Please see additional Important Safety Information on pages 12-15, and click here for full Prescribing Information and Patient Information.
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Please see additional Important Safety Information on pages 12-15, and click here for full Prescribing Information and Patient Information.
NON-SMALL CELL LUNG CANCER AND ALK

The ALK gene
Advances in genetic research have revealed that non-small cell lung cancer (NSCLC) is not a single disease, but rather many types of cancer with specific genetic differences. Because of these small but important differences, lung cancer medicines that target specific genes, such as anaplastic lymphoma kinase (ALK), can be developed.

About 2%-7% of people with NSCLC are considered to be ALK positive (ALK+). But genetic differences aren’t the only differences between people who have ALK+ NSCLC and people who have general NSCLC. Other important differences include age at diagnosis and smoking history.

Understanding disease progression and drug resistance
Although ALK+ NSCLC tumors can initially respond to ALK+ treatment, over time they may become resistant (or stop responding). This could happen within a year of treatment and may result in a relapse for the patient. Signs may include an increase in size of tumor or development of new tumors.

If you experience any health-related changes, it’s important to talk to your doctor.

Resistance to treatment may develop when:
- Mutations (or changes) to the ALK gene interfere with how a specific ALK inhibitor works
- Other genes with similar actions to ALK become active in the tumor
- Other mutations not affected by treatment appear within the tumor

Tumors that become resistant to one ALK inhibitor may still be responsive to a different ALK inhibitor.

Please see additional Important Safety Information on pages 12-15, and click here for full Prescribing Information and Patient Information.
WHAT IS ZYKADIA™ (ceritinib)?

ZYKADIA capsules is a prescription medicine that is used to treat people with non-small cell lung cancer (NSCLC) that:

- Is caused by a defect in a gene called anaplastic lymphoma kinase (ALK), and
- Has spread to other parts of the body (metastatic), and
- Who have taken the medicine crizotinib, but their NSCLC worsened or they cannot tolerate taking crizotinib.

The effectiveness of ZYKADIA in these patients is based on a study that measured two types of response to treatment (response rate and duration of response). There is no clinical information available to show if patients treated with ZYKADIA live longer or if their symptoms improve. There are ongoing studies to find out how ZYKADIA works over a longer period of time. It is not known if ZYKADIA is safe and effective in children.

How ZYKADIA works

The ALK gene is thought to play a critical role in the growth of some NSCLCs. ZYKADIA is an ALK inhibitor, which means it may block the action of the ALK gene. It’s believed that this helps to shrink or slow cancer growth.

You and your doctor need to discuss the possible benefits and risks of treatment with ZYKADIA, taking into account your medical history and current medications.

HOW ZYKADIA MAY HELP

Overall response and duration of response

In a clinical trial, ZYKADIA was shown to shrink or slow the growth of tumors. In this trial, 163 patients with ALK+ metastatic NSCLC who have taken the medicine crizotinib, but their NSCLC worsened or they could not tolerate taking crizotinib, were treated with ZYKADIA.

Overall response rate to treatment with ZYKADIA: **54.6%**

Median length of response to treatment: **7.4 months**

Of those who responded, 1.2% of patients had a complete response to treatment (which is not the same as being cured) and 53.4% of patients had a partial response. This means that in these patients the amount or spread of cancer decreased or tumors shrank. Response to treatment lasted a median of 7.4 months.

Important Safety Information

ZYKADIA can cause serious side effects in some people. Serious side effects associated with ZYKADIA include stomach and intestinal problems, liver injury, severe or life-threatening swelling of the lungs, and either very slow, very fast, or abnormal heartbeats. People who have diabetes or glucose intolerance, or who take a corticosteroid medicine, have an increased risk of high blood sugar with ZYKADIA. ZYKADIA can cause pancreatitis that has led to death.
**How should I take ZYKADIA™ (ceritinib)?**

Take ZYKADIA exactly as your doctor tells you. Do not change your dose or stop taking it unless your doctor tells you to.

- Take ZYKADIA once a day
- Take ZYKADIA on an empty stomach (ie, do not take ZYKADIA within 2 hours of a meal)

<table>
<thead>
<tr>
<th>FIVE CAPSULES ONCE DAILY ON AN EMPTY STOMACH</th>
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<td>No Food 2 Hours Before</td>
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Continue taking ZYKADIA for as long as your doctor tells you.

