TEPMETKO® (tepotinib) 225 mg Tablets

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

TEPMETKO FIRST

Achieve a **robust** and **lasting response**[1-3]

In the largest clinical trial in *MET*ex14+ mNSCLC with a long-term follow-up, **treatment-naïve** patients experienced[1,2]:

- 57% ORR (95% CI: 49, 65) with a DOR range of 1.3 to 56.6 months (n=164)
- 66% of responses lasted ≥6 months and 40% of responses lasted ≥12 months

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

Not an actual patient.

NCCN PREFERRED

Tepotinib is a National Comprehensive Cancer Network® (NCCN®): NCCN Category 2A preferred regimen for first-line/subsequent line*setting for patients with *MET*ex14+ mNSCLC[4†‡§]

*If *MET* inhibitors have not previously been given. †Category 2A definition: based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate. ‡See the NCCN Guidelines for detailed recommendations, including other preferred options. §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.[4]

CI=confidence interval; DOR=duration of response; mNSCLC=metastatic non-small cell lung cancer; ORR=overall response rate.

SELECTED SAFETY INFORMATION

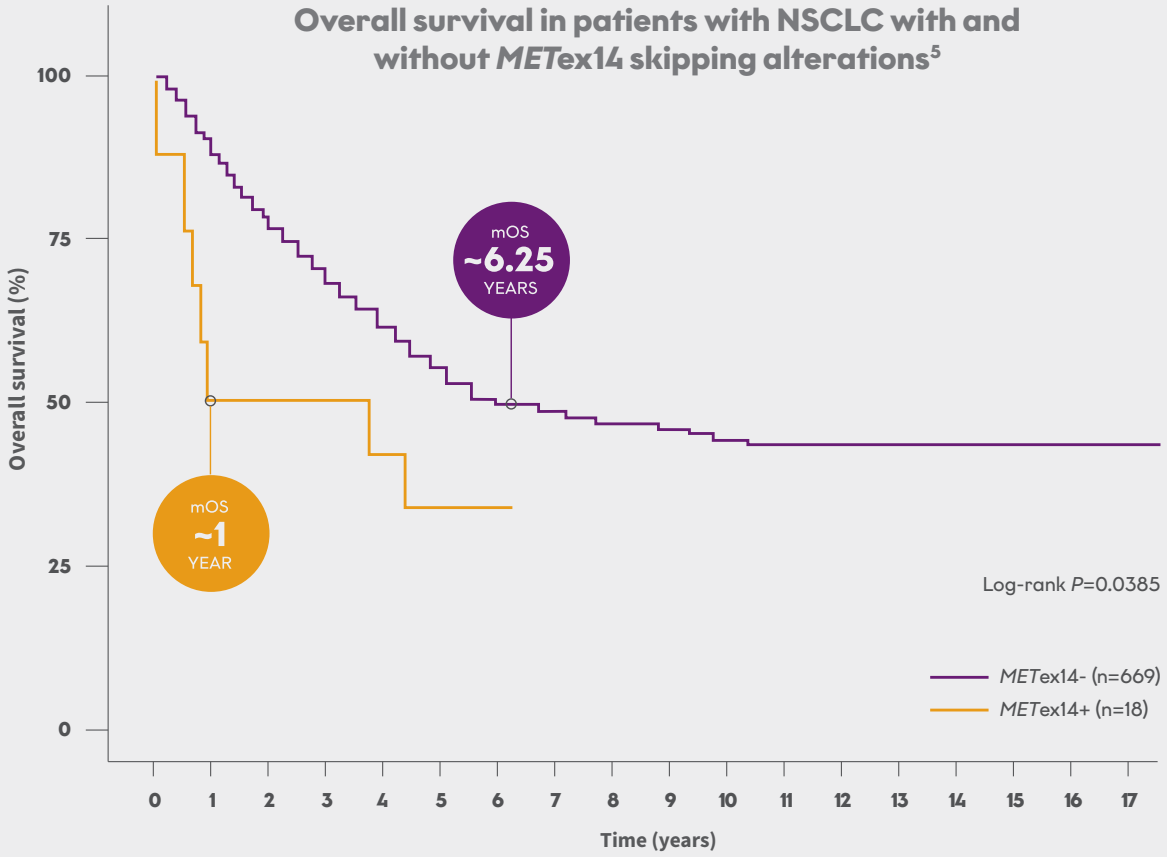
TEPMETKO can cause **interstitial lung disease (ILD)/pneumonitis**, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis and permanently discontinue 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 accompanying full Prescribing Information.

