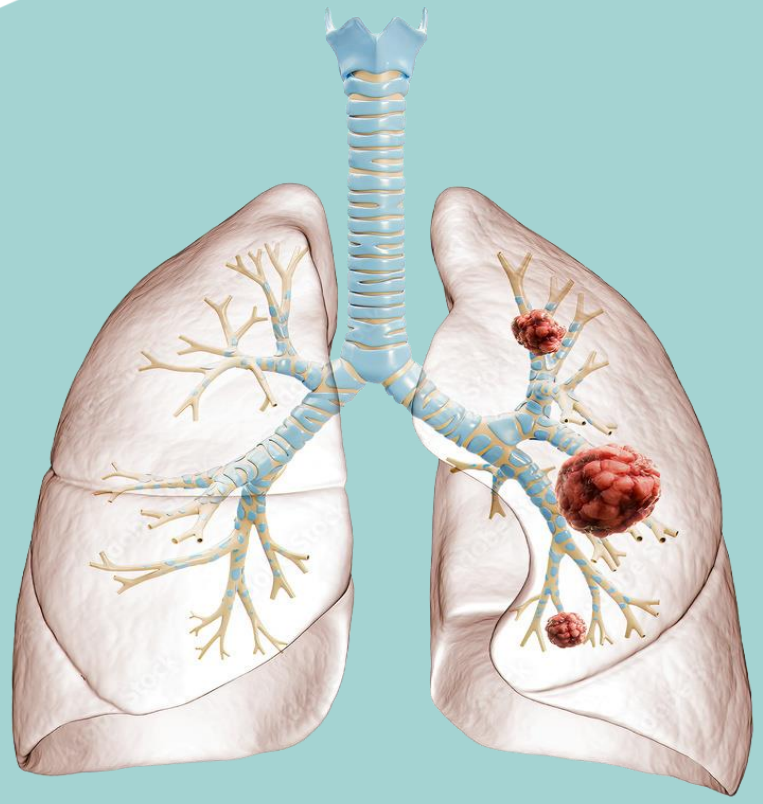


VISION OVERVIEW DECK

For additional resources, please visit our US Medical Resources Website Oncology page at https://medical.emdserono.com/en_US/medinfo/therapeutic-areas/oncology.html

©2026 Merck KGaA, Darmstadt, Germany or its affiliates. All rights reserved.
EMD Serono is the Healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada.
TEPMETKO is a registered trademark of Merck KGaA, Darmstadt, Germany or its affiliates.
US-TEP-00983 08/26

EMD SERONO

Table of Contents

1 NSCLC disease and background
2 Selected safety information
3 Indication, dosage, and administration
4 VISION clinical trial
  a Study design (Cohorts A and C)
  b Main data cut-offs (timeline & population)
5 VISION efficacy data
6 VISION safety data

NSCLC, non-small cell lung cancer.

NSCLC DISEASE AND BACKGROUND

Lung Cancer: Key US 2026 Statistics[1-4]

229,410 new cases of lung cancer are estimated in the US in 2026[1]

71
Median age at diagnosis[1]
(all cases: patients with driver mutations tend to be younger)[2]

229,410
New cases of lung cancer[1]
118,500 in women[3]
110,910 in men[3]

124,990
Deaths from lung cancer[1]
61,950 in women[3]
63,040 in men[3]

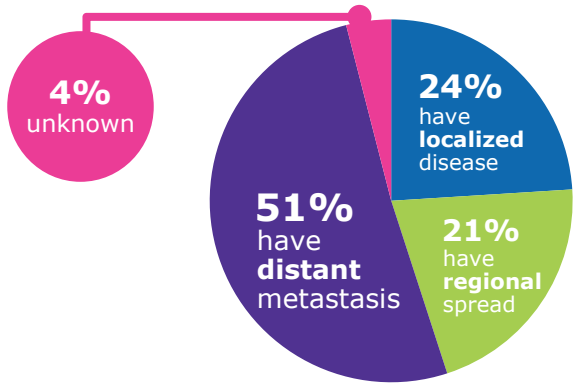
NSCLC accounts for 77% of these:
~176,646 patients[3]

~3% of these patients have *MET*ex14 skipping NSCLC:
~5,299 patients[4]

One patient with NSCLC harboring *MET*ex14 is diagnosed **every ~96 minutes***

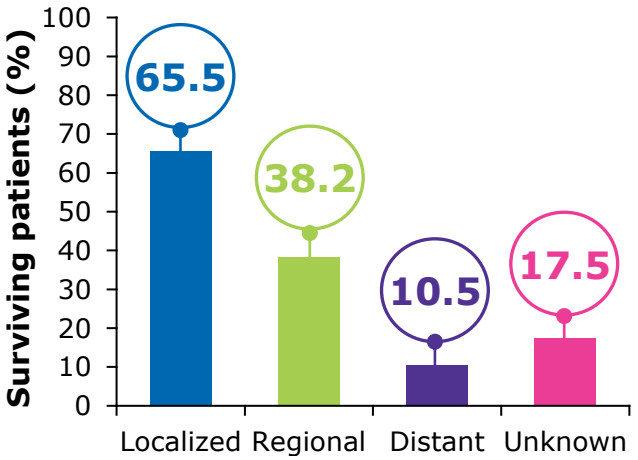
15 patients with NSCLC harboring *MET*ex14 are diagnosed **every day***

Stage at diagnosis[1]



~51% of patients with lung cancer are diagnosed with advanced or metastatic disease with a 5-year survival rate of 10.5%[1]

5-year relative survival by stage at diagnosis (2016–2022)[1]



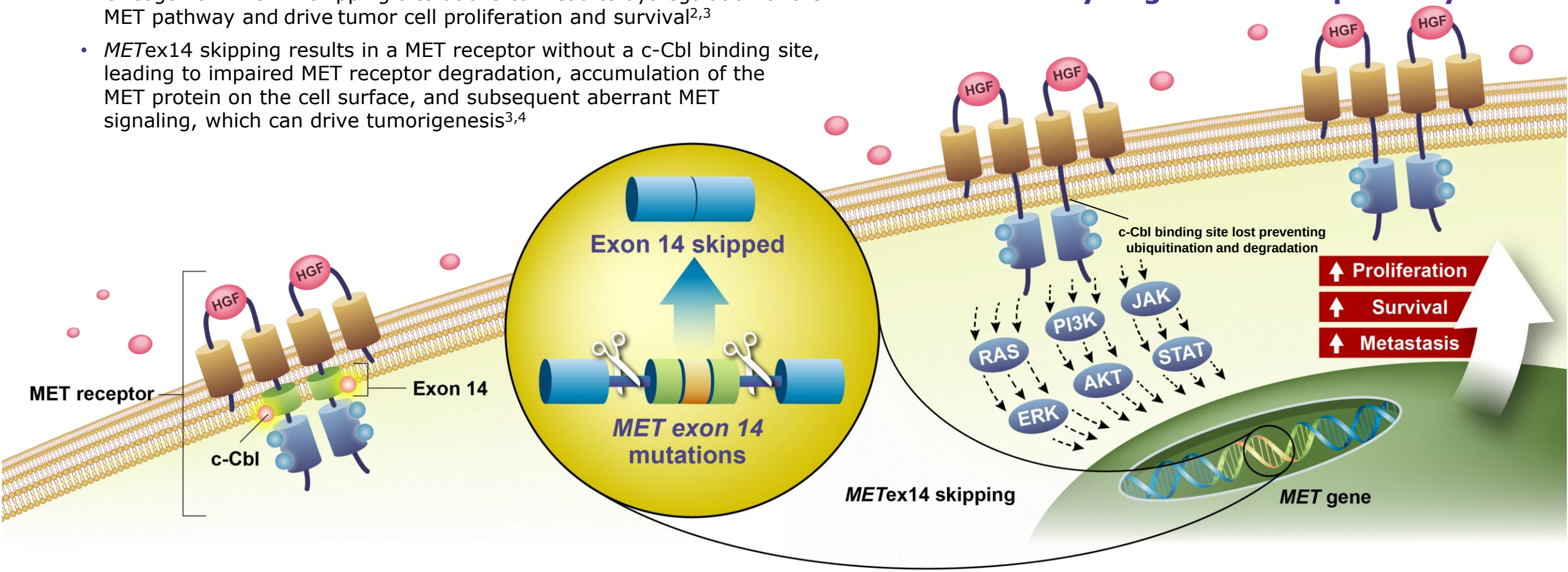
*Calculation: number of patients per year (5,299)/days in calendar year (365)=16.
*MET*ex14, *MET* exon 14; NSCLC, non-small cell lung cancer.

References: 1. Cancer Stat Facts: Lung and Bronchus Cancer. SEER Program, National Cancer Institute. https://seer.cancer.gov/statfacts/html/lungb.html (accessed July 2026); **2.** Suidan AM, et al. *J Glob Oncol*. 2019;5:1–8; **3.** Key Statistics for Lung Cancer. American Cancer Society. https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html (accessed July 2026); **4.** Salgia R, et al. *Can Treat Rev*. 2020;87:102022.

MET Signaling Can Drive Tumor Growth and Progression[1]

- MET is a receptor tyrosine kinase encoded by the *MET* gene[1]
- Oncogenic *MET*ex14 skipping alterations can lead to dysregulation of the MET pathway and drive tumor cell proliferation and survival[2,3]
- *MET*ex14 skipping results in a MET receptor without a c-Cbl binding site, leading to impaired MET receptor degradation, accumulation of the MET protein on the cell surface, and subsequent aberrant MET signaling, which can drive tumorigenesis[3,4]

*MET*ex14 skipping and dysregulated MET pathway[4,5]



AKT, protein kinase B; c-Cbl, casitas B-lineage lymphoma; ERK, extracellular regulatory kinase; HGF, hepatocyte growth factor; JAK, Janus kinase; *MET*ex14, *MET* exon 14; PI3K, phosphoinositide 3-kinase; RAS, rat sarcoma; STAT, signal transducer and activator of transcription.

References: 1. Paik PK, et al. *N Engl J Med*. 2020;383(10):1–40; **2.** Tong JH, et al. *Clin Cancer Res*. 2016;22(12):3048–3056; **3.** Liang H, Wang M. *Onco Targets Ther*. 2020;13:2491–2510; **4.** Drilon A, et al. *J Thorac Oncol*. 2017;12(1):15–26; **5.** Wu YL, et al. *Cancer Treat Rev*. 2017; 61:70–81.

*MET*ex14 Skipping Alterations Are Primary Oncogenic Drivers in NSCLC[1–7]

Patients with *MET*ex14 skipping alterations:



Have been associated with **advanced disease** and a **poor prognosis**[2]



Tend to be **considerably older** vs patients with other oncogenic drivers (average age of 54 to 65 years in *ALK, ROS1, EGFR, KRAS, and BRAF*)[1]



Are more frequently current or former smokers (60%) than never smokers (40%)[6]



_MET_ex14 skipping is the primary oncogenic driver in:

- 3% of adenocarcinomas[4,5]
- 2% of squamous cell carcinomas[5]
- 8% of sarcomatoid carcinomas[5]



Median age at diagnosis in patients with *MET*ex14 skipping alterations[7]:

~73 years

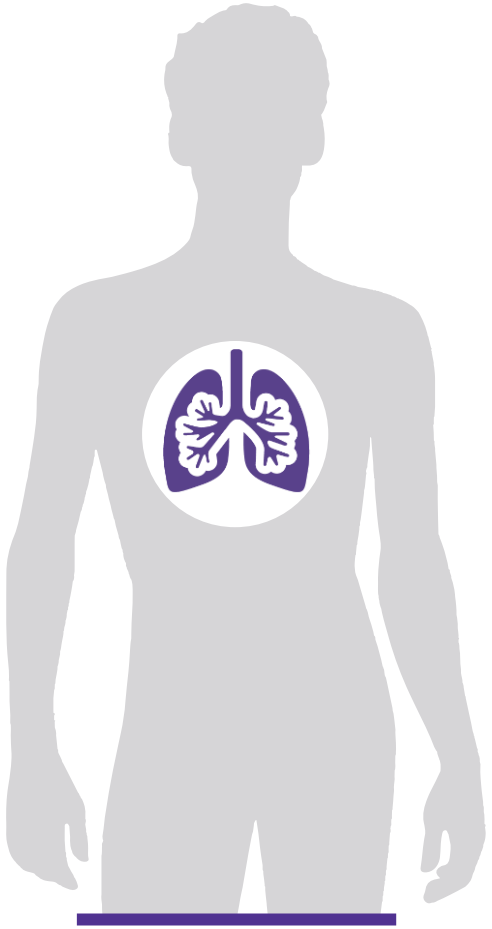
Testing to identify patients with *MET*ex14 skipping alterations can help inform treatment decisions[2,3]

ALK, anaplastic lymphoma kinase gene; *BRAF*, proto-oncogene B-Raf; *EGFR*, epidermal growth factor receptor gene; *KRAS*, Ki-ras2 gene; *MET*ex14, *MET* exon 14; NSCLC, non-small cell lung cancer; *ROS1*, ROS proto-oncogene 1.

References: 1. Tong JH, et al. *Clin Cancer Res*. 2016;22(12):3048–3056; **2.** Awad MM, et al. *Lung Cancer*. 2019;133:96–102; **3.** Salgia R. *Mol Cancer Ther*. 2017;16(4):555–565; **4.** Frampton GM, et al. *Cancer Discov*. 2015;5:850–859; **5**. Schrock AB, et al. *J Thorac Oncol*. 2016;11:1493–5102; **6.** Wolf J, et al. Presented at ENA, 2018, Poster 403; **7.** Khan A. *Int J Mol Sci*. 2026;27(13):5883.

