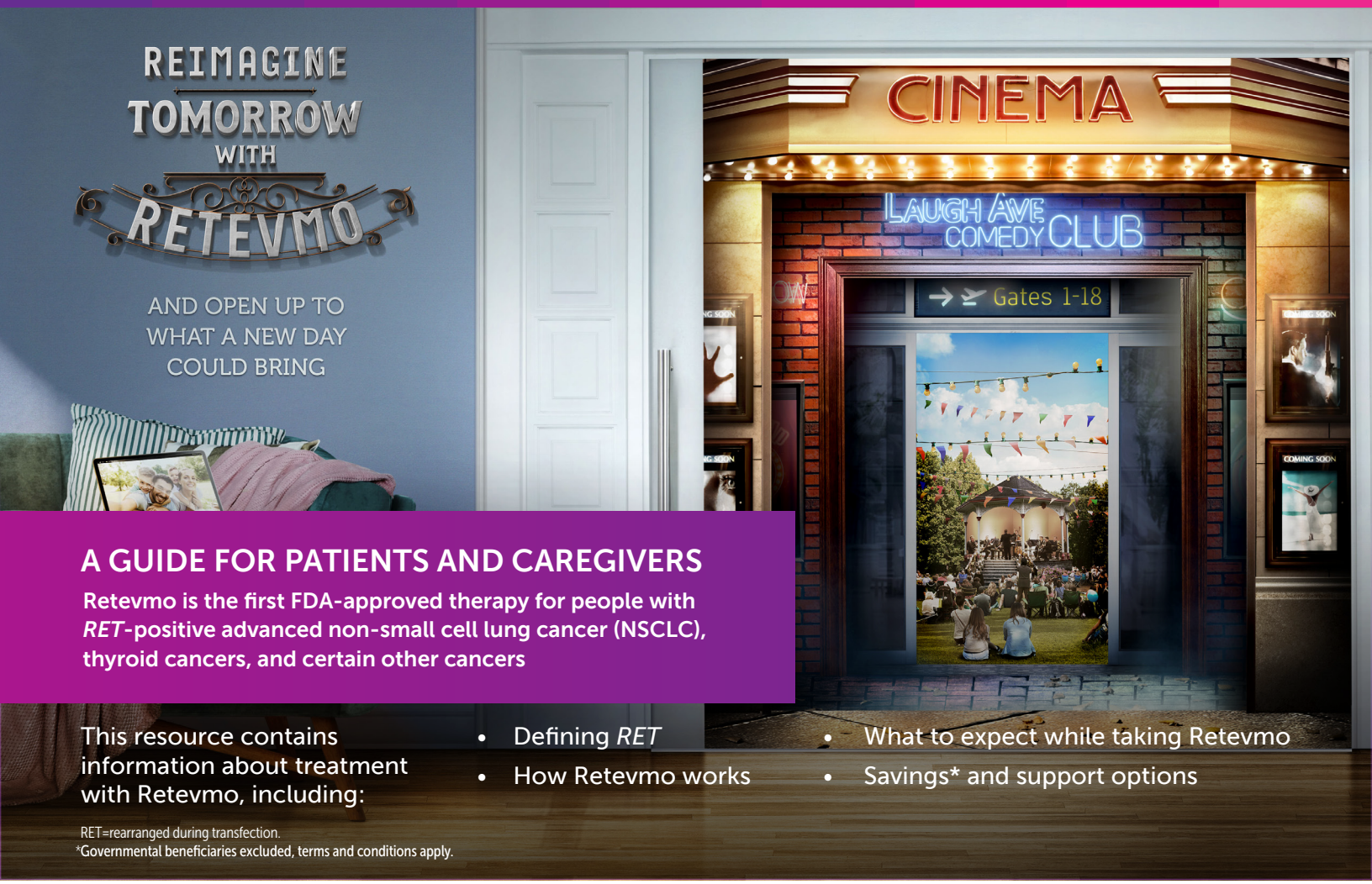

A GUIDE FOR PATIENTS AND CAREGIVERS

Retevmo is the first FDA-approved therapy for people with *RET*-positive advanced non-small cell lung cancer (NSCLC), thyroid cancers, and certain other cancers

This resource contains information about treatment with Retevmo, including:

- Defining *RET*
- How Retevmo works
- What to expect while taking Retevmo
- Savings* and support options

RET=rearranged during transfection.
*Governmental beneficiaries excluded, terms and conditions apply.

INDICATIONS

What is Retevmo?

Retevmo is a prescription medicine that is used to treat certain cancers caused by abnormal RET genes in:

- adults with locally advanced non-small cell lung cancer (NSCLC) or NSCLC that has spread
- adults and children 2 years of age and older with advanced medullary thyroid cancer (MTC) or MTC that has spread, who require a medicine by mouth or injection (systemic therapy)
- adults and children 2 years of age and older with advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection (systemic therapy), and who have received radioactive iodine and it did not work or is no longer working
- adults and children 2 years of age and older with locally advanced solid tumors (cancers) or solid tumors that have spread, and have gotten worse (progressed) on or after other treatment or there are no satisfactory treatment options†

Your healthcare provider will perform a test to make sure that Retevmo is right for you.

It is not known if RETEVMO is safe and effective when used:

- in children younger than 2 years of age, or in children with other conditions.

