 (46.6)    |

\*Nine patients had race reported as 'other' or was missing. <sup>†</sup>23 patients had histologies other than adenocarcinoma, squamous, and sarcomatoid. <sup>‡</sup>Smoking history was missing for 10 patients. <sup>§</sup>One patient had ECOG PS 2.

### Supplementary Table S2. Systemic efficacy in patients with and without brain metastases at baseline

| Systemic efficacy (IRC) |         | Patients with BM at baseline (n=57) | Patients without BM at baseline (n=256) |
|-------------------------|---------|-------------------------------------|---|
| ORR, n/N (%) [95% CI]   | Overall | 32/57 (56.1) [42.4, 69.3]           | 130/256 (50.8) [44.5, 57.1]             |
|                         | 1L      | 18/28 (64.3) [44.1, 81.4]           | 77/136 (56.6) [47.9, 65.1]              |
|                         | 2L+     | 14/29 (48.3) [29.4, 67.5]           | 53/120 (44.2) [35.1, 53.5]              |
| DCR, % (95% CI)         |         | 77.2 (64.2, 87.3)                   | 76.2 (70.5, 81.3)                       |
| mDOR, months (95% CI)   |         | 9.0 (5.6, 31.7)                     | 19.4 (13.4, 39.5)                       |
| mPFS, months (95% CI)   |         | 8.5 (6.8, 19.4)                     | 12.1 (9.7, 14.8)                        |
| mOS, months (95% CI)    |         | 17.5 (10.3, 22.3)                   | 19.8 (16.3, 23.2)                       |

Abbreviations: 1L, first line; 2L+, second-or-later line; BM, brain metastases; CI, confidence interval; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; L+, *MET*ex14 skipping detected by liquid biopsy; m, median; MET, mesenchymal-epithelial transition factor; *MET*ex14, *MET* exon 14; NSCLC, non-small cell lung cancer; OS, overall survival; PFS, progression-free survival; T+, *MET*ex14 skipping detected by tissue biopsy.

# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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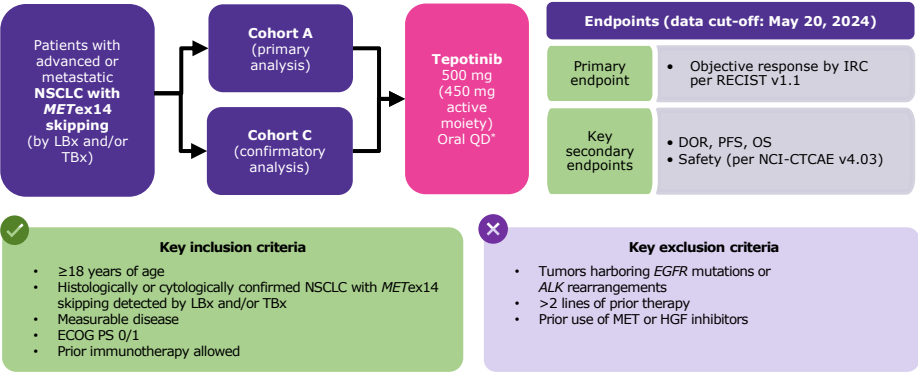
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## SUPPLEMENTARY RESULTS

### Supplementary Table S3. Intracranial efficacy in patients with brain metastases evaluable by RANO-BM

|   |                     | Overall (n=15)            |
|---|---------------------|---------------------------|
| <b>Intracranial BOR, n (%)</b>            | Complete response   | 3 (20.0)                  |
|   | Partial response    | 7 (46.7)                  |
|   | Stable disease      | 3 (20.0)                  |
|   | Progressive disease | 2 (13.3)                  |
|   | Not evaluable       | 0                         |
| <b>Overall</b>                            |                     | 10/15 (66.7) [38.4, 88.2] |
| <b>Intracranial ORR, n/N (%) [95% CI]</b> | 1L                  | 6/10 (60%)                |
|   | 2L+                 | 4/5 (80%)                 |
| <b>Intracranial DCR, % (95% CI)</b>       |                     | 86.7 (59.5, 98.3)         |

### Supplementary Figure S1. Study design, endpoints, and eligibility criteria of VISION



\*Treatment continues until disease progression, intolerable toxicity, or withdrawal of consent.

