For Adults With Liver Cancer (Hepatocellular Carcinoma) previously treated with sorafenib

DISCOVER A DIFFERENT CHOICE

OPDIVO + YERVOY will not work for everyone. Individual results may vary. Please see information about the Clinical Trial Results. Please see serious side effects on the next page.

What is OPDIVO + YERVOY?
OPDIVO is a prescription medicine used in combination with YERVOY (OPDIVO + YERVOY) to treat liver cancer (hepatocellular carcinoma). OPDIVO + YERVOY is for adults who:

✓ Have previously received treatment with sorafenib.

OPDIVO + YERVOY was approved based on response rate and how long patients’ responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO and OPDIVO + YERVOY for this use.

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

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

Information provided in this brochure is not a substitute for talking with your healthcare professional. Your healthcare professional is the best source of information about your disease.

Please see additional Important Facts for OPDIVO and YERVOY.
The first and only combination of two immunotherapies for HCC patients previously treated with sorafenib

You may be wondering what’s next and whether there may be another treatment option for you. Talk to your doctor about OPDIVO + YERVYO to learn if it may be an appropriate treatment option for you.

OPDIVO + YERVYO was studied in 49 people with HCC whose cancer spread or grew after treatment with sorafenib or who could not tolerate sorafenib therapy. This study was designed to look at overall response rate and duration of response.

The clinical trial is ongoing.

Nearly 1 out of 3 people responded

33% or 16 of 49 people responded to OPDIVO + YERVYO

- 24% (12 of 49) saw their tumors shrink (partial response)
- 8% (4 of 49) saw their tumors disappear completely (complete response)

The length of the responses

Of those who responded, half the people whose tumors shrunk or disappeared continued to respond to OPDIVO + YERVYO for at least

17.5 months

When the data were collected, of the 16 people who responded, the shortest response lasted 4.6 months; the longest response lasted 30.5 months. 88% of people had a response for 6 months or longer. 56% of people had a response for 12 months or longer. 31% of people had a response for 24 months or longer.

OPDIVO + YERVYO will not work for everyone. Individual results may vary.

Please see Important Facts about side effects on the right panel.

Ask your doctor if this treatment option is right for you. OPDIVO + YERVYO will not work for everyone. Individual results may vary.
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system problems that can happen with OPDIVO and YERVOY. Call or see your healthcare provider right away for any new or worsening signs and symptoms. Getting medical help right away may help keep these problems from becoming more serious.

Additional serious side effects observed include:

- Severe infusion reactions
- Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).

What are the most common side effects of OPDIVO + YERVOY?

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
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*The disappearance of any measurable tumors in response to treatment. This does not necessarily mean the cancer has been cured.

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Please see additional Important Facts for OPDIVO and YERVOY.
OPDIVO + YERVOY

OPDIVO + YERVOY join forces in different but complementary ways to help your active T cells.

With OPDIVO + YERVOY, more active T cells may be able to help seek and destroy cancer cells.

Some active T cells generated with YERVOY can become memory T cells, which may help recognize and defend against these threats in the future.

The clinical significance of memory T cells (how well their response could treat cancer) is not yet known or understood.

OPDIVO and YERVOY can cause your T cells to attack healthy cells contained within 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 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 YERVOY. Your doctor will check you for these problems during treatment. Your doctor may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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 YERVOY.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems that can happen...
YERVOY helps generate more active T cells.

OPDIVO helps active T cells identify cancer cells that are hiding.

Your immune system activates T cells to protect you from foreign threats, including cancer. But cancer cells can hide from T cells and make them inactive.

OPDIVO + YERVOY join forces in different but complementary ways to help your active T cells.

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Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
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OPDIVO when used in combination with YERVOY includes:
- 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. Talk to your healthcare team or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.
A treatment schedule with flexibility built in

Here’s a quick look at the 2-phase treatment schedule—including flexible options for the second phase.

OPDIVO and YERVOY are 2 different medicines that are delivered into your vein through an intravenous (IV) line. In the first phase of treatment, you will be given separate infusions of OPDIVO and then YERVOY during the same visit.

**Talk to your doctor to learn how many treatments may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointments to let them know how you’re feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

See Important Facts for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.
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**If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week to make them easier to remember. It is important to keep all appointments with your healthcare team. If you miss one, call your healthcare team as soon as possible to reschedule your appointment.

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Please see additional Important Facts for OPDIVO and YERVYO.
Questions and Answers

Where can I go to get infusions of this treatment?
You and your doctor should discuss the best place to get your infusions, whether it's at your doctor's office, an infusion center, or a community or university hospital.

How do I know if I'm responding to this treatment?
While undergoing treatment, your doctor will likely order periodic scans to evaluate whether there are any changes in the size of your tumors.

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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 YERVOY.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems that can happen.
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While undergoing treatment, your doctor will likely order periodic scans to evaluate whether there are any changes in the size of your tumors.

**Additional serious side effects observed include:**
- Severe infusion reactions
- Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).

**What are the most common side effects of OPDIVO + YERVOY?**
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
Questions and Answers

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- 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. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Please see additional **Important Facts** for **OPDIVO** and **YERVOY**.
Important Facts About OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)

This is a summary of important information that you need to know about OPDIVO and OPDIVO + YERVOY. Your healthcare team can work with you to help answer any questions you may have about these medications. Keep this information in a safe place so you can refer to it before and during your treatment.