Patients with *MET*ex14 skipping NSCLC face a significantly worse prognosis than those without the alterations[5]

3% to 4% of your patients with NSCLC may harbor *MET*ex14 skipping alterations[3,6,7]

- *MET*ex14 skipping NSCLC responds poorly to standard of care[8,9]



Adapted from Tong, et al. 2016.[5]

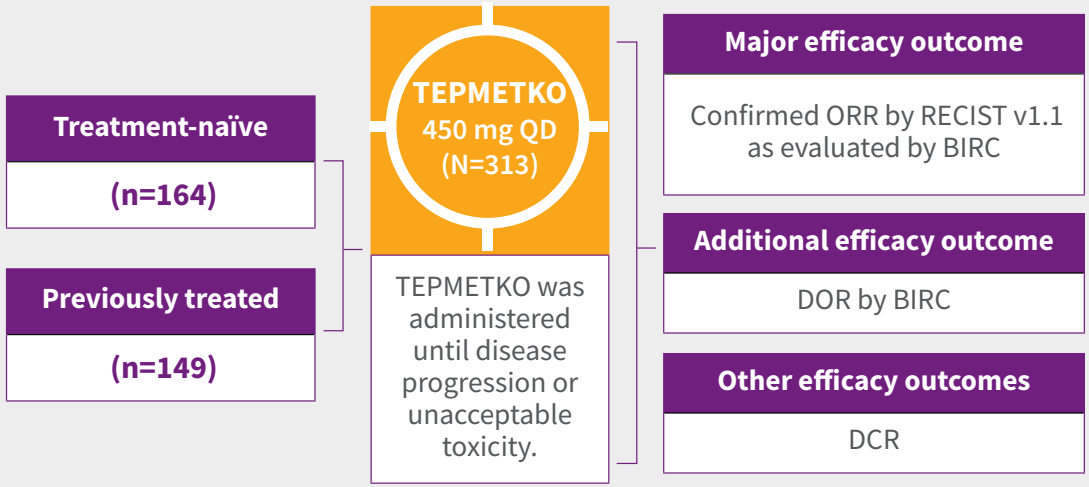
*MET*ex14=mesenchymal-epithelial transition gene exon 14; mOS=median overall survival; NSCLC=non-small cell lung cancer.

VISION Trial – the largest and longest clinical trial in *MET*ex14+ mNSCLC[1,2*]

Pivotal clinical trial

PRIMARY ANALYSIS[4]	LONG-TERM FOLLOW-UP[2]
Data cut-off: January 1, 2020	*Data cut-off:* November 20, 2022
Median follow-up: **>11.8** MONTHS (range: 0.3-37.1)	Median follow-up: **32.6** MONTHS (range: 0.3-71.9)

Trial design[1,2]



Eligibility[1]	Exclusions[1]
• Advanced, metastatic *MET*ex14+ NSCLC • *EGFR* wild-type and *ALK*-negative status • ≥1 measurable lesion by RECIST v1.1 • ECOG PS 0-1	• Symptomatic CNS metastases • Clinically significant uncontrolled cardiac disease • Prior treatment with any MET or HGF inhibitor

*Long-term follow-up of up to 6 years (range: 0.3-71.9 months).

ALK=anaplastic lymphoma kinase; BIRC=Blinded Independent Review Committee; CNS=central nervous system; DCR=disease control rate; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; *EGFR*=epidermal growth factor receptor; HGF=hepatocyte growth factor; MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer; NSCLC=non-small cell lung cancer; ORR=overall response rate; 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 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).

