In adult patients with metastatic non-small cell lung cancer (mNSCLC) harboring mesenchymal-epithelial transition gene exon 14 skipping alterations (*MET*ex14+)[1]

TEPMETKO® (tepotinib) 225 mg Tablets

Achieve a robust and lasting response with

TEPMETKO FIRST[1]

In the largest clinical trial (n=313) in *MET*ex14+ mNSCLC with a long-term follow-up of up to 6 years, **treatment-naïve patients experienced[1,2]:**

57%
ORR
(n=164)

(95% CI: 49, 65)

TEPMETKO was also studied in previously treated patients. See data within.

Actor portrayal.

CI=confidence interval; ORR=overall response rate.

SELECTED SAFETY INFORMATION

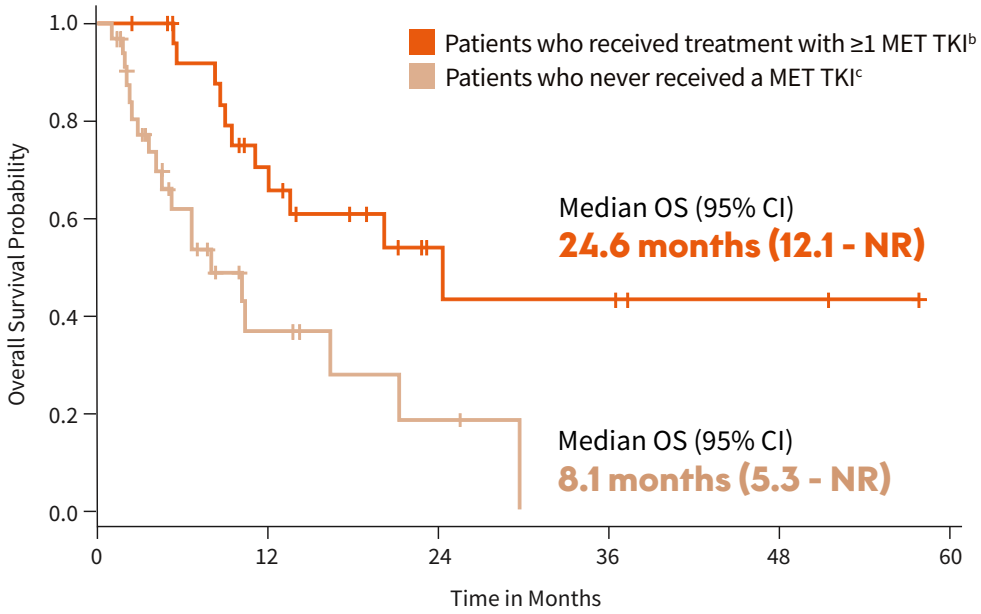
TEPMETKO can cause **interstitial lung disease (ILD)/pneumonitis,** which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified. ILD/pneumonitis occurred in 2% of patients treated with TEPMETKO, with one patient experiencing a Grade 3 or higher event; this event resulted in death.

Please see Selected Safety Information throughout and full Prescribing Information.

3%-4% of mNSCLC patients harbor *MET*ex14 skipping alterations[3]

These patients are associated with a poor prognosis and require a targeted treatment approach[4,5]

Real-world studies demonstrated poor outcomes in patients with *MET*ex14+ skipping who never received a MET inhibitor[4,5,a]



Number at Risk

27	15	5	4	2	0
34	6	2	0	0	0

What you choose matters[4,5]

National Comprehensive Cancer Network® (NCCN®) recommends[6]:

- Clinicians obtain molecular testing results for actionable biomarkers before administering first-line ICI therapy, if clinically feasible
- If a *MET*ex14 skipping mutation is discovered during first-line systemic therapy, interrupt current therapy[d] and start a MET inhibitor

[a]In a retrospective analysis using data from 12 institutions, 61 patients with *MET*ex14+ NSCLC met the inclusion criteria for survival analysis. Among these 61 patients, 34 never received treatment with a MET TKI.[5] [b]Overall survival of 27 patients with stage IV *MET*ex14 NSCLC who received treatment with at least one MET TKI.[5] [c]Overall survival of 34 patients with stage IV *MET*ex14 NSCLC who never received a MET TKI.[6] [d]If there is a good response to current therapy, the NCCN considers it reasonable to continue that therapy.[6]

ICI=immune checkpoint inhibitor; MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer; NR=not reached; OS=overall survival; TKI=tyrosine kinase inhibitor.