SELECTED SAFETY INFORMATION

Summary of Warnings and Precautions: Interstitial Lung Disease/Pneumonitis[1]



ILD/pneumonitis, which can be fatal, occurred in patients treated with tepotinib	
ILD/pneumonitis All grades ≥Grade 3	 2% 1 case; this event resulted in death
Discontinuation of tepotinib due to ILD/pneumonitis	1% (n=5)

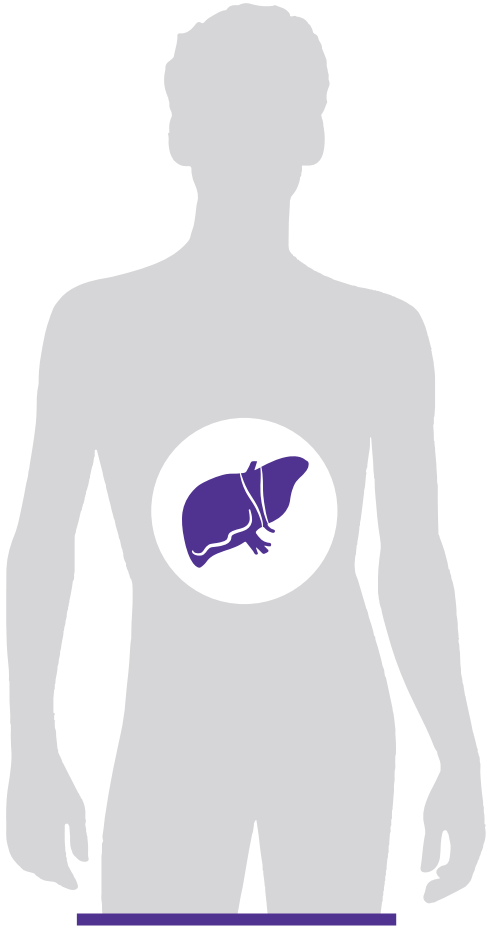
Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever)

Immediately **withhold** tepotinib in patients with suspected ILD/pneumonitis and **permanently discontinue** if no other potential causes of ILD /pneumonitis are identified

ILD, interstitial lung disease.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Summary of Warnings and Precautions: Hepatotoxicity[1]



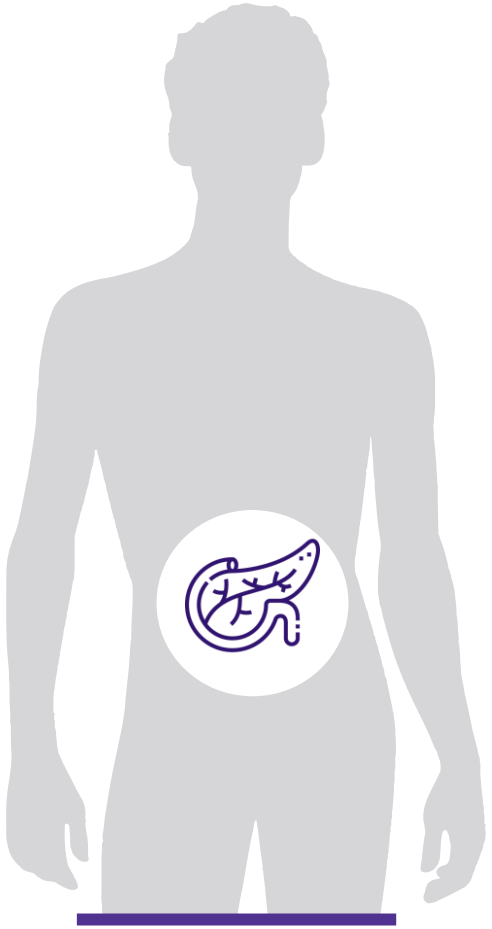
Hepatotoxicity, which can be fatal, occurred in patients treated with tepotinib	
Increased ALT/increased AST All grades Grade 3 or 4 increased ALT/AST	 18% 4.7%
Fatal AR of hepatic failure	0.2% (n=1)
Discontinuation of tepotinib due to increased ALT/AST	0.8% (n=4)
Median time to onset of Grade ≥3 increased ALT/AST	47 days (range: 1–262)

Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of tepotinib, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin*

Based on the severity of the AR, **withhold, dose reduce**, or **permanently discontinue** tepotinib

*Please note that this is as per prescribing information but could be inconsistent with practice patterns.
ALT, alanine aminotransferase; AR, adverse reaction; AST, aspartate aminotransferase.
Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Summary of Warnings and Precautions: Pancreatic Toxicity[1]



Elevations in amylase and lipase levels occurred in patients treated with tepotinib	
Increased amylase and/or lipase	
All grades	13%
Grade 3	5%
Grade 4	1.2%

Monitor amylase and lipase at baseline and regularly during treatment with tepotinib

Based on the severity of the adverse drug reaction, **temporarily withhold, dose reduce, or permanently discontinue** tepotinib

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Summary of Warnings and Precautions: Embryo-Fetal Toxicity and Drug Interactions[1]



- Based on findings in animal studies and its mechanism of action, tepotinib can cause fetal harm when administered to pregnant women
- Oral administration of tepotinib to pregnant rabbits during the period of organogenesis resulted in malformations (teratogenicity) and anomalies at exposures less than the human exposure based on AUC at the 450 mg daily clinical dose

Advise pregnant women of the potential risk to a fetus

Advise females of reproductive potential or males with female partners of reproductive potential to use effective contraception during treatment with tepotinib and for one week after the last dose

Drug interactions

- Avoid concomitant use of tepotinib with certain **P-gp substrates** where minimal concentration changes may lead to serious or life-threatening toxicities
- If concomitant use is unavoidable, reduce the P-gp substrate dosage if recommended in its approved product labeling

AUC, area under the curve; P-gp, P-glycoprotein.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Selected Safety Information[1]

Fatal adverse reactions

- **Fatal adverse reactions** occurred in one patient (0.3%) due to pneumonitis, one patient (0.3%) due to hepatic failure, one patient (0.3%) due to dyspnea from fluid overload, one patient (0.3%) due to pneumonia, one patient (0.3%) due to sepsis, and one patient (0.3%) due to unknown cause

Serious adverse reactions

- **Serious adverse reactions** occurred in 51% of patients who received tepotinib. Serious adverse reactions in >2% of patients included pleural effusion (6%), pneumonia (6%), edema (5%), general health deterioration (3.8%), dyspnea (3.5%), musculoskeletal pain (2.9%), and pulmonary embolism (2.2%)

Most common adverse reactions

- **The most common adverse reactions (≥20%)** in patients who received tepotinib were edema (81%), nausea (31%), fatigue (30%), musculoskeletal pain (30%), diarrhea (29%), dyspnea (24%), rash (21%), and decreased appetite (21%)

Clinically relevant adverse reactions

- **Clinically relevant adverse reactions** in <10% of patients who received tepotinib included ILD/pneumonitis, fever, dizziness, pruritis, and headache

Selected laboratory abnormalities

- **Selected laboratory abnormalities (≥20%)** from baseline in patients receiving tepotinib in descending order were decreased albumin (81%), increased creatinine (60%), decreased lymphocytes (57%), increased ALP (52%), increased ALT (50%), increased AST (40%), decreased sodium (36%), decreased hemoglobin (31%), increased GGT (29%), increased potassium (26%), increased amylase (25%), decreased leukocytes (25%), decreased platelets (24%), and increased lipase (21%)

Most common Grade 3-4 laboratory abnormalities

- **The most common Grade 3-4 laboratory abnormalities (≥2%)** in descending order were decreased lymphocytes (15%), decreased albumin (9%), decreased sodium (9%), increased GGT (6%), increased amylase (5%), increased lipase (5%), increased ALT (4.9%), increased AST (3.6%), and decreased hemoglobin (3.6%)

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyltransferase; ILD, interstitial lung disease.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

INDICATION, DOSAGE, AND ADMINISTRATION

FDA-Approved Indication, Dosage and Administration[1]

- TEPMETKO® (tepotinib) is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (mNSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations
- The recommended dosage of tepotinib is 450 mg (two 225 mg tablets) orally once daily with food until disease progression or unacceptable toxicity

AR, adverse reaction; FDA, Food and Drug Administration; mNSCLC, metastatic non-small cell lung cancer.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Tepotinib Dosage and Administration: Patient Selection[1]

- Select patients for treatment with tepotinib based on the presence of *MET*ex14 skipping alterations in plasma or tumor specimens
- Testing for the presence of *MET*ex14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained
- If an alteration is not detected in a plasma specimen, re-evaluate the feasibility of biopsy for tumor tissue testing

FDA, US Food and Drug Administration; *MET*ex14, *MET* exon 14; NSCLC, non-small cell lung cancer.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Tepotinib Dosage and Administration: Recommended Dosage and Modification[1]

Recommended dosage





- The recommended dosage of tepotinib is 450 mg* (two 225 mg tablets) orally **once daily with food** until disease progression or unacceptable toxicity
- Instruct patients to take their dose at approximately the same time every day and to swallow tablets whole. Do not chew, crush, or split tablets. Patients who have difficulty swallowing solids can disperse tablets in water
- Advise patients not to make up a missed dose within 8 hours of the next scheduled dose
- If vomiting occurs after taking a dose, advise patients to take the next dose at the scheduled time

Dose modifications for ARs

- The recommended dose reduction of tepotinib for the management of ARs is 225 mg orally once daily
- Permanently discontinue tepotinib in patients who are unable to tolerate the 225 mg dose
- See the full Prescribing Information for recommended dosage modifications of tepotinib

*Equivalent to 500 mg tepotinib hydrochloride hydrate.
AR, adverse reaction.
Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

VISION CLINICAL TRIAL

VISION: A Single-arm, Open-label, Multicenter, Non-randomized, Multicohort Study[1-3]

Tepotinib in adult patients with advanced or metastatic NSCLC harboring *MET*ex14 skipping alterations

Eligibility:

- Advanced, metastatic *MET*ex14+ NSCLC*
- *EGFR* wild-type and *ALK* negative status
- ≥1 measurable lesion by RECIST v1.1
- 1L, 2L, or 3L of therapy[2,3]
- ECOG PS 0–1

Exclusions:

- Symptomatic CNS metastases
- Clinically significant uncontrolled cardiac disease
- Prior treatment with any MET or HGF inhibitor

Cohort A†
*MET*ex14 skipping
Detection of alterations in plasma or tissue

Cohort B:
MET amplification
Not included in this presentation

Cohort C‡
*MET*ex14 skipping
Detection of alterations in plasma or tissue

Confirmatory Part 2 of study

Tepotinib
500 mg§ oral QD
(450 mg active moiety)

Tepotinib was administered until disease progression or unacceptable toxicity

Major efficacy outcome

- Confirmed ORR by RECIST v1.1 as evaluated by BIRC‖

Additional efficacy outcome

- DOR by BIRC‖, PFS[2,3], OS[2,3]
- Safety (per NCI-CTCAE v4.03)[2,3]

*Identification of *MET*ex14 skipping was prospectively determined using central laboratories employing either a PCR-based or NGS-based clinical trial assay using tissue and/or plasma samples. An FDA-approved test for detection of *MET*exon14 skipping alterations in NSCLC for selecting patients for treatment with tepotinib is not available. †Cohort A enrollment began on September 13, 2016. ‡Cohort C enrolment began on August 8, 2019. §450 mg active moiety. ‖Per IRC for February 20, 2022, cut-off.[2,3].

1L, first line; 2L, second line; 3L, third line; *ALK*, anaplastic lymphoma kinase; BIRC, Blinded Independent Review Committee; CNS, central nervous system; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; *EGFR*, epidermal growth factor receptor; FDA, US Food and Drug Administration; HGF, hepatocyte growth factor; IRC, Independent Review Committee; *MET*ex14, *MET* exon 14; NCI-CTCAE, National Cancer Institute - Common Terminology Criteria for Adverse Events; NGS, next-generation sequencing; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PCR, polymerase chain reaction; PFS, progression-free survival; QD, once daily; RECIST, Response Evaluation Criteria in Solid Tumors.

References: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf; **2.** Smit EF, et al. Presented at ESMO, 2022, Abstract 985P; **3.** Thomas M, et al. Presented at WCLC, 2022. Abstract OA03.05.

*MET*ex14 Skipping Patient Populations in VISION[1-16]

Main data cut-offs:

- January 2020 data cut-off (when 99/152 patients in Cohort A had ≥9 months of follow-up data)[1]: Primary efficacy analysis; not included in this deck
- July 2020 data cut-off[2,3] (Data submitted to FDA and included in USPI; full Cohort A and safety data for Cohorts A+C)
- February 2021[4,5] (not included in this deck) and February 2022[6-8] (see Backup section)
- November 2022 data cut-off[9-11] (Updated USPI after full approval; long-term follow-up based on full Cohorts A+C)
- May 2024 data cut-off[12-16] (≥3-year follow-up data)

July 2020 Data Cut-off[2,3] (Cohort A - Initial analysis)

Safety set (N=255)
All treated patients in Cohorts A + C

Efficacy analysis set (N=152) A
Full Cohort

Treatment naïve n=69	2L+ n=83

February 2022 Data Cut-off[6-8] (>9 months' follow-up)

Safety set (N=313)
All treated patients in Cohorts A + C

Confirmatory efficacy analysis set (N=161)
Full Cohort C

Treatment naive n=95	2L+ n=66

Efficacy analysis set (N=313)
Cohorts A + C

Treatment naive n=164	2L+ n=149

November 2022 Data Cut-off[9-11]

Safety set (N=313)
All treated patients in Cohorts A + C

Efficacy analysis set (N=313) A + C
Full Cohort

Treatment naïve n=164	2L+ n=149

May 2024 Data Cut-off[12-16] (≥3-year follow-up)

Safety set (N=313)
All treated patients in Cohorts A + C

Efficacy analysis set (N=313) A + C
Full Cohort

Treatment naïve n=164	2L+ n=149

Long-term responders n=26

2L+, second-or-later line; FDA, US Food and Drug Administration; *MET*ex14, *MET* exon 14; USPI, United States Prescribing Information.