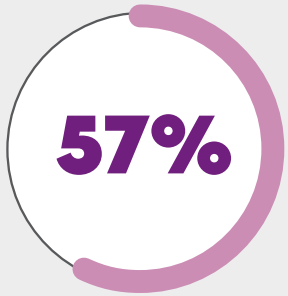
Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

*From the largest-ever clinical trial in patients with METex14+ with long-term follow-up[2]**

TEPMETKO (tepotinib) provided robust and lasting responses in treatment-naïve (n=164) patients[1-3]

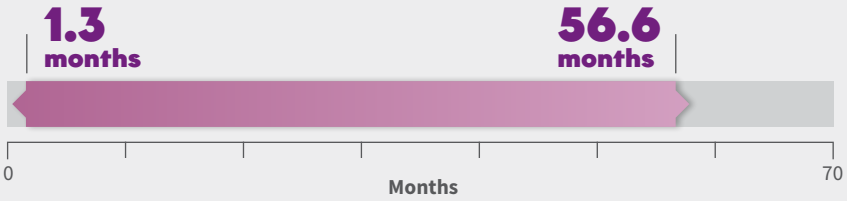
ORR (overall response rate)[2†]



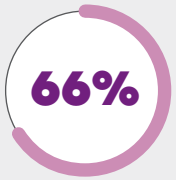
(95% CI: 49, 65)

DOR (duration of response)[1]

Duration of response



Percentage of patients responding



at ≥6 months

at ≥12 months

* Long-term follow-up of up to 6 years (range: 0.3-71.9 months).

† ORR according to RECIST v1.1 as evaluated by a BIRC.

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

SELECTED SAFETY INFORMATION

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.

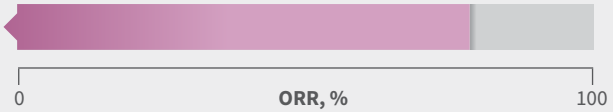
Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

Additional data from VISION Trial in treatment-naïve patients with long-term follow-up*

DCR (disease control rate)[12]

78.7% DCR
(95% CI: 71.6, 84.7)
(n=164)



Limitations:

- DCR (defined as confirmed CR + PR + SD lasting at least 12 weeks as the best overall response by IRC assessments) from first administration of study treatment to the first observation of PD.
- In a single-arm trial, it is not possible to determine if SD is a result of natural disease progression or treatment. DCR was analyzed in a descriptive manner.

Across all treatment-naïve and previously treated patients (n=313), 51% achieved a response with TEPMETKO (n= 161):[3,14]

- 68% responded within 6 weeks
- 81% responded within 12 weeks

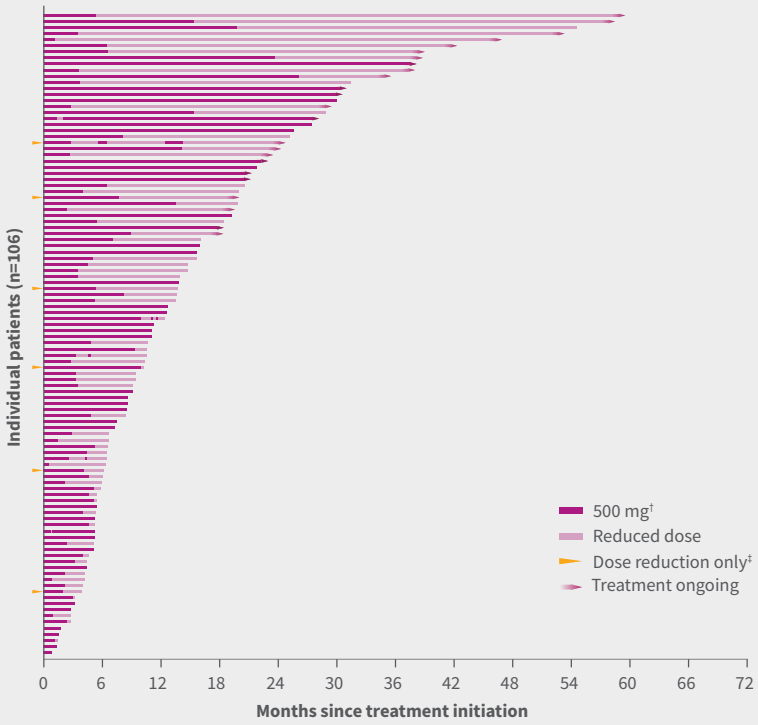
*Long-term follow-up of up to 6 years (range: 0.3-71.9 months).