Please see Selected Safety Information throughout and full Prescribing Information.

VISION—FIRST *MET*ex14+ trial with 300+ patients[1,2]

The largest clinical trial in *MET*ex14+ mNSCLC with a long-term follow-up of up to 6 years[1,2]

Pivotal clinical trial

LONG-TERM FOLLOW-UP

MEDIAN FOLLOW-UP: 32.6 months
(range: 0.3-71.9)

Trial design

N=313

- Treatment naïve (n=164)
- Previously treated (n=149)

TEPMETKO 450 mg QD[a]

Outcomes

Major efficacy outcome

- ORR[b]

Additional outcomes

- DOR
- Safety

ELIGIBILITY

- Advanced, metastatic *MET*ex14+ NSCLC
- *EGFR* wild-type and *ALK*-negative status
- ≥1 measurable lesion by RECIST v1.1
- ECOG PS 0-1

EXCLUSIONS

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

[a]TEPMETKO was administered until disease progression or unacceptable toxicity.[1] [b]ORR was confirmed by RECIST v1.1.[1]

ALK=anaplastic lymphoma kinase; CNS=central nervous system; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; *EGFR*=epidermal growth factor receptor; HGF=hepatocyte growth factor; ORR=overall response rate; MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer; QD=once daily; RECIST=Response Evaluation Criteria in Solid Tumors.

SELECTED SAFETY INFORMATION

TEPMETKO can cause **hepatotoxicity,** which can be fatal. Monitor liver function tests (including alanine aminotransferase [ALT], aspartate aminotransferase [AST], and total bilirubin) prior to the start of TEPMETKO, 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

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TEPMETKO® (tepotinib) 225 mg Tablets

As the FIRST treatment choice, TEPMETKO provided robust and lasting responses[1,2,7]

In the largest clinical trial in *MET*ex14+ mNSCLC, treatment-naïve patients (n=164) experienced[1,2]:

ORR[1,a]

(95% CI: 49, 65) (n=164)

Duration of response[1]

% of patients responding (n=94)

≥6 Months

≥12 Months

The DOR ranged from 1.3 months to 56.6 months

Onset of response[7,b]

% of patients responding (n=94)

66% responded within 6 weeks

80% responded within 12 weeks

[a]ORR according to RECIST v1.1 as evaluated by a BIRC.[1] [b]At 6 weeks, 62/94 patients responded. At 12 weeks, an additional 13 patients (75/94) responded.[7]

BIRC=Blinded Independent Review Committee; CI=confidence interval; DOR=duration of response; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer; ORR=overall response rate; RECIST=Response Evaluation Criteria in Solid Tumors.

SELECTED SAFETY INFORMATION

increased transaminases or total bilirubin. Based on the severity of the adverse reaction, withhold, dose reduce, or permanently discontinue TEPMETKO. Increased ALT/increased AST occurred in 18% of patients treated with TEPMETKO. Grade 3 or 4 increased ALT/AST occurred in 4.7% of patients. A fatal adverse reaction of hepatic failure occurred in one patient (0.2%). The median time-to-onset of Grade 3 or higher increased ALT/AST was 47 days (range 1 to 262).

TEPMETKO can cause **pancreatic toxicity** in the form of elevations in amylase and lipase levels. Increased amylase and/or lipase occurred in 13% of patients, with Grade 3 and 4 increases occurring in 5% and 1.2% of patients, respectively. Monitor amylase and lipase levels at baseline and regularly during treatment with TEPMETKO and temporarily withhold, dose reduce, or permanently discontinue based on severity of the adverse event.

