## **Getting to know TEPMETKO**

# THE **ONLY** APPROVED **ONCE-DAILY** ORAL TREATMENT\*

For people living with metastatic non-small cell lung cancer (mNSCLC) with *MET* exon 14 (*MET*ex14) skipping alterations<sup>†</sup>

#### What is TEPMETKO used for?

TEPMETKO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal epithelial transition (MET) gene. Your healthcare provider will perform a test to make sure that TEPMETKO is right for you.

It is not known if TEPMETKO is safe and effective in children.

\*Recommended dose is 450 mg once daily with food; see pages 12-13 to learn more.

<sup>†</sup> METex14 skipping is a biomarker representing specific abnormal changes in the MET gene that may drive cancer growth.

#### **SELECTED SAFETY INFORMATION**

#### What Warnings should I know about TEPMETKO?

TEPMETKO may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems, including: trouble breathing; shortness of breath; cough; or fever.



## **QUESTIONS YOU MAY HAVE ABOUT TEPMETKO**

You and your loved ones will likely have questions about your treatment. Here are some questions that may help you start the conversation with your healthcare team at your next appointment.

Remember—being open and honest about your questions and concerns can help you get the most out of your time together. Don't hesitate to ask for more information.

	How is TEPMETKO different from other treatments?
	Is there anything I should do before taking TEPMETKO?
	What can I expect during treatment?
	How will I know if TEPMETKO is working?
	What are the possible side effects of TEPMETKO, and how do I manage them?
	How long do I need to take TEPMETKO?
Write do	wn any other questions you may have:



## **GETTING TO KNOW TEPMETKO**

This brochure explains what metastatic NSCLC with *MET*ex14 skipping is and how treatment with TEPMETKO may help. It also includes clinical trial data, common side effects of the medicine, dosing instructions, and more.

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METex14=mesenchymal-epithelial transition exon 14; mNSCLC=metastatic non-small cell lung cancer; NSCLC=non-small cell lung cancer.



## WHAT IS mNSCLC WITH METex14 SKIPPING?

Based on 2024 estimates in the United States:

More than

Of those individuals,

234,000 | | | | | | | | | | | | 87%

individuals were newly diagnosed with lung cancer<sup>a</sup> have NSCLCb

There are many types of NSCLC, some of which have specific genetic differences that are not inherited. These genetic differences, or gene mutations, can cause lung cancer cells to grow and multiply.

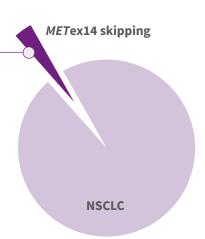
In a healthy individual, the MET gene plays a key role in organ development, tissue repair, and wound healing. METex14 skipping alteration is a genetic abnormality in which the MET gene is impaired, which can drive cancer growth in NSCLC.

## Approximately

3% to 4% °

of NSCLC cases (about 6,100 to 8,100 individuals) may have the **METex14 skipping** alterations biomarker<sup>a,b</sup>

METex14 can be detected by an FDA-approved comprehensive biomarker test. A positive result for METex14 skipping may guide your healthcare team in making treatment decisions.



<sup>&</sup>lt;sup>a</sup> https://seer.cancer.gov/statfacts/html/lungb.html

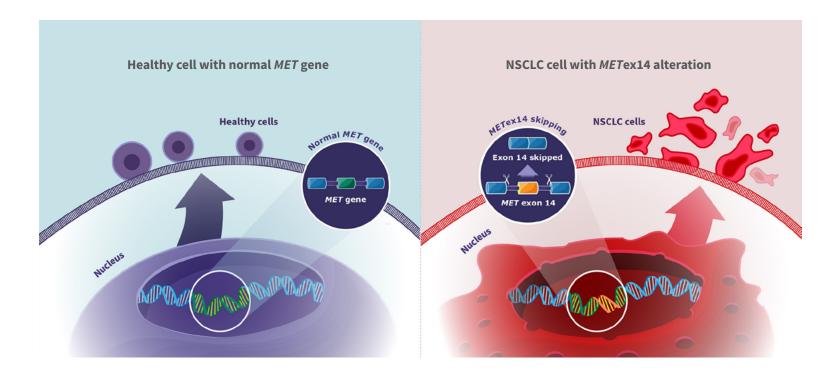
<sup>&</sup>lt;sup>b</sup> https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html

## **HOW DOES METex14 INFLUENCE LUNG CANCER?**

#### METex14 skipping is caused by mutations in the MET gene.

Some genetic changes, or mutations, can cause cells to multiply out of control. Certain mutations in the *MET* gene cause *MET*ex14 skipping, a specific genetic abnormality leading to the accumulation of cancer-driving proteins, which promote the growth of NSCLC tumors.