CI=confidence interval; CR=complete response; DCR=disease control rate; IRC=Independent Review Committee; ORR=overall response rate; PD=progressive disease; PR=partial response; SD=stable disease.

Duration of treatment with dose reductions and/or interruptions[13,14]

Of total patients, 69 patients (42.07%) had at least one dose reduction, and 100 patients (61%) had at least one dose interruption/delay.

†450 mg active moiety. ‡All other patients had ≥1 treatment interruptions.



- Median duration of treatment (n=164): 8.1 months (range: 0.03- 59.37)
- Median duration of treatment with at least one dose reduction or interruption (n=106): 11.1 months (range: 0.7-59.4)

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.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

*From the largest-ever clinical trial in patients with METex14+ with long-term follow-up[2]**

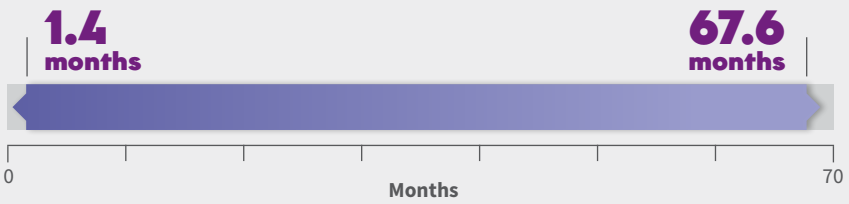
TEPMETKO (tepotinib) provided robust and lasting responses in previously treated (n=149) patients[1-3]

ORR (overall response rate)[2†]

(95% CI: 37, 53)

DOR (duration of response)[1]

Duration of response



Percentage of patients responding

at ≥6 months

at ≥12 months

*Long-term follow-up of up to 6 years (range: 0.3-71.9 months).

†ORR according to RECIST v1.1 as evaluated by a BIRC.

BIRC=Blinded Independent Review Committee; CI=confidence interval; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; 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.

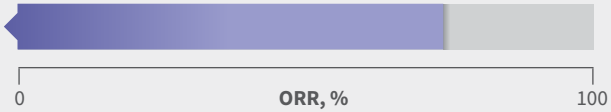
Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

Additional data from VISION Trial in previously treated patients with long-term follow-up*

DCR (disease control rate)[12]

73.8% DCR
(95% CI: 66.0, 80.7)
(n=149)



Limitations:

- DCR (defined as confirmed CR + PR + SD lasting at least 12 weeks as the best overall response by IRC assessments) from first administration of study treatment to the first observation of PD.
- In a single-arm trial, it is not possible to determine if SD is a result of natural disease progression or treatment. DCR was analyzed in a descriptive manner.

Across all treatment-naïve and previously treated patients (n=313), 51% achieved a response with TEPMETKO (n= 161):[3,14]

- 68% responded within 6 weeks
- 81% responded within 12 weeks

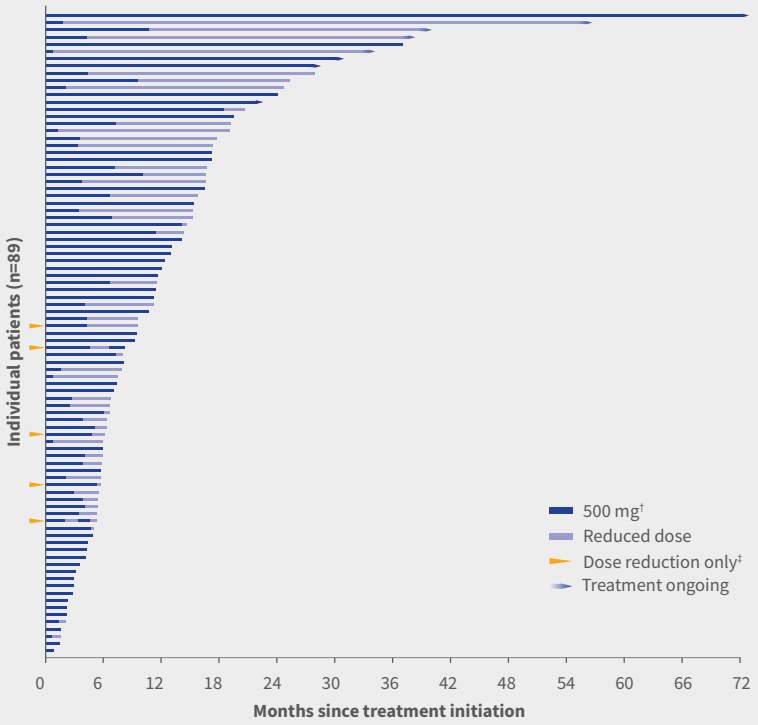
*Long-term follow-up of up to 6 years (range: 0.3-71.9 months).