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TEPMETKO® (tepotinib) 225 mg Tablets

TEPMETKO was designed to achieve maximal MET inhibition[8]

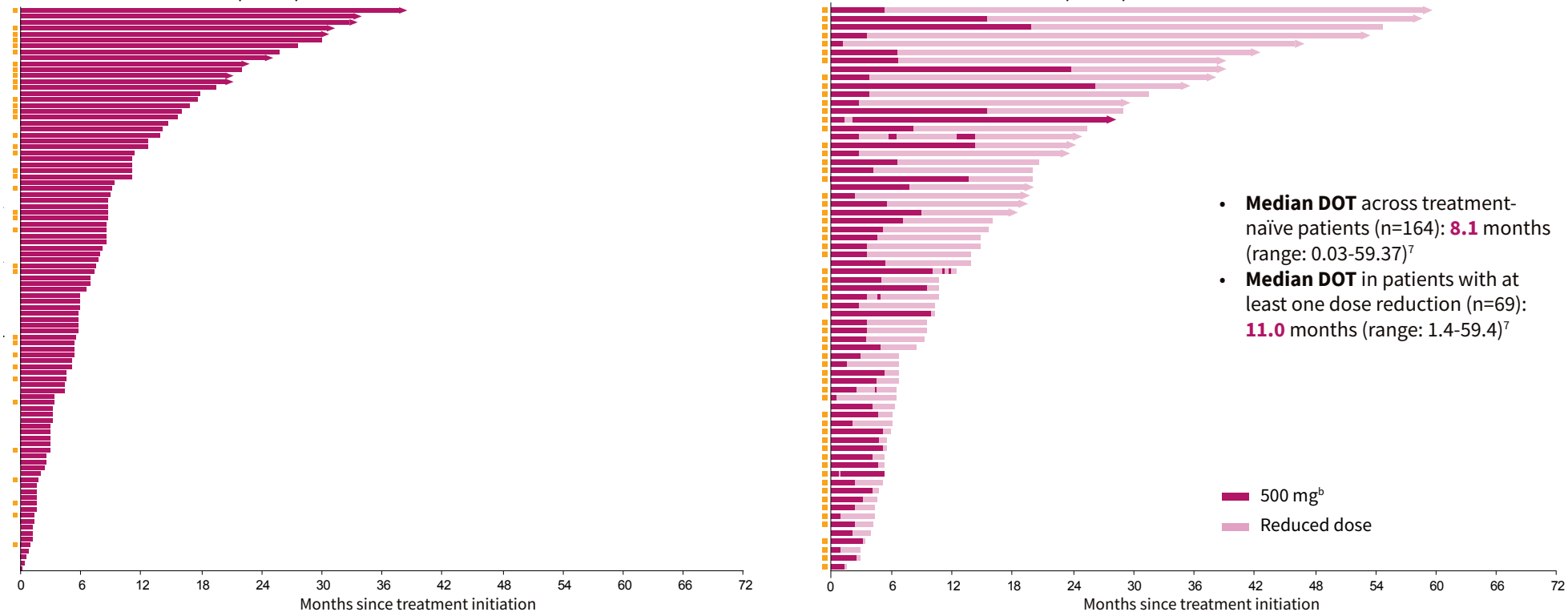
With a starting dose of 450 mg, ≥90% of patients achieve ≥95% MET inhibition[8,a]

Patients requiring treatment interruptions or dose reductions were able to continue to benefit from TEPMETKO

DOT in treatment-naïve patients:

No dose reductions (n=95)[9]

With dose reductions (n=69)[9]



Patients with ≥1 treatment interruption are denoted by a yellow square (■) on the left side of each panel. Patients with arrows were still on treatment.[9]
[a]Based on population pharmacodynamic simulation modeling.[8]
[b]450-mg active moiety.[2]
DOT=duration of treatment; MET=mesenchymal-epithelial transition.

SELECTED SAFETY INFORMATION

TEPMETKO can cause **embryo-fetal toxicity.** Based on findings in animal studies and its mechanism of action, TEPMETKO can cause fetal harm when administered to a pregnant woman. 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 TEPMETKO and for one week after the last dose.