If you vomit after taking ZYKADIA, do not take an additional dose, but continue with the next scheduled dose.

If you miss a dose, make up that dose unless the next dose is due within 12 hours.

**Important Safety Information**

The most common side effects experienced by patients in a clinical trial with ZYKADIA included diarrhea, nausea, vomiting, stomach-area pain, tiredness, decreased appetite, and constipation.

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**UNDERSTANDING SIDE EFFECTS**

Treatment for ALK+ metastatic NSCLC means staying on therapy as long as it continues to work. Many people are concerned about possible side effects that may result.

**Talk to your doctor about your side effects**

Be sure to tell your doctor how you are feeling or if you have any concerns about your treatment, especially if you think you are experiencing any treatment side effects. Some of the gastrointestinal side effects can be managed by supportive care with standard antiemetic (for nausea/vomiting), antidiarrheal medications, and/or fluid replacement. Consult your doctor to develop an appropriate side effects management plan. Your doctor may temporarily interrupt, reduce or discontinue your dose of ZYKADIA.

**Visit the National Cancer Institute at cancer.gov for additional information about side effects.**
HOW TO GET
ZYKADIA™ (ceritinib)

ZYKADIA is ordered through specialty pharmacies.

Visit ZYKADIA.com and get a head start!

• Download a Service Request Form (SRF) from ZYKADIA.com, complete the patient information section, and bring it with you to your doctor’s office
• If you’ve been prescribed ZYKADIA, your doctor will complete the SRF and fax it to a specialty pharmacy or simply call in the information
• ZYKADIA can only be ordered at 8 specialty pharmacies

Once your specialty pharmacy verifies your insurance coverage, they will contact you to arrange delivery.

Financial assistance
You may be eligible for immediate co-pay savings on your next prescription:

• Commercially insured patients pay no more than $25 per month until annual maximum is met
• Annual maximum of $15,000 per calendar year

To find out if you are eligible to save on your next prescription: call 877-577-7756 or visit us on www.copay.novartisoncology.com

See Co-pay Offer Terms and Conditions* on next page.

ZYKADIA Pharmacy Network

Accredo Specialty Pharmacy
Phone: 1-877-732-3431

Advanced Care Scripts (ACS)
Phone: 1-877-985-6337

Avella Specialty Pharmacy
Phone: 1-877-546-5779

Biologics Inc.
Phone: 1-800-850-4306

CVS Caremark Specialty Pharmacy
Phone: 1-800-237-2767

Diplomat Specialty Pharmacy
Phone: 1-877-977-9118

US Bioservices
Phone: 1-877-757-0667

Walgreens Specialty Pharmacy
Phone: 1-888-347-3416

If you have questions about how to order ZYKADIA, call us at 1-888-669-6682 or visit ZYKADIA.com.

*Co-pay Offer Terms and Conditions: This offer is valid only for those with commercial insurance. Offer not valid under Medicare, Medicaid, or any other federal or state program. Not valid for cash-paying patients, where product is not covered by patient’s commercial insurance, or where plan reimburses you for entire cost of your prescription drug. Offer is not valid where prohibited by law. Valid only in the United States and Puerto Rico. This program is not health insurance. Offer may not be combined with any other rebate, coupon, or offer. The card is the property of Novartis Pharmaceuticals Corporation and must be returned upon request. Novartis reserves the right to rescind, revoke, or amend the program without notice. Patient certifies responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting receipt of program rewards, if necessary, to any commercial insurer. This offer expires on December 31, 2017.

A free 14-day trial is available for eligible patients. Ask your doctor for more information.

Please see additional Important Safety Information on pages 12-15, and click here for full Prescribing Information and Patient Information.
IMPORTANT SAFETY INFORMATION ABOUT ZYKADIA™ (ceritinib) CAPSULES

ZYKADIA may cause serious side effects, such as:

Stomach and intestinal problems
ZYKADIA causes stomach and intestinal problems in most people, including diarrhea, nausea, vomiting, and stomach-area pain. These problems can sometimes be severe. Follow your health care provider’s instructions about taking medicines to help these symptoms. Call your health care provider for advice if your symptoms are severe or do not go away.