†Retevmo was approved based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long the response lasted. Studies are ongoing to confirm the benefit of Retevmo for this use.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Liver problems: Liver problems (increased liver enzymes) can happen during treatment with RETEVMO and may sometimes be serious. Your healthcare provider will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your healthcare provider right away if you get any of the following symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes (jaundice)
- dark, "tea-colored" urine
- sleepiness
- bleeding or bruising
- loss of appetite
- nausea or vomiting
- pain on the upper right side of your stomach area

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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A Lilly Medicine

What is *RET*?

RET is a gene that everyone has, but certain cancers can be driven by alterations in *RET*.

We all have something called *RET* in our bodies, similar to how we have faucets in our homes. When a person has a *RET* alteration, it's like that faucet gets stuck in the "on" position, allowing water to spread, just as *RET* alterations allow cancer to grow. Retevmo acts like a wrench that helps turn the faucet off.

Retevmo may affect both healthy cells and tumor cells, which can result in side effects, some of which can be serious.

KNOWING WHAT IS DRIVING YOUR TYPE OF CANCER CAN HELP YOU AND YOUR DOCTOR **CHOOSE THE RIGHT TREATMENT**

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Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

Testing for *RET*

Testing for *RET* is the first step: Your doctor will perform a test to help determine if Retevmo is right for you.

If you are unsure about your *RET* status, talk with your doctor about biomarker testing to find out if Retevmo is the right treatment for your cancer.

To determine if your cancer is *RET*-positive, your doctor may opt to perform a biomarker test. A biomarker test is a type of genetic test that can tell your doctor a lot about your cancer's DNA.

Step 1: Ask
Ask your doctor if you have received a broad biomarker test for less common alterations like *RET*.

Step 2: Talk
Talk to your doctor about the results of the biomarker test.

Step 3: Treat
Treatment with Retevmo may be an option if your cancer tests positive for *RET*.

Certain biomarker tests require your doctor to biopsy the tumor, which means removing some tissue or blood for testing. Some biopsies are surgical, may require sedation, and come with a risk of infection. Your doctor will select the right type of biopsy for your tumor. If your tumor has been biopsied previously, some tissue may already be available for testing.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

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

- shortness of breath
- cough
- fever

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Talking to your doctor

Here are a few questions to help guide the discussion with your doctor

"Have I been tested for all biomarkers that have available treatments?"

- Ask your doctor if they recommend a broad biomarker test that can show if you have a less common alteration like *RET*. The sooner it is determined whether your cancer is *RET*-positive, the sooner you and your doctor can determine if Retevmo is right for you.

"What does it mean to test positive for *RET*?"

- If your tumor tests positive for *RET*, this means *RET* may be what is driving your cancer.

TO DETERMINE IF YOUR CANCER IS *RET*-POSITIVE, YOUR DOCTOR MAY OPT TO PERFORM A BIOMARKER TEST

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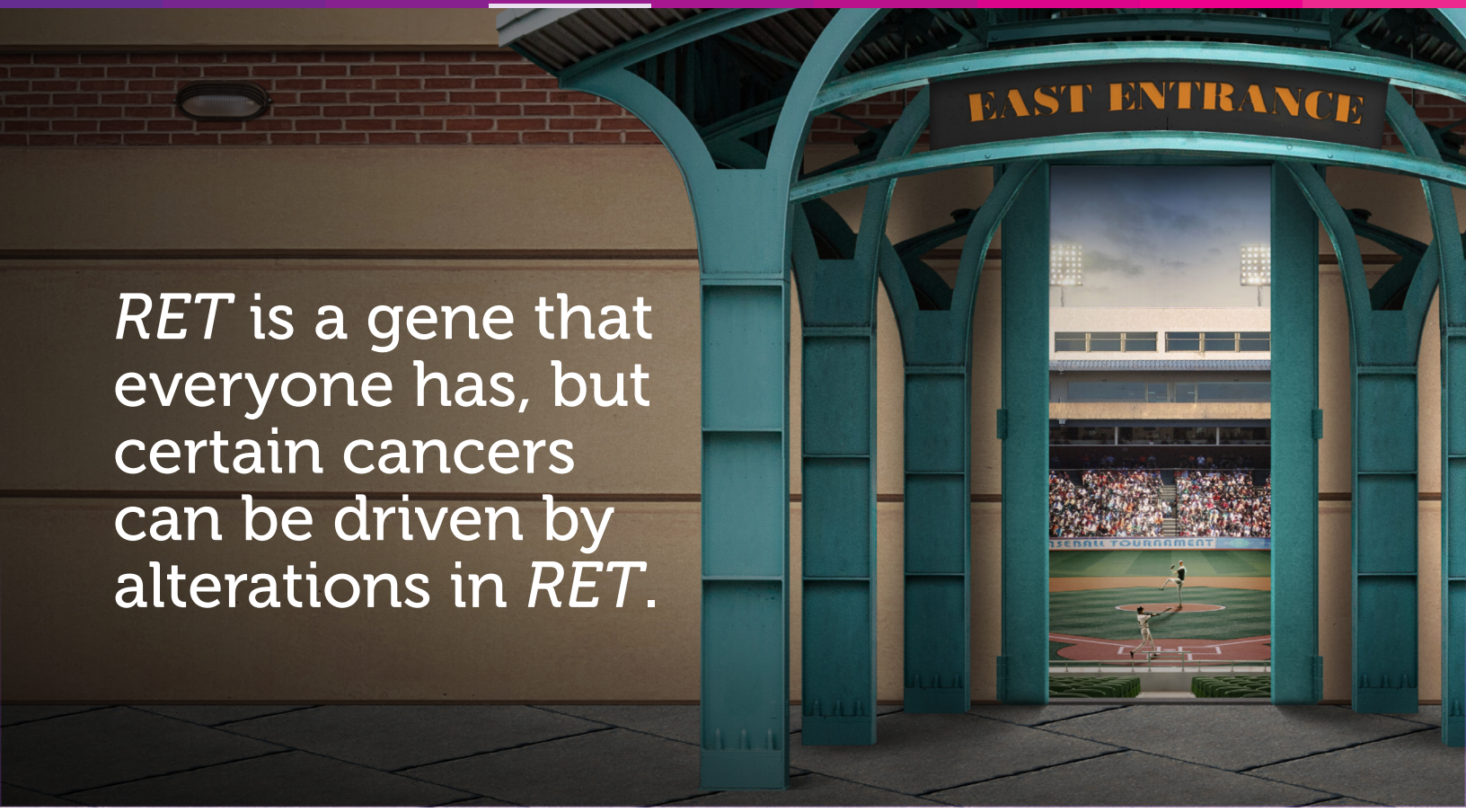

