

1 Information about the Patient Advocacy Group

Name of the drug and indication(s):

Aldesleukin (proleukin) for in-transit for
Melanoma

Name of registered patient advocacy group: Save Your Skin Foundation

Contact person: Kathleen Barnard

Title: President/Founder

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 came from one on one interview's with a number of late stage melanoma patients some of which have gone through the treatment under review. Section 3 came from interviews with patients that have undergone the treatment under review only.

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

2015/02/07

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 that are more important to control than others are pain from tumour growth and the pain from those tumours on the patients body especially in areas of movement (legs arms etc). The scars from surgery to remove tumours greatly impact the physical appearance of the patient

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.

Problems with surgery if tumour is in a difficult location on the body

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.

Few positive results recorded with any of the patients interviewed that underwent Interferon, DTIC, Temozolomide. 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 effects.

Other financial implications involved unemployment i.e. patients could not work while being administered the drugs and have to travel to specific centres for the IL2 injection

For patients with locally advanced melanoma, which develop in-transit cutaneous metastases, they feel surgery is a temporary measure with new lesions often arising quickly, adjacent to the surgical site. Radiation therapy patients feel only works in the direct area treated.

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 the right patient 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.

For patients with in-transit cutaneous metastases there are very limited options surgery and radiation.

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. The cost to the family to travel to centers for treatment is very difficult.

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?

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 effect of all patients was pain and swelling at the injection site, but all patients agreed that the discomfort was mild and short lived. Some patients had fever and flu like symptoms and a very few patients interviewed had mild nausea.

With all patients interviewed 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.

All patients 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.

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 were that some patients had a complete response and the complete disappearance of all signs of cancer. Other patients interviewed had other tumours appear but went for additional treatment.

All patients reported much more manageable symptoms of pain and swelling at the injection site and agreed they were short-lived. They were treated with painkillers.

All patients on this treatment found the side effects to be manageable compared to current therapies of surgery or radiation

Patient interviewed are hoping that this treatment will help with long-term survival and can add years to a very poor prognosis.

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 issue that this treatment was not offered to them in a timely fashion, some had to find this treatment on their own and most had to travel outside of their province to get the treatment. This added emotional and financial stress to an already very stressful diagnosis.

