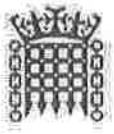

Parliamentary and Stakeholder Evidence Session
Called by Pauline Latham OBE MP

Ipilimumab as a first line treatment for advanced melanoma: NICE's preliminary recommendation

Report of meeting held in Parliament on 11th March 2014

On Tuesday 11th March 2014, Pauline Latham MP called together patients, carers, healthcare professionals, patient groups and Parliamentarians to voice their concerns about the National Institute for Health and Care Excellence's (NICE) provisional recommendation not to recommend ipilimumab (Yervoy) as a first line treatment for advanced melanoma. At the meeting, attendees discussed the clinical effectiveness of ipilimumab and considered arguments about cost effectiveness and value of using ipilimumab as a first line treatment.

This report explains the reasons why this meeting was held and outlines why stakeholders are concerned about NICE's provisional decision, as well as documenting the key themes of debate and proceedings of the Parliamentary Evidence Session. 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 23rd April 2014.

Treatment of advanced melanoma
NICE's provisional decision on ipilimumab (Yervoy)

Background: An overview of recent developments in melanoma treatment

Until 2011, treatment options for people with advanced melanoma had remained very limited for decades. Ipilimumab was the first treatment to receive a licence for advanced melanoma since the 1970s and signalled a step-change in the treatment options for these patients.

> *"NICE's decision is a step backwards for melanoma patients across the country. Denying earlier access to an innovative and life-saving treatment is vital to improving chances of survival. The Government, NICE and industry must do everything they can to ensure that patients are given the treatment they deserve."*
> Gill Nuttall, Melanoma UK

In 2011, the National Institute for Health and Clinical Excellence (now the National Institute for Health and Care Excellence) recommended that ipilimumab should not be available on the NHS. Following this decision, there was an outcry from Parliamentarians, clinical experts and the melanoma community, who joined together to urge NICE to overturn its original decision. When the decision was overturned in 2012, access to this new and innovative treatment gave hope to many patients with melanoma across the country.

Last year, ipilimumab received a European licence to be used as a first line treatment and therefore NICE is once again carrying out an assessment of its clinical and cost-effectiveness. Unfortunately, NICE has decided not to allow ipilimumab to be used as a first line treatment, except in clinical trials. This decision means that patients who currently need lifesaving treatment can be forced to endure months of treatment with the first line treatment used for this type of melanoma – dacarbazine. In its decision, the NICE Appraisal Committee acknowledged the views of clinicians that dacarbazine "has never been shown to have survival benefit."

About melanoma:

Skin cancer is the most common cancer in the UK – it affects about 100,000 people each year. In most cases it is detected early and is not life-threatening. However, melanoma – the most serious form of skin cancer – is much more life threatening and is the sixth most common cancer overall in the UK (if non melanoma skin cancer is excluded). Melanoma is an extremely aggressive disease and a diagnosis of advanced melanoma is devastating to patients and their families. Patients who are diagnosed with advanced melanoma have an average median survival of just six to nine months but when treated with ipilimumab some patients are still alive after a year and, in some cases, patients can live a great deal longer.

About ipilimumab

Ipilimumab works in a new way through a form of immunotherapy that encourages the immune system to produce more cancer-killing cells. Ipilimumab requires a single cycle of treatment, so it is not something patients have to receive again and again for the duration of their lives.

The decision not to allow ipilimumab to be used as a first line treatment for advanced melanoma can be extremely distressing for patients – delayed access to ipilimumab can be life threatening. This delay reduces the chance that patients will receive the full course of treatment and, as such, they are less likely to receive the full benefit.

It is difficult for patients to understand why the NHS will only initiate them onto a more effective treatment once they have gone through unsuccessful treatment with an older, ineffective drug (dacarbazine). Patients are acutely aware that the clock is ticking and their chances of long term survival could be greatly enhanced by earlier access to ipilimumab.