Look out for the following icons as you read:
- Talk to your healthcare team
- Call a healthcare provider right away
- Helpful information to remember

What is OPDIVO + YERVOY?
OPDIVO is a prescription medicine used in combination with YERVOY (OPDIVO + YERVOY) to treat liver cancer (hepatocellular carcinoma).
OPDIVO + YERVOY is for adults who:

- Have previously received treatment with sorafenib.

OPDIVO and OPDIVO + YERVOY were approved based on response rate and how long patients’ responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO + YERVOY for this use.

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

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

What is the most important information I should know about OPDIVO + 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. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

*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 these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your healthcare team may also need to delay or completely stop your treatment.

Prescribing Information:  
Medication Guide:  
OPDIVO  
YERVOY
What are the serious side effects of OPDIVO + YERVYO?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

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

**Lung problems** — Things to look out for may include:
- new or worsening cough
- shortness of breath
- chest pain

**Intestinal problems** — Things to look out for may include:
- 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** — Things to look out for may include:
- yellowing of your skin or the whites of your eyes
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal
- dark urine (tea colored)

**Hormone gland problems** — Things to look out for may include:
- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- 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** — Things to look out for may include:
- decrease in your amount of urine
- swelling of your ankles
- loss of appetite
- blood in your urine
• blood in your urine

**Skin problems** — Things to look out for may include:
• rash
• itching
• skin blistering or peeling
• painful sores or ulcers in the mouth or nose, throat, or genital area

**Eye problems** — Things to look out for may include:
• blurry vision, double vision, or other vision problems
• eye pain or redness

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems that can happen with OPDIVO and YERVOY. 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
• Persistent or severe muscle pain or weakness, muscle cramps
• Low red blood cells, bruising
• Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight

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**What are the possible side effects of OPDIVO + YERVOY?**

**OPDIVO + YERVOY can cause serious side effects, including:**

See the previous section, “What is the most important information I should know about OPDIVO + YERVOY?”

**Severe infusion reactions** — Things to look out for may include:
• chills or shaking
• itching or rash
• shortness of breath or wheezing
• dizziness
• fever
• back or neck pain
Tell your healthcare team right away if you get these symptoms during an infusion of OPDIVO or YERVOY.

Complications, including graft-versus-host disease (GVHD), 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 or YERVOY. Your healthcare provider will monitor you for these complications.

What are the most common side effects?
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
- upper respiratory tract infection
- headache
- low thyroid hormone levels (hypothyroidism)
- decreased weight
- dizziness
- shortness of breath

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

What should I discuss with my healthcare team before receiving OPDIVO or YERVOY?

Tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant
What should I discuss with my healthcare team before receiving OPDIVO or YERVOY?

Tell your healthcare provider about all 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 and YERVOY can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO or YERVOY passes into your breast milk. Do not breastfeed during treatment with OPDIVO or YERVOY and for 5 months after the last dose of OPDIVO or YERVOY.

Females who are able to become pregnant:

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

- You should use an effective method of birth control during your treatment and for at least 5 months after the last dose of OPDIVO or YERVOY. 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 or YERVOY. You or your healthcare provider should contact Bristol Myers Squibb at 1-844-593-7869 as soon as you become aware of a pregnancy.

Tell your healthcare provider about all the medicines you take, including:

- prescription medicines
- over-the-counter medicines
- vitamins
- herbal supplements

For more information, please see U.S. Full Prescribing Information and Medication Guide for OPDIVO. Please see U.S. Full Prescribing Information and Medication Guide for YERVOY, or talk to your healthcare team.
SIGN UP for OPDIVO with You.

OPDIVO with You means just that: we’re here to help you better understand OPDIVO, whether you or a loved one are just considering OPDIVO or already have an OPDIVO prescription. This complimentary program includes the following resources.

Sign up and you’ll receive:

**Helpful Information**
Get useful tips, tools, and educational materials that can help you learn more about OPDIVO and may help support your care.

**Support and Advocacy Groups**
We can direct you to organizations that may be helpful for the challenges you may face.

**A Care Counselor as Close as Your Phone**
If you are prescribed OPDIVO and sign up for this additional resource, you’ll be able to speak with a registered nurse. This personal Care Counselor can answer questions about treatment and help you to be a more informed partner with your doctor. Care Counselors cannot provide medical advice. Your healthcare professional is the best source of information about your health.

If you’d like to sign up for the OPDIVO with You program, or if you have general questions about OPDIVO, call 1-855-OPDIVO-1 (1-855-673-4861) 8 AM to 8 PM ET, Monday to Friday, or visit www.OPDIVOwithYou.com

For more information call 1-855-OPDIVO-1 or visit www.OPDIVO.com

Bristol Myers Squibb is committed to helping patients throughout their treatment.

Please see Important Facts for OPDIVO and YERVOY. Please see links below for full Prescribing Information and Medication Guides for OPDIVO and YERVOY.
Financial Resources

Patient Access, Reimbursement, and Co-Pay Support

Available through Bristol Myers Squibb Access Support®

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That’s why we offer the BMS Access Support program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

For more information, ask your doctor, visit BMS Access Support, or call BMS Access Support at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday.

Other Patient Resources*

Blue Faery
bluefaery.org

Blue Faery’s mission is to help prevent, treat and cure primary liver cancer, specifically Hepatocellular Carcinoma, through research, education and advocacy.

CancerCare
cancercare.org

CancerCare is a national nonprofit providing free, professional support services to anyone affected by cancer. Their comprehensive programs include counseling and support groups, educational resources and financial assistance.

*Bristol Myers Squibb does not endorse these organizations. The information and links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician’s medical advice.

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