RET is a gene that everyone has, but certain cancers can be driven by alterations in *RET*.

Retevmo is a targeted cancer therapy; it is not chemotherapy

Retevmo is a prescription oral therapy that was designed to block the primary driver of tumor growth in *RET*-positive advanced NSCLC, thyroid cancer, and certain other cancers.

Retevmo may affect both healthy cells and tumor cells, which can result in side effects, some of which can be serious.

TALK TO YOUR DOCTOR TODAY TO FIND OUT IF **RETEVMO IS RIGHT FOR YOU**

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be severe. You should check your blood pressure regularly during treatment with RETEVMO. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your healthcare provider if you have increased blood pressure readings or get any symptoms of high blood pressure, including:

- confusion
- headaches
- shortness of breath
- dizziness
- chest pain

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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Retevmo has been shown to shrink tumors in the majority of people with *RET*-positive advanced thyroid cancer

Retevmo was studied in the largest clinical trial of people 12 years of age and older with *RET*-positive cancers. The trial included people with advanced thyroid cancer (including medullary, papillary, poorly differentiated, anaplastic, and Hurthle cell), and had tumors that were eligible to be evaluated for shrinkage. The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long the response lasted.

For people with *RET*-positive advanced MTC:

76% of the 55 people **who had prior cancer treatments*** had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median† of 45.3 months

81% of the 88 people **who had not received certain standards of care‡** had an objective response

- Median† length of response has not yet been reached, as the trial is ongoing

For people with other *RET*-positive advanced thyroid cancer:

85% of the 41 people **who had prior cancer treatments§** had an objective response

- Responses lasted a median† of 26.7 months

96% of the 24 people **who had not received certain standards of care‖** had an objective response

- Median† length of response has not yet been reached, as the trial is ongoing

*Cabozantinib and/or vandetanib.
†Median is the middle number in a set of numbers.
‡Not treated with cabozantinib and/or vandetanib.
§Radioactive iodine in addition to other systemic therapy.
‖Not treated with systemic therapies other than radioactive iodine.

Objective response rate (ORR) is defined as the proportion of patients who have a partial or complete response to therapy.

Duration of Response (DoR) Duration of response, or DoR, is the length of time that a patient continues to respond to treatment without the cancer growing or spreading.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Heart rhythm changes (QT prolongation). RETEVMO may cause very slow, very fast, or irregular heartbeats. Your healthcare provider may perform tests before and during treatment with RETEVMO to check the activity of your heart and the levels of body salts (electrolytes) and thyroid-stimulating hormone (TSH) in your blood. Tell your healthcare provider right away if you get any of the following symptoms:

- loss of consciousness
- fainting
- dizziness
- a change in the way your heart beats (heart palpitations)

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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Retevmo was studied in a clinical trial of 291 people 12 years of age and older, with advanced or metastatic *RET*-driven medullary thyroid cancer (MTC).

The study compared Retevmo to cabozantinib or vandetanib and measured how long patients lived without their cancer getting worse.

In this clinical trial comparing Retevmo to cabozantinib or vandetanib (other types of cancer treatment)

14% of the 193 patients who recieved Retevmo saw their cancers get worse.

- also called "disease progression"

34% of the 98 patients who recieved cabozantinib or vandetanib saw their cancers get worse.

- also called "disease progression"

Progression-free survival (PFS) is the amount of time during and after treatment that the cancer doesn't get worse. In other words, PFS is how long cancer growth is delayed from the time a treatment is started.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Bleeding problems: RETEVMO can cause bleeding, which can be serious and may lead to death. Tell your healthcare provider if you have any signs of bleeding during treatment, including:

- vomiting blood or if your vomit looks like coffee-grounds
- pink or brown urine
- red or black stools that look like tar
- coughing up blood or blood clots
- unusual bleeding or bruising of your skin
- menstrual bleeding that is heavier than normal
- unusual vaginal bleeding
- nose bleeds that happen often
- drowsiness or difficulty being awakened
- confusion
- headache
- change in speech

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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Retevmo has been shown to shrink tumors in the majority of people with *RET*-positive advanced NSCLC

Retevmo was studied in the largest clinical trial of people with *RET*-positive cancers. The trial included people with advanced NSCLC, and 316 had tumors that were eligible to be evaluated for shrinkage. The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long the response lasted.