Incidence of melanoma:

Each year over 2,000 people in the UK die from melanoma and the incidence rate of the disease is on the rise. Over the last 25 years, the rate of malignant melanoma has risen faster than any of the top ten cancers in the UK. More than 11,700 people are diagnosed with malignant melanoma each year. While the majority of skin cancers are treatable, malignant melanoma kills over 2,000 people each year with an average 22 years of life lost from each melanoma death, which is more than most other cancers. In relation to other cancers, this aggressive disease disproportionately affects young people. Indeed, it is the second most common cancer in the 15-34 years age group and more than one third of melanoma diagnoses are for people under 55 years of age. Having a younger profile means that patients are often of a working age and many have young families – for these patients fast access to effective treatment is invaluable.

"The incidence of melanoma is rising significantly in the UK. Ipilimumab is a highly effective treatment, which would be even more effective for patients with advanced melanoma if it was given as a first line option. It is therefore vital that NICE reverses its decision not to allow ipilimumab to be used in this way."
[redacted]kin

Concern over NICE's decision:

Following NICE's provisional decision not to recommend ipilimumab as a first line treatment for advanced melanoma, patients and their carers have contacted Melanoma UK to raise their concerns about what the decision means for patients with melanoma both now and in the future. Parliamentarians, clinicians and other healthcare professionals have stressed their disappointment and concern that patients with advanced melanoma will not be able to have earlier access to ipilimumab. They are calling on NICE to approve ipilimumab for use as a first line option for the treatment of advanced melanoma. They believe that this will provide patients across the country with a better chance of survival and argue that these patients should not be denied earlier access to this treatment until the decision is reviewed in 2017.

Some of the comments received by Melanoma UK include the following:

'It was a very nerve-racking time for us. His lung tumours were growing fast and he was already symptomatic. His doctor was very worried that he wouldn't have time to get the ipilimumab treatment as he had to have three doses of dacarbazine first.'
- A carer describing the wait her husband faced to receive ipilimumab.

'I was put on ipilimumab and have been responding well ever since. It's sad that others have not had the chance that I did. Ipilimumab needs to be one of the first lines of defence. I feel so grateful and so lucky.'
- Patient

'My oncologist was upfront with me, saying that dacarbazine is pretty ineffective for melanoma...but that was what they would have to give me. With all the positivity round ipilimumab it seems nonsensical not to allow patients to receive it and plays with people's lives.'
- Patient

'I just hope that NICE remembers how quickly Stage IV melanoma patients tend to die and is able to make a positive decision quickly.'
- Patient

Parliamentary Evidence Session
Called by Pauline Latham OBE MP

Ipilimumab as a first line treatment for advanced melanoma: NICE's preliminary recommendation

Summary of stakeholder comments:

Ipilimumab: a revolutionary treatment?

It was clear throughout the evening that attendees considered ipilimumab as the 'best available option' for patients with advanced melanoma who are not BRAF-positive. Whilst they agreed that it was not effective in all patients, they stated that it was 'illogical' to deny earlier access to it. Attendees acknowledged that it is extremely important to ensure that a clinically effective treatment is available as a first line option for both the mental and physical health of patients with advanced melanoma. At present, the only first line treatment for advanced melanoma is dacarbazine, a treatment widely acknowledged by clinicians as ineffective.

Throughout the conversations, many members of the group commented on the 'revolutionary' nature of ipilimumab and the hope it has brought to so many patients with advanced melanoma. Indeed, prior to ipilimumab's licensing in 2011, no other treatment had received a license for advanced melanoma for over thirty years. Attendees agreed that this treatment is a step in the right direction and that it has brought significant hope to patients and the clinical community. Not recommending ipilimumab as a first line treatment for advanced melanoma is a step backwards and attendees agreed that this decision must be reversed. Patients cannot wait until 2017 for this decision to be reviewed.

Attendees heard that ipilimumab had been approved as a first line treatment in countries across Europe and in the United States. They acknowledged that Britain was behind the rest of the world in realising the value of using innovative treatments such as ipilimumab and agreed that ipilimumab is an effective first line treatment for advanced melanoma in some patients.