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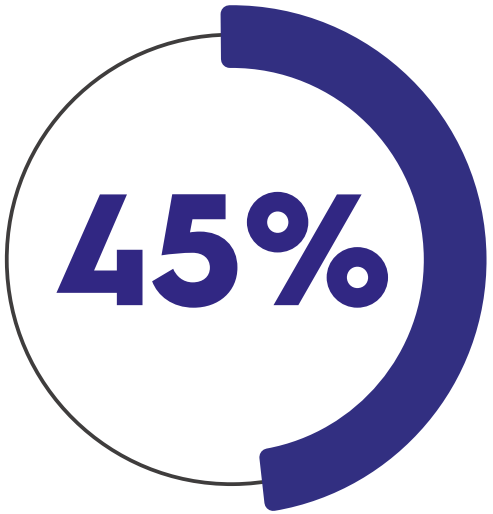
TEPMETKO® (tepotinib) 225 mg Tablets

TEPMETKO also provided robust and lasting responses in subsequent lines[1,2,7]

In the largest clinical trial in *MET*ex14+ mNSCLC, previously treated patients (n=149) experienced[1,2]:

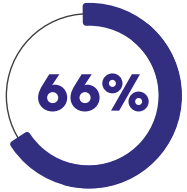
ORR[1,a]



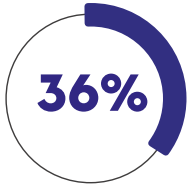
(95% CI: 37, 53) (n=149)

Duration of response[1]

% of patients responding (n=67)



≥6 Months



≥12 Months

The DOR ranged from 1.4 months to 67.6 months

Onset of response[7,b]

% of patients responding (n=67)

72% responded within 6 weeks

90% responded within 12 weeks

[a]ORR according to RECIST v1.1 as evaluated by a BIRC.[1] [b]At 6 weeks, 48/67 patients responded. At 12 weeks, an additional 12 patients (60/67) responded.[7]

BIRC=Blinded Independent Review Committee; CI=confidence interval; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; DOR=duration of response; ORR=overall response rate; RECIST=Response Evaluation Criteria in Solid Tumors.

SELECTED SAFETY INFORMATION

Avoid concomitant use of TEPMETKO 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.

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%) from unknown cause.

Serious adverse reactions occurred in 51% of patients who received TEPMETKO. 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%).

Please see Selected Safety Information throughout and full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

TEPMETKO was designed to achieve maximal MET inhibition[8]

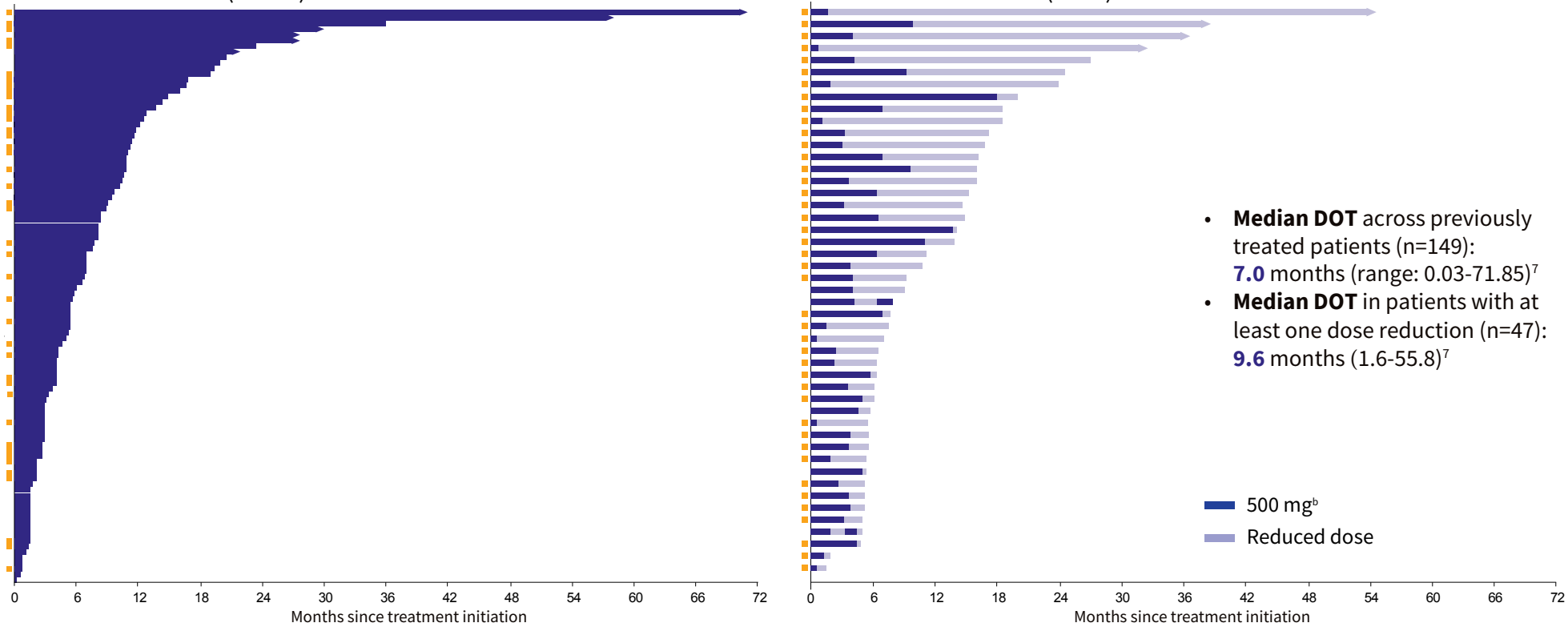
With a starting dose of 450 mg, ≥90% of patients achieve ≥95% MET inhibition[8,a]