Liver problems
ZYKADIA may cause liver injury. Your health care provider should do blood tests at least every month to check your liver while you are taking ZYKADIA. Tell your doctor right away if you experience any of the following symptoms:
- Tiredness (fatigue)
- Yellowing of skin or the whites of eyes
- Decreased appetite
- Urine turns dark or brown
- Itchy skin

Lung problems (pneumonitis)
ZYKADIA may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your doctor right away if you have any new or worsening symptoms, including:
- Trouble breathing or shortness of breath
- Cough, with or without mucous
- Fever
- Chest pain

Heart problems
ZYKADIA may cause very slow, very fast, or abnormal heartbeats. Your health care provider may check your heart during treatment with ZYKADIA. Tell your health care provider right away if you feel new chest pain or discomfort, dizziness or lightheadedness, faint, or have abnormal heartbeats. Tell your health care provider if you start to take or have any changes in heart or blood pressure medicines.

High blood sugar (hyperglycemia)
People who have diabetes or glucose intolerance, or who take a corticosteroid medicine have an increased risk of high blood sugar with ZYKADIA. Your health care provider will check your blood sugar level before starting ZYKADIA and as needed during treatment with ZYKADIA. Call your health care provider right away if you have any symptoms of high blood sugar, including:
- Increased thirst
- Headaches
- Urinating often
- Tiredness
- Increased hunger
- Trouble thinking or concentrating
- Blurred vision
- Your breath smells like fruit

Inflammation of the pancreas (pancreatitis)
ZYKADIA can cause pancreatitis that has led to death. You may develop increased pancreatic enzyme blood levels, which may be a sign of pancreatitis. Signs and symptoms of pancreatitis include upper abdominal pain that may spread to the back and get worse with eating. Your health care provider should do blood tests to check your pancreatic enzyme blood levels before you start ZYKADIA and as needed during your treatment.
IMPORTANT SAFETY INFORMATION ABOUT ZYKADIA™ (ceritinib) CAPSULES (cont’d)

Before you take ZYKADIA, tell your doctor about all of your medical conditions, including if you:

- Have liver problems
- Have diabetes or high blood sugar
- Have heart problems, including a condition called long QT syndrome
- Have or have had pancreatitis
- Are pregnant, think you may be pregnant, or plan to become pregnant. ZYKADIA may harm your unborn baby
- Women who are able to become pregnant must use an effective method of birth control during treatment with ZYKADIA and for at least 2 weeks after stopping ZYKADIA. Talk to your health care provider about birth control methods that may be right for you
- Are breastfeeding or plan to breastfeed
  It is not known if ZYKADIA passes into your breast milk. You should not breastfeed if you take ZYKADIA.

Tell your doctor about the medicines you take, including:

- Prescription medicines
- Over-the-counter medicines
- Vitamins
- Herbal supplements

The most common side effects of ZYKADIA include:

- Diarrhea
- Constipation
- Stomach-area pain
- Vomiting
- Nausea
- Decreased appetite
- Tiredness (fatigue)

Tell your doctor if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of ZYKADIA. For more information, ask your doctor or pharmacist. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

How to take ZYKADIA and what to avoid

- Take ZYKADIA exactly as your health care provider tells you. Do not change your dose or stop taking unless your health care provider tells you to
- Take ZYKADIA 1 time each day
- Take ZYKADIA on an empty stomach, do not eat for 2 hours before and do not eat for 2 hours after taking ZYKADIA
- If you vomit after taking ZYKADIA, do not take an additional dose, but continue with the next scheduled dose
- If you miss a dose of ZYKADIA, take it as soon as you remember. If your next dose is due within 12 hours, then skip the missed dose. Just take the next dose at your regular time
- You should not drink grapefruit juice or eat grapefruit during treatment with ZYKADIA. It may make the amount of ZYKADIA in your blood increase to a harmful level

Please click here for full Prescribing Information and the Patient Information for ZYKADIA™ (ceritinib) capsules.

NOTES:
ZYKADIA™
ceritinib 350 mg capsules

For more information and to register for updates, visit us at ZYKADIA.com

Please see additional Important Safety Information on pages 12-15, and click here for full Prescribing Information and Patient Information.

ZYKADIA is a registered trademark of Novartis Pharmaceuticals Corporation.