84% of the 69 people who had never received any cancer treatment had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 20.2 months

61% of the 247 people who had prior cancer treatment† had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 28.6 months

In the trial, Retevmo reduced the size of tumors in the brain in people with advanced *RET*-positive NSCLC

4 of the 5 people who had never received any cancer treatment, and whose advanced NSCLC had spread to their brain, saw their brain tumors either shrink by at least 30% or disappear completely, and 38% of responders had a response that lasted at least 12 months

14 of the 16 people who received prior cancer treatment,† and whose advanced NSCLC had spread to their brain, saw their brain tumors either shrink by at least 30% or disappear completely, and 39% of responders had a response that lasted at least 12 months

*Median is the middle number in a range of numbers.
†Platinum-based chemotherapy; some had also received other therapies.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Allergic reactions: RETEVMO can cause a fever, rash, or pain in muscles or joints, especially during the first month of treatment. Tell your healthcare provider if you get any of these symptoms.

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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See how Retevmo helped some adults in a clinical trial with certain RET-positive advanced cancers

Retevmo was studied in the largest clinical trial of people with *RET*-positive cancers. The trial included people with certain advanced cancers, like pancreatic cancer, colon cancer, and breast cancer, and all had tumors that were eligible to be evaluated for shrinkage. The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long the response lasted.

Retevmo has been shown to shrink tumors in some adults with certain RET-positive advanced cancers

44% of the 41 people had an objective response, meaning their tumors shrank by 30% or more

- Responses lasted a median* of 24.5 months

*Median is the middle number in a range of numbers.

RETEVMO MAY HELP BY TARGETING WHAT IS DRIVING CERTAIN *RET*-POSITIVE ADVANCED CANCERS

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Tumor lysis syndrome (TLS): TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure, the need for dialysis treatment, and an abnormal heartbeat. TLS can lead to hospitalization. Your healthcare provider may do blood tests to check you for TLS. You should stay well hydrated during treatment with RETEVMO. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with RETEVMO:

- nausea
- vomiting
- weakness
- swelling
- shortness of breath
- muscle cramps
- seizures

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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How to take Retevmo

Retevmo is taken by itself and not in combination with additional cancer therapies

Retevmo is usually taken orally twice daily, with each dose 12 hours apart

Retevmo can be taken at home, with or without food.* Swallow Retevmo whole. Do not break, chew or crush. Do not give Retevmo capsules to children if they are unable to swallow capsules.

Common questions about how to take Retevmo

How often should I take Retevmo?

Take Retevmo exactly as your doctor tells you. Your doctor may change your dose, if needed. Do not change your dose or stop taking Retevmo without talking to your doctor.

If I'm taking other medicines, do these medicines affect how I take Retevmo?

*If you take:

- a proton-pump inhibitor, take Retevmo with food. Examples of PPIs include dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole
- an H2 blocker, take Retevmo 2 hours before or 10 hours after taking the H2 blocker. Examples of H2 blockers include famotidine, nizatidine, and cimetidine
- an antacid that contains aluminum, magnesium, calcium, simethicone, or buffered medicines, take Retevmo 2 hours before or 2 hours after taking the antacid

What should I do if I miss a dose or get sick after taking a dose?

Do not take a missed dose of Retevmo unless it is more than 6 hours until your next scheduled dose.

If you get sick after taking a dose, do not take an extra dose, and take your next dose at your regular time. In the event that you take too much Retevmo, call your doctor or go to the nearest hospital emergency room right away.

If you have questions about Retevmo or need more information on how to take it, you should talk to your doctor. You can also call Lilly Support Services™ for Retevmo® at **1-800-LillyRx (1-800-545-5979).**

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Risk of wound healing problems: Wounds may not heal well during treatment with RETEVMO. Tell your healthcare provider if you plan to have any surgery before or during treatment with RETEVMO.

- You should stop taking RETEVMO at least 7 days before planned surgery.
- Your healthcare provider should tell you when you may start taking RETEVMO again after surgery.

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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What are some possible side effects?

- Retevmo may cause serious side effects, including liver problems, lung problems, high blood pressure (hypertension), heart rhythm changes (QT prolongation), bleeding problems, allergic reactions, tumor lysis syndrome, risk of wound healing problems, low levels of thyroid hormone (hypothyroidism), risk to unborn babies, and hip joint problems in children.
- Common side effects in adults include swelling of your arms, legs, hands, and feet (edema), diarrhea, tiredness, dry mouth, abdominal pain, constipation, rash, nausea, and headache. The most common severe abnormal laboratory test results include lower white blood cell count, higher levels of liver enzymes, lower sodium levels in the blood, and lower calcium levels in the blood.
- Common side effects in children 2 years and older include muscle and bone pain, diarrhea, headache, nausea, vomiting, coronavirus infection, abdominal pain, tiredness, fever, and bleeding. The most common severe abnormal laboratory test results include decreased levels of calcium in the blood, decreased red blood cell count, and decreased white blood cell count.

Retevmo may affect fertility in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

In one clinical trial, *some* people stopped taking Retevmo due to side effects.

- Adverse reactions resulting in permanently stopping Retevmo in some patients included increased liver enzymes, tiredness, and serious infection (sepsis).