Patients requiring treatment interruptions or dose reductions were able to continue to benefit from TEPMETKO

DOT in previously treated patients:

No dose reductions (n=102)[9]

With dose reductions (n=47)[9]



- **Median DOT** across previously treated patients (n=149): **7.0** months (range: 0.03-71.85)[7]
- **Median DOT** in patients with at least one dose reduction (n=47): **9.6** months (1.6-55.8)[7]

Patients with ≥1 treatment interruption are denoted by a yellow square (■) on the left side of each panel. Patients with arrows were still on treatment.[9]

[a]Based on population pharmacodynamic simulation modeling.[8]

[b]450-mg active moiety.[2]

DOT=duration of treatment; MET=mesenchymal-epithelial transition.

SELECTED SAFETY INFORMATION

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

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

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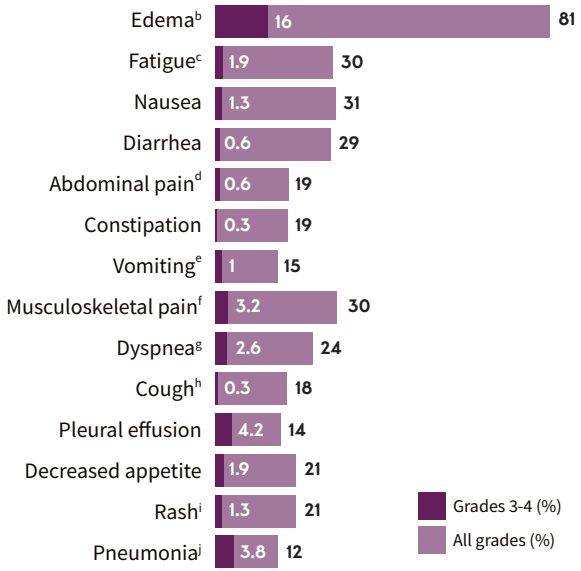
TEPMETKO® (tepotinib) 225 mg Tablets

The safety and tolerability of TEPMETKO were established in 313 patients[1]

Most adverse reactions observed in the VISION trial were mild to moderate (Grade 1 or 2)[1]

ARs in ≥10% of patients with mNSCLC harboring *MET*ex14+[a]



Laboratory abnormalities[1,a,k]

- **Selected laboratory abnormalities** (≥20%) from baseline in patients receiving TEPMETKO 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%)
- **The most common Grades 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%)

Due to an AR in patients who received TEPMETKO[1]