Targeted therapies, called MET inhibitors, are available to treat patients with METex14 skipping NSCLC.



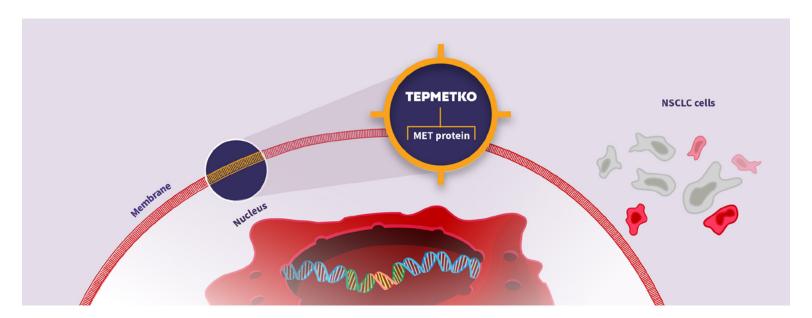
#### WHAT IS TEPMETKO?

TEPMETKO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene

#### **How does TEPMETKO work?**

TEPMETKO works by binding to and blocking MET proteins to help prevent cancer from growing.



#### SELECTED SAFETY INFORMATION

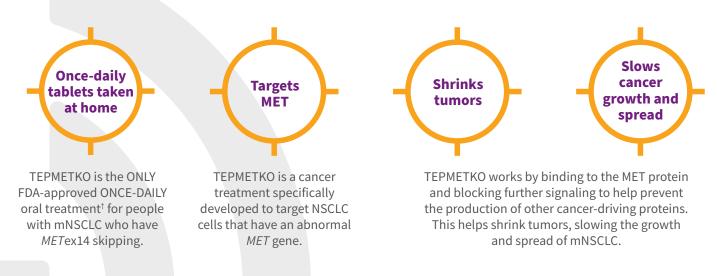
#### What Warnings should I know about TEPMETKO? (continued)

TEPMETKO may cause abnormal liver blood test results. One patient died from liver failure. Your healthcare provider will do blood tests to check your liver function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including: your skin or the white part of your eyes turns yellow; dark or "tea colored" urine; light-colored stools (bowel movements); confusion; tiredness; loss of appetite for several days or longer; nausea and vomiting; pain, aching, or tenderness on the right side of your stomach-area (abdomen); weakness; or swelling in your stomach-area.



#### WHY TEPMETKO?

Tepotinib (TEPMETKO) has been used to treat mNSCLC since 2021. It is recommended as a **preferred treatment for** *MET***ex14 skipping mNSCLC by the National Comprehensive Cancer Network® (NCCN®).** <sup>1\*</sup> The criteria for NCCN preferred status is based on effectiveness, safety, and evidence.



<sup>\*</sup>In patients taking TEPMETKO as their first treatment and those previously treated before taking TEPMETKO, if previous treatment did not include a MET inhibitor. ¹Recommended dose is 450 mg once daily with food; see pages 13-14 to learn more.

FDA=US Food and Drug Administration; MET=mesenchymal-epithelial transition; METex14=mesenchymal-epithelial transition exon 14; mNSCLC=metastatic non-small cell lung cancer; NSCLC=non-small cell lung cancer.

Reference: 1. Referenced with permission from the NCCN Guidelines for Patients based on the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer, Version 3. 2025 (https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1450) — copyright date April 23, 2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 26, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

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#### SELECTED SAFETY INFORMATION

#### What Warnings should I know about TEPMETKO? (continued)

TEPMETKO may cause increases in your blood amylase and lipase levels that may indicate a problem with your pancreas. Your healthcare provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider right away if you develop upper stomach (abdominal) pain, weight loss, nausea, or vomiting.

Please see Selected Safety Information throughout and accompanying full <a href="Prescribing Information">Prescribing Information</a> for TEPMETKO.



#### **HOW WAS TEPMETKO STUDIED?**

The effectiveness of TEPMETKO was studied in the largest clinical trial in *MET*ex14 skipping mNSCLC, with 313 adults divided into 2 groups:

1 164 people who were NOT PREVIOUSLY TREATED before taking TEPMETKO 2 149 people who were PREVIOUSLY TREATED before taking TEPMETKO

#### The clinical trial measured:



#### Overall response rate

The percentage of people who saw their tumors shrink or disappear\*



#### **Duration of response**

How long their cancer continued to respond to treatment without growing or spreading

\*In some people, tumors become smaller or the number of tumors decrease. Tumors can also disappear (not the same as a cure). METex14=mesenchymal-epithelial transition exon 14; mNSCLC=metastatic non-small cell lung cancer.

