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Skcin's comments on the ACD for the appraisal of Ipilimumab for previously treated advanced (unresectable or metastatic) malignant melanoma.

About Skcin and Skin Cancer UK

National skin cancer charity Skcin (the Karen Clifford Skin Cancer Charity) was founded by Richard Clifford after his wife Karen passed away on New Year's Eve in 2005, after a courageous battle against skin cancer. The charity campaigns to raise awareness of skin cancer, with the emphasis on sun safety education for behavioural change and skin cancer awareness resulting in early detection of the disease. Skcin is also passionate about improving patient care and access to treatment for all affected by skin cancer.

Skcin coordinates Skin Cancer UK, a coalition of organisations campaigning for action regarding the alarming increase in the incidence of the disease.

General comments

We would like to thank the NICE Technology Appraisal Committee for providing Skcin with the opportunity to respond to the Appraisal Consultation Document (ACD).

We believe that it is important for organisations such as Skcin to comment on issues affecting people diagnosed with melanoma given the charity's specific interest in skin cancer, skin cancer prevention, and of course, melanoma.

We concur with the views of the patient experts who presented evidence to the NICE Technology Appraisal Committee. As outlined in the Evaluation Report, they stated that if Ipilimumab is not made available to NHS patients, then they would be denied a therapy that might prolong survival and enable patients to continue their usual activities and maintain quality of life. We therefore urge the NICE Appraisal Committee to reconsider its decision and ensure that it is taking into account all of the evidence and representations received from patients and patient support groups over the past few weeks.

In particular, when considering the evidence, we believe that it is important that the Committee acknowledge that melanoma is now often referred to as the 'skinderella' of all the cancers. Skcin believes that it is time that greater choice and more treatment options should be made available to the growing number of people diagnosed with melanoma across the UK.

We would ask the NICE Technology Committee to consider that in the time between the first Appraisal Committee meeting on 20 September 2011 and the second ACD meeting on 16 November 2011, at least another 318 patients across the UK may have died from advanced melanoma[1] due to the limited treatment options available to them.

To conclude, we believe that NICE's draft negative guidance on Ipilimumab is a devastating blow to patients with advanced melanoma and if not overturned, patients will continue to have very limited treatment options.

We would like to respond to a number of the questions asked by NICE's Technology Appraisal Committee as part of its consultation process:

- **Has all of the relevant evidence been taken into account?**

Whilst we acknowledge that the NICE Technology Appraisal Committee has considered all evidence presented to it, we do not believe that sufficient consideration has been given to the fact that there are few treatment options available for patients diagnosed with advanced melanoma. Currently, patients can only access Dacarbazine, which is chemotherapy first licensed over three decades ago. As the NICE Technology Appraisal Committee will be aware, melanoma is an extremely aggressive disease and without effective new therapies, the prognosis for patients is poor. It has been suggested that the 5-year survival rate is approximately 5 – 15% and the median survival is 6 to 9 months. 6 months is very little time to get

[1] 318 figures is estimated on the premise that there are 2000 deaths from melanoma across the UK.

your affairs in order, come to terms with a diagnosis and say goodbye to family and friends. We therefore believe that if patients are given extra months and years, with a good quality of life, then this treatment is worth being reconsidered by Appraisal Committee A.

Following discussions with a number of leading oncologists and clinical nurse specialists, we also believe that clinicians, as well as patients, should be able to have a choice of a range of treatment options available to them. By issuing negative guidance for Ipilimumab, this only serves to continue to limit treatment prescribing options for clinicians who may believe that their patients would benefit from Ipilimumab.

We also believe the NICE Technology Appraisal Committee should reconsider its decision by looking at the innovation behind this therapy. Again, given that this is the first treatment for this patient group to be introduced to the market in over 30 years, the fact that the treatment works in a new way – through immunotherapy – should also be taken into further consideration by the NICE Technology Appraisal Committee.

- **Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

The NICE Technology Appraisal Committee has acknowledged in its ACD issued on 14 October that few advanced have been made in the treatment of advanced melanoma in recent years and Ipilimumab could be considered a significant innovation for a disease with a high unmet clinical need. Skcin agrees with the Committee's understanding that this treatment is a "step change" and therefore we do not believe that these provisional recommendations are a sound and suitable basis for guidance to the NHS.

On the basis that these provisional recommendations **are not** a sound and suitable basis for guidance, we urge the NICE Technology Appraisal Committee to reverse its decision. As well as being clearly innovative and a step change in the treatment for people with advanced melanoma, the incidence of melanoma is still rising. In fact, it is set to rise on a devastating scale in the coming decades, proving further the value and worth of this treatment to a growing pool of patients.

As the NICE Appraisal Technology Committee will be aware, melanoma is a growing public health problem. We know that over the last 25 years the rate of melanoma has risen faster than any other of the top 10 cancers in the UK and incidence rates in Britain have more than quadrupled over the last 30 years. This is a worrying trend which we know is set to continue.

In addition, we urge the NICE Technology Appraisal Committee to recognise that, tragically, melanoma often strikes at a younger ages compared to other cancers. Melanoma is the second most common form of cancer among young adults aged 15-34 years and it is the fastest growing cancer in men and the second fastest in women. It has been estimated that an average 22 years of life is lost from each melanoma death – more than any other cancer. Skcin therefore believes that Ipilimumab, which we understand can prolong survival and help prognosis, will allow patients to return to 'normal life' for a longer period of time. Without the positive approval of Ipilimumab by the NICE Appraisal Committee, the contribution by many young melanoma sufferers to the workplace and society will be cut short.

- **Are there any equality-related issues that need special consideration and are not covered in the appraisal consultation document?**

Skcin believes that equal access to treatments for people with advanced melanoma must be considered by the NICE Technology Appraisal Committee. As previously mentioned, Ipilimumab is a significant innovation for a disease with a high unmet clinical need. To demonstrate the extent of this unmet need, we can observe that in the last 10 years, NICE has recommended 81 Single Technology Appraisals for oncology. However, there have been no Technology Appraisals specifically for people with melanoma which, although is beyond the control of NICE, is concerning as it demonstrates that there is a real gulf between the number of treatments available across the spectrum of cancers. In light of this unmet need, we believe that equality between different cancer patients should be taken into account, allowing for the fact that this is the first licensed treatment for this patient group since the 1970s.