- **Permanent discontinuation (25%):** The most frequent adverse reactions (>1%) leading to permanent discontinuations of TEPMETKO were edema (8%), pleural effusion (1.6%), and general health deterioration (1.6%)
- **Dosage interruptions (53%):** ARs which required dosage interruption in >2% of patients who received TEPMETKO included edema (28%), increased blood creatinine (6%), pleural effusion (3.5%), nausea (3.2%), increased ALT (2.9%), pneumonia (2.6%), decreased appetite (2.2%), and dyspnea (2.2%)
- **Dose reductions (36%):** ARs which required dose reductions in >2% of patients who received TEPMETKO included edema (22%), increased blood creatinine (2.9%), fatigue (2.2%), and pleural effusion (2.2%)

- Fatal adverse reactions occurred in 1.9% of patients who received TEPMETKO, including pneumonitis (0.3%), hepatic failure (0.3%), dyspnea from fluid overload (0.3%), pneumonia (0.3%), sepsis (0.3%), and death of unknown cause (0.3%)[1]
- Serious adverse reactions occurred in 51% of patients who received TEPMETKO. 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%)[1]

[a]Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.[1] [b]Edema includes eye edema, face edema, generalized edema, localized edema, edema, genital edema, peripheral edema, peripheral swelling, periorbital edema, and scrotal edema.[1] [c]Fatigue includes asthenia and fatigue.[1] [d]Abdominal pain includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain, and hepatic pain.[1] [e]Vomiting includes retching and vomiting.[1] [f]Musculoskeletal pain includes arthralgia, arthritis, back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, myalgia, non-cardiac chest pain, pain in extremity, and spinal pain.[1] [g]Dyspnea includes dyspnea, dyspnea at rest, and dyspnea exertional.[1] [h]Cough includes cough and productive cough.[1] [i]Rash 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.[1] [j]Pneumonia includes pneumonia, pneumonia aspiration, and pneumonia bacterial.[1] [k]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 posttreatment value.[1]

ALP=alkaline phosphatase; ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; GGT=gamma-glutamyl transferase; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer.

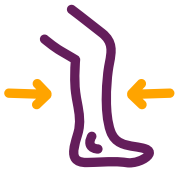
Please see Selected Safety Information throughout and full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

Peripheral edema was observed with TEPMETKO and can be managed[1,2,10]

Compensatory management of peripheral edema included[10]:

Limb elevation



Compression stockings

Dietary salt reduction

Diuretics

Edema was managed with[10]:

Dose reduction

Temporary interruption

Discontinuation

- TRAEs due to peripheral edema occurred in 67.1% of patients, with 11.2% experiencing Grade 3 or higher instances[2]
- Proactive monitoring for peripheral edema is recommended[10]
- TEPMETKO can be dose reduced in one step from two 225-mg tablets (450 mg total) to one 225-mg tablet[1]

TRAEs=treatment-related adverse events.

TEPMETKO® (tepotinib) 225 mg Tablets

Please see Selected Safety Information throughout and full Prescribing Information.

TEPMETKO is the ONLY FDA-approved, once-daily oral MET inhibitor that offers a convenient one step-dose reduction[1]

Once-daily dosing[1]

Starting dosage: 450 mg (two 225-mg tablets)

Advise patients to:

- Take their dose at approximately the same time every day with food until disease progression or unacceptable toxicity
- Swallow tablets whole. Do not chew, crush, or split tablets
- Never make up a missed dose within 8 hours of the next scheduled dose. If vomiting occurs after taking a dose, take the next dose at the scheduled time

Can be dissolved for patients who have difficulty swallowing or have a nasogastric tube[1]

One-step dose reduction[1]

Convenient dosing—remove one tablet to reduce dose to 225 mg once daily

- Permanently discontinue in patients who are unable to tolerate the 225-mg once-daily dose
- Management of some ARs may require temporary interruption or permanent discontinuation. See the full Prescribing Information for recommended dose modifications of TEPMETKO

AR=adverse reaction; FDA=US Food and Drug Administration; MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer.

SELECTED SAFETY INFORMATION

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

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%).