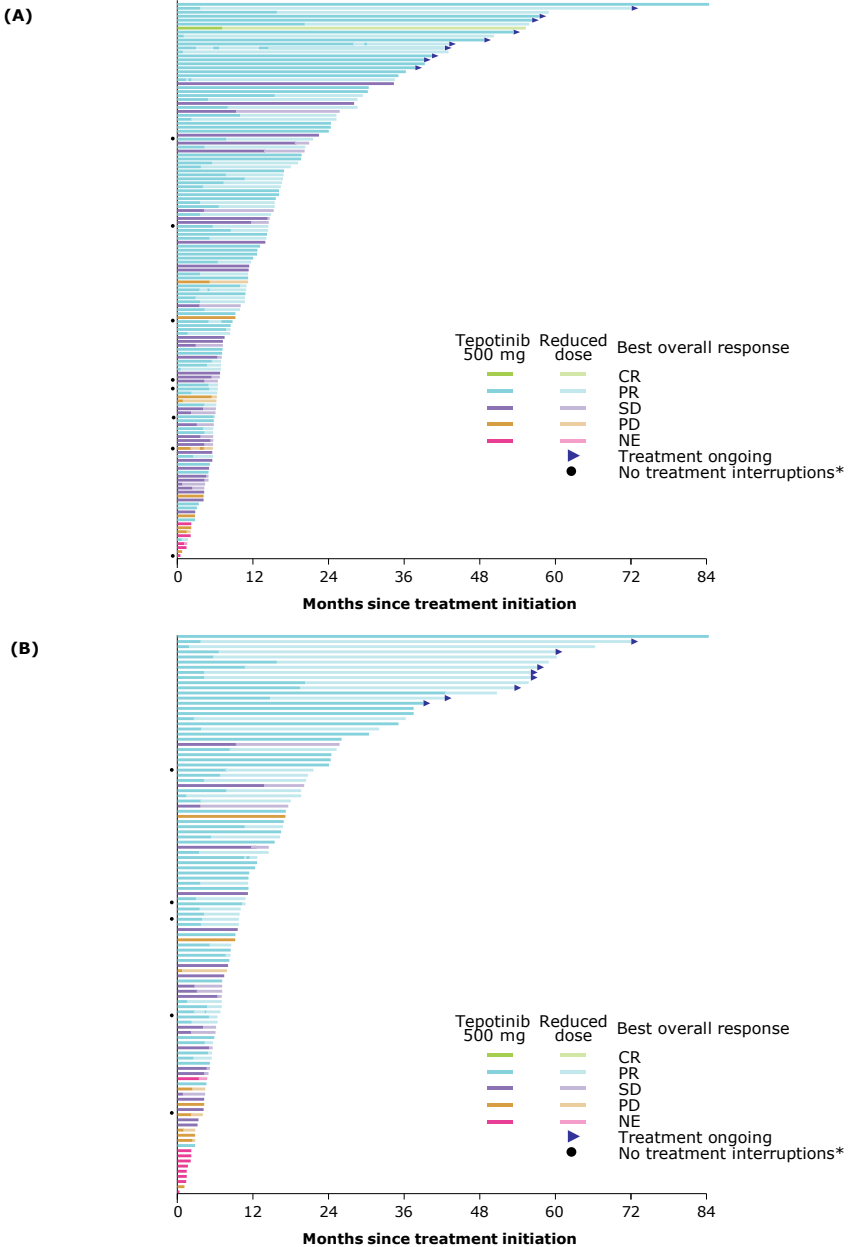
# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

**Supplementary Figure S2. Swimmer plots highlighting duration of tepotinib treatment in (A) T+ patients and (B) L+ patients**



Abbreviations: CR, complete response; L+, *MET*ex14 skipping detected by liquid biopsy; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease; T+, *MET*ex14 skipping detected by tissue biopsy.