'Ipilimumab does work [...] I'm sure they [NICE] are making the decisions for the best reasons but they made the wrong decision in this instance.'
Pauline Latham MP

"I feel it is very important to make you all aware that NICE, in its provisional decision, acknowledged the clinical consensus that dacarbazine "has never been shown to have survival benefit."
Gill Nuttall

'A few years ago, melanoma was a death sentence. Drugs like ipilimumab give more treatment options.'
[redacted]

'For melanoma patients, the big thing in 2012 in the UK wasn't the Olympics, it was ipilimumab. If surgery is no longer an option, then there was only dacarbazine. This is a really revolutionary drug.'
[redacted]

'Europe and the rest of the world recognise the importance of using ipilimumab first line in almost all cases of advanced metastatic melanoma.'
[redacted]

Efficacy of ipilimumab as a first line treatment

Several examples of the effectiveness of early treatment were provided and it was noted that patients who were treated earlier were less likely to suffer disease-related disability and thus require social care services in the future. Indeed, examples were given about cases where a patient received ipilimumab as a first line treatment and was able to achieve stability and live a normal life. On the other hand, patients who have to wait to receive ipilimumab as a second line treatment necessarily have to wait for the first line treatment to fail and for their disease to progress. This can mean that they are unable to receive the full course of treatment or, if they do achieve stability, the effects of allowing the melanoma to progress can result in the chances of full recovery diminishing.

As such, attendees mentioned that many patients could have a better quality of life if they could access ipilimumab without first having to be treated with dacarbazine and they noted that the true cost of ipilimumab should therefore be considered in conjunction with the societal benefits that the treatment can bring. They agreed that ipilimumab can, in some patients, provide extra, quality, years of life.

'I was given ipilimumab when I had a low tumour. A friend of mine with skin melanoma was also given ipilimumab at the same time as me, but she had a higher tumour growth rate. We both achieved stability after an initial regression. Now I can do what I want which means driving, going abroad – my friend is wheelchair bound and needs help with the tasks of daily living. How would you expect your healthcare system to treat you: early with hope of symptom free stability like me, or left untreated and to have stability but be grossly disabled?'

[redacted]

'This is the first new drug in 30 years which has come along, so I'm very surprised that NICE haven't agreed to it because those people who have it are doing very well, and much better than any other treatment. To rule it out just seems wrong.'

Pauline Latham MP

'Patients have real difficulty in understanding why they can only access a more effective treatment once they have gone through an unsuccessful treatment with an older, ineffective drug.'

Gill Nuttall

'If we are going to have it second line, most patients are going to have it anyway, but just later. That doesn't make sense.'

[redacted]

'It is important for patients to have that resource (ipilimumab).'

[redacted]

'We knew that the chemotherapy wasn't going to cure him – we were hoping to get him well enough for the ipilimumab trial. I don't saying that ipilimumab would have saved his life, but it could have given him another couple of years – maybe given him the chance to see his son grow up.'

[redacted] (patient representative)

'I was prescribed ipilimumab on a compassionate access programme. Early scans showed significant reduction of tumours and since, I've gone from being bed ridden to being able to walk, drive and live my life. I know that it is a second line treatment but had it been offered in the first line, a great deal of anxiety, pain and distress would have been avoided.'

Patient (anonymised)

Patient Population

A number attendees highlighted that melanoma disproportionally affects young people. Melanoma is the second most common form of cancer in the 15 – 34 age group, with the average age of diagnosis being just 50. Given that the patient population is generally younger for melanoma than for other cancers, the importance of effectively treating the disease in a timely manner was raised. The importance of ensuring that every effort is made to help patients to recover without disability and enable them to return to work and contribute to society was noted as being extremely significant.

Concerns were raised about survival rates of advanced melanoma patients and about a lack of education of the younger population. It was noted that there is often a lack of understanding about the causes and effects of melanoma and attendees commented that more must be done to help this age group protect themselves, wherever possible, against this aggressive and life threatening disease. Whilst awareness and education are important, access to appropriate and timely treatment upon diagnosis is also vital.