References: 1. Paik PK, et al. *N Engl J Med.* 2020;383(10):931-943; **2.** TEPMETKO® (tepotinib) [prescribing information]. EMD Serono; 2021; **3.** Le X, et al. *Clin Cancer Res.* 2022;28(6):1117-1126; **4.** Thomas M, et al. Presented at DGHO Annual Meeting, 2021, Abstract 52; **5.** Garassino M, et al. Presented at AMCP Annual Meeting, 2022, Abstract C6; **6.** Thomas M, et al. Presented at WCLC, 2022, Abstract OA03.05; **7.** Smit EF, et al. Presented at ESMO, 2022, Abstract 985P; **8.** Griesinger F, et al. Presented at ELCC, 2023, Poster 34P; **9.** Paik P, et al. Presented at ASCO Annual Meeting, 2023, Abstract 9060; **10.** Mazieres J, et al. *JAMA Oncol*. 2023;9(9):1260–1266; **11.** TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf. **12.** Mazières J, et al. Presented at ELCC, 2025, Poster 81P. **13.** Felip E, et al. Presented at WCLC, 2025, Poster P3.12.40. **14.** Viteri S, et al. Presented at ESMO, 2025, Poster 1995P. **15.** Griesinger F, et al. Presented at ESMO, 2025, Poster 1996P; **16.** Paik P, et al. Presented at ASCO, 2026, Poster 402P.

Timeline[1-19]

January 2020 data cut-off

Paik PK, et al. *N Engl J Med*. 2020 (Cohort A, ≥9 months follow-up, N=99 [efficacy], N=152 [safety])[1]

Le X, et al. *Clin Cancer Res*. 2022 (Cohort A, 16.4 months median follow-up, N=152 [efficacy], N=255 [safety])[2]

July 2020 data cut-off

USPI February 2021[3] (based on accelerated, conditional approval)

February 2021 data cut-off

Thomas M, et al. DGHO, 2021 (Cohorts A+C, ≥3 months follow-up)[4]

Garassino M, et al. AMCP, 2022 (Cohorts A+C, ≥3 months follow-up)[5]

N=275 (efficacy), N=291 (safety)[4,5]

February 2022 data cut-off

Thomas M, et al. WCLC, 2022 (Cohort C, >9 months follow-up, N=161 [efficacy & safety])[6]

Smit EF, et al. ESMO, 2022 (Cohorts A+C, N=313 [efficacy & safety])[7]

Griesinger F, et al. ELCC, 2023 (Cohorts A+C, N=313 [efficacy & safety])[8]

Paik P, et al. ASCO, 2023 (Cohorts A+C, N=313 [efficacy & safety])[9]

November 2022 data cut-off

Ahn M-J, et al. WCLC, 2023 (Cohorts A+C (Asian patients), N=106 [efficacy & safety])[10]

Rolfo C, et al. ESMO, 2023 (Cohorts A+C, N=313 [LBx and TBx])[11]

Viteri S, et al. ESMO, 2023 (Cohorts A+C, N=313 [2L+, 149; 2L, 92; 3L+, 57] [efficacy, prior and post tepotinib])[12]

Full USPI based on traditional approval in Feb 2024[13]: Mazieres J, et al. *JAMA Oncology*, 2023 (Cohorts A+C, N=313 [long-term follow-up)[14]

May 2024 data cut-off

Mazières J, et al. ELCC, 2025 (Cohorts A+C, N=313 [efficacy & safety; ≥3-year follow-up])[15]

Felip E, et al. WCLC, 2025 (Cohorts A+C, N=313 [safety; ≥3-year follow-up])[16]

Viteri S, et al. ESMO, 2025 (Cohorts A+C, N=313 [efficacy; ≥3-year follow-up])[17]

Griesinger F, et al. ESMO, 2025 (Cohorts A+C, N=313 [efficacy & safety; ≥3-year follow-up])[18]

Paik P, et al. ASCO, 2026 (Cohorts A+C [long-term responders], N=26 [efficacy & safety; ≥3-year follow-up])[19]

USPI, United States Prescribing Information.

References: 1. Paik PK, et al. *N Engl J Med.* 2020;383(10):931-943; **2.** Le X, et al. *Clin Cancer Res.* 2022;28(6):1117-1126; **3.** TEPMETKO® (tepotinib) [prescribing information]. EMD Serono, Inc., Rockland, MA; 2021; **4.** Thomas M, et al. Presented at DGHO Annual Meeting, 2021, Abstract 52; **5.** Garassino M, et al. Presented at AMCP Annual Meeting, 2022, Abstract C6; **6.** Thomas M, et al. Presented at WCLC, 2022, Abstract OA03.05; **7.** Smit EF, et al. Presented at ESMO, 2022, Abstract 985P; **8.** Griesinger F, et al. Presented at ELCC, 2023, Poster 34P; **9.** Paik P, et al. Presented at ASCO Annual Meeting, 2023, Abstract 9060; **10.** Ahn M-J, et al. Presented at WCLC 2023. Poster P2.11-02; **11.** Rolfo C, et al. Presented at ESMO, 2023, Poster 1382P; **12.** Viteri S, et al. Presented at ESMO 2023, Poster 1380P; **13.** TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf; 2024; **14.** Mazieres J, et al. *JAMA Oncol*. 2023;9(9):1260–1266; **15.** Mazières J, et al. Presented at ELCC, 2025, Abstract 81P; **16.** Felip E, et al. Presented at WCLC, 2025, Poster P3.12.40. **17.** Viteri S, et al. Presented at ESMO, 2025, Poster 1995P; **18.** Griesinger F, et al. Presented at ESMO, 2025, Poster 1996P; **19.** Paik P, et al. Presented at ASCO, 2026, Poster 402P.

VISION EFFICACY DATA

Due to the single-arm design of the VISION Trial for TEPMETKO, no formal statistical comparisons were conducted, and data, including PFS and OS, were analyzed in a descriptive manner.

For these reasons, results from this analysis should be interpreted with caution.

Baseline Characteristics by Line of Therapy[1,2]

May 2024 cut-off

- Of 313 patients enrolled, median age was 72 years (range 41-94); the majority (66.5%) were T+

Baseline characteristics		Cohorts A+C		
		Overall (N=313)	1L (n=164)	2L+ (n=149)
Median age, years (range)		72.0 (41–94)	74.0 (47–94)	70.8 (41–89)
Sex, n (%)	Male	154 (49.2)	83 (50.6)	71 (47.7)
	Female	159 (50.8)	81 (49.4)	78 (52.3)
Race,* n (%)	White	195 (62.3)	112 (68.3)	83 (55.7)
	Asian	106 (33.9)	50 (30.5)	56 (37.6)
ECOG PS,† n (%)	0	81 (25.9)	45 (27.4)	36 (24.2)
	1	231 (73.8)	118 (72.0)	113 (75.8)
Smoking history,‡ n (%)	Yes	149 (47.6)	88 (53.7)	61 (40.9)
	No	154 (49.2)	75 (45.7)	79 (53.0)
Histology,§ adenocarcinoma, n (%)		252 (80.5)	131 (79.9)	121 (81.2)
***MET*ex14 skipping detection, n (%)**	TBx	208 (66.5)	111 (67.7)	97 (65.1)
	LBx	178 (56.9)	95 (57.9)	83 (55.7)

- In Cohorts A+C, treatment was ongoing in 18 patients
  - In 1L setting, treatment was ongoing in 12 patients while in the previously treated setting, treatment was ongoing in six patients
  - In total, 99 patients had a treatment duration of ≥12 months (58 in 1L and 41 in 2L+), of whom four patients (1 in 1L and 3 in 2L+) received treatment for ≥60 months[3]

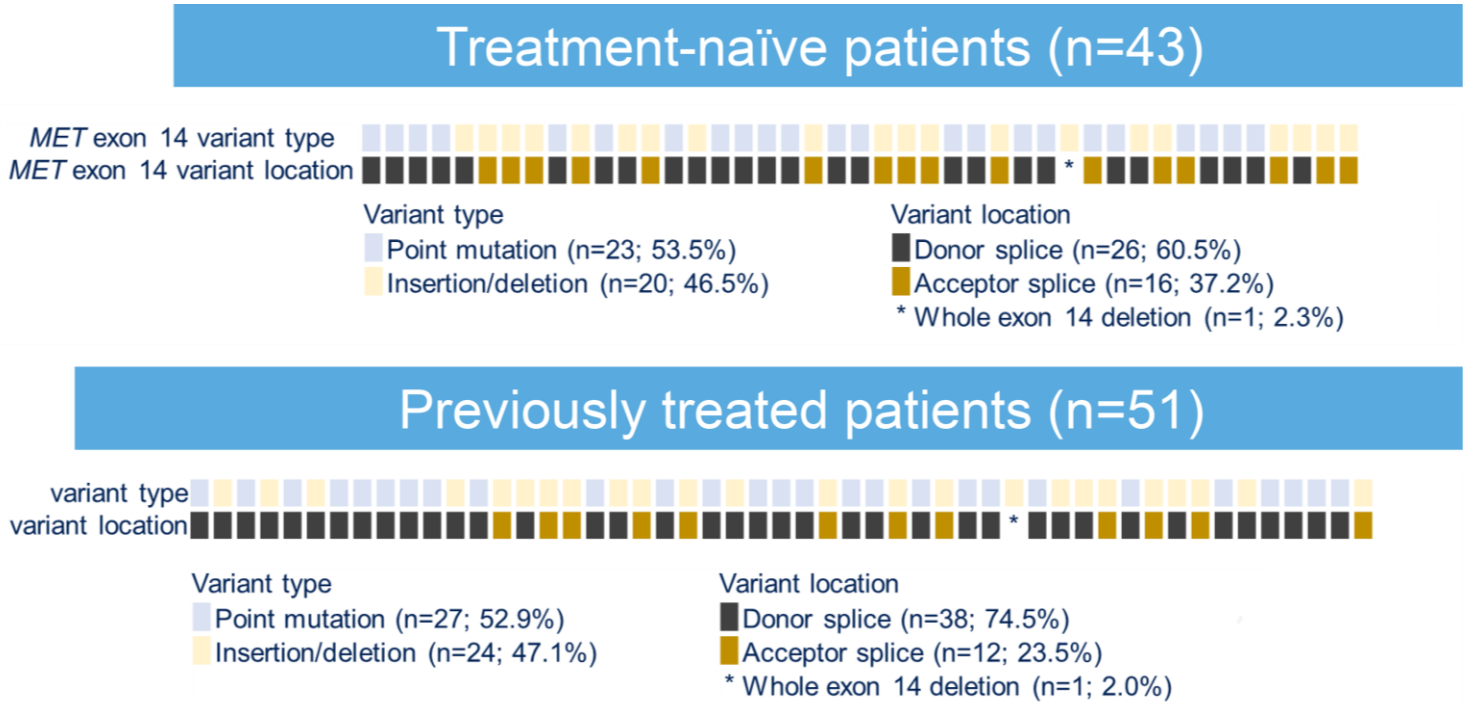
Note: 'T+' used here denotes 'known TBx positives'

*Nine patients had race reported as "other' or missing or not collected at the site. †One 1L patient was ECOG PS 2. ‡Smoking history was missing in 10 patients (one in 1L and nine in 2L+). §Fifty-nine patients had histologies other than adenocarcinoma (32 in 1L and 27 in 2L+), and two had missing histology information (one each in 1L and 2L+).
1L, first line; 2L+, second-or-later line; ECOG PS, Eastern Cooperative Oncology Group performance status; LBx, liquid biopsy; *MET*ex14, *MET* exon 14; TBx, tissue biopsy; T+, known positive detection of *MET*ex14 skipping in tissue biopsy (TBx).
Reference: 1. Viteri S, et al. Presented at ESMO, 2025, Poster 1995P; **2.** Griesinger F, et al. Presented at ESMO, 2025, Poster 1996P; 3. Mazières J, et al. Presented at ELCC, 2025, Poster 81P.

Mutational Profile at Baseline[1]

Jul 2020 cut-off

Mutational profile of *MET*-skipping alterations



Mutational profile based on liquid biopsies indicated a balanced distribution between *MET* indels and point mutations, as well as donor and acceptor splice sites in both treatment-naive and previously treated patients

EGFR amplification occurred in 1/43 treatment-naive patients (2.3%) and 8/51 previously treated patients (15.7%)

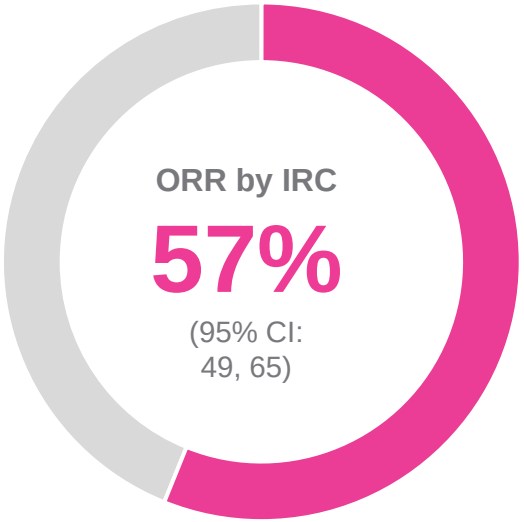
EGFR, epidermal growth factor receptor gene; *MET*ex14, *MET* exon 14.

Reference: 1. Paik PK, et al. Presented at ASCO Annual Meeting, 2021, Abstract 9012.

