

For certain adults with newly diagnosed non-small cell lung cancer that has spread



## 1<sup>ST</sup> + ONLY

# CHEMO-FREE COMBO OF 2 IMMUNOTHERAPIES

If you have **advanced non-small cell lung cancer**, there's been a new development. Today, if you test positive for PD-L1, the chemo-free combo OPDIVO® + YERVOY® is **now FDA-approved** and may be your first treatment. Ask your doctor if the **chemo-free combo OPDIVO + YERVOY** is right for you.

Learn more at [lungcancerhope.com](http://lungcancerhope.com) or call 1-833-OPDIVOYERVOY

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

#### What is OPDIVO + YERVOY?

OPDIVO® is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of advanced stage lung cancer (called non-small cell lung cancer) 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 GFR or ALK gene.

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

#### Important Safety Information for OPDIVO + YERVOY

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO 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. These problems 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.

#### Serious side effects may include:

**Lung problems (pneumonitis).** Symptoms of pneumonitis may include: new or worsening cough; chest pain; and 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; blood in your stools or dark, tarry, sticky stools; and severe stomach area (abdomen) pain or tenderness.

**Liver problems (hepatitis).** Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes; severe 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; and decreased energy.

**Hormone gland problems (especially the thyroid, pituitary, 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; 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; and 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; and loss of appetite.

**Skin problems.** Signs of these problems may include: rash; itching; skin blistering; and ulcers in the 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; and 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; and 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; and numbness or tingling in hands or feet.

**Eye problems.** Symptoms may include: blurry vision, double vision, or other vision problems; and 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.

#### OPDIVO and OPDIVO + YERVOY can cause serious side effects, including:

**Severe infusion-related reactions.** Tell your doctor or nurse right away if you get these symptoms during an infusion: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; and feeling like passing out.

#### Pregnancy and Nursing:

• Tell your healthcare provider if you are pregnant or plan to become pregnant. OPDIVO and YERVOY can harm your unborn baby. If you are a female who is able to become pregnant, your healthcare provider should do a pregnancy test before you start receiving OPDIVO. Females who are able to become pregnant 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.

• Before receiving treatment, tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if either treatment passes into your breast milk. Do not breastfeed during treatment and for 5 months after the last dose.

#### Tell your healthcare provider about:


• Your health problems or concerns if you: have immune system problems such as autoimmune disease, Crohn's disease, ulcerative colitis, lupus, or sarcoidosis; have had an organ transplant; have lung or breathing problems; have liver problems; or have any other medical conditions.

• All the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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; and dizziness.

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see Important Facts for OPDIVO and YERVOY, including Boxed WARNING for YERVOY regarding immune-mediated side effects, on the following page.**

 Bristol Myers Squibb™

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