'Patients are often of a working age and have families and possibly also contribute significantly to their local community – you know I often wonder just how much NICE take into account the impact on the complete picture that surrounds the patient. Perhaps then the cost factor – whatever it is per patient – would reflect a truer appraisal and with such a common cancer with such a limited median survival time – does it not warrant a degree of priority.'
[redacted]

'Some of my friends still use sun beds, even though they're well aware of my condition. I think young people don't realise how dangerous melanoma can be.'
[redacted] melanoma patient)

'It is a disease that primarily hits young people. As a healthy 30 year old I didn't expect a diagnosis like this.'
[redacted] melanoma patient)

Early Diagnosis

Several attendees gave testimony to the importance of early diagnosis and noted that this has one of the biggest impacts on treatment outcomes. Indeed, in the early stages of melanoma it is generally treatable and patients can return to their normal life. However, where melanoma is not caught early, it can become an extremely aggressive and life threatening disease. Attendees agreed that, where the disease is diagnosis at a later stage, and particularly in conditions such as ocular melanoma where patients rapidly regress, earlier access to effective treatment is key to improving survival chances.

'It seems ridiculous that if it [Ipilimumab] is effective, that it isn't available as a primary treatment.'
[redacted] melanoma patient)

'Why should patients have to wait when they know there is something else which works?'
Pauline Latham MP

'I'm still passionate about the advantages of early diagnosis. Early diagnosis and early referral are essential.'
Baroness Masham of Ilton

Growing incidence

Attendees noted with concern that the incidence of melanoma has the biggest projected increase of any form of cancer. They discussed that this means more patients will be diagnosed in the future and noted the potential impact of this rise. At a time when more and more patients are likely to present with the condition, participants highlighted the growing need to ensure that there is an effective treatment available as a first line option. Attendees reiterated that it is vital for NICE to approve appropriate and efficacious treatments for use at the most clinically appropriate stage, in line with the international community. Otherwise, an increasing number of patients will not have access to a treatment which has the potential to save their life and give them extra years of quality survival.

'There can be no doubt that the incidence of melanoma is rising significantly in the UK. Ipilimumab has been clearly demonstrated as a most effective treatment and would be even more effective if given at an earlier stage.'

[redacted]

The Patient Perspective

Healthcare professionals recounted the difficulty of explaining to patients why they had to receive a clinically ineffective treatment first before being able to access a treatment which is known to be extremely efficacious in some patients.

There was a consensus amongst the attendees that not enough is done to keep patients informed of the decisions that NICE makes regarding their treatment pathways. It was also felt that there was not enough patient involvement when deciding on trials or treatment. Patients identified that a lack of information and contact can be very difficult for patients with melanoma and that it was important for them to feel like they were being given the best possible care. Healthcare professionals, patients and patient group representatives all agreed that, at present, patients simply do not understand why they are being denied access to a treatment that can be so effective.

Whilst accessing ipilimumab in clinical trials will help some patients, it was agreed that all patients should be able to receive ipilimumab if their clinician feels it would be appropriate.

'I was extremely lucky- I was not forced to have dacarbazine first before I had access to ipilimumab. This was because they accepted that I did not want to poison myself with an ineffective drug. They accepted that dacarbazine- traditionally used for the last 20 years to treat ocular melanoma- has a response rate of less than one per cent in ocular melanoma. It was more likely to harm me than give me any benefit.'

[redacted]

'It's very hard for clinicians when there is a drug there which is more effective which cannot be used. Ipilimumab really should be available to all patients based on clinicians' judgements.'

[redacted]

decisions from any of my doctors.'

trial applications] and now you don't know what is happening,
ion is made without you.'

ision about me is made without me" What happened to that?"

the criteria that NICE uses to assess first line treatment, and
.'