\*All patients had treatment interruptions except those indicated with a circle.

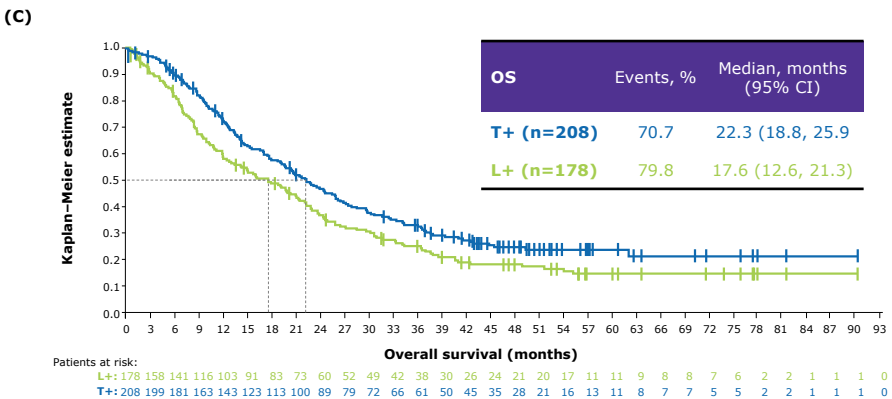
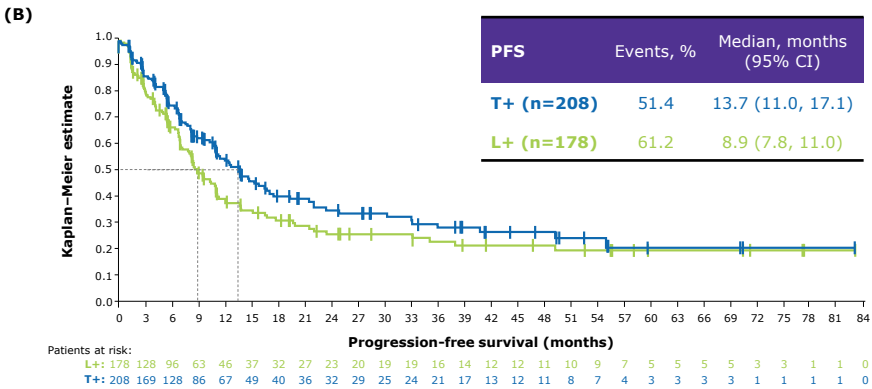
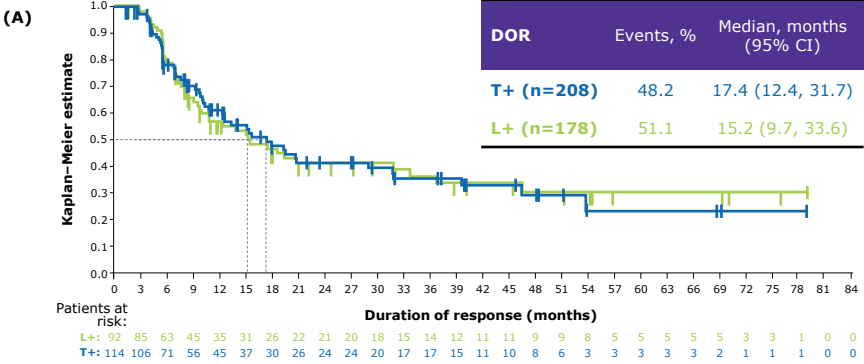
# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

### Supplementary Figure S3. KM curves for (A) DOR\*, (B) PFS and (C) OS according to *MET*ex14 skipping detection method



\*Only patients with a response were included in the Kaplan-Meier analyses.

