Interim Proposal for the use of Peptide Receptor Radionuclide Therapy (PRRT) Lutetium-177 DOTA Octreotate for patients with progressive, inoperable neuroendocrine cancer.

Dear Rt Hon Jeremy Hunt MP,

We write to you as the national non-profit organisation working solely to support the neuroendocrine cancer community, with a proposal to try and alleviate the devastating side effect of removing an outstanding, life changing treatment.

In 2000 the UK was a relative backwater for neuroendocrine tumour (NET) management. We are now one of the leading countries in the world for NET patient care with the largest number of "ENETS Centres of Excellence" - 10 in total in England. The energy, time, investment and training gone in to achieving this should not be undervalued. The decision to remove access to PRRT from the CDF sets the NET care in the NHS back by years for what is ultimately a small cost to the NHS in regard of patient numbers and the fact that many are carrying on their “normal” lives with the therapy. Two years ago we held a meeting in the House of Commons and it was with pride that we could say how fantastic NHS England was in delivering this PRRT therapy to our patients no matter where and who they were. Now only patients in the devolved nations can access the treatment as the Welsh, Northern Irish and Scottish health boards all approve this treatment, and the referral of patients to England to receive it.

PRRT is a standard of care in Europe being available for use in many larger centres.

PRRT was removed from the Cancer Drugs Fund in November 2015, one week prior to the publication of evidence showing a large progression free survival benefit. This is an ironic situation as we have previously had full access to PRRT prior to this and now just as the strongest evidence is available, access is denied. This trial showed that when you compare patients who were given 60mg of octreotide (a somatostatin analogue) to those given 177Lu-DOTATE(a form of PRRT) treatment, the time until the tumours started growing again was significantly different for the patients given the 177Lu-DOTATE. In fact the magnitude of effect in terms of survival is greater than many other cancer treatments and the change in quality of life is clearly shown in many patient testimonials from around the globe.

PRRT is to be reviewed by NICE, this year but that outcome will be unknown until Autumn 2017. We need to have an interim measure to support these patients needing treatment. If we do not, patients will die.

We want the UK to continue to be a flagship country for NET management and highlight what we have achieved in the NHS. To do this we need to allow the specialist Centres who deliver PRRT treatment, adhering to clear guidelines and standards of care, to have interim funds with estimated cost predicted to be 3 million pounds per annum, enabling Centres to continue their outstanding work and save lives. This interim fund should be made available until such time as NICE has made its decision. (NHS England may treat 300 patients per year at a cost of £10,000 per treatment and this would equate to £3,000,000).

We wish to request a meeting to discuss this proposal with some urgency.

Yours sincerely,

Catherine Bouvier
“The International Neuroendocrine Cancer Alliance (INCA), is the umbrella organization uniting NET patient advocacy groups from around the world as the global voice for neuroendocrine cancer patients. INCA declares its dedicated support to elevate the standards of care for our patients on a global level. Independent scientific research, including the recently published results from the NETTER-1 trial, provide substantial evidence of the benefits of PRRT, further substantiating its role as an effective and vital standard of care for patients with Neuroendocrine Tumors (NETs). Having access to PRRT has been a critical element of NET patient care in the UK.

To remove that access would be a significant step backward.”

Ronald Hollander
President, International Neuroendocrine Cancer Alliance

“PLANETS fully support the NPF and the details contained within this letter. We represent the NET patients and clinicians from Hampshire, the Isle of Wight, Dorset, West Sussex and Wiltshire.

As one of the European Centres of Excellence, providing comprehensive care (including PRRT) to NET patients from a 3.5 million catchment area in the central south coast, we are desperate to see the return of this vital treatment.

