

PAULINE LATHAM OBE MP

Mid Derbyshire



HOUSE OF COMMONS

LONDON SW1A 0AA

Professor Sir Mike Rawlins
Chairman
NICE
Mid City Place
71 High Holborn
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Wednesday 9th November 2011

Dear *Professor Sir Mike Rawlins*

Please find enclosed a hard-copy of the report from last night's Parliamentary and Stakeholder Investigation for consideration by NICE Appraisal Committee A.

This report was also sent by e-mail to [REDACTED] the Technology Appraisals Project Manager - Committee A, within the requested deadline.

Thank you for your assistance. We look forward to the outcome of the meeting on 16 November.

Yours sincerely,

Pauline Latham

Pauline Latham OBE MP

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PARLIAMENTARY AND STAKEHOLDER INVESTIGATION Called by Pauline Latham OBE MP

Treatment of advanced melanoma NICE's preliminary negative guidance on Ipilimumab (Yervoy)

Report of meeting held in Parliament on 8 November 2011

On Tuesday 8 November 2011 Pauline Latham MP held a high profile stakeholder investigation in Parliament to enable patients, carers, clinicians and Parliamentarians to vocalise their concerns about the negative preliminary guidance by the National Institute for Health and Clinical Excellence (NICE) on Ipilimumab for previously treated advanced (unresectable or metastatic) malignant melanoma. Attendees at the meeting discussed the clinical effectiveness of Ipilimumab (Yervoy) and considered arguments about innovations in healthcare.

This dossier documents the background to the meeting and why this issue is important, as well as the key themes of debate and proceedings of the meeting. The report will be submitted to NICE as evidence in response to the Appraisal Consultation Document. It is anticipated that this evidence will be considered ahead of the NICE Technology Appraisal Committee meeting on 16 November 2011.

Contributors:

Pauline Latham, Conservative MP for Mid Derbyshire

[REDACTED] Founder and Trustee, Skcin

[REDACTED] Clinical Oncologist, St James' University Hospital, Leeds

[REDACTED] – melanoma patient representative

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Gill Nuttall, Founder, Factor50

Charlotte Fionda – on behalf of the British Association of Skin Cancer Specialist Nurses

John Glen MP, Conservative MP for Salisbury

Treatment of advanced melanoma NICE's preliminary negative guidance on Ipilimumab (Yervoy)

About skin cancer and melanoma: Skin cancer is the most common cancer in the UK and can be divided into two main types: non-melanoma skin cancer and melanoma skin cancer (often referred to as malignant melanoma). Non-melanoma skin cancer is almost eight times as common as malignant melanoma¹. Skin cancer is relatively common and affects about 100,000 people in the UK each year. In most cases it is detected early and is not life-threatening. Melanoma is less common but much more serious. Each year, over 2,000 people in the UK die from melanoma.

Melanoma is a very aggressive disease and the average survival time for advanced melanoma is just six to nine months.

"Patients with in-transit metastases have a poor prognosis, with a 5-year survival rate of only 25%. Treatment for many patients is therefore essentially palliative."

NICE Cancer service guidance CSGSTIM

Risk factors for melanoma: Ultraviolet light is the main risk factor for melanoma. Ultraviolet light comes from the sun or sunbeds. Some people are more at risk of getting melanoma than others. Risk factors related to sun exposure include: a high number of moles; being very fair skinned; sunburn (this includes being sunburnt as a child); where you were born – fair skinned people born in a hot country, such as Australia or Israel, have a higher risk of melanoma throughout their life; sun exposure – on holiday, as well as sitting in the sun, sunbathing and using sunbeds (particularly before the age of 35). Other risk factors include a family history of melanoma or a weakened immune system.

Incidence of melanoma: There has been a marked increase in the incidence of advanced melanoma in the UK over the past few decades, yet the outlook for patients with this aggressive disease has been poor, with no major advances in treatment.

"The incidence of melanoma is set to rise by 52% in both men and women by 2030."

British Journal of Cancer, 2011

One of the most tragic aspects of advanced melanoma is that it disproportionately affects younger people relative to other cancers. More than one third of all cases of melanoma occur in people under the age of 55, and in the UK it is the second most common cancer in the 15-34 age group. Each year over 2,000 people in the UK die from melanoma, and this figure is set to rise. Worryingly a study published (October 2011) in the British Journal of Cancer, *Cancer in the United Kingdom: Projections to the year 2030*, claims that although overall cancer rates are projected to be stable over the next 20 years, melanoma incidence is set to rise by 52% in both men and women by 2030. The study predicts the disease will become the fourth most common cancer in men and the fifth most common in women over this period.

Current treatment options: There have been no major advances in treatment for advanced melanoma for over three decades. For those patients who could qualify for Ipilimumab, the current treatment available to them is a chemotherapy called Dacarbazine which was first licensed in the 1970s.