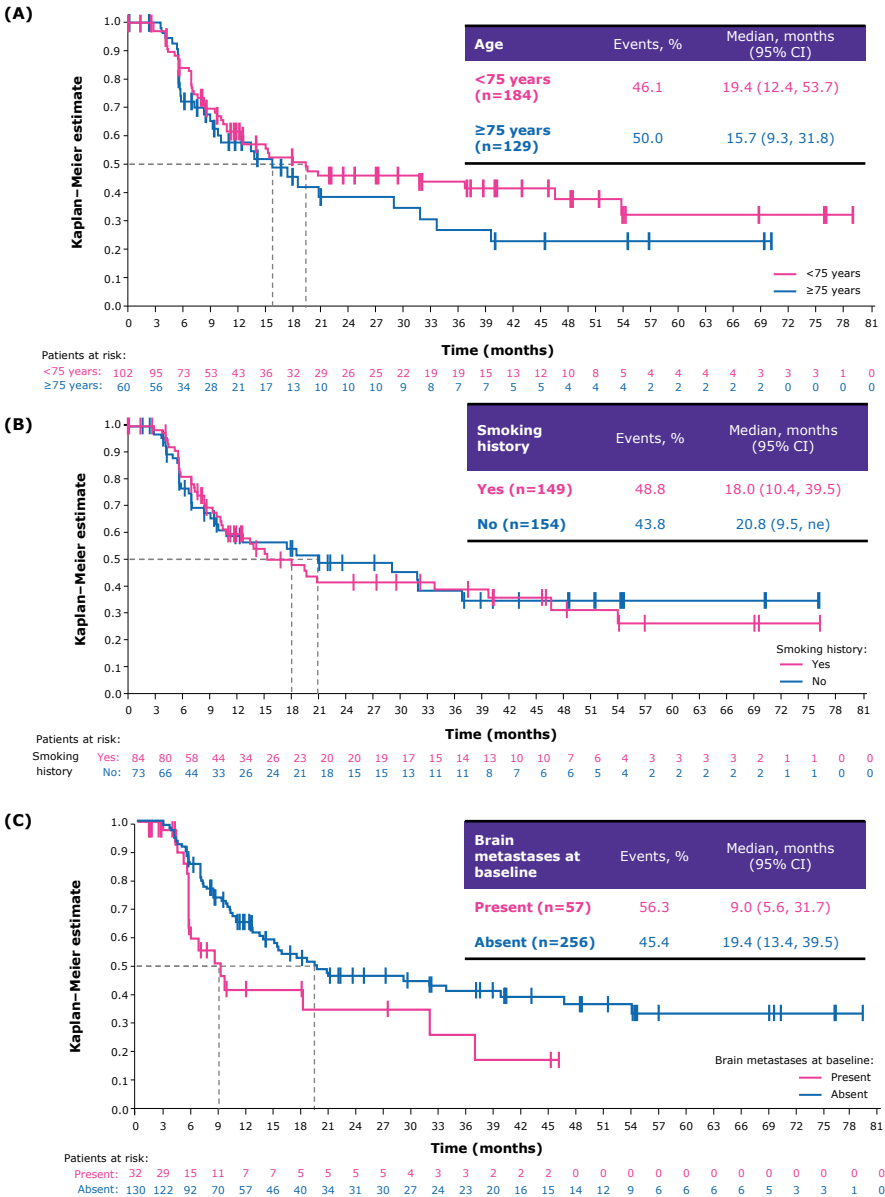
# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

Supplementary Figure S4. DOR\* KM curves according to patient (A) age, (B) smoking status, and (C) presence of brain metastases at baseline