Side effects requiring dosage interruption or a lowered dose in some of patients included increased liver enzymes, diarrhea, heart rhythm changes (QT prolongation), tiredness, allergic reactions, swelling of the arms, legs, hands, and feet (edema), and high blood pressure (hypertension).

These are not all of the possible side effects of Retevmo. If you experience side effects while on treatment, it is important that you speak with your doctor or pharmacist. You are encouraged to report side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**. You may also report side effects to Eli Lilly and Company at **1-800-LillyRx (1-800-545-5979)**.

You should avoid taking St. John's wort, proton-pump inhibitors (PPIs such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole), H2 blockers (such as famotidine, nizatidine, and cimetidine), and antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines during treatment with Retevmo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RETEVMO may affect the way other medicines work, and other medicines may affect how RETEVMO works, and may increase your risk of side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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Retevmo savings and support

Learn how you can save on Retevmo treatment

Retevmo Savings Card

Paying for treatment shouldn't be an additional concern for you and your loved ones, so we've created the Retevmo Savings Card, which may help you manage treatment costs.

Eligible commercially insured covered patients pay as little as $0 a month.*

*Month is defined as 30 days.

Need a Savings Card?
Visit **https://retevmo.lilly.com/savings-support** for more information.

Your Retevmo support starts here.

Starting a new cancer therapy can be overwhelming. Whether you have questions about your Retevmo prescription or are looking for some additional support starting treatment, Lilly Support Services™ for Retevmo® is here for you. Call **1-800-LillyRx (1-800-545-5979)** to connect with an agent who may be able to help.

By enrolling in and using the Retevmo Savings Card Program ("Program") and using the Retevmo Savings Card ("Card"), you attest that you meet the eligibility criteria, and you agree to comply with the terms and conditions described below:

Card Eligibility:

(1.) You have been prescribed Retevmo® (selpercatinib) for an approved use consistent with FDA-approved product labeling;
(2.) You are enrolled in a commercial drug insurance plan and have coverage for Retevmo:
(3.) **You are not enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program;**
(4.) You are a resident of the United States or Puerto Rico; and
(5.) You are 18 years of age or older.

Card Terms and Conditions

For patients with commercial drug insurance coverage for Retevmo: You must have commercial drug insurance that covers Retevmo and a prescription for an approved use consistent with FDA-approved product labeling to pay as little as $0 for a 1-month prescription fill of Retevmo. Month is defined as 30-days. Card savings are subject to a maximum monthly savings of wholesale acquisition cost plus usual and customary pharmacy charges and separate maximum annual savings of up to $9,200 per calendar year. Card may be used for a maximum of up to 14 prescription fills per calendar year. Except where prohibited by applicable state law, Card monthly and annual savings are reduced if Lilly identifies that you are enrolled in a plan or program, sometimes called a maximizer plan, that adjusts your cost sharing amount to be equal to or include some portion of the savings provided by the Card and attempts to prevent the savings from this Card from being applied to your out-of-pocket costs, including but not limited to copayments, coinsurances, and deductibles ("Maximizer"). If the Program identifies you are enrolled in a Maximizer, Card savings are reduced to a maximum monthly savings of up to $25 and a separate maximum annual savings of up to $350 per calendar year. If you have reason to believe that the Program erroneously identified enrollment in a Maximizer, please call the Retevmo Savings Card Program at 1-866-615-3716. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason. Card expires and savings end on 12/31/2025.

Additional Program Terms and Conditions

If you have an insurance plan that is participating in an alternate funding program ("AFP") that requires you to apply to the Retevmo Savings Card Program or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of Retevmo, you are not eligible for and are prohibited from using the Retevmo Savings Card Program. AFPs include programs where coverage, reimbursement, or patient out of pocket costs for a product in some way vary based on the availability of a manufacturer co-pay program. AFPs may modify, delay, deny, restrict, or withhold insurance benefits or coverage from patients, or exclude Lilly products from coverage contingent upon a member's use of Retevmo Savings Card Program. You agree to inform the Retevmo Savings Card Program if you are or become a member of such an alternative funding program. You are responsible for any applicable taxes, fees, and any amount that exceeds the monthly or annual maximum Card savings. Monthly and annual maximum savings are set at Lilly's sole and absolute discretion and may be changed with or without notice at any time for any reason. At its sole discretion and with or without notice, Lilly may reduce, eliminate, or otherwise modify the Card savings for any reason, including but not limited to if your commercial drug insurance plan imposes additional requirements which limits or prevents you from receiving coverage for Retevmo, only allows partial coverage for Retevmo, removes coverage for Retevmo and requires you to utilize the Card, does not provide a material level of financial assistance for the cost of Retevmo, or does not apply Card payments to satisfy your co-payment, deductible, or coinsurance for Retevmo. Card savings are not valid for: Massachusetts residents if an AB-rated generic equivalent is available; California residents if an FDA-approved therapeutic equivalent is available. You must meet the Card eligibility criteria, terms and conditions every time you use the Card. If at any time you begin receiving drug coverage under any state, federal, or government funded healthcare program, you understand that you will no longer be eligible for the Retevmo Savings Card and agree to call the Retevmo Savings Card Program at 1-866-615-3716 to stop participation. Card activation is required. You may not seek reimbursement from your health insurance, any third party, or any health savings, flexible spending, or other healthcare reimbursement accounts, for any amount of the savings received through the Card. By utilizing the Card, you agree that if you are required to do so under the terms of your insurance coverage for this prescription or are otherwise required to do so by law, you will notify your Insurance Carrier of your redemption of the Card. Card savings cannot be combined or utilized with any other program, discount, discount card, cash discount card, coupon, incentive, or similar offer involving Retevmo. You agree that this Card savings is intended solely for the benefit of you, the patient, and that the Card benefits are nontransferable. It is prohibited for any person to sell, purchase, or trade; or to offer to sell, purchase, or trade, or to counterfeit the Card. **THIS CARD IS NOT INSURANCE.** Lilly has the sole right to interpret and apply Card eligibility criteria, and terms and conditions. Card eligibility, and terms and conditions may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Lilly's sole discretion to terminate, rescind, revoke, or amend Card eligibility and/or Card terms and conditions includes the right to terminate any individual Card if Lilly determines, in its sole discretion, that a patient does not satisfy the Card's eligibility criteria or is using or has attempted to use the Card inconsistently with these terms and conditions. Eligibility criteria, and terms and conditions for the Retevmo Savings Card Program may change from time to time; the most current version can be found at https://retevmo.lilly.com/savings-support. You may be required to obtain a new Card, including if any Card terms and conditions have been terminated, rescinded, revoked, or amended by Lilly. Card void where prohibited by law. Subject to Lilly's right to terminate, rescind, revoke or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason. Card expires and savings end on 12/31/2025.