#### SELECTED SAFETY INFORMATION

What Warnings should I know about TEPMETKO? (continued)

TEPMETKO can cause harm to an unborn baby in pregnant women.

#### Females who are able to become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with TEPMETKO.
- You should use effective birth control (contraception) during treatment and for 1 week after the last dose of TEPMETKO. Talk to your healthcare provider about birth control methods that may be right for you.

**Males with female partners who are able to become pregnant** should use effective birth control during treatment with TEPMETKO and for 1 week after the last dose of TEPMETKO.

Please see Selected Safety Information throughout and accompanying full <a href="Prescribing Information">Prescribing Information</a> for TEPMETKO.



#### **HOW MAY TEPMETKO HELP?**

Among 164 people **NOT PREVIOUSLY TREATED** for mNSCLC with *MET*ex14 skipping, **TEPMETKO was proven to help shrink or help slow the growth of tumors** 

## Nearly 6 in 10 people

(57%) saw their tumors shrink or disappear



Among those who saw their tumors shrink or disappear with TEPMETKO treatment:

66%

of responses lasted at least **6 months** 

40%

of responses lasted at least 12 months

Tumors did not grow or spread for a range of 1.3 to 56.6 months

(up to  $\sim$ 4.7 years)

METex14=mesenchymal-epithelial transition exon 14; mNSCLC=metastatic non-small cell lung cancer.

#### **SELECTED SAFETY INFORMATION**

#### What should I tell my health care provider?

Tell your healthcare provider about all of your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- · have or have had liver problems
- have or have had pancreatic problems
- are pregnant or plan to become pregnant. TEPMETKO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TEPMETKO passes into your breast milk. Do not breastfeed during treatment and for 1 week after the last dose of TEPMETKO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



## **HOW MAY TEPMETKO HELP?** (CONTINUED)

Among 149 people **PREVIOUSLY TREATED** for mNSCLC with *MET*ex14 skipping, **TEPMETKO** was proven to help shrink or help slow the growth of tumors

## Over 4 in 10 people

(45%) saw their tumors shrink or disappear



Among those who saw their tumors shrink or disappear with TEPMETKO treatment:

66%

of responses lasted at least **6 months** 

36%

of responses lasted at least **12 months** 

Tumors did not grow or spread for a range of 1.4 to 67.6 months

(up to  $\sim$ 5.6 years)

METex14=mesenchymal-epithelial transition exon 14; mNSCLC=metastatic non-small cell lung cancer.



WHAT ARE THE POSSIBLE SIDE EFFECTS OF TEPMETKO?

#### The most common side effects of TEPMETKO include:

- Swelling
- Muscle and joint pain

- Nausea
- Diarrhea
- Tiredness
- Diaminea
- Shortness of breath
- Loss of appetite
- Rash
- Changes in certain blood tests

## Managing edema (swelling)

Swelling in the face or other parts of the body was the most common side effect observed in the TEPMETKO clinical trial.

Talk to your healthcare provider about ways to manage swelling, including:

Limb elevation

- Diuretics
- Compression stockings
- Exercising regularly

• Dietary salt intake

## If you are experiencing or concerned about these or other side effects, contact your healthcare provider, who may:

- · Change your dosage
- Temporarily stop treatment
- Permanently stop treatment

These are not all of the possible side effects of TEPMETKO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## Using TEPMETKO safely and effectively

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TEPMETKO for a condition for which it was not prescribed. Do not give TEPMETKO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TEPMETKO.



## WHAT ARE THE POSSIBLE SIDE EFFECTS OF TEPMETKO?

(CONTINUED)

While less common, there are some additional side effects that you should be aware of. Talk to your healthcare provider to better understand the potential side effects that could occur while taking TEPMETKO.

## Lung problems

TEPMETKO may cause severe or lifethreatening swelling (inflammation) of the lungs during treatment that can lead to death. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems, including:

- Trouble breathing
- Shortness of breath
- Cough
- Fever

## Liver problems

TEPMETKO may cause abnormal liver blood test results. Your healthcare provider will do blood tests to check your liver function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:

- Your skin or the white part of your eyes turns yellow
- Dark or "tea colored" urine
- Light-colored stools (bowel movements)
- Confusion
- Tiredness
- · Loss of appetite for several days or longer
- Nausea and vomiting
- Pain, aching, or tenderness on the right side of your stomach-area (abdomen)
- Weakness
- Swelling in your stomach-area

#### Pancreas problems

TEPMETKO may cause increases in your blood amylase and lipase levels that may indicate a problem with your pancreas. Your healthcare provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TEPMETKO. Tell your healthcare provider right away if you develop any signs and symptoms of pancreas problems, including:

- Upper stomach (abdominal) pain that may spread to your back and get worse with eating
- Weight loss
- Nausea
- Vomiting



## **HOW IS TEPMETKO TAKEN?**

#### TEPMETKO should be taken exactly as your doctor prescribed.



## Take 450 mg of TEPMETKO once a day with food.

Do not change your dose or stop taking TEPMETKO unless recommended by your doctor.