PRRT is essential for treating patients with advanced but "Slow growing" disease. This small group of patients are often not eligible or suitable for any form of chemotherapy and have no other effective treatment option. We know from our experience that PRRT works; improves quality and duration of life and saves lives. Now finally there is good quality trial evidence to prove this and yet perversely the treatment is no longer available following an incomprehensible and illogically timed decision by the cancer drugs fund. This has led to 2-tier health care where this can only be provided to private patients or non-English, NHS patients from the rest of the UK. Our patients are well informed, know the evidence and demand this treatment. Our clinicians cannot offer any sensible explanation why this therapy isn't available to relieve their suffering.

We respectfully request that an interim funding mechanism is put in place to provide essential care to this group of patients”.

Mr Neil Pearce DM, FRCS
Associate Medical Director - University Hospital Southampton
PLANETS Charity Founder

“This letter has strong backing from UKINETS which is the main professional organisation for doctors and nurses treating NET patients in the UK. We completely support the dedicated efforts to raise standards of care for these cancer patients.”

Professor J Ramage
Lead Clinician for the Gastroenterology department at Hampshire Hospitals and Lead Clinician for the Kings Health Partners Kent and Hampshire Hospitals Centre of Excellence for Neuroendocrine Tumours.

Chair UKINETS.
“In the last decade the UK/NHS has been at the forefront looking after NET patients and leading research into these rare cancers. It is something to be very proud of and to deny patients in NHS England the opportunity for it's patients to receive a standard of care, which it has done so much to establish, is a very backward step for NHS England and the care of NET patients. On behalf of the European Neuroendocrine Tumour Society (the largest international organisation for NET clinicians and researchers) we strongly support the continued use of PRRT/Lutetium-177 DOTA Octreotate as highlighted in this letter.”

Professor Martyn Caplin
Immediate past President European Neuroendocrine Tumor Society.
Clinical Lead Royal Free Hospital NHS Trust European Centre of Excellence for Neuroendocrine Tumours

“I am quite frankly devastated with the decisions that have been made since November as unfortunately, just a week after the announcement was made, I found out that I had a new NET tumour and would myself need PRRT treatment.

I have been successfully fighting NET cancer for 7 years now (40 hours of operations in total from an amazing world class NET team at Southampton) and I feel that the NHS/Government are now taking away my human rights to gain access to PRRT – which will hugely impact my fight for life and ability to take care of my 7 year old son.

Furthermore, it seems that the way in which the NHS evaluates new drugs is inherently biased against rare diseases for which it is almost impossible to collect large scale trial data, because there simply aren't enough patients to populate the trial !?- this is utterly unfair and contradicts the governments own Cancer Strategy that was put in place, just last year.

I sincerely hope that a satisfactory and permanent resolution can be made quickly, to prevent lives from being lost as a result of this dreadful decision.

Please listen to what is being said and reconsider this ill advised decision - I do not want to be one of the patients that die because of this decision- my son needs his mother”.

Layla Stephen
NET Patient – East Hampshire
PLANETS Fund Manager
Appendix 1- Example patient testimonials and example responses to the decision to remove PRRT from the CDF:

“I am writing to you to outline the improvement in my quality of life since my Lutetium Octreotate treatment. Prior to the treatment I was spending all my time either on the sofa or in bed primarily because of the severe pain due to my bone and liver cancer. I was taking a raft of pain killers on a daily basis (Gabapentin 400mg 3 times a day, Dexamethasone 4mg, Zapping 30mg/500mg 2 tablets three times a day, Oromorph and Voltarol 12 hours gel which my wife rubbed on my whole back and chest morning and evenings and a 25 mg Fentanyl patch every 3 days). I had numerous visits by the out of hours GPs, because in spite of the medication I ended up with unbearable pains, not to mention the number of times I had to be admitted to A&E.

Because of the severe pain which prohibited me from moving at nights I had a bottle next to my bed to urinate in, this lasted for numerous weeks. My weight was dropping at a rate of 1.5 kilos a week even though I was eating well. By the time I started my treat my weight had dropped from 80 kilos down to 61 kilos.

