

For certain adults with newly diagnosed metastatic non-small cell lung cancer (NSCLC) that tests positive for PD-L1

OPDIVO + **YERVOY** = A CHANCE FOR MORE GAME DAYS
(nivolumab) (ipilimumab)

A Chance to Live Longer™

THE 1ST AND ONLY FDA-APPROVED
CHEMO-FREE COMBINATION
OF 2 IMMUNOTHERAPIES THAT
WORKS DIFFERENTLY

In a study of newly diagnosed advanced NSCLC patients, half of those on OPDIVO + YERVOY were alive at 17.1 months versus 14.9 months on platinum-based chemotherapy.

Results may vary.

Indication & Important Safety Information for OPDIVO (nivolumab) + YERVOY (ipilimumab)

Only your healthcare professional knows the specifics of your condition and how OPDIVO in combination with YERVOY may fit into your overall therapy. The information below does not take the place of talking with your healthcare professional, so talk to them if you have any questions.

What are OPDIVO and YERVOY?

OPDIVO and YERVOY are prescription medicines used to treat people with a type of advanced stage lung cancer called non-small cell lung cancer (NSCLC). OPDIVO may be used in combination with YERVOY as your first treatment for NSCLC when your lung cancer has spread to other parts of your body (metastatic), and your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.

It is not known if OPDIVO and YERVOY are safe and effective when used in children younger than 18 years of age.

What is the most important information I should know about OPDIVO and YERVOY?

OPDIVO and YERVOY are medicines that may treat certain cancers by working with your immune system. OPDIVO and YERVOY can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death and may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when OPDIVO is used in combination with YERVOY.

YERVOY can cause serious side effects in many parts of your body which can lead to death. These problems may happen anytime during treatment with YERVOY or after you have completed treatment.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse. Do not try to treat symptoms yourself.

• **Lung problems (pneumonitis).** Symptoms of pneumonitis may include: new or worsening cough; chest pain; shortness of breath

• **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include: diarrhea (loose stools) or more bowel movements than usual; mucus or blood in your stools or dark, tarry, sticky stools; stomach-area (abdomen) pain or tenderness; you may or may not have fever

• **Liver problems (hepatitis) that can lead to liver failure.** Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes; nausea or vomiting; pain on the right side of your stomach area (abdomen); drowsiness; dark urine (tea colored); bleeding or bruising more easily than normal; feeling less hungry than usual; decreased energy

• **Hormone gland problems (especially the thyroid, pituitary, and adrenal glands; and pancreas).** Signs and symptoms that your hormone glands are not working properly may include: headaches that will not go away or unusual headaches; extreme tiredness or unusual sluggishness; weight gain or weight loss; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness; hair loss; feeling cold; constipation; voice gets deeper; excessive thirst or lots of urine

• **Kidney problems, including nephritis and kidney failure.** Signs of kidney problems may include: decrease in the amount of urine; blood in your urine; swelling in your ankles; loss of appetite

• **Skin problems.** Signs of these problems may include: skin rash with or without itching; itching; skin blistering or peeling; sores or ulcers in mouth or other mucous membranes

• **Inflammation of the brain (encephalitis).** Signs and symptoms of encephalitis may include: headache; fever; tiredness or weakness; confusion; memory problems; sleepiness; seeing or hearing things that are not really there (hallucinations); seizures; stiff neck

• **Problems in other organs.** Signs of these problems may include: changes in eyesight; severe or persistent muscle or joint pains; severe muscle weakness; chest pain

Additional serious side effects observed during a separate study of YERVOY alone include:

• **Nerve problems that can lead to paralysis.** Symptoms of nerve problems may include: unusual weakness of legs, arms, or face; numbness or tingling in hands or feet

• **Eye problems.** Symptoms may include: blurry vision, double vision, or other vision problems; eye pain or redness

Get medical help immediately if you develop any of these symptoms or they get worse. It may keep these problems from becoming more serious. Your healthcare team will check you for side effects during treatment and may treat you with corticosteroid or hormone replacement medicines. If you have a serious side effect, your healthcare team may also need to delay or completely stop your treatment with OPDIVO and YERVOY.

What should I tell my healthcare provider before receiving OPDIVO and YERVOY? Before you receive OPDIVO and YERVOY, tell your healthcare provider if you: have immune system problems (autoimmune disease) such as Crohn's disease, ulcerative colitis, lupus, or sarcoidosis; have had an organ transplant; have lung or breathing problems; have liver problems; have any other medical conditions; are pregnant or plan to become pregnant. OPDIVO and YERVOY can harm your unborn baby. **Females who are able to become pregnant:** Your healthcare provider should do a pregnancy test before you start receiving OPDIVO and YERVOY.

- You should use an effective method of birth control during and for at least 5 months after the last dose. Talk to your healthcare provider about birth control methods that you can use during this time.

- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment. You or your healthcare provider should contact Bristol Myers Squibb at 1-800-721-5072 as soon as you become aware of the pregnancy.

- **Pregnancy Safety Surveillance Study:** Females who become pregnant during treatment with YERVOY are encouraged to enroll in a Pregnancy Safety Surveillance Study. The purpose of this study is to collect information about the health of you and your baby. You or your healthcare provider can enroll in the Pregnancy Safety Surveillance Study by calling 1-844-593-7869.

If you are breastfeeding or plan to breastfeed: It is not known if OPDIVO or YERVOY passes into your breast milk. **Do not** breastfeed during treatment and for 5 months after the last dose.

Talk to your doctor about OPDIVO + YERVOY

www.OPDIVOYERVOY.com 1-855-OPDIVOYERVOY

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

Know the medicines you take. Keep a list of them to show your healthcare providers and pharmacist when you get a new medicine.

What are the possible side effects of OPDIVO and YERVOY?

OPDIVO and YERVOY can cause serious side effects, including:

- See "What is the most important information I should know about OPDIVO and YERVOY?"
- **Severe infusion reactions.** Tell your doctor or nurse right away if you get these symptoms during an infusion of OPDIVO or YERVOY: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; feeling like passing out


The most common side effects of OPDIVO when used in combination with YERVOY include: feeling tired; diarrhea; rash; itching; nausea; pain in muscles, bones, and joints; fever; cough; decreased appetite; vomiting; stomach-area (abdominal) pain; shortness of breath; upper respiratory tract infection; headache; low thyroid hormone levels (hypothyroidism); decreased weight; dizziness.

These are not all the possible side effects of OPDIVO and YERVOY. Call your doctor for medical advice about side effects.

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.

OPDIVO (10 mg/mL) and YERVOY (5 mg/mL) are injections for intravenous (IV) use.

This is a brief summary of the most important information about OPDIVO and YERVOY. For more information, talk with your healthcare provider, call 1-855-673-4861, or go to www.OPDIVO.com.

 Bristol Myers Squibb™

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