#### Swallow whole.

#### Do not chew, crush, or split tablets.

- If you cannot swallow TEPMETKO tablets whole:
  - Place your prescribed dose of TEPMETKO tablets in a glass that contains 30 mL (1 ounce) of noncarbonated water. **Do not** use or add any other liquids
- Stir the TEPMETKO tablets and water until the TEPMETKO tablets are in small pieces (the tablets will not completely dissolve). **Do not** crush TEPMETKO tablets
- Drink the TEPMETKO and water mixture right away or within 1 hour. Make sure to swallow the mixture.
   Do not chew pieces of the tablet
- Add another 30 mL of non-carbonated water to the glass and drink it right away to get your full dose of TEPMETKO.
- If a nasogastric tube is needed, follow the same instructions for dissolving, and the tube manufacturer instructions for giving the water and TEPMETKO through the tube within 1 hour



## Stay on schedule.

Take your dose at about the same time each day.



## **HOW IS TEPMETKO TAKEN? (CONTINUED)**

#### What if I miss a dose of TEPMETKO?



- If you miss a dose of TEPMETKO, take it as soon as you remember. If your next dose is due within 8 hours, skip the missed dose and take your next dose at your regular scheduled time
- If you vomit after taking a dose of TEPMETKO, take your next dose at your regular scheduled time
- Remember, following a routine dosing schedule can help keep your treatment on track

#### How should I store/handle TEPMETKO?



Store TEPMETKO at room temperature

68°F to 77°F (20°C to 25°C)



Store TEPMETKO tablets in original packaging

(blister cards with child-resistant blister foil)



Keep TEPMETKO and all medicines out of the reach of children



**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.\*

#### **Program provides:**

- Reimbursement support
- Bridge program for new patients with insurance delays
- Co-pay assistance for privately insured patients
- Patient assistance program/free drug program for eligible patients
- Complimentary TEPMETKO Patient Support Kit for all new patients

Your complimentary TEPMETKO Patient Support Kit may be requested by calling CoverOne or at <u>TEPMETKO.com</u>

## CoverOne.com

Learn more at TEPMETKO.com

## Our Access Navigators are committed to helping eligible patients access TEPMETKO

Please contact us if you have any questions or fax a completed CoverOne Enrollment Form to verify patient-specific coverage or request assistance. **Enrollment forms and complete program information are available through CoverOne.com.** 

You may find additional resources at\*: lungevity.org metcrusaders.org

\*Additional program rules and restrictions or conditions may apply. These organizations are independent nonprofit organizations. Their inclusion here does not indicate or imply endorsement of TEPMETKO or EMD Serono, Inc. In addition, EMD Serono, Inc. has no control over and takes no responsibility for the content of these websites.

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# TEPMETKO IS THE ONLY APPROVED ONCE-DAILY ORAL TREATMENT

for people living with mNSCLC with METex14 skipping alterations

- Specifically developed to help shrink or help slow the growth of tumors in METex14 skipping mNSCLC
- Studied in a clinical trial of 313 adults with METex14 skipping mNSCLC taking TEPMETKO as their first treatment or who had been previously treated
  - Nearly 6 in 10 people (57%) who were not previously treated saw their tumors shrink or disappear
  - More than 4 in 10 people (45%) who were previously treated saw their tumors shrink or disappear
  - For 66% of people in both groups, responses to treatment lasted at least 6 months



- The most common side effect of TEPMETKO is swelling in the face or other parts of the body—talk to your doctor about ways to manage swelling
- Resources are available to support you while you are being treated with TEPMETKO

## ASK YOUR DOCTOR IF TEPMETKO IS THE RIGHT CHOICE FOR YOU

Learn more at **TEPMETKO.com** 

 $\textit{MET} ex 14 = mesenchymal-epithelial\ transition\ exon\ 14; mNSCLC = metastatic\ non-small\ cell\ lung\ cancer.$ 

#### SELECTED SAFETY INFORMATION

#### What are the side effects of TEPMETKO?

The most common side effects of TEPMETKO include: swelling in your face or other parts of your body; nausea; tiredness; diarrhea; muscle and joint pain; diarrhea; shortness of breath; loss of appetite; rash; and changes in certain blood tests. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with TEPMETKO if you develop serious side effects during treatment. These are not all of the possible side effects of TEPMETKO. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.