CI=confidence interval; CR=complete response; DCR=disease control rate; IRC=Independent Review Committee; ORR=overall response rate; PD=progressive disease; PR=partial response; SD=stable disease.

Duration of treatment with dose reductions and/or interruptions[13,14]

Of total patients, 47 patients (31.5%) had at least one dose reduction, and 84 patients (56%) had at least one dose interruption/delay.

†450 mg active moiety. ‡All other patients had ≥1 treatment interruptions.



- Median duration of treatment (n=149): 7.0 months (range: 0.03-71.85)
- Median duration of treatment with at least one dose reduction or interruption (n=89): 9.4 months (range: 0.7-71.9)

SELECTED SAFETY INFORMATION

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.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

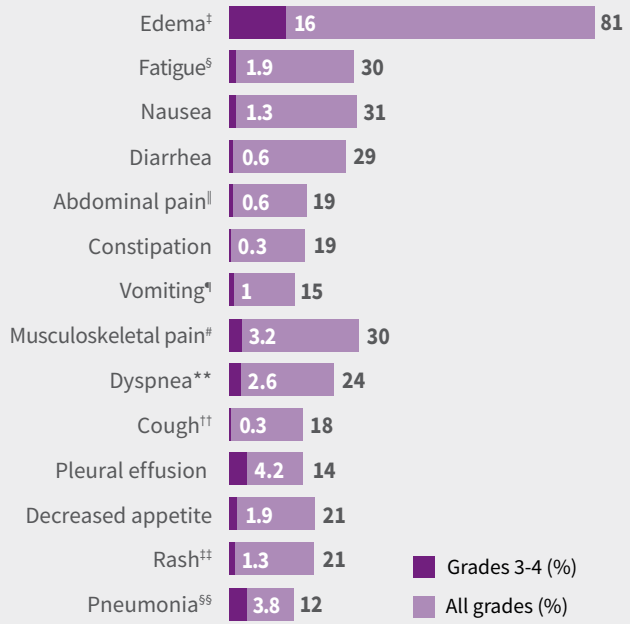
TEPMETKO® (tepotinib) 225 mg Tablets

*From the largest-ever clinical trial in patients with METex14+ with long-term follow-up[2]**

The safety and tolerability of TEPMETKO (tepotinib) were established in 313 patients[1,2]

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 METex14+[1†]



Laboratory abnormalities[1†‖‖]

- **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%)
- 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%)

*Long-term follow-up of up to 6 years (range: 0.3-71.9) †Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03. ‡Edema includes eye edema, face edema, generalized edema, localized edema, edema, genital edema, peripheral edema, peripheral swelling, periorbital edema, and scrotal edema. §Fatigue includes asthenia and fatigue. ‖Abdominal pain includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, gastrointestinal pain, and hepatic pain. ¶Vomiting includes retching and vomiting. #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. **Dyspnea includes dyspnea, dyspnea at rest, and dyspnea exertional. ††Cough includes cough, and productive cough. ‡‡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. §§Pneumonia includes pneumonia, pneumonia aspiration, and pneumonia bacterial. ‖‖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; AR=adverse reaction; AST=aspartate aminotransferase; GGT=gamma-glutamyltransferase; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

Peripheral edema was observed in the VISION Trial and can be managed[2,12]

Edema was managed with dose reduction, temporary interruption, or discontinuation[1,3]

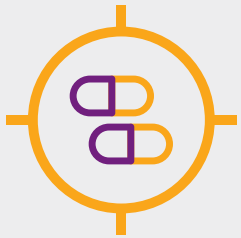
- TRAEs due to peripheral edema occurred in 67.1% of patients, with 11.2% experiencing Grade 3 or higher instances[2,12]
- Proactive monitoring for peripheral edema is recommended[3]
- TEPMETKO can be dose reduced in one step from two 225 mg tablets (450 mg total) to one 225 mg tablet

Compensatory management of peripheral edema included[3]:

Limb elevation

Compression stockings

Dietary salt reduction



Diuretics

TRAE=treatment-related adverse event.