The new choice of treatment for people with advanced melanoma **should be welcomed**, but on 14 October 2011, NICE released its negative guidance for Ipilimumab – the first treatment for this group of patients licensed for over thirty years. The recommendation that it not be approved was made on the grounds of cost.

"I am not particularly unique, in my journey almost all of the patients I have met are family people, under 60 and with very good jobs and a special outlook on life and the community."

Melanoma patient

¹ Cancer Research UK: Skin cancer – UK incidence statistics, <http://info.cancerresearchuk.org/cancerstats/types/skin/incidence/#source6> (accessed March 2011)

Following this decision there was dismay from clinicians, patients and professional groups who believe that the approval of Ipilimumab would be a significant addition to the limited treatment options currently available for clinicians to prescribe.

This meeting was therefore called in order to gather expert evidence and opinion on the use of Ipilimumab, its cost, efficacy, safety and what it would mean to clinicians, their patients and carers if this drug was to be made available. This report will be distributed to NICE ahead of its second Appraisal Committee meeting.

Concern over NICE's decision: Since the draft guidance was issued by NICE, the patient group Factor50 and the skin cancer charity Skcin (The Karen Clifford Skin Cancer Charity) have received calls, emails and letters from patients, carers and clinicians wishing to protest against NICE's preliminary decision. The vast majority of the concern focuses on:

- Unmet need
- Rising incidence
- The importance of being able to access a wide range of effective treatment options.

Some of the comments received by Factor50 and Skcin included:

"I am absolutely NOT prepared to lose out on any further advances in the treatment of this disease. I am very anxious to try anything at all that is on the market, as I do not want to die sooner than necessary when there is a drug that is now available which may help to prolong my life by even a matter of months"

"I feel very frustrated at what I hear regarding new and standard treatments. I am fully aware that the standard treatments have little or no success and given that this really is a matter of life or death, I feel very strongly that any new drugs such as Ipilimumab should be available on the NHS"

"I have spoken to the nurses who said that if I wanted to be treated with Ipilimumab at some point in the future, there are no guarantees I would be able to. I feel that if there is a drug available that could prolong the lives of melanoma patients it should be available to those patients that will benefit...I've never claimed anything at all in the past, if there is a chance I can prolong my life, I'd like to be able to take whatever I can get"

"I know there is no cure for this disease, but I desperately want to be here for my children for as long as I can. I want to be given the opportunity to see them grow for a little longer. I don't have many chances as it is, but if Ipilimumab is not available, then that is one less chance"

"Three months are a long time in the life of a melanoma patient. These are extraordinary times in melanoma treatment."

"As a 40 year old, otherwise fit, father of 3 young children Ipilimumab offers me the best chance to "win" my war with melanoma. It has the possibility to return me to a normal life made of the things most people take for granted and that I, and my family, can now value every single day. Currently I am living with a maximum time horizon of 8 weeks to accommodate trial requirements, personal investigation in new clinical trials and the wider uncertainty about life"

"I am absolutely disgusted that there is the slightest suggestion that this drug may not be made available. I consider that Ipilimumab might be my only hope in the future for a prolonged life with my family"

"I need to live. I HAVE to live for my children. I just want a few more years so that my boys will remember me"

We have also witnessed the publication of an open letter to the Prime Minister by 14 leading clinicians as well as coverage in the press.

This backlash and outcry was the very reason that the Parliamentary and Stakeholder Investigation was called – to allow patients, clinicians and professional associations to have a voice and debate this draft negative guidance.

Parliamentary and Stakeholder Investigation Meeting

Summary of stakeholder comments:

Efficacy

The efficacy of Ipilimumab was raised on a number of occasions. Patients and patient representatives gave examples of case studies where patients had received Ipilimumab and were still alive a number of years later. Attendees also discussed the social value placed on those lives and the ability to continue with work and engage in family life after the successful use of Ipilimumab.

"Ipilimumab is the first drug to show an increased survival but for me, the three month median survival shift is less compelling than the fact that you are doubling the proportion of people who are alive at a year and two years. If you say to someone that this drug may not work but it is doubling your chances of being alive in a year I think that means more to people than saying that they may live for an extra three months achieved through four months of treatment."

[REDACTED] Oncologist, St James' University Hospital

[REDACTED] was at the point of planning his own funeral. He was treated with Ipilimumab, had some terrible side effects, which he was expecting, but he is still here. He is putting back into society as a headteacher, he has got two little children, and not going to be a drain on a society. Three years down the line he is still with us, so that shows you just what this drug was able to do for him."

Gill Nuttall, Founder, Factor50

[REDACTED] who lives down in [REDACTED] is stage IV. He has been coming from [REDACTED] the Marsden for the Ipi trial, and his message says, 'I had four doses at three week intervals from mid-December until early February. I had no side effects until after the last days when I got severe colitis. I spent eight days in hospital; however the results have been worth it. There are a few specs still showing up on my liver scan, but nothing like the tumour showing in December. My oncologist says that I would have died some considerable time ago without the Ipi treatment.'

[REDACTED] Patient