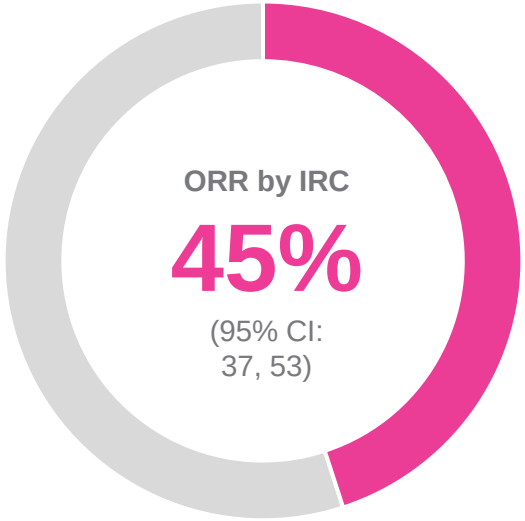
ORR[a,b] and DOR[1]

US PI
(Nov 2022 data)

Treatment-naive (n=164)



Previously treated (n=149)



Efficacy parameter	Treatment-naïve (n=164)	Previously Treated (n=149)
DOR		
Range in months[c]	1.3+, 56.6+	1.4+, 67.6+
Patients with DOR ≥6 months[c]	66%	66%
Patients with DOR ≥12 months[c]	40%	36%

+denotes ongoing response; [a]BIRC review. [b]Confirmed responses. [c]Based on observed duration of response.
BIRC, blinded independent review committee; CI, confidence interval; DOR, duration of response; IRC, Independent Review Committee; ORR, overall response rate.

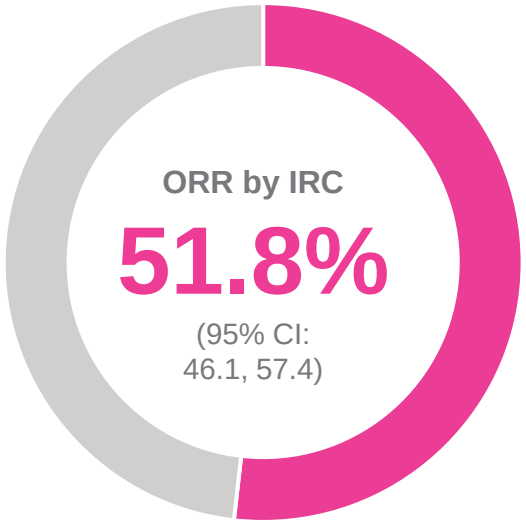
References: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Primary Endpoint: ORR[1,2]

May 2024 cut-off

Previously treated

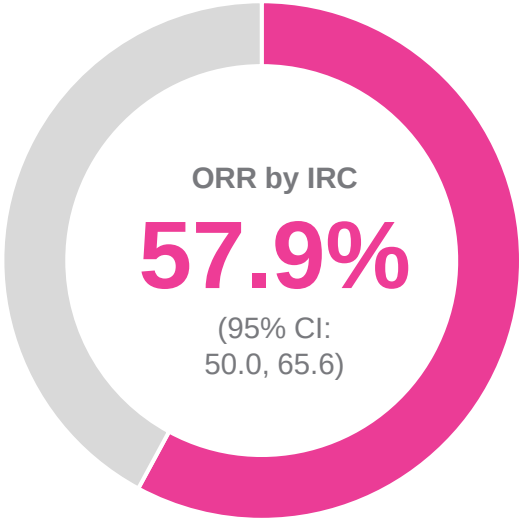
Overall (N=313)



T+ (n=208)
54.8% (95% CI: 47.8, 61.7)

L+ (n=178)
51.7% (95% CI: 44.1, 59.2)

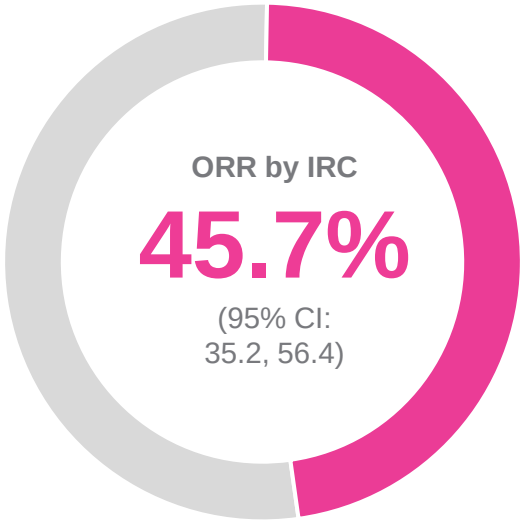
Treatment-naïve (n=164)



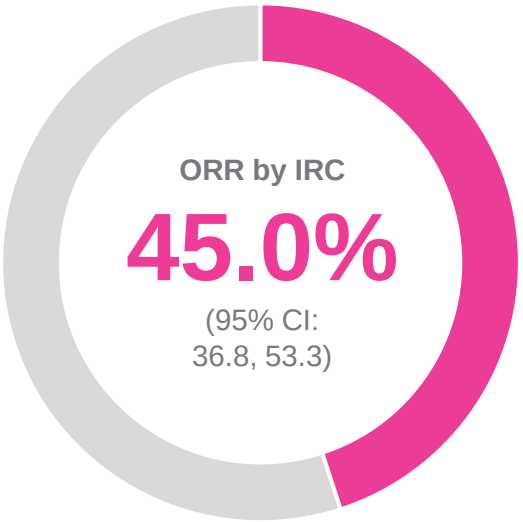
T+ (n=111)
59.5% (95% CI: 49.7, 68.7)

L+ (n=95)
58.9% (95% CI: 48.4, 68.9)

Second-line tepotinib (1 previous treatment) (n=92)



Second-line+ tepotinib (1 or more previous treatment) (n=149)



T+ (n=97)
49.5% (95% CI: 39.2, 59.8)

L+ (n=83)
43.4% (95% CI: 32.5, 54.7)

Note: 'T+' used here denotes 'known TBx positives'

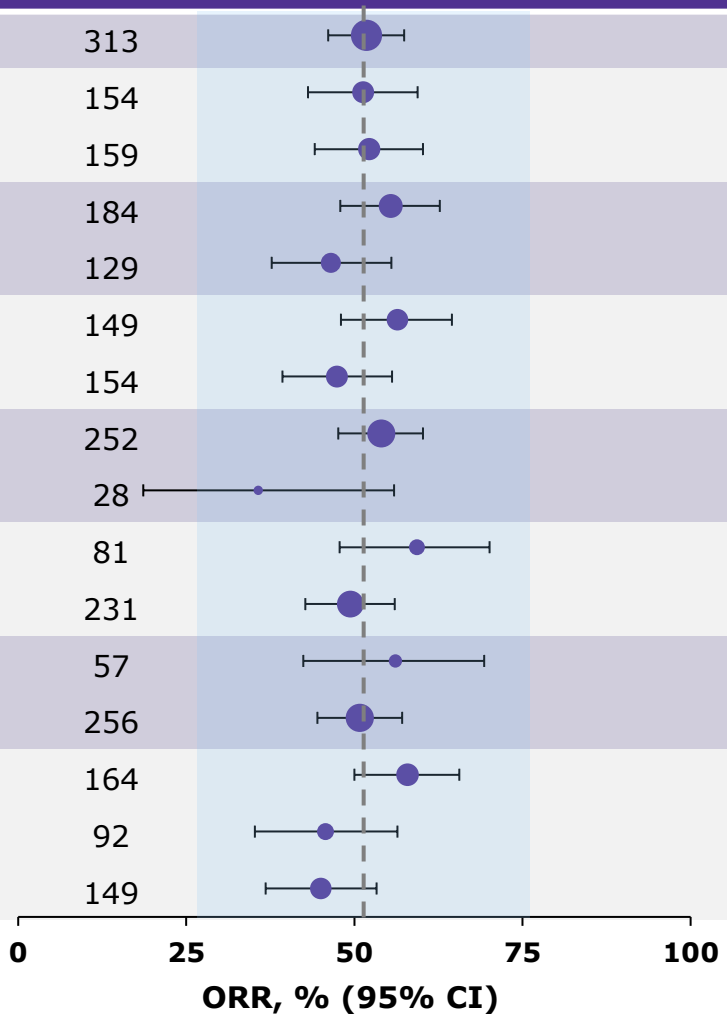
CI, confidence interval; IRC, Independent Review Committee; L+, positive for *MET*ex14 skipping in liquid biopsy; *MET*ex14, *MET* exon 14; ORR, overall response rate; T+, known positive for *MET*ex14 skipping in tissue biopsy (TBx).

References: 1. Mazières J, et al. Presented at ELCC, 2025, Abstract 81P. 2. Viteri S, et al. Presented at ESMO, 2025, Poster 1995P.

ORR by Baseline Characteristics[1]

May 2024 cut-off

Subgroup		n	ORR (95% CI)
Overall		313	51.8 (46.1, 57.4)
Sex	Male	154	51.3 (43.1, 59.4)
	Female	159	52.2 (44.1, 60.2)
Age	<75 years	184	55.4 (47.9, 62.7)
	≥75 years	129	46.5 (37.7, 55.5)
Smoking history*	Yes	149	56.4 (48.0, 64.5)
	No	154	47.4 (39.3, 55.6)
Histology†	Adenocarcinoma	252	54.0 (47.6, 60.2)
	Squamous	28	35.7 (18.6, 55.9)
ECOG PS‡	0	81	59.3 (47.8, 70.1)
	1	231	49.4 (42.7, 56.0)
Brain metastases at baseline§	Yes	57	56.1 (42.4, 69.3)
	No	256	50.8 (44.5, 57.1)
Line of therapy	1L	164	57.9 (50.0, 65.6)
	2L	92	45.7 (35.2, 56.4)
	2L+	149	45.0 (36.8, 53.3)



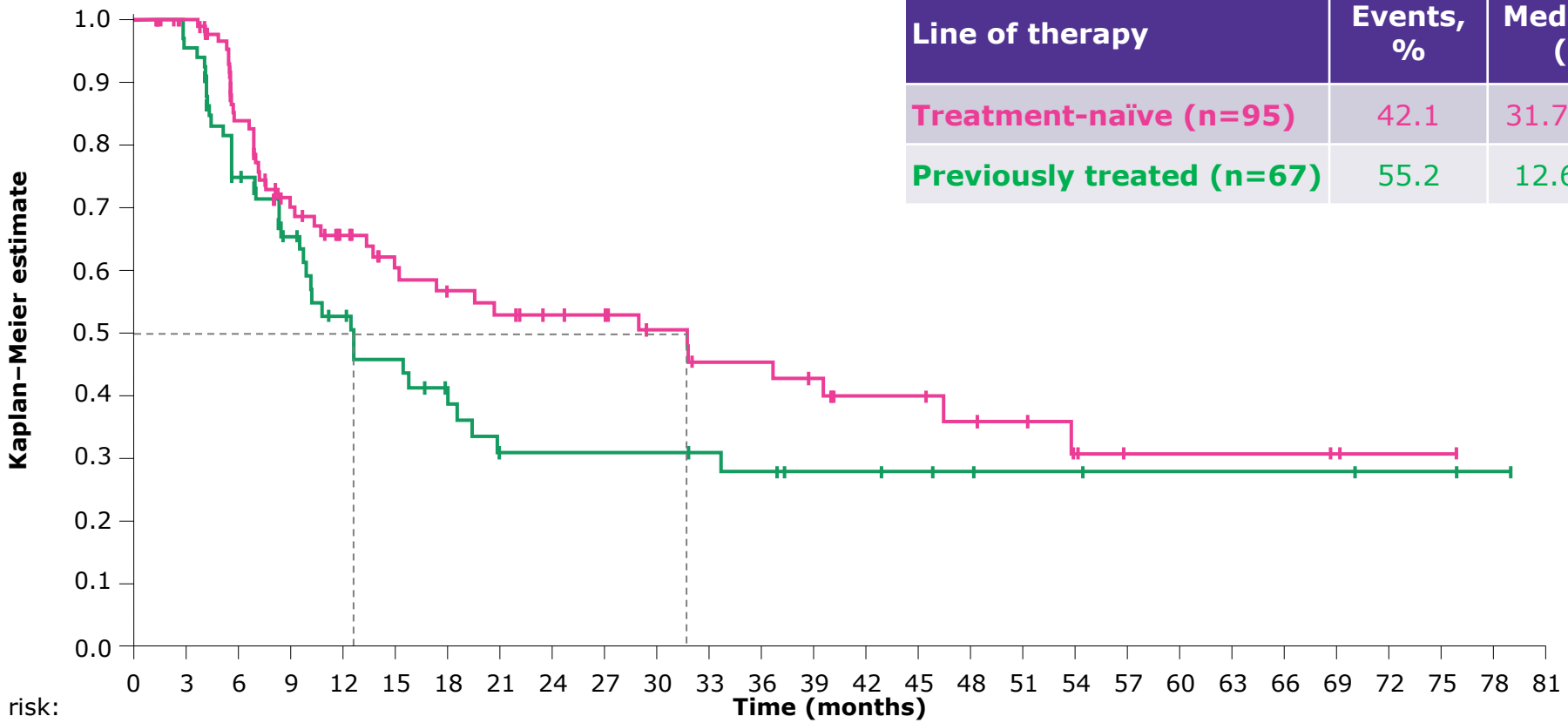
*Smoking history was missing for 10 patients. †Thirty-three patients had histology other than squamous and adenocarcinoma. ‡One patient had ECOG PS 2. §Identified at baseline (investigator or independent review).
1L, first line; 2L, second line; 2L+, second-or-later line; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; ORR, objective response rate.

Reference: 1. Griesinger F, et al. Presented at ESMO 2025, Poster 1996P.

DOR by Line of Therapy[1]

May 2024 cut-off

Line of therapy	Events, %	Median, months (95% CI)
Treatment-naïve (n=95)	42.1	31.7 (13.8, 46.4)
Previously treated (n=67)	55.2	12.6 (9.5, 18.5)



Patients at risk:																											
Treatment-naïve	95	88	63	49	40	33	30	28	25	24	20	17	17	15	11	11	9	8	5	3	3	3	3	2	1	1	0	0
Previously treated	67	63	44	32	24	20	15	11	11	11	11	10	9	7	7	6	5	4	4	3	3	3	3	3	2	2	1	0

CI, confidence interval; DOR, duration of response.