SELECTED SAFETY INFORMATION

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%).

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.

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

TEPMETKO (tepotinib) is the ONLY approved once-daily oral MET inhibitor[1]

Provide your patients with mNSCLC with a convenient dosing regimen

One Dose. Once a Day.

Recommended starting dosage: 450 mg (two 225 mg tablets)

Advise patients to:

- Take their dose at approximately the same time every day 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 and/or have a naso-gastric tube

Patient selection

Select patients for treatment with TEPMETKO based on the presence of *MET*ex14+ in plasma or tumor specimens. Testing for the presence of *MET*ex14+ 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, reevaluate the feasibility of biopsy for tumor tissue testing. An FDA-approved test for detection of *MET*ex14+ in mNSCLC for selecting patients for treatment with TEPMETKO is not available.

One-step dose reduction

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

The only MET inhibitor that offers a convenient one-step dose reduction.

AR=adverse reaction; FDA=US Food and Drug Administration; *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%).

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

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

Available to help eligible patients gain appropriate access to TEPMETKO in the United States

Reimbursement support

- Patient-specific benefit verification
- Formulary research: Medicare Part D, private Rx payers, Medicaid
- Information on NDCs/relevant billing codes for TEPMETKO
- Prior authorization assistance
- Appeals assistance

Bridge program for new patients with insurance delays

- Assists eligible patients diagnosed with the FDA approved indication in accessing their initial prescription of TEPMETKO free of charge, in the event the patient's insurer has not provided a coverage determination for at least 5 business days

Co-pay assistance for privately insured patients*

- Assists privately insured patients on TEPMETKO who meet the program eligibility criteria with co-pay/co-insurance responsibilities
- Government insured patients, including Medicare Part D/Medicare Advantage and Medicaid beneficiaries, are not eligible for the CoverOne Co-Pay Assistance Program
- Enrolled patients may be eligible to pay as little as a $0 co-pay for each prescription of TEPMETKO, up to a maximum of $15,000 per year

Patient Assistance Program/Free Drug Program for eligible patients

- Provides TEPMETKO at no charge for patients who meet certain insurance (i.e., uninsured), income, and residency eligibility criteria
- If eligible, the CoverOne PAP will ship the free supply of TEPMETKO to the patient

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 Eastern Time]

*The CoverOne Co-Pay Assistance Program is entirely for the benefit of the enrolled patient on TEPMETKO. Full terms and conditions apply.
NDC=National Drug Codes; PAP=patient assistance program; Rx=medical prescription.
CoverOne® for TEPMETKO® (tepotinib). https://www.coverone.com/en/home.html

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

TEPMETKO FIRST

TEPMETKO achieved robust and lasting responses in both treatment-naïve and previously treated patients[1-3,12]

- Largest clinical trial in *MET*ex14+ mNSCLC to date
- Evaluated in patients diagnosed by tissue and/or liquid biopsy
- Established safety profile
- The ONLY approved once-daily oral MET inhibitor

For all eligible patients with *MET*ex14+ mNSCLC, start with TEPMETKO.

NCCN PREFERRED

Tepotinib is an NCCN Category 2A preferred regimen for first-line/subsequent line* setting for patients with *MET*ex14+ mNSCLC[4†‡§]

*If *MET* inhibitors have not previously been given. †Category 2A definition: based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate. ‡See the NCCN Guidelines for detailed recommendations, including other preferred options. §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.[4]

MET=mesenchymal-epithelial transition; *MET*ex14+=mesenchymal-epithelial transition gene exon 14 skipping alterations; mNSCLC=metastatic non-small cell lung cancer.

TEPMETKO® (tepotinib) 225 mg Tablets

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 accompanying full Prescribing Information.

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