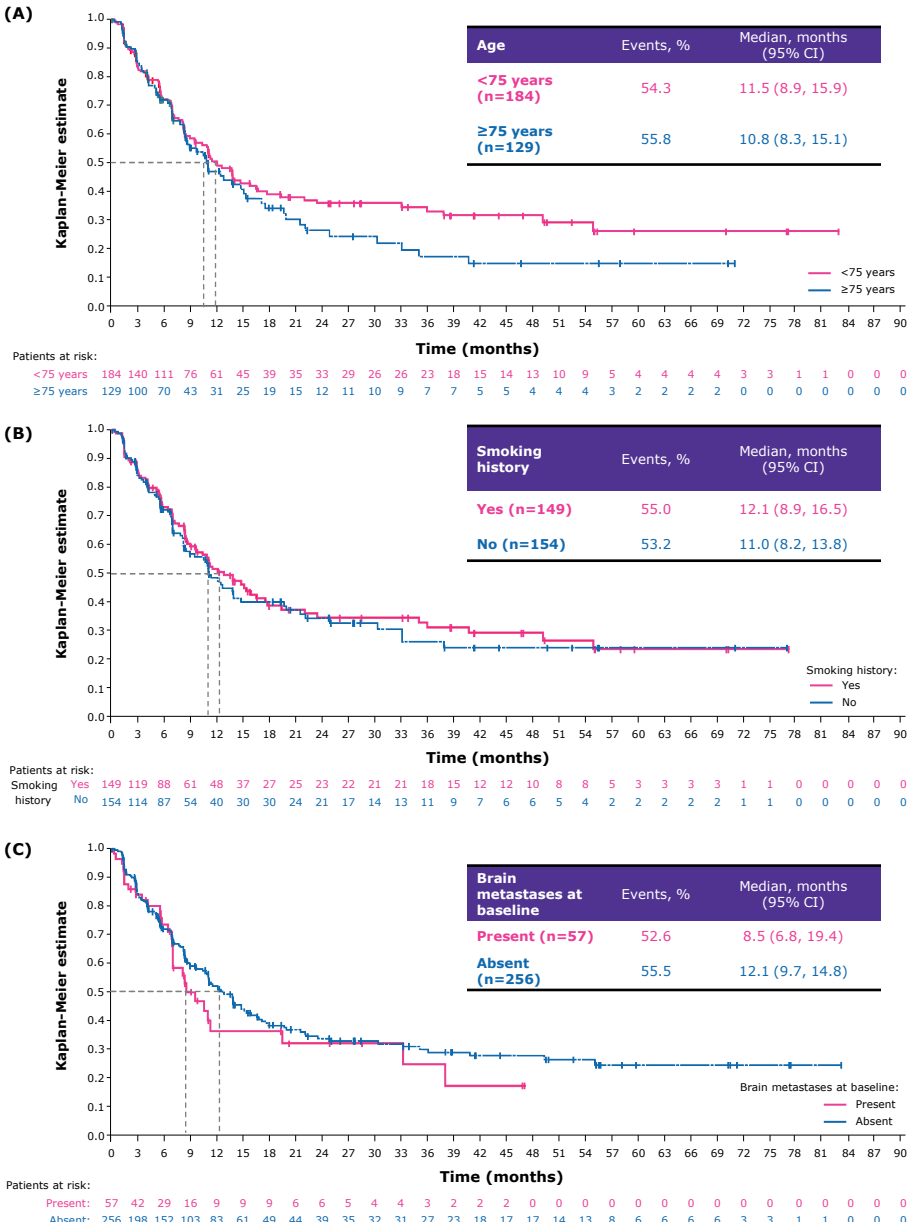
# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

**Supplementary Figure S5. PFS KM curves according to patient (A) age, (B) smoking history, and (C) presence of brain metastases at baseline**



Abbreviations: CI, confidence interval; KM, Kaplan-Meier; PFS, progression-free survival.

# Long-term outcomes with tepotinib for clinically relevant subgroups of patients (pts) with *MET* exon 14 (*MET*ex14) skipping NSCLC in the VISION study: A $\geq 3$ -year follow-up

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## SUPPLEMENTARY RESULTS

**Supplementary Figure S6. Swimmer plots highlighting duration of tepotinib treatment in patients with brain tumors as target lesions evaluable by RANO-BM. (A) Patients receiving tepotinib in 1L (n=10), and (B) patients receiving tepotinib in 2L+ (n=5)**