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Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

Indications and safety summary

RETEVMO® (reh-TEHV-moh) is used to treat certain cancers caused by abnormal *RET* genes in:

- adults with locally advanced non-small cell lung cancer (NSCLC) or NSCLC that has spread.
- adults and children 2 years of age and older with advanced medullary thyroid cancer (MTC) or MTC that has spread, who require a medicine by mouth or injection (systemic therapy).
- adults and children 2 years of age and older with advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection (systemic therapy), and who have received radioactive iodine and it did not work or is no longer working.
- adults and children 2 years of age and older with locally advanced solid tumors (cancers) or solid tumors that have spread, and have gotten worse (progressed) on or after other treatment or there are no satisfactory treatment options.*

Your healthcare provider will perform a test to make sure that RETEVMO is right for you.

- It is not known if RETEVMO is safe and effective when used in children younger than 2 years of age for the treatment of:
  - advanced MTC or MTC that has spread who require a medicine by mouth or injection.
  - advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection, and have received radioactive iodine and it did not work or is no longer working.
  - locally advanced solid tumors or solid tumors that have spread, and have gotten worse on or after other treatment or there are no satisfactory treatment options.
- in children for other conditions.

* This use is approved based on how many patients responded to treatment and how long they responded. Studies are ongoing to provide additional information about clinical benefit of Retevmo for this use.

Warnings - RETEVMO may cause serious side effects, including:

Liver problems: Liver problems (increased liver enzymes) can happen during treatment with RETEVMO and may sometimes be serious. Your healthcare provider will do blood tests before and during treatment with RETEVMO to check for liver problems. Tell your healthcare provider right away if you get any of the following symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes (jaundice)
- dark, "tea-colored" urine
- sleepiness
- bleeding or bruising
- loss of appetite
- nausea or vomiting
- pain on the upper right side of your stomach area

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

- shortness of breath
- cough
- fever

High blood pressure (hypertension): High blood pressure is common with RETEVMO. It may sometimes be severe. You should check your blood pressure regularly during treatment with RETEVMO. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure. Tell your healthcare provider if you have increased blood pressure readings or get any symptoms of high blood pressure, including:

- confusion
- headaches
- shortness of breath
- dizziness
- chest pain

Heart rhythm changes (QT prolongation). RETEVMO may cause very slow, very fast, or irregular heartbeats. Your healthcare provider may perform tests before and during treatment with RETEVMO to check the activity of your heart and the levels of body salts (electrolytes) and thyroid-stimulating hormone (TSH) in your blood. Tell your healthcare provider right away if you get any of the following symptoms:

- loss of consciousness
- fainting
- dizziness
- a change in the way your heart beats (heart palpitations)

CONTINUE >

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Indications and safety summary (continued)

Warnings (continued)

Bleeding problems: RETEVMO can cause bleeding, which can be serious and may lead to death. Tell your healthcare provider if you have any signs of bleeding during treatment, including:

- vomiting blood or if your vomit looks like coffee-grounds
- pink or brown urine
- red or black stools that look like tar
- coughing up blood or blood clots
- unusual bleeding or bruising of your skin
- menstrual bleeding that is heavier than normal
- unusual vaginal bleeding
- nose bleeds that happen often
- drowsiness or difficulty being awakened
- confusion
- headache
- change in speech

Allergic reactions: RETEVMO can cause a fever, rash, or pain in muscles or joints, especially during the first month of treatment. Tell your healthcare provider if you get any of these symptoms.

Tumor lysis syndrome (TLS): TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure, the need for dialysis treatment, and an abnormal heartbeat. TLS can lead to hospitalization. Your healthcare provider may do blood tests to check you for TLS. You should stay well hydrated during treatment with RETEVMO. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with RETEVMO:

- nausea
- vomiting
- weakness
- swelling
- shortness of breath
- muscle cramps
- seizures

Risk of wound healing problems: Wounds may not heal well during treatment with RETEVMO. Tell your healthcare provider if you plan to have any surgery before or during treatment with RETEVMO.

