

OPDIVO® (nivolumab) + Chemotherapy is the first-and-only immunotherapy-based option before surgery for early-stage non-small cell lung cancer patients

In a clinical trial, this combination showed a lower risk of cancer spreading or returning

The U.S. Food and Drug Administration (FDA) approved OPDIVO in combination with chemotherapy that contains platinum and another chemotherapy medicine given before surgery for non-small cell lung cancer. OPDIVO is an immunotherapy treatment that helps your immune system launch a response that fights cancer. OPDIVO (pronounced op-DEE-voh) is given as an infusion with chemotherapy every three weeks for nine weeks before surgery. It is not known if OPDIVO is safe and effective in children younger than 18 years of age.

“At Bristol Myers Squibb, we are committed to bringing innovative options to patients facing cancer, from earlier stages to advanced forms of the disease,” said Adam Lenkowsky, senior vice president and general manager, U.S. Cardiovascular, Immunology and Oncology, Bristol Myers Squibb. “Today’s approval builds on that commitment and expands the role of OPDIVO-based treatment in non-small cell lung cancer, the most common form of lung cancer, so patients may benefit earlier in the course of their disease.”

OPDIVO immunotherapy with chemotherapy, given before surgery, showed a lower risk of cancer spreading or returning. In a clinical trial of 358 patients with non-small cell lung cancer who were able to have surgery, 179 patients were treated with OPDIVO and chemotherapy, while 179 were treated with chemotherapy. Half of patients treated with OPDIVO and chemotherapy were alive at 31.6 months without cancer spreading or returning after surgery versus 20.8 months for those treated with chemotherapy alone.

In addition, OPDIVO with chemotherapy, given before surgery, delivered a better response rate than chemotherapy alone. In the same clinical trial, 24% of patients treated with OPDIVO and chemotherapy achieved a response in which the tumor was no longer detected after the procedure compared to 2.2% for those treated with only chemotherapy. Individual results may vary. OPDIVO with chemo will not work for every patient.

Select Important Safety Information

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 severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

The most common side effects of OPDIVO, when used in combination with chemotherapy, include: nausea, constipation, feeling tired, decreased appetite, and rash.

Please see additional Important Safety Information below.

Indications

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early-stage lung cancer (called non-small cell lung cancer).

OPDIVO® (nivolumab) 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 EGFR or ALK gene.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) and 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine, 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 or grown, or comes back, **and** your tumor does not have an abnormal EGFR 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® (nivolumab)

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

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 severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

- **Lung problems:** new or worsening cough; shortness of breath; chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdominal) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); bleeding or bruising more easily than normal
- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heart beat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine; blood in your urine; swelling in your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in the mouth or nose, throat, or genital area

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include

- Chest pain; irregular heartbeat; shortness of breath; swelling of ankles
- Confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs
- Double vision; blurry vision; sensitivity to light; eye pain; changes in eye sight
- Persistent or severe muscle pain or weakness; muscle cramps
- Low red blood cells; bruising

Getting medical help right away may help keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. Your healthcare team may also need to delay or completely stop your treatment if you have severe side effects.

Possible side effects of OPDIVO

OPDIVO can cause serious side effects, including:

- **See “What is the most important information I should know about OPDIVO?”**
- **Severe infusion reactions.** Tell your healthcare team right away if you get these symptoms during an infusion of OPDIVO: chills or shaking; itching or rash; flushing; shortness of breath or wheezing; dizziness; feel like passing out; fever; back or neck pain
- **Complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO. Your healthcare provider will monitor you for these complications.

The most common side effects of OPDIVO, when used in combination with chemotherapy, include: nausea, constipation, feeling tired, decreased appetite, and rash.

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Before receiving OPDIVO, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO and for 5 months after the last dose of OPDIVO.

Females who are able to become pregnant:

Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.

- You should use an effective method of birth control during your treatment and for at least 5 months after the last dose of OPDIVO. 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 may be pregnant during treatment with OPDIVO.

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

Please see U.S. Full Prescribing Information and Medication Guide for OPDIVO at OPDIVO.com.