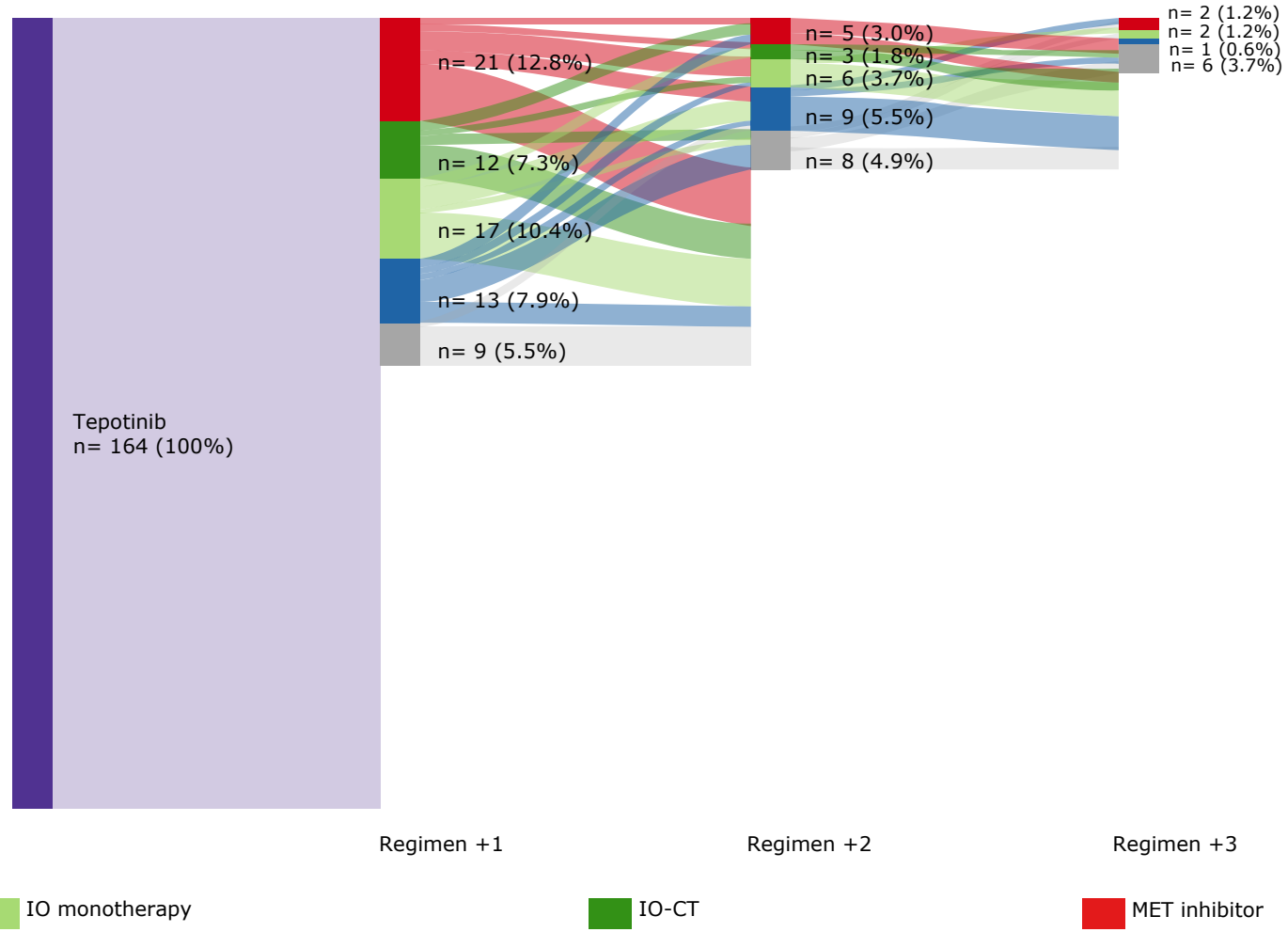
Reference: 1. Mazieres J, et al. Presented at ELCC, 2025, Poster 81P.

Sankey Plots for Patients Receiving Tepotinib in 1L[1]

May 2024 cut-off

Subsequent treatments

- Among patients who received tepotinib in 1L (n=164), 152 (92.7%) discontinued tepotinib, of whom 72 (43.9%) started a subsequent treatment

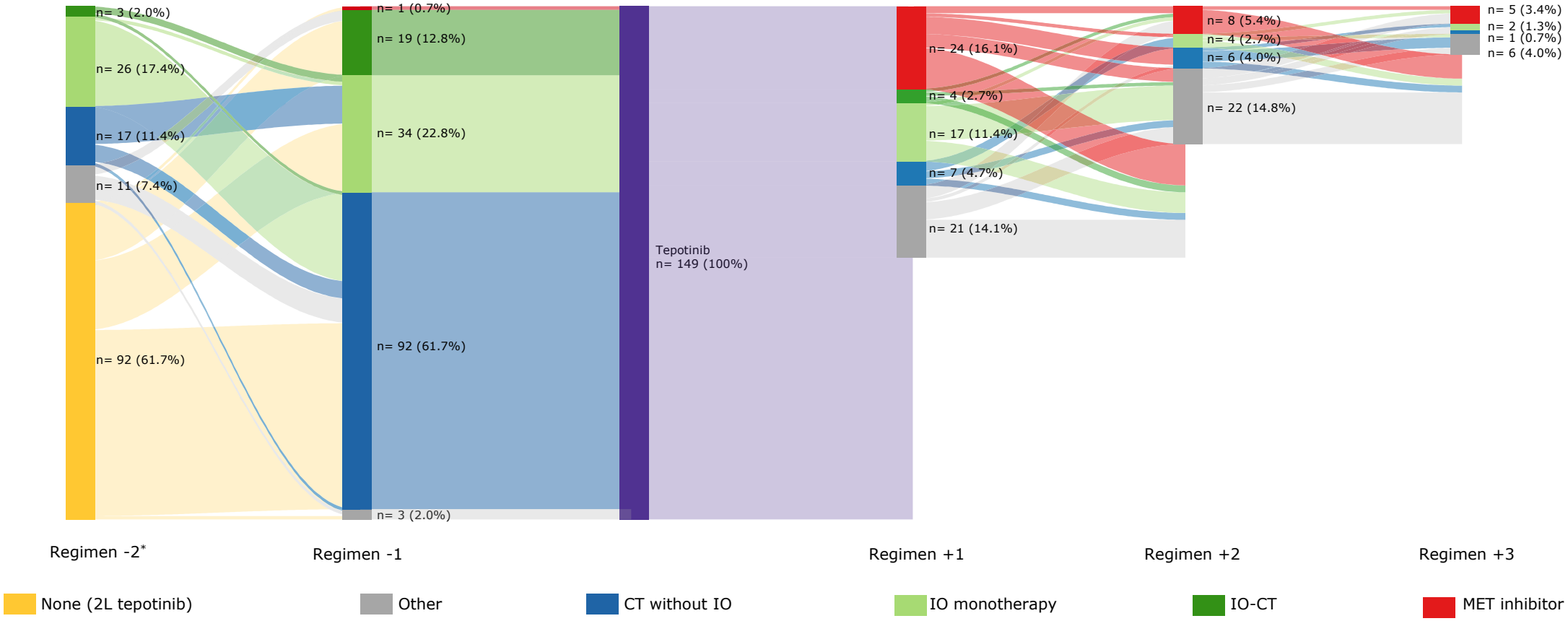


1L, first line; CT, chemotherapy; IO, immunotherapy.

Reference: 1. Viteri S, et al. Presented at ESMO 2025, Poster 1995P.

Sankey Plots for Patients Receiving Tepotinib in 2L+[1]

May 2024 cut-off



- Among patients who received tepotinib in 2L+ (n=149), 143 (96.0%) discontinued tepotinib, of whom 73 (49.0%) started a subsequent treatment

*In Regimen -3, one patient received chemotherapy without concurrent immunotherapy, and two patients received 'other' therapy.
2L+, second-or-later line; CT, chemotherapy; IO, immunotherapy.

Reference: 1. Viteri S, et al. Presented at ESMO 2025, Poster 1995P.

LONG-TERM RESPONDER DATA

Due to the single-arm design of the VISION Trial for TEPMETKO, no formal statistical comparisons were conducted, and data, including PFS and OS, were analyzed in a descriptive manner.

For these reasons, results from this analysis should be interpreted with caution.

Baseline Characteristics for Long-term Responders[1]

May 2024 cut-off

- Of 313 patients enrolled, 26 patients were considered long-term responders (DOR >36 months [range: 36.6–78.9]); 53.8% of patients were L+ and 65.4% were T+; median duration of treatment was 50.7 months (range: 15.9–83.1)

Baseline characteristics		Cohorts A+C	
		Overall population (N=313)[2]	Long-term responders (n=26)[1]
Median age, years (range)		72.0 (41–94)	67.7 (52–84)
Sex, n (%)	Male	154 (49.2)	14 (53.8)
	Female	159 (50.8)	12 (46.2)
Race,* n (%)	White	195 (62.3)	13 (50.0)
	Asian	106 (33.9)	9 (34.6)
ECOG PS,† n (%)	0	81 (25.9)	9 (34.6)
	1	231 (73.8)	17 (65.4)
Smoking history,‡ n (%)	Yes	149 (47.6)	14 (53.8)
	No	154 (49.2)	11 (42.3)
Histology,§ adenocarcinoma, n (%)		252 (80.5)	24 (92.3)
Line of treatment, n (%)	1L	164 (52.4)	17 (65.4)
	≥2L	149 (47.6)	9 (34.6)

- Patients who achieved long-term responses to tepotinib in VISION had similar clinical characteristics and safety outcomes to the overall population of patients from VISION[2]

Note: 'T+' used here denotes 'known TBx positives'

*Nine patients in the overall population had race reported as "other' or missing, race was reported as 'other' or not collected at the site for four patients. †One patient had an ECOG PS of 2 in the overall population. ‡Smoking history was missing in 10 patients in the overall population and one patient in those with a long-term response. §In the overall population, 21 patients had 'other' histologies and two had missing data; among those with a long-term response, one patient had 'adenocarcinoma, sarcomatoid' histology.

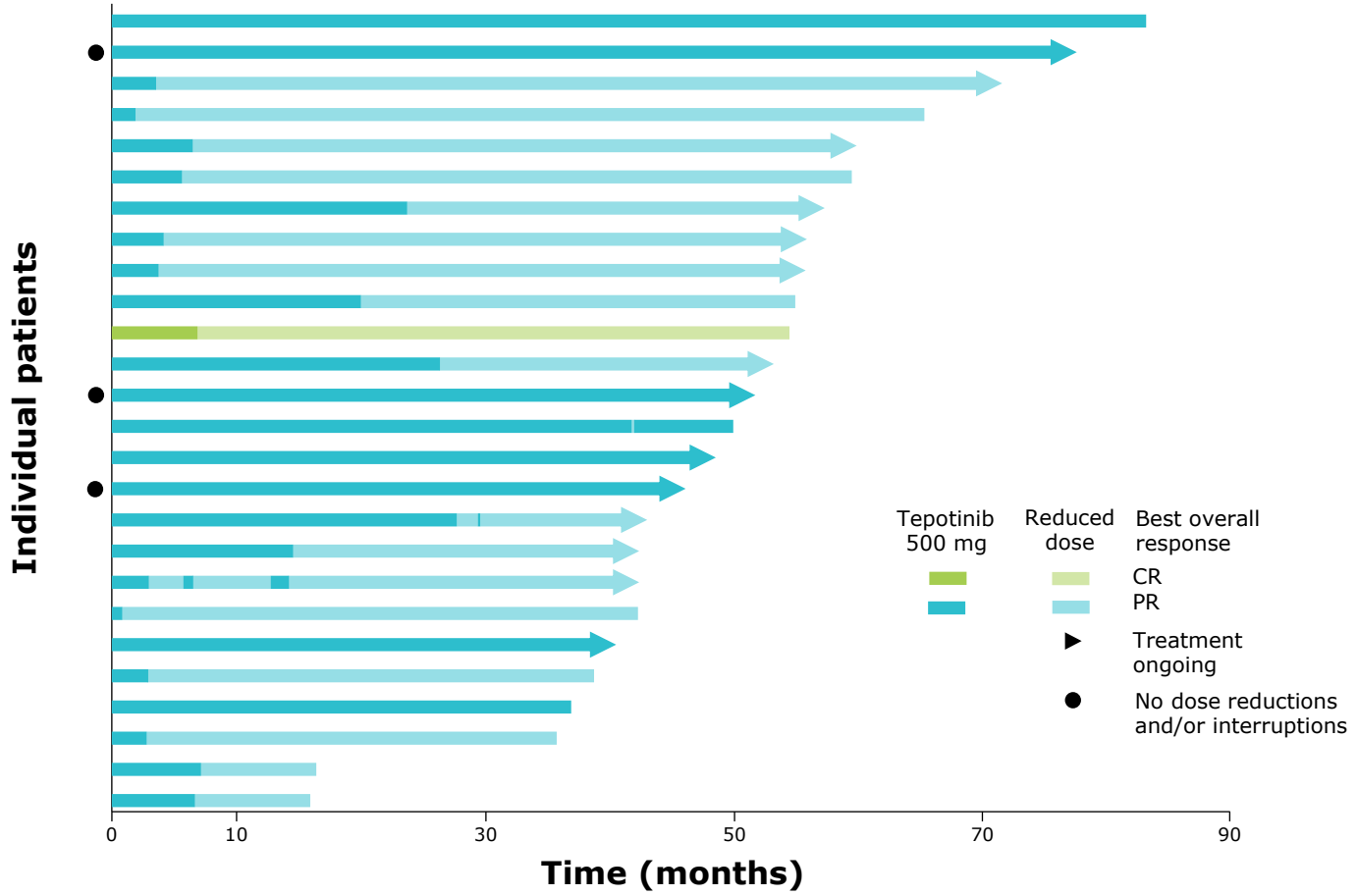
1L, first line; ≥2L, second-or-later line; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; L+, positive for *MET*ex14 skipping in liquid biopsy; TBx, tissue biopsy; T+, known positive detection of *MET*ex14 skipping in tissue biopsy (TBx).