Overview of Main Speeches:

Introduction

Pauline Latham MP Conservative MP for Mid Derbyshire

I would like to thank those here today for taking the time and effort to attend this important meeting on the NICE consultation on the use of ipilimumab as a first line in the treatment of advanced melanoma. It is great that we are able to come together at an event like this where patients, patient groups, healthcare professionals and Parliamentarians can discuss NICE's recent decision, and I hope the discussions that we have here are effective in assisting both us parliamentarians and other interested parties in bringing pressure to bear on NICE to reverse their decision. This is not a political issue, it is a cross party issue which affects everybody. Addressing my honourable friends in the House, I cannot emphasise enough how important it is for us to work together, in spite of political persuasions, to get a positive outcome in this regard.

Whilst NICE's negative decision on this occasion may have deflated some of your hopes, I would remind you that two years ago, a similar campaign, which I participated in, was run to get ipilimumab approved as a second line treatment which succeeded. The success of this campaign is a clear indication that your contributions as stakeholders do matter and that you can affect NICE's licensing policy. In fact, the discussions that we have in today's meeting will be recorded and submitted in the form of a report to NICE ahead of next week's deadline.

In today's meeting, you will be hearing from Richard Clifford from Skcin and Gill Nuttall from Melanoma UK about melanoma, the incidence and the current treatment options for people with advanced melanoma. We'll also hear about the NICE process to date. Then we will open up the floor to patients and their families to talk about their experiences of late-stage melanoma and their opinions on NICE's decision.

The reason I'm interested is that my brother had melanoma 12 years ago and had very little treatment. He knew he would not survive but, since he was ill, treatment has improved significantly.

Unfortunately some GPs are unable to spot the early signs of melanoma, which is crucial to survival. If patients are worried they must push for an appointment for a referral.

It is without further ado that I would like to introduce this evening's first guest speaker, Richard Clifford, who is the founder of the charity Skcin. Skcin is aimed at providing education about sun safety and the early detection of melanoma, and it is a privilege to have him speaking at today's event.

Melanoma: the growing incidence

[redacted] Founder and Trustee, Skcin

It is now two and half years – in fact it was in November, 2011 when I spoke at a Parliamentary Stakeholder Investigation into the treatment of advanced melanoma. This followed negative preliminary guidance by NICE for Yervoy for previously treated melanoma. I believe that the original matrix submission was made in March 2011 and so – here we are some three years on admittedly with some " negotiated " progress - but with a marvellous ground-breaking drug only as a second line treatment. But it is as a first line treatment that this drug is urgently needed replacing an existing treatment which has such a relatively poor record of success.

For those of us present – clinicians and the charities and various organisations that battle on a daily basis with the huge issue of the increasing incidence of melanoma in the UK - the information and statistics that I am about to voice are commonplace.

It must also be appreciated that these statistics and projections are based on 2010/11 data. I am reliably informed, however, that a more up to date set of figures are due to be published in the not too distant future - figures that will undoubtedly yet again grab the headlines.

So let's consider - in some detail -- the alarming increase in the incidence of melanoma.

The registered charity Melanoma Focus which represents many an eminent consultant can perhaps claim the most concise and telling statement in relation to the issue of the alarming increase when they state that melanoma incidence has the biggest projected increase of any form of cancer. Let me repeat – the biggest projected increase of any form of cancer.

In the last 30 years rates of melanoma in the UK have in fact risen five-fold since the 1970s.

The British Journal of Cancer also reported in 2011 the fact that malignant melanoma had the largest predicted rate of increase of cancers studied and added that it was set to rise by an estimated 52 per cent over the following 20 years. Indeed the study went on to predict that melanoma would become the fourth most common cancer in men and the fifth in women.

Other findings state that over the next 25 years melanoma rates in the UK will have risen faster than any other top ten common cancer.

Cancer Research UK also advise that more than 13,300 people (37 a day) are diagnosed with melanoma and young women appear to be most at risk and we are told that in the 15 – 34 age bracket melanoma is the most common cancer.

Like most cancers, skin cancer is more common with increasing age but melanoma rates are disproportionately higher in people aged under 55.

