FDA Approves Nivolumab in Adjuvant Setting—Is it a Big Deal?

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The US FDA approved the use of nivolumab (Opdivo) in the adjuvant setting on December 20, 2017. This means that nivolumab may be used to treat melanoma patients with lymph node involvement or metastatic disease after complete surgical resection to reduce the risk of their disease recurring.

This is exciting news?

Definitely! Why? Because the data underpinning this most recent FDA approval showed that at 18 months, only 1/3 of patients being treated with nivolumab had a recurrence of their disease compared to about half of patients getting one of the current adjuvant treatments (ipilimumab aka Yervoy). That's a big jump in improvement.

Well, 1 of 3 vs 1 of 2 doesn't sound that great. Is it really that exciting?

You bet! Prior to this approval, patients with melanoma that's spread to the lymph nodes (around 9% of patients) and have surgery to remove the disease either:

1) wait to see if the melanoma comes back; or,
2) take one of two treatments (interferon or high-dose ipilimumab).

These options are pretty poor because they don't work that great and come with really significant side-effects. For example, over 42% of patients who got ipilimumab stopped treatment because of side-effects but only 9% of those who got nivolumab stopped treatment because of side-effects.

Simply put, about 60% of Stage III melanoma patients whose melanoma is removed will not have a recurrence of their disease even without treatment with ipilimumab or interferon, so the big decision for patients heretofore has been try a treatment at the cost of significant toxicity or to wait and hope you're in that group who'll do just fine with surgery alone.

Ok – now it sounds pretty awesome. Is there a catch?
Not a catch per se, but we don't yet know if the treatments will result in long term Overall Survival. The decreased rate of recurrence is definitely encouraging but it's just too soon to

tell. Also, even though the side-effects are fairly minimal compared to ipilimumab or interferon, 25% of patients had serious Grade 3 or 4 treatment related toxicities. That's a pretty high fraction of patients and some of those side-effects can be life-altering. So, whether to take treatment is a slam-dunk decision remains to be seen when there's a better than 50:50 chance your surgery alone has been curative. Still, having the option is amazing.

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