Reference: 1. Paik P, et al. Presented at ASCO, 2026, Poster 402P; **2.** Mazières J, et al. Presented at ELCC, 2025, Poster 81P.

Duration of Treatment in Patients with Long-Term Treatment Response[1]

May 2024 cut-off

- Twenty-four patients experienced a >50% decrease in the sum of longest diameters from baseline, while 6 patients had a >80% decrease
- Eighteen patients' cancer had not progressed at the data cut-off (May 20, 2024), and 14 patients were still receiving treatment

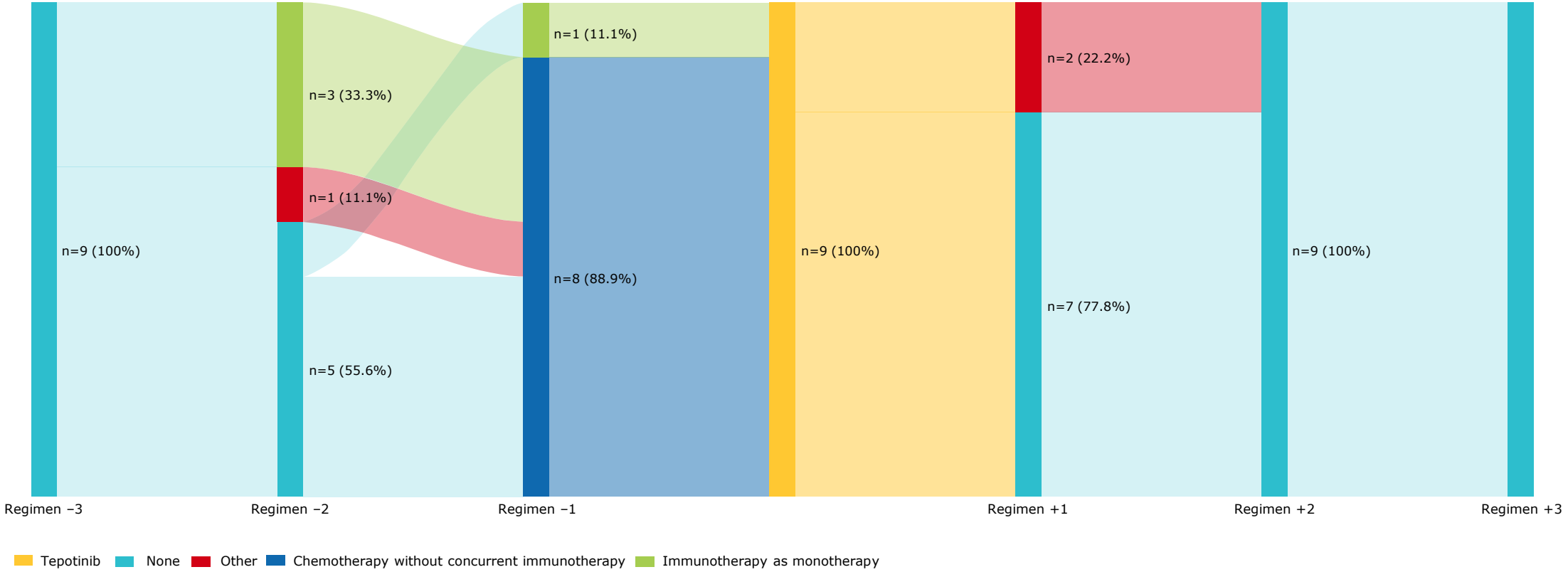


CR, complete response; PR, partial response.

Reference: 1. Paik P, et al. Presented at ASCO, 2026, Poster 402P.

Sankey Plot for Previously Treated Patients With Long-term Treatment Response[1]

May 2024 cut-off



- Of the 9 patients who received anticancer treatment prior to tepotinib, 4 patients received immunotherapy alone, and 8 patients received chemotherapy without immunotherapy

Reference: 1. Paik P, et al. Presented at ASCO, 2026, Poster 402P.

Biomarker Analysis in Patients with Long-term Responses[1]

May 2024 cut-off

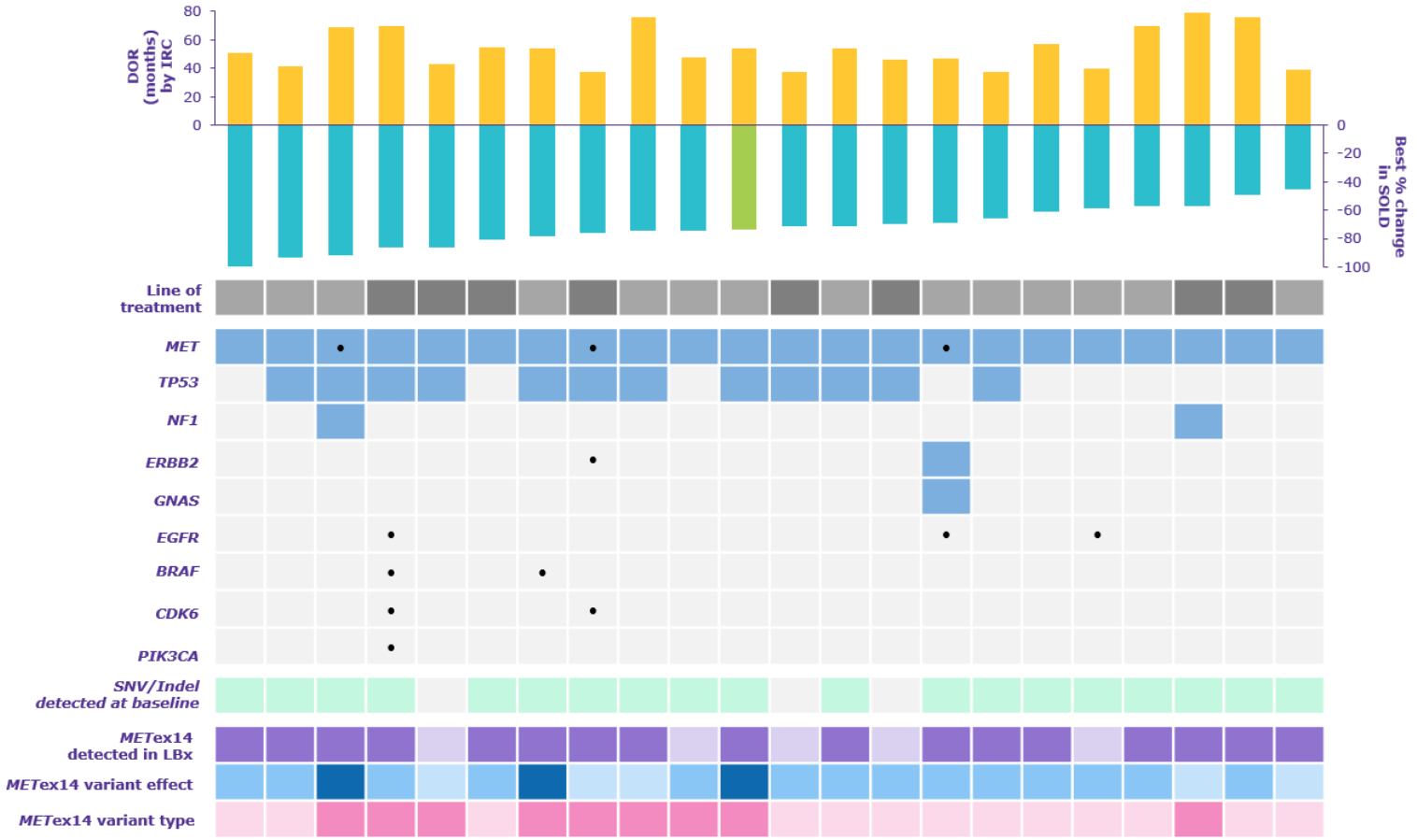
- Baseline DNA NGS profiles were available for 22/26 (84.6%) patients with long-term response to tepotinib
  - TP53 mutations were common and observed in 12/22 (54.5%) patients
  - No oncogenic *ALK*, *ROS*, or *RET* fusions were detected
  - No concomitant point mutations or indels in *KRAS*, *NRAS*, *BRAF*, *PIK3CA*, *PTEN*, *EGFR*, or *RB1* were found
  - High-level *MET*amp was observed in 3/22 (13.6%) patients
- At Week 6, complete molecular response, defined as clearance of *MET*ex14 skipping in ctDNA, was observed in 9/15 patients, while 6/15 patients had persistently undetectable in ctDNA from baseline through Week 6
  - A similar pattern was observed at Week 12, with 9/15 clearance and 6/15 undetectable from baseline through Week 12
- NGS baseline profiles of these patients did not reveal any other targetable oncogenic mutations

ctDNA, circulating tumor DNA; DNA, Deoxy-ribonucleic acid; *MET*amp, *MET* amplification; *MET*ex14. *MET* exon 14; NGS, next-generation sequencing.

Reference: 1. Paik P, et al. Presented at ASCO, 2026, Poster 402P.

Clinical Outcomes According to Baseline ctDNA Profile in Patients With Long-term Treatment Response[1]

May 2024 cut-off



DOR (months)

Best overall response
- Complete response
- Partial response

Line of treatment
- First line
- Second-or-later line

Type of gene alteration present
- Mutation
- Amplification
- Both mutation and amplification

Any SNV/Indel detected in plasma at baseline
- Yes
- Not evaluable

***METex14* detected in LBx**
- Yes
- No

***METex14* variant effect**
- Splice acceptor
- Splice donor
- Polypyrimidine tract

***METex14* variant type**
- SNV
- Indel

Click above to access safety data

ctDNA, circulating tumor DNA; DNA, Deoxy-ribonucleic acid; DOR, duration of response; IRC, independent review committee; LBx, liquid biopsy; SNV, single nucleotide variant; SOLD, sum of longest diameter.

Reference: 1. Paik P, et al. Presented at ASCO, 2026, Poster 402P.

VISION SAFETY DATA

Due to the single-arm design of the VISION Trial for TEPMETKO, no formal statistical comparisons were conducted, and data, including PFS and OS, were analyzed in a descriptive manner.

For these reasons, results from this analysis should be interpreted with caution.

Overall Safety Profile of Tepotinib

May 2024 cut-off

Summary of AEs per VISION study (≥3-year follow-up; May 2024 data)[1]

Patients with at least one, n (%)	Cohort A+C (N=313)	
	All-cause AE	TRAEs
Any AE	310 (99.0)	287 (91.7)
Serious AEs	171 (54.6)	50 (16.0)
Grade ≥3 AE	214 (68.4)	113 (36.1)
Grade ≥4 AE	59 (18.8)	12 (3.8)
AE leading to dose reduction	114 (36.4)	104 (33.2)
AE leading to temporary discontinuation (interruption)	172 (55.0)	137 (43.8)
AE leading to permanent discontinuation	84 (26.8)	49 (15.7)
AE leading to death	43 (13.7)	3 (1.0)

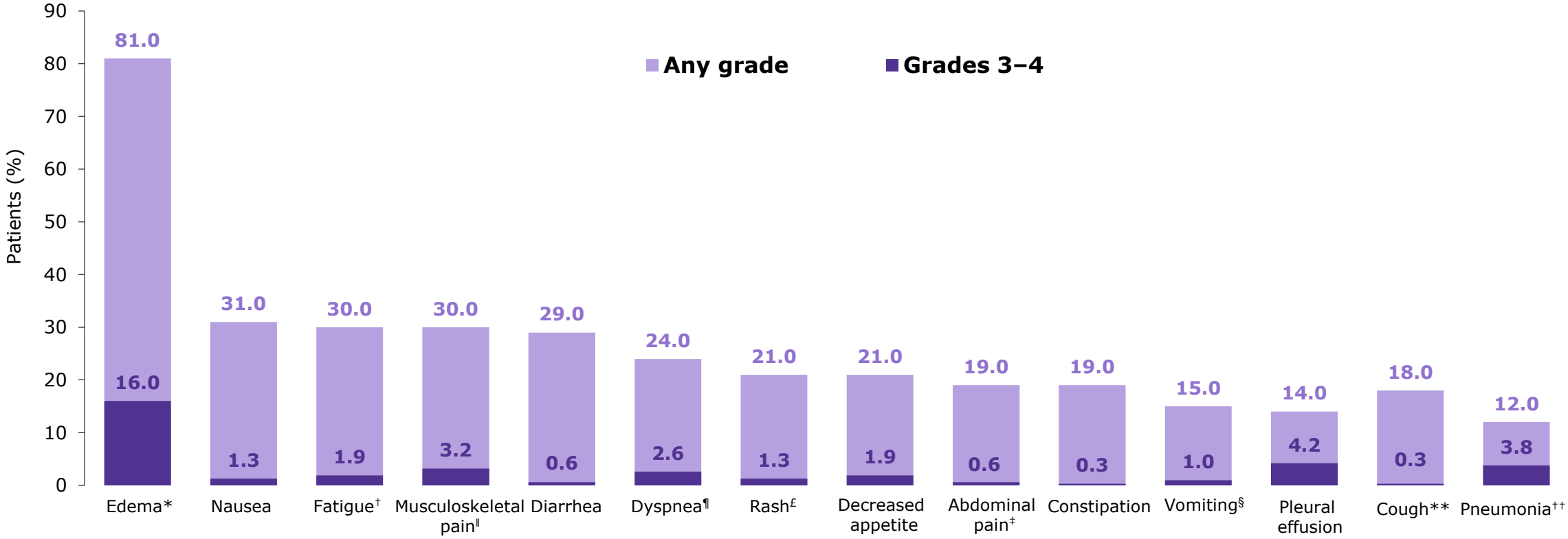
AE, adverse event; AR, adverse reaction; TRAE, treatment-related adverse event.

