



## Advancements In Metastatic Melanoma



**Advances in the treatment of metastatic melanoma are helping doctors and patients in their fight against the disease.**

to significantly extend survival for patients in a phase III study, which was a pivotal moment in the treatment of this disease.”

Yervoy® (ipilimumab) can cause serious side effects in many parts of the body, which can lead to death. These serious side effects may include: inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis; inflammation of hormone glands (especially the pituitary, adrenal and thyroid glands) that may affect how these glands work; and inflammation of the eyes.

These side effects are most likely to begin during treatment; however, side effects can show up months after the last infusion. Healthcare providers should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with Yervoy. The oncologist may

decide to delay or stop Yervoy (ipilimumab).

Patients should call their healthcare provider if they have any signs or symptoms or they get worse. Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed. Patients should not try to treat symptoms themselves.

Rick is a patient who was diagnosed with metastatic melanoma. “I was frightened when I was diagnosed with this disease. I had been through multiple treatments, but it kept coming back. After much discussion with my physician, we decided Yervoy may be the best option for me.” Throughout the course of his treatment, Rick had strong support from his family and friends. “Having that support helped me greatly and gave me renewed hope.”

### Extending Survival for Some Patients

Yervoy is approved for the treatment of patients with metastatic melanoma or melanoma that cannot be removed through surgery (unresectable), and works through the immune system. Yervoy may not work in all patients and may affect healthy cells, too, which could result in serious side effects in many parts of the body. Some of these side effects may lead to death.

In a phase III clinical study, some Yervoy patients lived much longer than patients who did not receive it. People treated with Yervoy lived a median of 10 months, compared to a median of six months for those who were treated with an experimental

drug alone. Of the 676 patients in this trial, 137 patients (20 percent) received Yervoy (ipilimumab) alone, 136 patients (20 percent) received another experimental drug alone, and 403 patients (60 percent) received both treatments. In the trial, patients were previously treated with one or more of the following: aldesleukin, dacarbazine, temozolomide, fotemustine or carboplatin. The primary goal was to measure how long patients lived with Yervoy in combination with the experimental drug compared to the experimental drug alone. Over the course of the study, treatment with Yervoy decreased the risk of death by about one-third compared to patients who received the experimental drug. Individual results will vary. It is important for patients to ask their doctors if Yervoy is right for them.

As follow-up of these patients continued, it was estimated that 46 percent of patients taking Yervoy alone were alive at one year and 24 percent were alive at two years. By comparison, 25 percent of patients taking the experimental drug alone were alive at one year and 14 percent at two years.

In addition to the serious side effects, the most common side effects of Yervoy are tiredness, diarrhea, itching and rash. These are not all of the possible side effects of Yervoy. Please see the Important Safety Information below for additional information.

Talk to your healthcare provider about any questions you may have about your health or Yervoy. To learn more, visit [www.Yervoy.com](http://www.Yervoy.com).

(NAPSA)—Cancer is one of the most widespread diseases and the leading cause of death worldwide. Nearly one in 24 Americans are living with some form of cancer, so chances are you know someone with the disease.

While the rates of certain cancers have declined due to increased screening tests, other cancers continue to grow in numbers. This includes melanoma, a form of skin cancer in which cells that produce the skin’s pigment—called melanocytes—grow out of control.

Melanoma accounts for about 5 percent of all skin cancers, yet it is the cause of the vast majority of skin cancer deaths. Metastatic melanoma is the deadliest form of the disease. It occurs when cancer spreads beyond the surface of the skin to other organs such as the lymph nodes, lungs, brain or other areas of the body. For the past 30 years, the number of people diagnosed with this cancer has been rising.

“Historically, treating metastatic melanoma has been a challenge due to limited treatment options, resulting in an average survival rate of just six months and 75 percent of patients dying within a year of diagnosis. However, we now have additional treatment options that are helping us fight metastatic melanoma,” said Asim Amin, M.D., Ph.D., co-director of the immunotherapy program at the Levine Cancer Institute in Charlotte, N.C. “One of these treatment options is Yervoy, also known as ipilimumab. Upon its approval by the U.S. Food & Drug Administration in 2011, it became the first treatment for metastatic melanoma

### Important Safety Information

**Yervoy (ipilimumab) can cause serious side effects in many parts of your body, which can lead to death. These serious side effects may include inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis; inflammation of hormone glands (especially the pituitary, adrenal and thyroid glands) that may affect how these glands work; and inflammation of the eyes.**

**These side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with Yervoy. Your oncologist may decide to delay or stop Yervoy.**

**Call your healthcare provider if you have any signs or symptoms or they get worse. Even seemingly mild symptoms can lead to severe or even life-threatening condi-**

**tions if not addressed. Do not try to treat symptoms yourself.**

### Serious side effects may include:

- **Inflammation of the intestines (colitis)** that can cause tears or holes (perforation) in the intestines. Signs and symptoms of colitis may include:
  - o diarrhea (loose stools) or more bowel movements than usual
  - o blood in your stools or dark, tarry, sticky stools
  - o stomach pain (abdominal pain) or tenderness
- **Inflammation of the liver (hepatitis) that can lead to liver failure.** Signs and symptoms of hepatitis may include:
  - o yellowing of your skin or the whites of your eyes
  - o dark urine (tea colored)
  - o nausea or vomiting
  - o pain on the right side of your stomach
  - o bleeding or bruising more easily than normal
- **Inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis).** Signs and symptoms of severe skin reactions may include:
  - o skin rash with or without itching
  - o sores in your mouth
  - o your skin blisters and/or peels
- **Inflammation of the nerves that can lead to paralysis.** Symptoms of nerve problems may include:

- o unusual weakness of legs, arms or face
- o numbness or tingling in hands or feet
- **Inflammation of hormone glands (especially the pituitary, adrenal and thyroid glands) that may affect how these glands work.** Signs and symptoms that your glands are not working properly may include:
  - o persistent or unusual headaches
  - o unusual sluggishness, feeling cold all the time, or weight gain
  - o changes in mood or behavior such as decreased sex drive, irritability or forgetfulness
  - o dizziness or fainting
- **Inflammation of the eyes.** Symptoms may include:
  - o blurry vision, double vision or other vision problems
  - o eye pain or redness

### Pregnancy and Nursing:

- Tell your healthcare provider if you are pregnant or plan to become pregnant. Yervoy (ipilimumab) may cause stillbirth, premature delivery and/or death of your unborn baby. Before starting Yervoy, tell your healthcare provider if you are breast-feeding. It is advised that nursing mothers do not breast-feed while taking Yervoy.

**Tell your healthcare provider about:**

- Your health problems if you:
  - o have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn’s disease, lupus or sarcoidosis.
  - o had an organ transplant, such as a kidney transplant
  - o have liver damage from diseases or drugs
  - o have any other medical conditions
- All the medicines you take including:
  - o all prescription and nonprescription medicines
  - o steroids or other medicines that lower your immune response
  - o vitamins
  - o herbal supplements

You should not start a new medicine before you talk with your healthcare provider who prescribes you Yervoy.

### Most Common Side Effects:

The most common side effects of Yervoy (ipilimumab) include tiredness, diarrhea, itching and rash.

These are not all of the possible side effects of Yervoy. If you have any questions about your health or medicines, talk to your healthcare provider.

Please visit [www.Yervoy.com](http://www.Yervoy.com) for **U.S. Full Prescribing Information**, including **Boxed WARNING regarding immune-mediated side effects**, and **Medication Guide**, for Yervoy.