

1 Information about the Patient Advocacy Group

Name of the drug and indication(s): Yervoy (Ipilimumab) - First Line

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?

Information obtained to complete Sections 2 and 3 came from one on one interview's with a number of late stage melanoma patients who've received Yervoy 2nd line as well as patients undergoing 1st line treatment before being eligible for Yervoy. Information was also gathered from personal experience with Yervoy.

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.

[REDACTED]

Signature

2014/09/12

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.

- **The aspects of melanoma more important to control than others are:**
 - pain from tumour growth
 - physical appearance
 - Scars from surgery to remove tumours greatly impacted the physical appearance of the patient.
- **Ongoing symptoms from patients included:**
 - loss of energy
 - various psychological effects (fear, anxiety, depression)
 - All of the patients experienced moderate to severe emotional distress with battling melanoma.
 - Some patients suffered fatigue, mood swings, vitality, and energy levels
- **Limitations included are:**
 - Inability to mentally and physically return to work
 - inability to exercise and return to what used to be a part of my daily life
 - anxiety and depression due to their prognosis; therefore they were unable to continue to work.
 - Patients have also suffered from loss of mobility due to muscle and tissue removal from surgery.

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 2nd line.
- Few positive results recorded with any of the patients interviewed that underwent 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.
- Adverse side effects that were difficult to tolerate; extreme fatigue, diarrhea, skin issues, nausea, rash, low sodium levels, colitis. Many side effects have been so severe that patients have not been able to perform daily functions.
- 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 interview receiving Yervoy where disappointed that they had to go through a first line of treatment before they were eligible and were unsure the reasoning on why this process was mandatory. All patients felt that timing was important in their survivorship and they would have liked the more options of in a timely fashion. A number of patients were still not getting access to new treatment options in their communities and had to travel outside their communities for treatment.
- Other financial implications involved unemployment i.e. patients could not work while being administered the drugs.

- **Needs that are not being met are:**
- Current therapies have a better survival rate but there still not enough treatment options available and are not available in a timely fashion.
- 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 concern that the psychological aspect is being ignored. One patient said , “I feel that current therapy ignores the effects of melanoma surgeries and the psychological toll that this diagnosis takes on a person.”
- 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:

- 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 affects 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 found that the problem with the older therapies is that there was a small survival rate and their loved ones could die if they were not given access to the newer drugs in a timely fashion.

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?

- Yervoy will give melanoma patients the opportunity to extend their life expectancy. Ten of the patients interviewed had a complete response from treatment and another has lived past their life expectancy. For the patient, it's extra time spent with loved ones, extra Christmases, and birthdays. For two of our patients, it's seeing the birth of their child and becoming a grandmother for the first time.
- Yervoy is expected to improve the lives of melanoma patients using this drug. The treatment is expected to have milder side effects and more manageable treatment protocols than current therapies being used. The drug is also expected to increase the survival rate of a patient with metastatic melanoma.
- There is a large, unmet need for melanoma in Canada. There still hasn't been enough advancement in the treatment of melanoma. It took over 30 years for patient to get treatments with a better survival rate than the older, current therapies with very low survival rates.
- The most common side affects are:
 - fatigue
 - diarrhea
 - Rash
 - Itching
 - Colitis

The majority of the patients interviewed who used Yervoy experienced a mild form of these side affects. One patient had more severe reactions but they were quickly remedied with medications. With Yervoy, the benefits 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.

Yervoy will require fewer hospital visits and treatment for melanoma patients. Most current therapies used for melanoma require vigorous treatment regimes for up to

12 months (Interferon).

Patients interviewed who used Yervoy that experience more severe form of side affects said that there reactions were quickly remedied as most Health Care providers were more familiar with this treatment and were able to treat those severe side affects before they became life threatening. These patients also said in the above that they would still be willing to re-take the treatment knowing those sever side effects.

Some patients interviewed have had re-occurrence of their disease after their Yervoy but feel that if they had had the Yervoy sooner it might have made a difference in outcome and also feel that without access to the Yervoy they would not be here today to get to another new treatment option.

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:

- What positive and negative effects does the drug have on the disease?
- Which symptoms does the drug manage better than the existing therapy and which ones does it manage less effectively?
- Does the drug cause adverse effects?
- Which adverse effects are acceptable and which ones are not?
- Is the drug easier to use?
- How is the drug expected to change patients' long-term health and well-being?

Positive effects: two patients are disease free (one patient had complete tumour regression after 3 months and are both 7 and 8 year years disease free). Five patient's Yervoy treatment is ongoing and another patient has surpassed their life expectancy given by their oncologist after receiving Yervoy.

Negative effects: some side effects of treatment include diarrhea, skin breakouts and itching. However, all side affects were quickly remedied with other treatments.

- Some patients reported much more manageable symptoms of fatigue and nausea. Any other major symptoms reported were quickly remedied by visiting their oncologists for treatment. One patient interviewed is not sure at this time.
- All patients on Yervoy found the adverse affects to be manageable compared to current therapies.
- All patients interviewed who received Yervoy said that this drug is easier to use than current therapies.
- This drug is expected to help with long-term survival and add years to a very poor prognosis. A couple of the patients interviewed who have received Yervoy are now cancer free with one patient living past their life expectancy (originally given 6 months) since receiving Yervoy.

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.

All patients interviewed had the same common sentiment.

That these melanoma treatments need to be available in a more timely access. Time is of the essence with late stage melanoma patients and the stress of having to undergo a first line treatment first that has very little rate of survival is not a luxury that they feel they have. There is added stress to patients/caregivers and families while waiting to get to the treatments and also some patients were not given this treatment option from their original oncologist and had to find the centre and oncologist that were treating with this treatment.

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