Liver problems (increased liver enzymes) are common with Retevmo and may sometimes be serious. Your doctor will do blood tests before and during treatment with Retevmo to check for liver problems. Tell your doctor right away if you get any of the following signs of liver problems:

- Fatigue
- Dark urine
- Pale or yellow skin or the whites of your eyes (jaundice)
- Nausea or vomiting
- Yellowing of your skin or the white part of your eyes
- Decreased appetite
- Fatigue
- Shortness of breath
- Dark "tea-colored" urine
- Nausea or vomiting

It is not known if Retevmo is safe and effective in children younger than 12 years of age. Use Retevmo in children 12 years of age and older.

How to take

Retevmo is a targeted therapy, which means it was designed to pick out and attach to certain parts of your body's cells. Retevmo alters the RET signaling pathway, which can result in side effects, some of which can be serious. 1

About Retevmo™ (reh-TEHV-moh).  It is also known as selpercatinib.

RET is a gene that everyone has. But, for some people, changes in the RET gene cause certain cancers. Retevmo is a targeted therapy that works by blocking the RET signaling pathway. 1

How is Retevmo taken?

Retevmo can be taken at home, with or without food.* Retevmo should be taken exactly as prescribed by your doctor. If you miss a dose of Retevmo, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your next dose at the regular time.

If you take a proton-pump inhibitor (PPI; such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole), take RETEVMO with food. If you take an H2 blocker (such as famotidine, nizatidine, and cimetidine), take RETEVMO 2 hours before or 10 hours after taking the H2 blocker. You should avoid taking St. John's wort, proton pump inhibitors (PPIs; such as dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, and rabeprazole), or H2 blockers, or antacids, see the "How to take" 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.

You may need to avoid certain foods and other things during treatment with RETEVMO. Ask your doctor or pharmacist what you can and cannot eat during treatment with RETEVMO.

How does Retevmo work?

Retevmo is a targeted therapy. A targeted therapy is a type of treatment that affects cancer cells and makes them stop growing or die. Cancer cells have multiple receptors that help cancer cells grow and divide. Cancer cells also have insulin-like growth factor receptors (IGFRs) that are needed for cancer cells to grow and divide. RETEVMO stops the growth of cancer cells by blocking RET, which is needed by RETEVMO to divide. 1

Fever:

RETEVMO can cause a fever, rash, muscle or joint pain, especially in the first month of treatment. Tell your doctor if you have a fever. A fever is when your body temperature is higher than normal.

Rash:

RETEVMO can cause a rash. This is a sign of an allergic reaction. Call your doctor right away if you have a rash.

High blood pressure (hypertension):

RETEVMO can cause high blood pressure, which can be serious and may lead to death. Tell your doctor right away if you have any signs of high blood pressure.

Bleeding problems:

RETEVMO can cause bleeding, which can be serious and may lead to death. Tell your doctor if you have any signs of bleeding problems.

• dark "tea-colored" urine
• yellowing of your skin or the white part of your eyes
• fatigue
• shortness of breath
• nausea or vomiting
• hair loss
• fever
• cold sores or blisters, such as on your mouth

Common side effects

- increased cholesterol levels
- decreased levels of calcium in the blood
- hypothyroidism
- constipation
- red or black (looks like tar) stools
- vomiting blood or if your vomit looks like coffee-grounds
- dry mouth
- cough
- weakness
- shortness of breath
- dizziness
- confusion
- drowsiness or difficulty being awakened
- fast heartbeat
- altered mental activities
- muscle pain
- joint pain

Common side effects may not always result in disruption to your daily life. Side effects that are very common are normal even during treatment with RETEVMO.

How was Retevmo evaluated?

Retevmo was studied in clinical trials in adults with certain cancers. It is also known as selpercatinib. Retevmo is a targeted therapy, which means it was designed to recognize and attach to certain proteins in your body's cells. These proteins are part of the RET signaling pathway. The RET signaling pathway is needed to grow and divide cancer cells.

The trial evaluated how many people responded to treatment, which means their tumors either shrank or disappeared completely, and how long their response lasted. Studies are ongoing to confirm the benefit of Retevmo in certain cancers. 1

The trial included adults and children 12 years of age and older with NSCLC and advanced or metastatic thyroid cancers. 1

How to report side effects

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

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