After the first Lutetium treatment, within a couple of days my bone pain significantly reduced whereby my wife did not have to rub the voltarol 12 hour gel twice a day on my body. I was able to walk around the house and within weeks able to have short walks outside. I started to gain weight and by the time I had my second Lutetium treatment my weight stabilised around 74 kilos. Since my second treatment I have managed to ween myself off most of the drugs were by I am now only taking 300mg of gabapentin 3 times a day and using only a 12.5 mg fentanyl patch to manage my pains. No more need for out of hours doctors nor A&E visits. According to my latest CT scan, not only has the treatment stopped the growth of my tumours, but it is actually shrinking them.

The turn around for me has been absolutely amazing and I am only half way through the treatment. My quality of life over the last 5 months has improved immensely.

Mr A A
CG: “Count me in. I had PRRT three years ago and on the CT scan last year it showed that the tumours were still shrinking.”

SS: “Oh my goodness. This kept my husband alive for five years. I'm in on this fight. This isn't a drug that gives you a couple of months! This gave my forty six year old husband five/six years! Some many more.
I'm sure I speak for lots of us, patients and carers past and present. We're in this together.
We will lobby we will march we will sign petitions, go on telly, anything. We have to get this back.”

WO: “Count me in too ... This was my treatment plan after surgery.”

PG: “I am totally shocked. It has given me over 2 years of stable disease.”

AN: “This is scary news. Although stable at the moment (diagnosed Mar 2014)
I expected this to be the next port of call at some point. This news makes our futures even shadier!”
“I really am quite frightened now!”

RH: “It's given me 7 years of stable disease and counting! This treatment must be available!”

PD - “To hear this treatment is to be withdrawn is extremely worrying as it keeps me alive. Without It I do no feel I would be alive. The people I have met via conferences Facebook Groups and forums are all extremely concerned that such a life saving drug could be withdrawn by the Cancer Drug Fund. Living with this disease has its challenges surely we should not have to worry about whether the CDF will continue to fund such a valuable drug that keeps many people alive.
I hope once the evidence is reviewed the treatment will once again be available to patients such as myself.”

Tobias Kvant, CARPA, Sweden
“In Sweden, we have 3 cities who use this treatment method; Uppsala, Gothenburg and Lund.
We have no restrictions in financing, it is the specialist who takes the decision, normally in the "advisory" conference with other specialists.”

Katharina Mellar, Netzwerk Neuroendokrine Tumoren (NeT) e. V., Germany
“In Germany the situation is similar to Sweden. Normally the tumour board of the clinic decides together. If the PRRT is recommended there are no restrictions. The costs are covered by health insurance.
In Germany we have at least 30 clinics where PRRT is done.”

Dr John Leyden, Unicorn Foundation, Australia
“Luckily for Australian patients, we (the Unicorn Foundation) have lobbied long and hard over the last 5 years and most patients, if they are suitable for PRRT can receive it at a centre in each state,(in NSW alone we have a budget for 90 individual patients per year).“
“My story started approximately ten years ago, whereby I was diagnosed with a Neuroendocrine Tumour to the pancreas. I was at my Doctors surgery and I noticed that they were providing well man checks for the over 40s male. I decided to take these basic checks. After a couple of weeks the initial blood test that I had given came back with abnormalities. After further checks I was sent to the local hospital for an ultrasound check. Not long after having this check within minutes I was given a CT scan that resulted in a large mass being located on my right hand side of my upper body that was the size of a football. I had felt no pain.

It was diagnosed with a Neuroendocrine Tumour to my pancreas that must had been secreted there for years and years. The surgeons moved quickly and remarkably it was supposedly all removed and I was given the all clear. I lost my spleen and tail end of my pancreas during surgery as well as the large tumour.

This remained the same until approximately seven years later, when I returned to the doctor’s for an unrelated matter. Due to my mental state at that time the Doctor recommended me for another CT scan, which showed that tumours had returned to my liver and pancreas and were inoperable.