Reference: 1. Felip E, et al. Presented at WCLC 2025. Poster P3.12.40.

ARs[1]

US PI
(Nov 2022 data)

- Adverse reactions in ≥10% of patients with NSCLC with *MET*ex14 skipping alterations who received tepotinib in VISION (N=313)[1]



- Clinically relevant adverse reactions in <10% of patients who received tepotinib included ILD/pneumonitis, fever, dizziness, pruritus, and headache

*Includes eye edema, face edema, generalized edema, localized edema, edema, genital edema, peripheral edema, peripheral swelling, periorbital edema, and scrotal edema; †Includes asthenia and fatigue; ‖Includes arthralgia, arthritis, back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, myalgia, neck pain, non-cardiac chest pain, pain in extremity, and spinal pain; ¶Includes dyspnea, dyspnea at rest, and dyspnea exertional; £Includes rash, palmar-plantar erythrodysaesthesia syndrome, rash maculo-papular, eczema, exfoliative rash, rash erythematous, rash pustular, skin exfoliation, dermatitis acneiform, drug eruption, dermatitis, rash pruritic, dermatitis bullous, toxic skin eruption; ‡Includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain, and hepatic pain; §Vomiting includes retching and vomiting; **Includes cough and productive cough; ††Includes pneumonia, pneumonia aspiration, and pneumonia bacterial. AR, adverse reaction; ILD, interstitial lung disease; *MET*ex14, *MET* exon 14; NSCLC, non-small cell lung cancer.

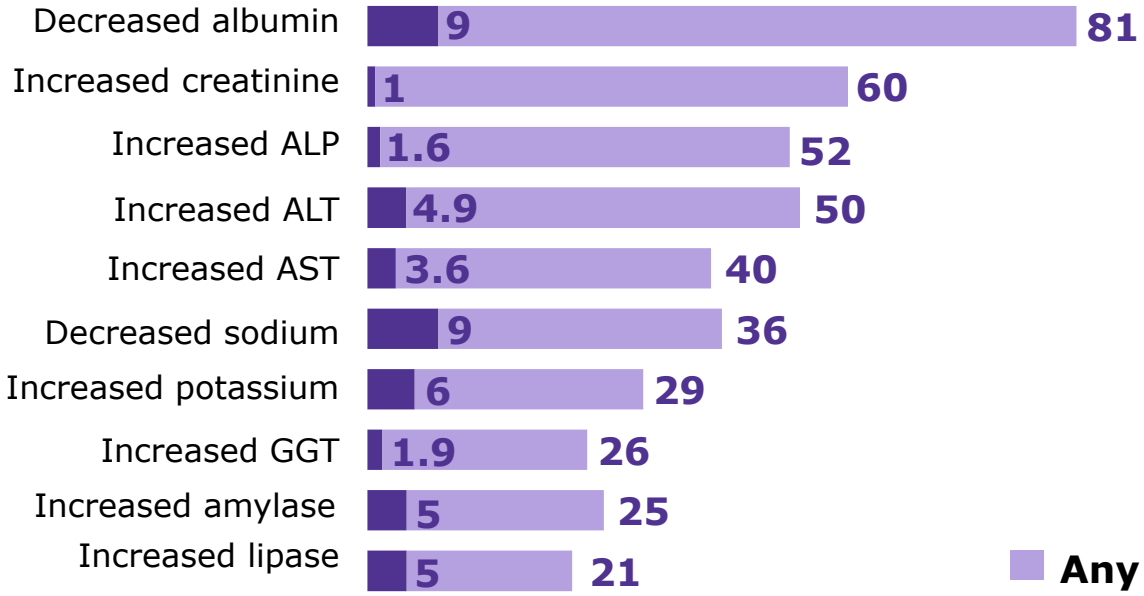
Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Laboratory Abnormalities[1]

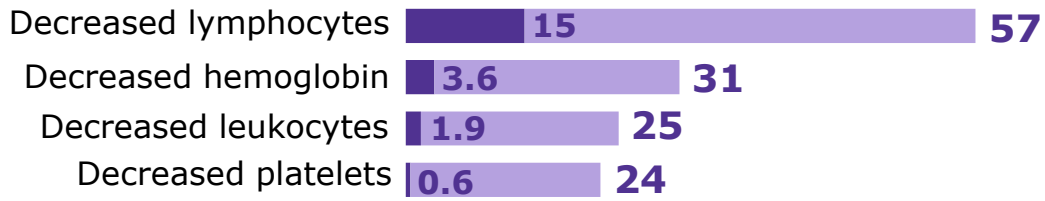
US PI
(Nov 2022 data)

- Select laboratory abnormalities (≥20%) that worsened from baseline in patients who received tepotinib in VISION*[1]

Chemistry



Hematology



Any grade (%) Grades 3–4 (%)

- Decreased albumin was the most commonly occurring laboratory abnormality

*The denominator used to calculate the rate varied from 268 to 309 based on the number of patients with a baseline value and at least one post-treatment value.
ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase.

Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Permanent Discontinuations, Dosage Interruptions, Dose Reductions, and Dose Modifications for ARs[1]

US PI
(Nov 2022 data)

Dose reductions (Overall 36.0%)

Most frequent ARs (>2%) leading to dose reductions of tepotinib	Patients (%)
Edema	22.0
Increased blood creatinine	2.9
Pleural effusion	2.2
Fatigue	2.2

Dosage interruptions (Overall 53.0%)

Most frequent ARs (>2%) leading to dosage interruption of tepotinib	Patients (%)
Edema	28.0
Increased blood creatinine	6.0
Pleural effusion	3.5
Nausea	3.2
Increased ALT	2.9
Pneumonia	2.6
Decreased appetite	2.2
Dyspnea	2.2

Permanent discontinuation (Overall 25.0%)

Most frequent ARs (>1%) leading to permanent discontinuation of tepotinib	Patients (%)
Edema	8.0
Pleural effusion	1.6
General health deterioration	1.6

Dose modifications for ARs[1]

- Management of some ARs may require temporary withhold, dose reduction, or permanent discontinuation
- The recommended dose reduction of tepotinib for the management of ARs is 225 mg orally once daily
- Permanently discontinue tepotinib in patients who are unable to tolerate the 225 mg dose
- See the full prescribing information for recommended dosage modifications of tepotinib

Data cut-off: Nov 20, 2022 (N=313).
AR, adverse reaction; ALT, alanine aminotransferase.
Reference: 1. TEPMETKO® (tepotinib) [Prescribing Information], https://www.emdserono.com/us-en/pi/tepmetko-pi.pdf.

Overall safety - Summary of all-cause AEs and TRAEs[1]

May 2024 cut-off

- The majority of patients had TRAEs of Grade 1/2 and TRAEs leading to permanent treatment discontinuation were reported in 15.7% of patients
- Peripheral edema was the most common TRAE (any grade: 67.7%, Grade ≥3: 11.8%)
- No new safety signals were observed in Cohort A+C with a longer follow-up

Patients with at least one, n (%)	Cohorts A+C (N=313)	
	All-cause AEs	TRAEs
Any AE	310 (99.0)	287 (91.7)
Serious AE	171 (54.6)	50 (16.0)
Grade ≥3 AE	214 (68.4)	113 (36.1)
Grade ≥4 AE	59 (18.8)	12 (3.8)
AE leading to death	43 (13.7)	3 (1.0)
AE leading to dose reduction	114 (36.4)	104 (33.2)
AE leading to temporary discontinuation (interruption)	172 (55.0)	137 (43.8)
AE leading to permanent discontinuation	84 (26.8)	49 (15.7)

AE, adverse event; TRAE, treatment-related adverse event.

Reference: 1. Felip E, et al. Presented at WCLC, 2025, Poster P3.12.40.

Summary of TRAEs in >10% of Patients[1]

May 2024 cut-off

Patients with at least one, n (%)	Any grade, n (%)	Grade ≥3, n (%)
Peripheral edema	212 (67.7)	37 (11.8)
Hypoalbuminemia	79 (25.2)	12 (3.8)
Nausea	73 (23.3)	2 (0.6)
Diarrhea	71 (22.7)	1 (0.3)
Blood creatinine increased	69 (22.0)	4 (1.3)
Alanine aminotransferase increased	44 (14.1)	7 (2.2)
Decreased appetite	36 (11.5)	1 (0.3)
Aspartate aminotransferase increased	35 (11.2)	6 (1.9)
Amylase increased	33 (10.5)	6 (1.9)

TRAE, treatment-related adverse event.

Reference: 1. Felip E, et al. Presented at WCLC, 2025, Poster P3.12.40.

Dose Reductions, Dosage Interruptions, and Permanent Discontinuations for TRAEs[1]

May 2024 cut-off

Dose reductions (≥1% of patients)

	Any grade, n (%)
Peripheral edema	48 (15.3)
Generalized edema	10 (3.2)
Edema	7 (2.2)
Pleural effusion	5 (1.6)
Blood creatinine increased	8 (2.6)
Hypoalbuminemia	4 (1.3)
Fatigue	3 (1.0)
Asthenia	3 (1.0)
Localized edema	3 (1.0)

Dosage interruptions (>2% of patients)

	Any grade, n (%)
Peripheral edema	59 (18.8)
Alanine aminotransferase increased	8 (2.6)
Generalized edema	15 (4.8)
Edema	11 (3.5)
Pleural effusion	10 (3.2)
Blood creatinine increased	18 (5.8)
Localized edema	7 (2.2)
Nausea	7 (2.2)

Permanent discontinuation (≥1% of patients)

	Any grade, n (%)
Peripheral edema	19 (6.1)
Generalized edema	3 (1.0)
Edema	4 (1.3)
Pleural effusion	3 (1.0)
Interstitial lung disease	3 (1.0)
Pneumonitis	3 (1.0)

TRAE, treatment-related adverse event.

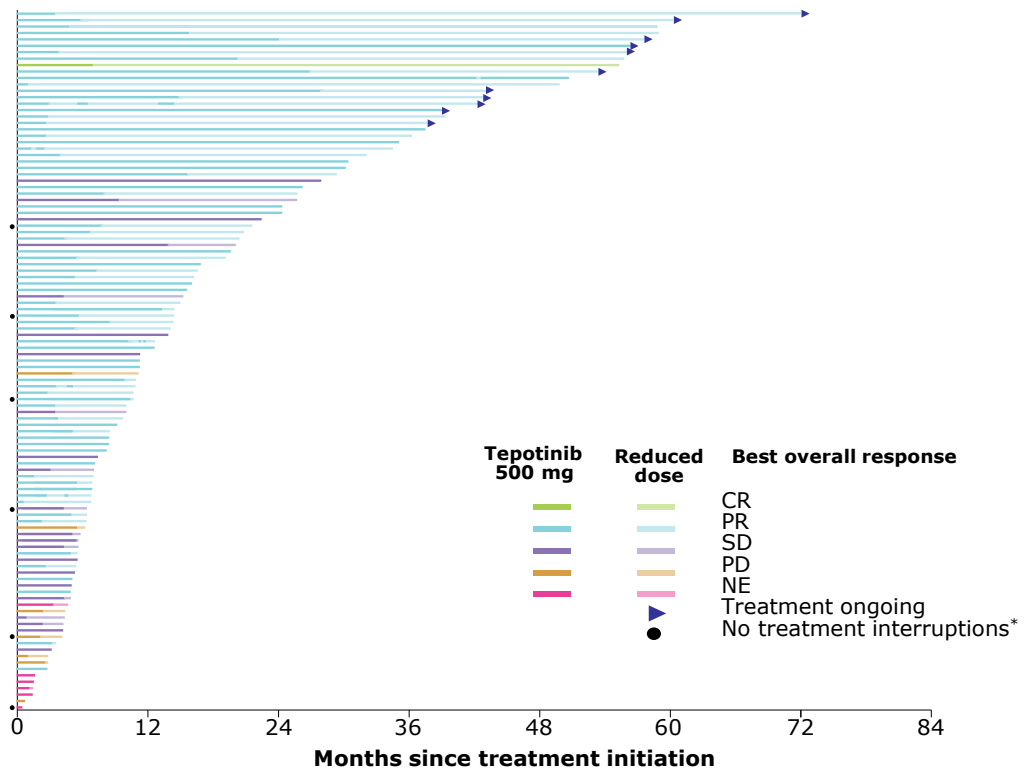
Reference: 1. Felip E, et al. Presented at WCLC, 2025, Poster P3.12.40.

