

1 Information about the Patient Advocacy Group

Name of the drug and indication(s):

Nivolumab (Opdivo) for Melanoma

Name of registered patient advocacy group: Save Your Skin Foundation

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1.1 Information Gathering

Please briefly identify how the information to complete Sections 2 and 3 was obtained. Was it obtained, for example, through personal experience, surveys, focus groups, one-to-one conversations with a number of patients using current therapy, printed sources, etc?

80% of patients and caregivers were re-interviewed for section 2 and 4 and 20% of patients and caregivers in section 3 were treated by treatment being reviewed. Information obtained to complete Sections 2 and 3 came from one on one interview's, focus groups, and surveys with 68 late stage melanoma patients and caregivers. Section 3 came from patients that are undergoing the treatment under review only. 68% of interviewees were female, roughly 94% were between the ages of 40-60 or older and ranged from across Canada

1.2 Confirmation of Authorship

I have the authority to declare this patient advocacy group has sole authorship of this submission and to confirm that no other parties have written or participated in the writing of the submission.



Signature

2015/08/17

Date (YYYY/MM/DD)

2 Condition and Current Therapy Related Information

1.3 Experience Patients Have with This Type of Cancer

The diagnosis of cancer impacts all aspects of patients' lives. Furthermore, different cancers, and stages of cancer, affect patients in different ways. Recognizing this, the focus of the information requested in this section relates to the impact of the cancer for which the drug under review is indicated. What are the symptoms and problems associated with this cancer that impact a patient's day-to-day life and quality of life? Examples of the type of information that could be included are:

- Which aspects (e.g., cough, pain, edema, appearance) of this cancer are more important to control than others?
- How do ongoing symptoms affect day-to-day life?
- Describe any limitations as a result of the cancer.

Ongoing symptoms from patients included loss on energy, fear, anxiety and depression. All of the patients experienced moderate to sever emotional distress. Some patients suffered fatigue, mood swings, vitality and low energy levels.

Limitations included are the inability to mentally and physically return to work, the inability to return to "normal" daily life, and anxiety and depression due to their prognosis, therefore unable to continue to work. Patients have also suffered from loss of mobility due to muscle and tissue removal of surgery or treatment.

1.4 Patients' Experience with Current Therapy

How well are patients managing their disease with currently available treatments?
Examples of the types of information that might be included are:

- What therapies are patients using to treat this type of cancer?
- How effective is the current therapy in controlling the common aspects of this cancer, e.g., pain, fatigue?
- What are common adverse effects and are some more difficult to tolerate than others?
- Would patients be willing to tolerate potential adverse effects resulting from treatment, if the benefits were only short-term?
- Are there hardships in accessing current therapy? Can patients readily access available treatments in their own communities?
- In addition to the drug cost, are there other financial implications to patients or caregivers (e.g., traveling costs, drug disposal issues, drug administration supplies)?
- Are there needs, experienced by some or many patients that are not being met by current therapy? What are these needs?

Current drugs used to treat melanoma are Interferon, surgery, radiation, Decarbazine(DTIC), Temozolomide, Stereotactic Radiation(used on brainstem tumours) Zelboraf, Yervoy, Mekinist, and Tafinlar, Pembro (under review)

-10 % of patients interviewed had positive results recorded with Interferon, DTIC, Temozolomind. Patients experienced fatigue and pain from the cancer while undergoing treatment regimes using these therapies. Patients felt these treatments probably slowed the spread of disease, but were not effective in preventing metastasis.

-40% of patients interviewed have positive results recorded with Zelboraf, Yervoy, Mekinist, Tafinlar

75 % of the patients above had adverse side effects that were most difficult to tolerate; fever, hair loss, extreme fatigue, diarrhea, skin issues, nausea, rash, joint pain, colitis. But all agreed symptoms were manageable with medications and would undergo treatment again if necessary.

- 50% of patients interviewed have previously current treatments (above) with either no response or temporary response. All agreed again that side effects could be difficult to tolerate but manageable if watched closely. All agreed they would undergo treatment for as long as needed despite side effects.

90% of the patients responded “yes” that they would “try anything” to win their fight with this cancer. The other 10% responded, “yes” depending on the severity of the side of effects.

All patients interviewed agreed that the needs that are not being met are the lack of treatments for Melanoma patients in a timely fashion. Current therapies have a better survival rate but getting to the right treatment in the right centers are big issues.

Many patients were not offered newer treatment options from their oncologist and were disappointed that there was no unified melanoma protocols across the country.

Many melanoma patients are still dying because there are still not enough treatment options available in a timely fashion. There is also concern that their needs are not being met and that their issues are not being heard.