- You should stop taking RETEVMO at least 7 days before planned surgery.
- Your healthcare provider should tell you when you may start taking RETEVMO again after surgery.

Low thyroid hormone levels in your blood (hypothyroidism). Your healthcare provider will do blood tests to check your thyroid function before and during treatment with RETEVMO. Tell your healthcare provider right away if you develop signs or symptoms of low thyroid hormone levels, including:

- weight gain
- feeling cold
- tiredness that worsens or does not go away
- constipation

Hip joint problems (slipped capital femoral epiphysis or slipped upper femoral epiphysis) in children. Tell your healthcare provider right away if you develop sign and symptoms of hip problems, including hip or knee pain or a painless limp.

Common side effects

The most common side effects of RETEVMO in adults with solid tumors include:

- swelling of your arms, legs, hands, and feet (edema)
- diarrhea
- tiredness
- dry mouth
- stomach-area (abdominal) pain
- constipation
- rash
- nausea
- headache

The most common side effects of RETEVMO in children 2 years and older with solid tumors include:

- muscle and bone pain
- diarrhea
- headache
- nausea
- vomiting
- coronavirus infection
- stomach-area (abdominal) pain
- tiredness
- fever
- bleeding

CONTINUE >

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Indications and safety summary (continued)

The most common severe abnormal laboratory test results with RETEVMO in adults with solid tumors include decreased white blood cell count, increased liver enzymes, decreased levels of sodium in the blood, and decreased levels of calcium in the blood.

The most common severe abnormal laboratory test results with RETEVMO in children 2 years and older with solid tumors include decreased levels of calcium in the blood, decreased red blood cell count, and decreased white blood cell count.

RETEVMO may affect the ability to have children for both females and males. Talk to your healthcare provider if you want to have children and you are thinking about starting treatment with RETEVMO.

- RETEVMO can harm your unborn baby. You should not become pregnant during treatment with RETEVMO.
- **If you are able to become pregnant:**
  - Your healthcare provider will do a pregnancy test before you start treatment with RETEVMO.
  - You should use effective birth control (contraception) during treatment and for **1 week** after your last dose of RETEVMO. Talk to your healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with RETEVMO.
- **Males with partners who are able to become pregnant** should use effective birth control during treatment with RETEVMO and for **1 week** after your last dose of RETEVMO.

These are not all the possible side effects with RETEVMO. If you are concerned about side effects, talk to your doctor. Tell your doctor about any side effects you have. You can also report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before using

Before taking RETEVMO, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems
- have lung or breathing problems other than lung cancer
- have high blood pressure
- have heart problems, including a condition called QT prolongation
- have bleeding problems
- plan to have surgery. You should stop taking RETEVMO at least 7 days before your planned surgery.
- are pregnant or plan to become pregnant. See section above for additional information.
- are breastfeeding or plan to breastfeed. It is not known if RETEVMO passes into your breast milk. Do not breastfeed during treatment with RETEVMO and for 1 week after your last dose.

Also tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RETEVMO may affect the way other medicines work and other medicines may affect how RETEVMO works, and may increase your risk of side effects.

- During treatment with RETEVMO, you should avoid taking:
  - St. John's wort,
  - proton-pump inhibitors (PPIs) such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole,
  - H2 blockers such as famotidine, nizatidine, and cimetidine,
  - antacids that contain aluminum, magnesium, calcium, simethicone, or buffered medicines.

If you cannot avoid taking PPIs, H2 blockers, or antacids, see the "How to take with certain other medicines" section below for more information. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

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CONTINUE >

Indications and safety summary (continued)

How to take RETEVMO

- Take RETEVMO exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with RETEVMO if you have side effects. Do not change your dose or stop taking RETEVMO unless your healthcare provider tells you.
- Swallow RETEVMO capsules and tablets whole. Do not break, crush, or chew.
- Do not give RETEVMO capsules to your child if they are unable to swallow a capsule.
- Take RETEVMO with or without food.
- If you vomit after taking a dose of RETEVMO, do not take an extra dose. Take the next dose of RETEVMO at your scheduled time.
- Do not take a missed dose of RETEVMO unless it is more than 6 hours until your next scheduled dose.
- If you take too much RETEVMO, call your healthcare provider or go to the nearest hospital emergency room right away.

How to take RETEVMO with certain other medicines

- If you take a PPI (such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, or rabeprazole), take RETEVMO with food.
- If you take an H2 blocker (such as famotidine, nizatidine, or cimetidine), take RETEVMO 2 hours before or 10 hours after taking the H2 blocker.
- If you take an antacid that contains aluminum, magnesium, calcium, simethicone, or buffered medicines, take RETEVMO 2 hours before or 2 hours after taking the antacid.

Learn more

RETEVMO is a prescription medicine available as 40 mg and 80 mg capsules, and 40 mg, 80 mg, 120 mg, and 160 mg tablets. For more information, call 1-800-545-5979 or go to **www.Retevmo.com.**

This summary provides basic information about RETEVMO. It does not include all information known about this medicine. Read the information that comes with your medicine each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other health care provider about RETEVMO and how to take it. Your doctor is the best person to help you decide if RETEVMO is right for you.