Finally and strikingly, we are advised that melanoma is the second most common cancer in young adults. Every day two young people between the ages of 15 and 34 are diagnosed with malignant melanoma.

So let us bracket the first and final statements of fact together:- Melanoma has:-

1 .[the biggest projected increase of any form of cancer] and it has become –
2 .[the second most common cancer in young adults]

If we consider the statistics provided by Skin Cancer UK, published in November 2013, for the three devolved countries, whilst geographically the South of England and the South West are the areas where cases are most frequently reported, the situation north of the border is just as serious. In Wales, the incidence is higher than in the rest of the UK and across the Irish Sea, skin cancer (non- melanoma) is the most common cancer with melanoma comparatively rare but nevertheless on the increase.

In Scotland in 2010 1,141 people were diagnosed with melanoma making it the sixth most common cancer. The incidence of melanoma in Wales has been increasing over time. In 2010 there were 740 new cases also making it the sixth most common cancer. In Northern Ireland the figures report for the same year also placed melanoma as the sixth most common cancer.

In order to obtain a wider perspective on the incidence of melanoma, if we consider the European scene, the UK sits seventh in the melanoma incidence league table with Sweden and Denmark topping the list of 29 countries.
It is interesting to note that four years ago, aware of the increasing incidence of skin cancer, the Danes consulted widely in Australia on matters of awareness, early detection and patient care. Clearly the Aussie approach is recognised as "best practice" and I have no doubt whatsoever that the UK would benefit hugely from this approach. For example, we are told that for every Australian dollar expended on awareness and prevention, there is an estimated saving of 2.3 dollars to the Australian Health Department.

With such a disproportionate number of young people involved in the UK, it means that patients are often of a working age and have families and possibly also contribute significantly to their local community. You know, I often wonder just how much NICE take into account the impact on the complete picture that surrounds the patient. Perhaps then the cost factor – whatever it is per patient – would reflect a truer appraisal and with such a common cancer with such a limited median survival time – does it not warrant a degree of priority?

One of the medical professions journals refers to NICE as one of the UK's "cost watchdogs" - call them what you will - but each and every time I read their appraisals, I only see specific reference to the patient and their life expectancy – surely in their capacity of cost watchdogs, they should be considering the overall impact – the cost to family, workplace, business and community.

So the horse has bolted – how do we keep that stable door locked and reduce the incidence?

At Skcin whilst strongly believing in the improvement of the patient pathway and contributing to its development, we also target awareness and early detection. Where better to concentrate those activities than amongst the very young – planting the seeds of UV awareness in the classroom.

Our widely acclaimed nationwide schools awareness programme (Sunsafe Schools) is developing at a pace and will continue for a second year with the support of a major sponsor with a registered starting base of over 1,100 primary and pre-schools participants.

Shortly with the assistance of a major London advertising agency (the same one that devised the multi award winning (Computertan.com) we will be announcing a similar campaign targeting the outdoor workforce (Sunsafe Workplaces) and, as always, we will be involved in sports, leisure and travel.

There can be no doubt that the incidence of melanoma is rising significantly in the UK. Ipilimumab has been clearly demonstrated as a most effective treatment and would be even more effective if given at an earlier stage.

I urge you to read the patient testimonials. They say it all! We can restore hope for patients and their families but in order to do this – we need your help. We cannot wait for 2017 for NICE to reconsider.

The NICE Appraisal Process: what this decision means for patients

Gill Nuttall Founder, Melanoma UK

Good evening everyone – my name is Gill Nuttall and I am from Melanoma UK.

Firstly I would like to extend a very warm and grateful thank you to Pauline Latham for agreeing to host this session this evening. I have had many messages of thanks from patients up and down the country who are very grateful indeed for your continued support.

During the course of the last couple of weeks I have been speaking with several patients and the families of patients and we are very fortunate to have some of these people here with us this evening. If you can all just raise your hands as I say your name, so that Pauline and other people present will know who you are. Gaynor, Lesley, Colin, Colin, Kate, Will and Maria. These are all people with very interesting messages about melanoma and we will hear from them later on this evening.