1.5 Impact on Caregivers

What challenges do caregivers face in caring for patients with this type of cancer? How do treatments impact a caregiver’s daily routine or lifestyle? Are there challenges in dealing with adverse effects related to the current therapy?

For this section, a number of caregivers who had a close family member who was diagnosed with melanoma were interviewed:

The emotional distress due to an uncertain prognosis and unknown treatment plan, cancellation of any long-term plans, and time away from work to assist the patient all impacted the routine of the caregiver.

The challenge for the caregiver was confusion over the effects related to the current therapy. The caregivers interviewed found it difficult to know if the symptoms were treatment or cancer related. Lack of information about the side effects was noted by the caregivers, resulting in confusion and distress.

The main challenge for some caregivers was finding treatments that might work for the loved one. They cost to the family to travel to centers for treatment is very difficult.

“My spouse is thrilled with the effect the drug has had on the cancer and with the minimal side effects. Mentally this drug has given him the most positive impact since diagnosis.”

3 Related Information about the Drug Being Reviewed

3.1 What Are the Expectations for the New Drug or What Experiences Have Patients Had To Date with the New Drug?

- How much improvement in the condition would be considered adequate with this drug compared with current drug therapy?
- Is it expected that the lives of patients will be improved by this drug, and how?
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- What are the potential risks associated with the drug and do they outweigh the benefits?
- What other benefits might this drug have—for example, fewer hospital visits or less time off work?

Over 50% of patients interviewed heard about treatment options from an advocacy group. They all felt that Melanoma was a more known type of cancer but there were still not a lot of Health Care Professionals up to date on Melanoma treatment options. The other 40% of patients interviewed were told about the treatment options by their Health Care professional but over 50% of them had to travel outside their cancer center to receive treatment. Over 50% still had to get a second opinion to reach the melanoma oncologist that they needed to see.

100% of patients interviewed agreed that more clinical trials needed to be available to them.

All patients interviewed the benefits of this treatment outweigh the risks of the drug. Symptoms seem to be much more tolerable than current therapies and it increases the overall survival rate of a patient with melanoma.

Most interviewed were disappointed that they had to find this treatment themselves and that they had to travel outside their provinces to obtain the treatment. They also felt that if they had received this treatment sooner the end result might have been better for them.

This treatment in comparison to another similar treatment would mean more hospital visits and more time off, as it was being administered every two weeks. All patient and caregivers felt this was a small inconvenience to pay for their life, and insisted that the decision on which cancer treatment a patient needs should be

the decision of an oncologist and patient. All patients agreed that having choice when dealing with any type of cancer is pertinent and that course of treatment should also be the decision of the oncologist and their patient.

Based on patients' experiences with the drug as part of a clinical trial or through a manufacturer's compassionate supply or by paying for it out of pocket or through private insurance:

1. If you are or have been treated with the **Nivolumab**, what side effects (if any) of the treatment did you or are you experiencing.
2. Where the side effects of the treatment manageable or worth it in your opinion.
3. Has treatment with **Nivolumab** improved your quality of life?
4. What has been the outcome of the treatment with **Nivolumab** for you?
5. If it worked to eliminate your melanoma, how long has it been since you were treated?
6. What does your spouse, family member and or caregiver say about the impact of this drug on their daily life?

1. Side effects of the treatment were:

Diarrhea/colitis over 40% of patients

Headaches over 20% of patients

40 % of patients had not side effects.

2. 100% of patients interviewed said that side effects to treatment were manageable

3. 100% of patients interviewed said that **Nivolumab** improved their quality of life.

“My tumours have mostly disappeared and the remainder have shrunk significantly. Treatments are very easy to manage”

4. 100% of patients said that this treatment gave them hope. They have all had tumour shrinkage and for some full disappearance of growth.

“I have hope that this treatment is working for me, tumours are disappearing completely and others shrinking. When diagnosed my prognosis was poor.”

5. All patients interviewed are still undergoing treatment.

6. “My family has hope with this treatment and as the minimal side effects we have been able to continue on with our “normal” life.

4 Additional Information

Please provide any additional information that would be helpful to pCODR. This could include suggestions for improving the patient input process, indicating whether the questions are clear, etc.

Over 60% of patients were able to access treatment through their oncologist at a centre close to them. 40% of patients found it difficult to find a centre close to their home. Had difficulty getting on a trial as they only accepted a small number of participants.

All patients interviewed had the same common issue that this treatment was not offered to them in a timely fashion, some had to find this treatment on their own and some had to travel a great distance to get the treatment. This added emotional and financial stress to an already very stressful diagnosis. But all patients were extremely grateful that there are now treatment options available to them.

Appendix A: pCODR Patient Advocacy Group Conflict of Interest Declarations

Name of registered patient advocacy group: Save Your Skin Foundation

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Date: Aug 17th 2015