What Melanoma Patients Need to Know about Opdualag

"It is a really important development for our patients."

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You may have heard of Opdualag, a new therapy that recently earned FDA approval for advanced melanoma. Opdualag, which combines two different immunotherapies into one medicine, is earning attention as an effective – and more easily tolerated – combination therapy. One that improves upon the effectiveness of existing immunotherapies without dramatically increasing side effects. This opens the doors of combination immunotherapy to more patients.

If you have questions about Opdualag, keep reading:

What is Opdualag?

Opdualag is a new FDA-approved melanoma treatment that combines two different immunotherapies to help energize your immune system against melanoma. Once energized, your immune system attacks and destroys melanoma cells.

More specifically, Opdualag combines nivolumab with relatlimab. Both are drugs called checkpoint immunotherapies that work by releasing the brakes of the immune system, allowing it to attack cancer cells. Nivolumab (brand name Opdivo), approved first in melanoma in 2014, targets the immune checkpoint PD-1 and is widely used to treat melanoma and many other cancers. Relatlimab is a new drug targeting a different immune checkpoint, LAG-3, and is the first anti-LAG-3 therapy to earn FDA approval.

What does the research say about Opdualag?

The FDA approval for Opdualag is based on results from the Phase 2/3 RELATIVITY-047 trial that compared Opdualag against Opdivo in over 700 patients. The trial determined that patients receiving Opdualag lived more than 2x longer without melanoma growing, spreading, or getting worse when compared to patients receiving only Opdivo. In addition, while side effects were more common for patients receiving Opdualag, they were overall well tolerated.

Researchers and clinicians will continue to monitor patients enrolled in this study to provide

greater insight into patient outcomes.

What's the big deal about Opdualag?

Researchers and advocates alike are excited about Opdualag because it represents a new chapter in melanoma combination immunotherapy, with a new first-in-class treatment (targeting LAG3 and PD-1). Previously, combination immunotherapy has proved to be more effective than single-agent therapy, but at the cost of dramatically higher rates of side effects that range from annoying to life threatening. These side effects can also require treatment delays or discontinuation altogether.

While Opdualag hasn't been compared head-to-head in a clinical trial against the approved immunotherapy combination Yervoy + Opdivo (ipilimumab+nivolumab), it appears to be associated with fewer of these serious side effects. Less than 20% of patients who received Opdualag reported serious side effects, compared with nearly 60% patients who received Yervoy + Opdivo.

How does Opdualag compare against existing melanoma therapies?

Opdualag has earned FDA approval as a first-line treatment for advanced melanoma, but has only been compared directly against Opdivo (nivolumab). This means we don't scientifically know how it stacks against other therapies.

That said, Opdualag is a compelling alternative for clinicians and patients who may have previously selected a single-agent immunotherapy or even the Yervoy + Opdivo combination.

Who is eligible to receive Opdualag?

The U.S. Food and Drug Administration (FDA) approved the use of Opdualag to treat adult and pediatric patients 12 years of age or older who have advanced melanoma:

- Stage III Melanoma that is unresectable (unable to be completely removed by surgery)
- Stage IV Melanoma also known as metastatic disease (melanoma cells that have spread to organs and other parts of the body)

How is administered Opdualag?

Patients receive Opdualag intravenously (into a blood vein) every four weeks at your doctor's office or an infusion clinic. Opdualag is infused over 30 minutes, although your appointment might take longer due to any bloodwork or follow-up care.

What do the experts say about Opdualag?

“Since the approval of the first immune checkpoint inhibitor more than 10 years ago, we’ve seen immunotherapy, alone and in combination, revolutionize the treatment of patients with advanced melanoma,” said F. Stephen Hodi, MD, director of the Melanoma Center and the Center for Immuno-Oncology at Dana-Farber Cancer Institute. “Today’s approval is particularly significant, as it introduces an entirely new combination of two immunotherapies that may act together to help improve anti-tumor response by targeting two different immune checkpoints — LAG-3 and PD-1.”

“It is exciting to see a new, first in class, immunotherapy against the checkpoint LAG-3, a veritable roadblock suppressing the immune systems from attacking cancers, be approved for the treatment of advanced melanoma,” said Melanoma Research Alliance Chief Executive Officer Marc Hurlbert, PhD. “The potential therapeutic use of LAG-3 therapeutics in melanoma was identified by Drew Pardoll, MD, PhD, whose work was funded in part by a 2009 MRA Team Science Award. Today’s approval also marks the 15th approved melanoma therapy over the last decade – truly astonishing progress for researchers and patients alike.”

“It is a really important development for our patients,” said Hussein Tawbi, MD, professor of the Department of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center, and principal investigator in the RELATIVITY-047 trial. “We know that single agent PD-1 has been capable of curing almost 40% of our patients with unresectable or metastatic melanoma. We really think that [Opdualag] will add a significant proportion of successfully treated patients.… From my perspective, Opdualag will replace single-agent PD-1 inhibitors.”

Do you still have questions about Opdualag?

Post your questions to MRA’s online discussion community, the Melanoma > Exchange, here to discuss Opdualag or other treatment options, research advances, or more!

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