A brief introduction to Melanoma UK then. Melanoma UK began life as Factor 50 in 2007, when I realised that a very close family friend was not going to survive Melanoma. His name was Jon Herron and he was just 29 years old. He had been struggling with Melanoma since he was 22 and died a month after his 30th birthday. I made up my mind that I would do a little bit of fundraising and raise some awareness of the disease. My initial remit was to do this for about a year and then walk away – I guess there is a message for us all to be careful what we wish for, as 7 years later I am now running Melanoma UK and this is my full time role.

Melanoma UK exists now as a support network for patients and families. Our aim is to provide much needed support to patients and this can range from putting a patient in contact with another patient in a similar position, helping a patient find a suitable doctor, assisting a patient who is looking for information on a particular treatment or wishing to participate in a clinical trial and anything in between. We also offer support to bereaved families.

The reason we are here today follows the NICE decision not to allow ipilimumab to be used as a first line treatment in the treatment of advanced melanoma apart from in clinical trials. The rationale behind this decision is that the Committee felt that in order to calculate reliable cost and clinical effectiveness estimates they need more precise and accurate evidence. Their proposal is that they wait until 2017 to review this decision. That is 3 years away. You will hear from the patients shortly as to what that means to them.

You may recall that in 2011 NICE recommended that ipilimumab should not be available on the NHS at all. After over 30 years of no treatments for late stage melanoma patients, you can imagine what a devastating blow this was – not only to the patients, but to the doctors who treat these people every day. Following a similar campaign and much support from Pauline and many other MPs, NICE overturned their original decision and the treatment was approved for use as a second line treatment.

Before patients can access ipilimumab, they must first have a standard chemotherapy treatment dacarbazine, which is generally accepted by clinicians as having little or no effect. Only then can a patient access ipi. I feel it is very important to make you all aware that NICE, in its provisional decision, acknowledged the clinical consensus that dacarbazine 'has never been shown to have survival benefit.'

Patients have real difficulty in understanding why they can only access a more effective treatment once they have gone through an unsuccessful treatment with an older, ineffective drug. Even more alarming for patients is that last year, ipilimumab received a European licence to be used as a first line treatment. It seems that once again NICE is carrying out an assessment of it clinical and cost effectiveness. Patients and other interested parties are now making their representations to NICE and we hope that NICE will fully consider all of the evidence prior to their final decision.

So, this evening is really all about the patients. It is not me you really need to hear from, it is the patients, the people who live with this illness, the people who are desperate for help. Anyone who was present at the last meeting will remember two men who were with us that evening: Ian and Taron. Between them, these two men had nine children. They were typical of the kind of patient that I am talking about today. Ian and Taron died a few weeks after we met, never managing to access the treatment.

As I've said, tonight is about the patients, but before Pauline invites them to speak, I have a message from another patient who lives in Penzance and couldn't join us today:-

I was diagnosed with Melanoma in August 2009. I had it in my axilla, gallbladder and a lymph node in my abdomen. By December that year it had spread to my liver and I was told I was terminal. I was referred to a MEK inhibitor with Dacarbazine trial and saw some shrinkage of tumours in my liver, but by September they were back with a vengeance. I was prescribed ipilimumab on a compassionate access programme. Early scans showed significant reduction of tumours and since 2011 all scans have shown my disease is stable. This treatment has, quite simply, saved my life. I know I had it as a second line treatment but had I been prescribed this first line, a great deal of anxiety, pain and discomfort would have been avoided. I am going to write to NICE to urge reconsideration of its decision. There is significant evidence that when various first line treatments cease to be effective that the melanoma returns with much more vigour and therefore becomes more difficult to treat.

A very powerful story, from a man who without this treatment, would no longer be with us.

I hope that gives you an idea of the work of Melanoma UK but more importantly, the plight of many people who are living with this disease.

Thank you all again for joining us this evening, on behalf of melanoma patients may I thank you all for your valuable support. It does mean a lot.