Submission from **Roy Castle Lung Cancer Foundation,** for consideration by NICE, in their review of **Ceritinib** in the treatment of previously treated Anaplastic Lymphoma Kinase (ALK)-positive Non Small Cell Lung Cancer (nsclc) [**ID729**].

Submitting Organisation

Roy Castle Lung Cancer Foundation is a UK wide lung cancer charity. We fund lung cancer research, tobacco control initiatives and work in lung cancer patient care (information, support and advocacy activity).

The Foundation has contact with patients/carers through its UK wide network of over 50 monthly Lung Cancer Patient Support Groups, online Forums and its Lung Cancer Information Helpline.

Clearly, our patient group members and contacts are a self-selected group, who have taken the step to seek out information or have accessed specialist support services. As most lung cancer sufferers tend to be older, from lower social class groups and with the five year survival being only 7%, less physically well, we acknowledge that our patients are perhaps not representative of the vast majority of lung cancer patients, who are not so well informed. It is, however, important that the opinions expressed to us, be passed on to NICE, as it considers the place of this product in the management of non small cell lung cancer (NSCLC).

General Points

1. For the overwhelming majority of NSCLC patients, cure is not a treatment option. In this scenario, improving quality of life and even small extensions in duration of life are of considerable significance to the individual and their family.

2. As active treatment options are limited in NSCLC and as overall outcomes remain poor, the availability of new choices, offer 'hope' for patients

3. The issue of "inverse weighting for duration of life" must be stressed. When considering the cost of treatment, it is not appropriate, for example, to give the same weighting to the final six months of life as to all other six months of life. It is important for this to be part of any numeric equation, which is looking at cost and quality of life. This point is of crucial importance to patients and relatives in this situation

4. Improvement in symptoms. Patients with advanced non small cell lung cancer are often debilitated with multiple and distressing symptoms. Symptoms such as

breathlessness are very difficult to manage clinically. Therapies with anti-tumour activity often provide the best option for symptom relief. The reality, however, is that few active options currently exist.

5. The potential of improving quality of life brings obvious benefits. These patients, in general, have quite limited life expectancy. It is of paramount importance, both to them and their families, that they are able to function as fully as is possible, for as long as possible.

This Product

1. Well tolerated
   Oral therapy - therefore, ease of administration.

   We understand that common side effects associated with Ceritinib include gastrointestinal symptoms such as diarrhea, nausea and vomiting. In the anecdotal patient experience reported to us, it is well tolerated – in particular, when compared with current standard cytotoxic therapy for nsclc.

2. Very targeted population.
   The ALK gene rearrangement is found in about 2% to 7% of patients with nsclc. Crizotinib has, globally, become the standard of care in this small patient population. Crizotinib was, however, rejected by NICE appraisal but, is available in England, through the Cancer Drugs Fund. It is clear that some patients become resistant to Crizotinib and until now, there has been no other targeted therapy to offer these patients. Ceritinib, with positive NICE appraisal, will be able to fill this role. Thus, this therapy represents a targeted treatment option, providing benefit to a clearly defined segment of non small cell lung cancer patients.

3. As noted above, even relatively small benefits can be disproportionately large for patients.

   Our observations come from a combination of one-to-one discussion with lung cancer patients, published research and our patient information helpline.

In summary

Patients with advanced and metastatic lung cancer are in a particularly devastating situation. Even with the currently recommended options, the outlook for the majority is relatively poor. It is for this reason that the availability of additional options is very

important. Ceritinib represents a new therapy option, for a very small number of clearly defined patients.

We urge NICE, in its deliberations of this submission, to recommend the use of this therapy

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