I was subsequently allocated a Specialist Professor. He took care of me for the next four years providing routine treatments in order to control the tumours. This worked for about five years whereby I was able to live a normal life with hospital visits whilst still living with my cancer.

Following this period I was allocated another Specialist Professor who continued the treatments. He also used other treatments in order to control the tumours. Also during this time I was provided with a nuclear scan that was supposed to light up the areas affected by the tumours. A number of limited areas showed up on the scan. I was provided with Everolimus, but due to my low immune system I contracted encephalitis and nearly died as a result. I was seriously ill and at this time I had to retire from my job as a Detective Sergeant serving 26 years with the police.

During this time my family were very worried and struggled to cope and became increasingly worried and aware that my treatments were becoming limited and that my options were running out as my calcium had also started to rise as the tumours sought more calcium from my body and my levels started to increase alarmingly.

This continued for approximately two years whereby I was in and out of hospital on a regular basis. Whilst in hospital I was provided with fluids and other medications that did not succeed at lowering my calcium levels, which continued to rise. The doctors became worried because nothing would lower my calcium levels.

It was also starting to take its control over myself. I began to lose my speech and ability to hold a conversation. I also could hardly walk a few feet as my legs were becoming increasingly weak. I was more or less bed bound at this time. It also made me increasingly susceptible to loud noises and I became withdrawn in myself.
It was also very hard for my family who had to increasingly get used to my regular mood swings. It was also impossible for me to button my shirt or my trousers due to my deteriorating health. During this time I also suffered heavy falls in hospital and at home leaving me badly bruised and sore. The specialist staff continued to give me treatments that did not work and allowed my calcium to get to dangerous levels threatening my bone marrow and other parts of the body.

By this time my normal treatment options for reducing calcium were ending and showed no signs of any improvement and I continued my very poor health remaining weak and withdrawn. About six months to nine months ago, I was being considered for palliative care at home such was my state of health.

The root of all my problems was my calcium levels being so high and were affecting my basic bodily functions.

At this point Professor X recommended me to Sheffield to speak with Doctor Y who was performing a relatively new treatment that involved nuclear medicine that was non-invasive and injected into my arms. It was clear to the Professor that one of the tumours appeared to stand out and was requesting the extra calcium to enter the blood stream.

An earlier nuclear scan was provided to Dr Y along with my medical records. The scan showed up limited areas where I had been affected.

Despite my very poor health I was accepted for the Lutetium treatment by Dr Y. In October 2016, I had my first treatment staying overnight at the hospital before leaving the next day. Nothing really happened for the next week apart from me being tired but I suffered no real side effects.

Within a week and without any warning I started to feel subtle changes and the benefits of the treatment.

It was life changing because all of a sudden I was able to join in conversations and my coordination became back allowing me to eventually walk five miles. The change was unbelievable and people started to comment on how well and coordinated I had become. My memory is becoming sharper as I am able to recognise names and faces again. I also more tolerant with family and friends. I can now dress myself and walk and run in a straight line. It’s incredible how this has become true after only one treatment.

My family and myself have recognised a massive change in my overall health and the fact that they are having to perform fewer tasks on my behalf. I am now also able to get up early in the morning and occupy myself rather than staying in bed until lunchtime or late afternoon. The health benefits have been terrific and unbelievable. I feel like a person reborn and given another chance in life. Before I always used to think how long I have got and when am I going to die? Now these thoughts have gone and I intend to live my life to the full with the help of Dr Y whom took that chance with me and that has handsomely paid off with added bonuses to my health. Only recently, I am able to compile this report to you as it was impossible previously.

I am now so enthusiastic about life and enjoying it with my family. Life is now a joy as I communicate on Facebook with my many friends and tell my story to give help to others with the message never to give up. I am sure that this treatment will provide others with the unbelievable health benefits that I have achieved through the treatment.”

Mr A N