Time on Treatment in Patients With Dose Reductions and/or Interruptions

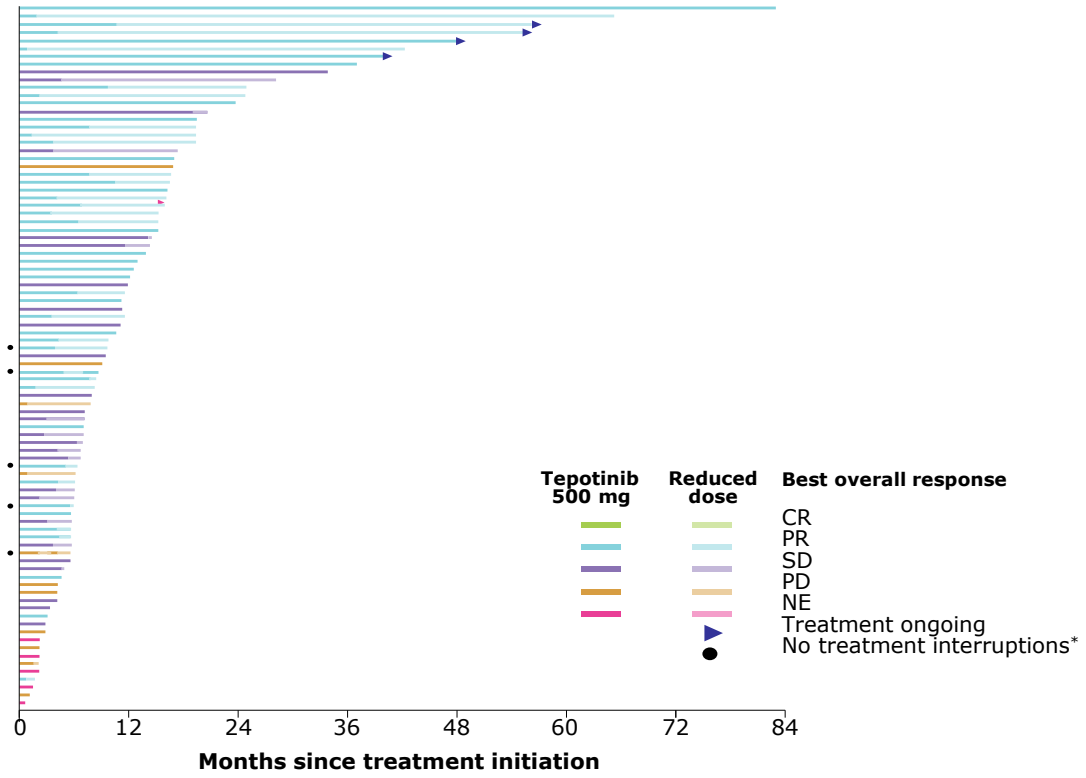
May 2024 cut-off

- Patients requiring treatment interruptions and dose reductions were able to continue treatment with tepotinib[1]

Time on treatment in 1L patients with dose reductions and/or interruptions (n=108)



Time on treatment in 2L+ patients with dose reductions and/or interruptions (n=89)



- Median duration of treatment was 10.7 months (range: 0.7–83.1) in both 1L and 2L+ patients with dose reductions and/or interruptions (n=197). Median duration of treatment in overall population was 7.5 months (range: 0.03-83.12)

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

1L, first line; 2L, second-or-later line; CR, complete response; NE, not estimable; PD, progressive disease; PR, partial response; SD, stable disease.

Reference: 1. Viteri S, et al. ESMO 2025, Poster 1995P.

DOR, PFS, and BOR in Patients With Long-term Response Who Stopped Treatment Due to AE[1]

May 2024 cut-off

- In 12 patients who discontinued treatment, reasons for discontinuation were: adverse events (n=5), disease progression per investigator (n=3), non-compliance with study protocol requirements (n=1), consent withdrawal (n=1), and other reasons (n=2)
  - Among the five patients who discontinued treatment due to adverse events, these included edema (n=1), peripheral edema (n=2), diarrhea (n=1), and dyspnea (n=2)
- Among four patients with long-term responses who stopped treatment early due to adverse events (prior to disease progression), continued responses were observed for up to 52 months after tepotinib discontinuation without any further subsequent anticancer treatment

Patient	Treatment duration (months)	DOR (months)	PFS (months)	BOR, IRC
1	59.4	75.9	77.3	PR
2	16.3	68.7*	70.1	PR
3	15.9	48.1	49.4	PR
4	35.7	40.1	41.4	PR

*Response was ongoing as of February 26, 2026 without any further anticancer treatment.

Click above to return to clinical outcomes based on ctDNA profile

AE, adverse event; BOR, best overall response; DOR, duration of response; IRC, independent review committee; PFS, progression-free survival; PR, partial response.

Reference: 1. Paik P, et al. ASCO 2026, Poster 402P.

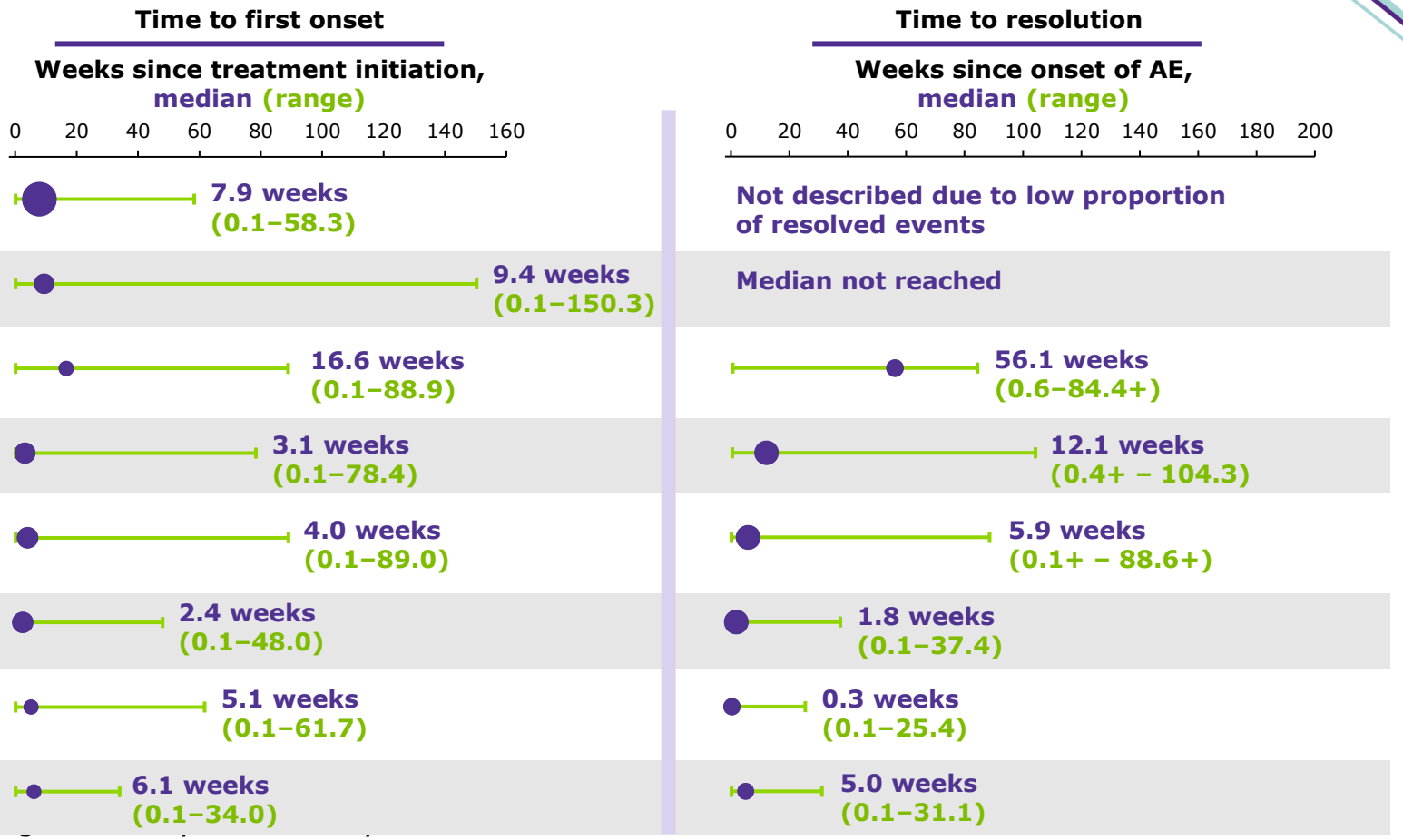
AECIs[1]

Patient population used is not the full Cohorts A + C population

Jul 2020 cut-off

Time to first onset and time to resolution of AECIs[1]

	Patients, n	Total events, n	Events resolved, n	Time to first onset: Weeks since treatment initiation, median (range)	Time to resolution: Weeks since onset of AE, median (range)
Edema	178	337	115	7.9 weeks (0.1–58.3)	Not described due to low proportion of resolved events
Hypoalbuminemia	61	74	25	9.4 weeks (0.1–150.3)	Median not reached
Pleural effusion	34	39	15	16.6 weeks (0.1–88.9)	56.1 weeks (0.6–84.4+)
Creatinine increase	66	96	67	3.1 weeks (0.1–78.4)	12.1 weeks (0.4+ – 104.3)
Nausea	68	87	67	4.0 weeks (0.1–89.0)	5.9 weeks (0.1+ – 88.6+)
Diarrhea	67	112	102	2.4 weeks (0.1–48.0)	1.8 weeks (0.1–37.4)
Vomiting	33	47	44	5.1 weeks (0.1–61.7)	0.3 weeks (0.1–25.4)
ALT and/or AST increase	31	56	46	6.1 weeks (0.1–34.0)	5.0 weeks (0.1–31.1)



- There was no clear association between edema, hypoalbuminemia, pleural effusion, and creatinine increase when analyzed irrespective of event timing

Plots indicate the median value (blue circles, size proportional to the number of patients) and range (green bars). The '+' signs denote censored values.
AE, adverse event; AECI, adverse event of clinical interest; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

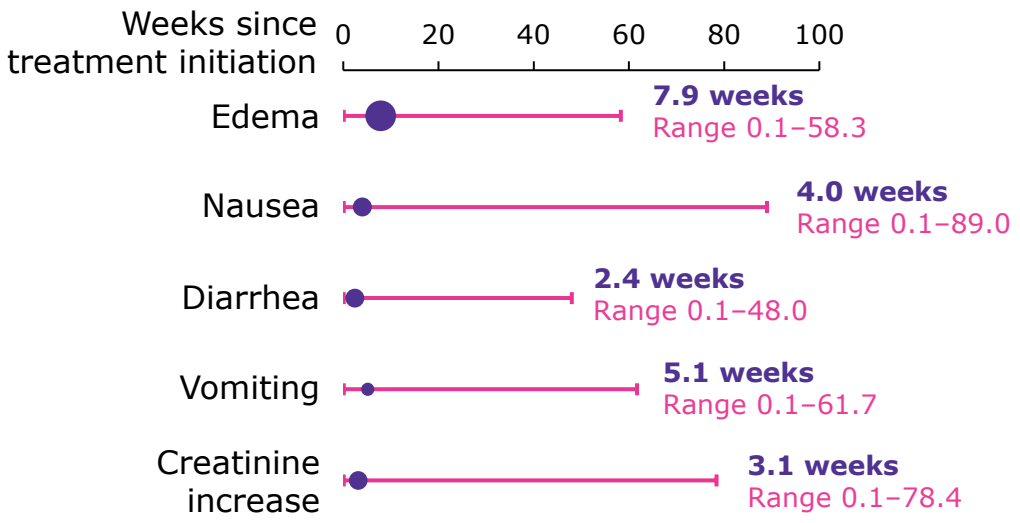
Reference: 1. Veillon R, et al. Clin Lung Cancer. 2022;23(4):320-332.

AEs of Clinical Interest: Time to First Onset and Resolution[1]

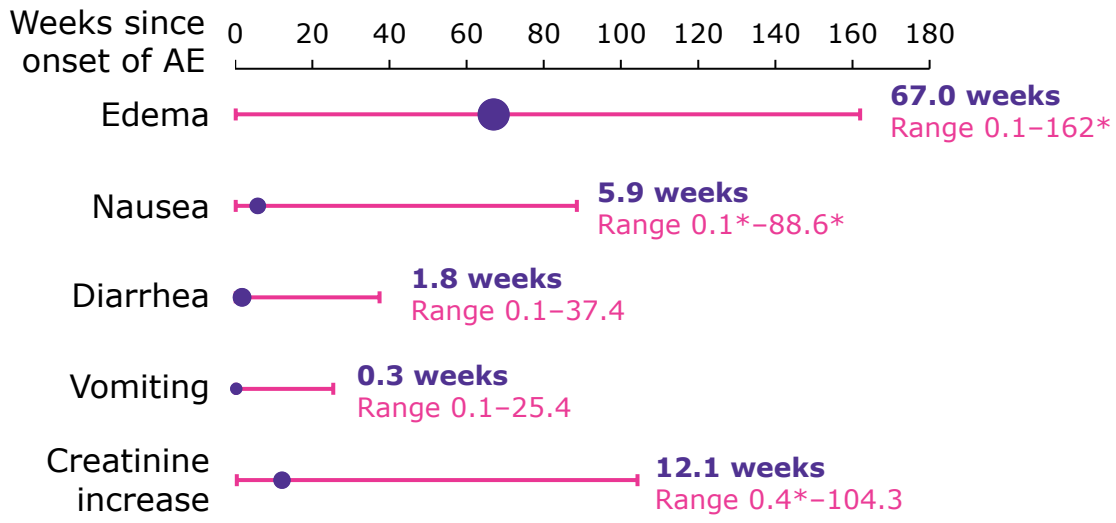
Patient population used is not the full Cohorts A + C population

Jul 2020 cut-off

Median time to first onset



Median time to resolution



AE (patients with ≥1 event)	Edema (n=178)	Nausea (n=68)	Diarrhea (n=67)	Vomiting (n=33)	Creatinine increase (n=66)
Total events	337	87	112	47	96
Events resolved at time of analysis	115	67	102	44	67

Analyses of time to first onset and time to resolution were carried out for AEs of clinical interest, including composite categories comprising preferred terms, and were analyzed irrespective of causal relation to study treatment. Time to first onset was described by median and range for observed AEs, not accounting for competing events. Time to resolution was analyzed using Kaplan–Meier methods in a descriptive manner, not accounting for the fact that one patient could contribute by more than one event of the respective AE.

*Denotes a censored value.

AE, adverse event.

Reference: 1. Veillon R, et al. Presented at WCLC, 2020, Abstract 821.