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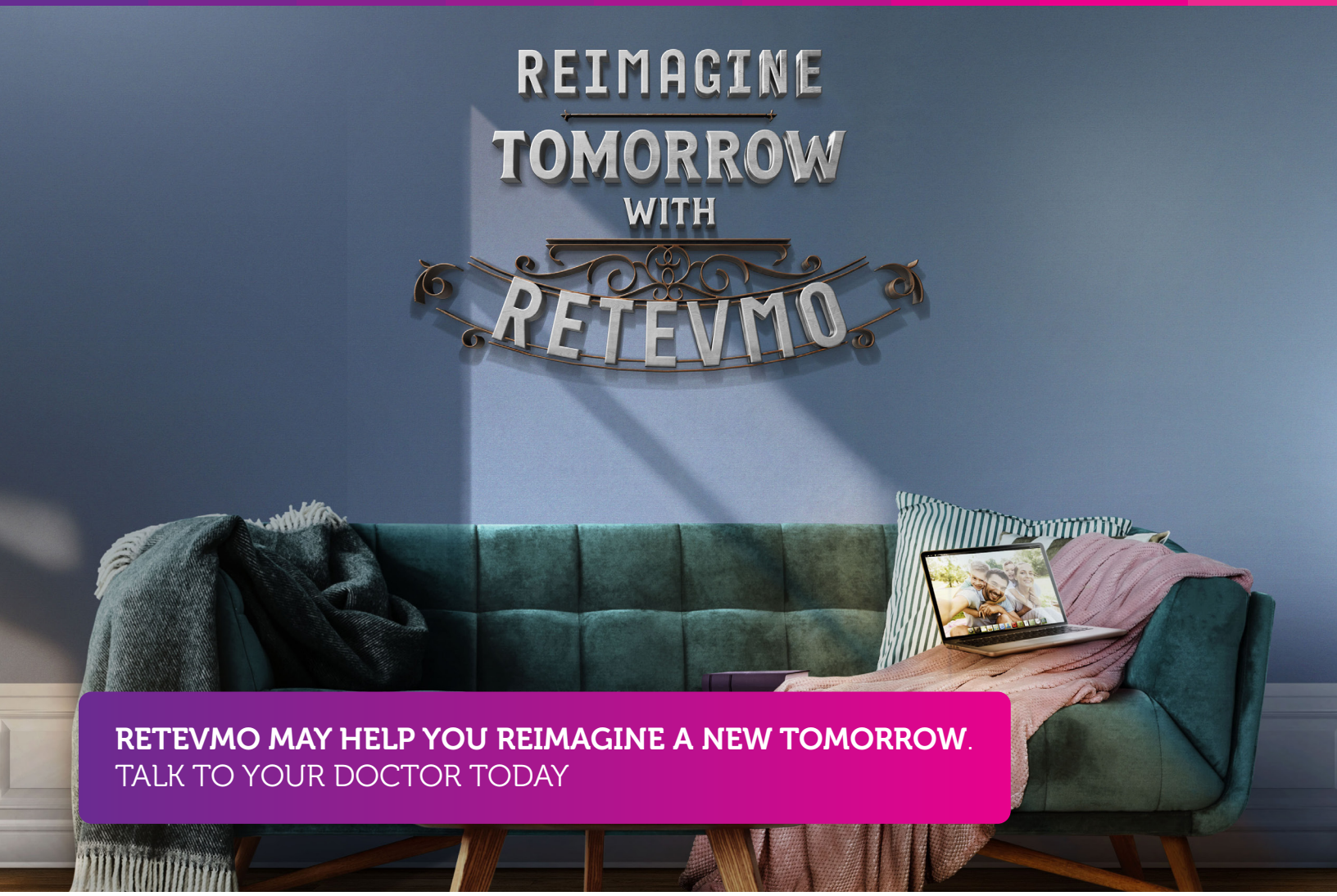

What is Retevmo?

Retevmo is a prescription medicine that is used to treat certain cancers caused by abnormal *RET* genes in:

- adults with locally advanced non-small cell lung cancer (NSCLC) or NSCLC that has spread
- adults and children 2 years of age and older with advanced medullary thyroid cancer (MTC) or MTC that has spread, who require a medicine by mouth or injection (systemic therapy)
- adults and children 2 years of age and older with advanced thyroid cancer or thyroid cancer that has spread who require a medicine by mouth or injection (systemic therapy), and who have received radioactive iodine and it did not work or is no longer working
- adults and children 2 years of age and older with locally advanced solid tumors (cancers) or solid tumors that have spread, and have gotten worse (progressed) on or after other treatment or there are no satisfactory treatment options*

Your healthcare provider will perform a test to make sure that Retevmo is right for you.

It is not known if RETEVMO is safe and effective when used:

- in children younger than 2 years of age, or in children with other conditions.

*Retevmo was approved based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long the response lasted. Studies are ongoing to confirm the benefit of Retevmo for this use.

SELECT SAFETY INFORMATION

Warnings - RETEVMO may cause serious side effects, including:

Low thyroid hormone levels in your blood (hypothyroidism). Your healthcare provider will do blood tests to check your thyroid function before and during treatment with RETEVMO. Tell your healthcare provider right away if you develop signs or symptoms of low thyroid hormone levels, including:

- weight gain
- feeling cold
- tiredness that worsens or does not go away
- constipation

Please see **Indications and Safety Summary** for Retevmo on pages **13-16**.

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