Please see Selected Safety Information throughout and full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

EMD Serono's CoverOne® is a patient access and reimbursement support program

Programs are available to help eligible patients taking TEPMETKO

Reimbursement support

- Help your patients receive TEPMETKO, including prior authorization assistance

Co-pay assistance program[a]

- Help eligible patients get TEPMETKO at a reduced cost

Bridge program for new patients with insurance delays

- Assist eligible patients to access their initial prescription of TEPMETKO while they await coverage

Patient Assistance Program (PAP)

- Provide TEPMETKO to eligible patients at no charge

Additional patient support

- A Patient Support Kit is available for TEPMETKO patients and may be requested by calling CoverOne® or at TEPMETKO.com

- Clinical nurse calls available for TEPMETKO patients through CoverOne®

CoverOne®

Our Access Navigators are committed to helping eligible patients access TEPMETKO
CoverOne.com | Phone: 1-844-826-8371 | **Fax:** 1-800-214-7295 | **Monday-Friday:** 8 AM – 8 PM EST

[a]The CoverOne Co-Pay Assistance Program is entirely for the benefit of the enrolled patient on TEPMETKO. Full terms and conditions apply.

TEPMETKO® (tepotinib) 225 mg Tablets

Please see Selected Safety Information throughout and full Prescribing Information.

TEPMETKO FIRST

Achieved robust and lasting responses[1]

- Largest clinical trial in *MET*ex14+ mNSCLC[1,2]
- The ONLY FDA-approved, once-daily oral MET inhibitor[1]
- Established safety profile[1]

NCCN PREFERRED

Tepotinib (TEPMETKO) is a National Comprehensive Cancer Network® (NCCN®) recommended option as an NCCN Category 2A–preferred regimen for **both first-line and subsequent-line**[a] settings for patients with *MET*ex14+ mNSCLC[6,b-d]

Start with TEPMETKO FIRST for all eligible patients with *MET*ex14+ mNSCLC

[a]If MET inhibitors have not previously been given.[6] [b]Category 2A definition: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.[6] [c]See the NCCN Guidelines for detailed recommendations, including other preferred options.[6] [d]The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested, and recommend testing techniques, but do not endorse any specific commercially available biomarker assays or commercial laboratories.[6]

FDA=US Food and Drug Administration; MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer.

SELECTED SAFETY INFORMATION

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%).

Please see Selected Safety Information throughout and full Prescribing Information.

REFERENCES: 1. TEPMETKO. Prescribing information. EMD Serono, Inc. **2.** Mazieres J, Paik PK, Garassino MC, et al. Tepotinib treatment in patients with *MET* exon 14–skipping non–small cell lung cancer: long-term follow-up of the VISION phase 2 nonrandomized clinical trial. *JAMA Oncol*. 2023;9(9):1260-1266. **3.** Salgia R. MET in lung cancer: biomarker selection based on scientific rationale. *Mol Cancer Ther*. 2017;16(4):555-565. **4.** Asad Zadeh Vosta Kolaei F, Cai B, Kanakamedala H, et al. Biomarker testing patterns and treatment outcomes in patients with advanced non-small cell lung cancer and *MET* exon 14 skipping mutations: a descriptive analysis from the US. *Front Oncol*. 2022;12:786124. **5.** Awad MM, Leonardi GC, Kravets S, et al. Impact of MET inhibitors on survival among patients with non-small cell lung cancer harboring *MET* exon 14 mutations: a retrospective analysis. *Lung Cancer*. 2019;133:96-102. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.1.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed November 10, 2025. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **7.** Data on file, 2024. **8.** Falchook GS, Kurzrock R, Amin HM, et al. First-in-man Phase I trial of the selective MET inhibitor tepotinib in patients with advanced solid tumors. *Clin Cancer Res.* 2020;26(6):1237-1246. **9.** Paik PK, Garassino MC, Le X, et al. Long-term outcomes of tepotinib in patients with *MET* exon 14 skipping NSCLC from the VISION study. Abstract presented at the American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, Illinois. Abstract 9060. **10.** Paik PK, Felip E, Veillon R, et al. Tepotinib in non–small-cell lung cancer with *MET* exon 14 skipping mutations. *N Engl J Med*. 2020;383(10):931-943.

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